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Clinical Advisory: Infant botulism Outbreak Linked to Infant Formula

November 11, 2025

- CDC and FDA have reported a multistate outbreak of infant botulism associated with a commercial, powdered infant formula (ByHeart Whole Nutrition Infant Formula) that has been nationally distributed. All lots of this product have been recalled by the manufacturer.
- Providers are asked to be vigilant for infants presenting with findings compatible with infant botulism who have consumed this formula, regardless of lot number.
- Please contact DPH 24/7 at 617-983-6800 immediately for consultation regarding testing and treatment if botulism is suspected.
- Treatment with BabyBIG antitoxin can be lifesaving and should be initiated based on clinical criteria prior to the availability of test results.

Background: In response to notifications from CDC, FDA, and public health officials in several states, the Massachusetts Department of Public Health (DPH) is alerting providers to a multistate outbreak of infant botulism linked to ByHeart Whole Nutrition infant formula. As of November 10, 2025, 15 cases have been reported in 12 states: Arizona, California (2), Illinois (2), Kentucky, Minnesota, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas (2), and Washington. Laboratory confirmation for some cases is ongoing. Illness onset dates range from mid-August to November 2025. All 15 infants were hospitalized and treated with BabyBIG (Botulism Immune Globulin Intravenous (Human) (BIG-IV). Infants ranged in age from 16 to 157 days. There have been no deaths. No cases have been reported in Massachusetts.

ByHeart Whole Nutrition infant formula is a powdered product that has been distributed widely including by large national retail stores and online distributors.

Caregivers are advised not to use ByHeart Whole Nutrition Infant Formula All lots of this product have been voluntarily recalled by the manufacturer and should be discarded or returned to point of purchase. This includes all lot numbers and all sizes of cans and single serve packets.

Parents and caregivers whose babies have consumed ByHeart formula and have concerns about their baby's health, should contact their healthcare provider immediately. Infants who have consumed ByHeart formula but do not have symptoms should be monitored for 30 days as symptoms may develop days to weeks after exposure. Not all infants who have been exposed will develop illness. Please note that WIC (the Special Supplemental Nutrition Program for Women, Infants and Children), which supports many children in Massachusetts, does not include ByHeart on its formulary.

Providers: DPH recommends that providers maintain heightened vigilance for infants presenting with findings compatible with infant botulism who may have consumed ByHeart formula. In addition, providers should ask which formula brand is fed to their infant patients, alert parents/guardians to the ByHeart recall, and ensure recalled formula is not used. Additional information is available from CDC [here](#).

Infant botulism is the most common form of botulism seen in the US; in the past 5 years there have been 4 confirmed cases in Massachusetts. It is seen after infants ingest spores of *Clostridium botulinum*, which germinate in the infant GI tract and produce toxin. It typically presents in infants under 12 months of age. Frequent findings include initial constipation, loss of appetite, weakness, poor suck (inability to latch), ocular palsies, an altered cry, and a loss of head control. Symptoms can progress to include flaccid paralysis and difficulty breathing and can be fatal without treatment.

Infant botulism is treated with supportive care and special attention to feeding and respiratory support. BabyBIG, a human-derived botulism antitoxin, should be rapidly administered to infants with strong clinical suspicion of infant botulism. Treatment with BabyBIG immediately ends their toxemia and enables motor nerve regeneration to begin.

Report all suspected cases immediately to DPH by calling 617-983-6800 (24/7) and speaking to the epidemiologist on call. If consultation supports the diagnosis of infant botulism, DPH will assist in obtaining BabyBIG from the California Infant Botulism Treatment and Prevention Program. Treatment with BabyBIG should be initiated prior to test results. DPH will provide instruction on the clinical specimen(s) that should be collected for botulism testing and how to submit them to the Massachusetts State Public Health Laboratory.

Ask caregivers to photograph the implicated formula container with the lot number visible. This information should be shared with DPH who will communicate information to CDC and FDA as part of the national investigation.

Laboratory Testing

Testing of patient specimens is available through DPH when there is strong clinical suspicion that leads to the administration of BabyBIG. Clinical testing is not available for asymptomatic infants or for low suspect cases where treatment is not necessary.

All specimens submitted to the Massachusetts State Public Health Laboratory (SPHL) for *Clostridium botulinum* testing must be approved by the DPH Division of Epidemiology: (617) 983-6800.

Stool is the preferred specimen for infants. As much stool as possible should be collected (minimum of 10g preferred). Unpreserved stool should be collected in a wide-mouth, sterile, leak-proof container and must be stored and shipped at 2-8°C. Serum is not recommended for infants. If collection of stool is not possible due to constipation, a rectal swab can be collected in a sterile container. Specimens should be stored at 2-8°C and transported by courier as soon as possible. Each specimen must be submitted with the MA State Public Health Lab's General Specimen Submission Form (link below); the "additional patient information" section should be completed.

References/links:

[Massachusetts State Public Health Laboratory Manual of Laboratory Tests and Services Specimen Submission Form](#)

[Infant Botulism Outbreak Linked to Infant Formula, November 2025 | CDC](#)

[Outbreak Investigation of Infant Botulism: Infant Formula \(November 2025\) | FDA](#)

[In Response to a Broader FDA Investigation, ByHeart Initiates a Voluntary Recall of Two Batches of Infant Formula | FDA](#) *Includes pictures of the recalled product and how to find lot code information.*