

Health Advisory: Infant Botulism Outbreak Linked to Infant Formula

Minnesota Department of Health, Mon, Nov 10 14:00 CST 2025

Action Steps

Local and tribal health departments: Please forward to hospitals, clinics, urgent care centers, and emergency departments in your jurisdiction.

Hospitals, clinics and other facilities: Please forward to infection preventionists, infectious disease physicians, emergency department staff, hospitalists, intensivists, and pediatric providers and other primary care clinicians.

Health care providers:

- Consider infant botulism initially based on clinical symptoms: initial constipation followed by difficulty feeding (sucking and swallowing), a weak and altered cry, and lack of head control.
- Call the [California Infant Botulism Treatment and Prevention Program](#) **immediately at 510-231-7600** for consultation of suspect cases. Consultation is available 24/7.
- Begin treatment with BabyBIG® (obtained from California Department of Health) as soon as possible if clinical consultation supports infant botulism. Do not wait for laboratory confirmation.
- Contact MDH (651-201-5414 or 877-676-5414) to get testing approval, then send clinical specimens to the Minnesota Department of Health Public Health Laboratory MDH PHL for testing.
- Report all suspect cases to MDH by phone immediately (651-201-5414 or 877-676-5414).

Background

CDC and public health officials in several states, the Infant Botulism Treatment and Prevention Program, and FDA are investigating a multistate outbreak of infant botulism linked to **ByHeart Whole Nutrition infant formula**. One case has been reported in Minnesota. Infant botulism occurs when swallowed *Clostridium botulinum* spores germinate in an infant's large intestine and produce toxin. Infant botulism often starts with constipation but is usually first noticed as difficulty feeding (sucking and swallowing), a weak and altered cry, and lack of head control.

As of November 8, 2025, 13 infants with suspected or confirmed infant botulism have been reported from 10 states as part of this outbreak: Arizona, California (2), Illinois (2), Minnesota, New Jersey, 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 13 infants were hospitalized and treated with BabyBIG. No deaths have been reported. Infants ranged in age from 16 to 157 days.

State and local public health officials are interviewing caregivers about the foods infants were fed in the month before they got sick. Parents of all 13 infants reported feeding them ByHeart Whole Nutrition infant formula.

On November 8, 2025, ByHeart Inc. recalled two lots of Whole Nutrition Infant Formula:

- Lot: 206VABP/251261P2 ("Use by 01 Dec 2026")
- Lot: 206VABP/251131P2 ("Use by 01 Dec 2026")

ByHeart Whole Nutrition Infant Formula is available for sale online and at major retailers nationwide. ByHeart Whole Nutrition Infant Formula makes up less than 1% of all infant formula sales in the United States and this outbreak does not create shortage concerns of infant formula for parents and caregivers.

Laboratory Testing

If clinical consultation supports infant botulism, begin treatment with BabyBIG® as soon as possible. Do not wait for laboratory confirmation. Confirmatory testing for botulism uses the mouse bioassay to identify toxin in feces and can take up to two weeks to get results. The MDH PHL is the regional botulism laboratory. Contact MDH at 651-201-5414 to get approval for testing prior to sending clinical specimens. Ideally, 10 grams of feces should be collected. If an enema is needed, use sterile, non-bacteriostatic water. Save powdered infant formula consumed by suspected infant botulism patients. If the patient is confirmed to have botulism, the MDH PHL may test the powdered infant formula. The MDH PHL is not testing formula of asymptomatic patients.

Guidance for Parents/Guardians

Parents should not use recalled infant formula and throw it away or return it to where it was purchased. If concerned that their infant may be ill, parents should seek immediate health care if their infant has consumed ByHeart Whole Nutrition Infant Formula and has any of these symptoms:

- Poor feeding
- Loss of head control
- Difficulty swallowing
- Decreased facial expression

For more information

- [FDA: Outbreak Investigation of Infant Botulism: Infant Formula \(November 2025\)](https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025) (<https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025>)
- [CDC: Infant Botulism Outbreak Linked to Infant Formula, November 2025](https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html) (<https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html>)
- [CDC: Clinical Overview of Infant Botulism](https://www.cdc.gov/botulism/hcp/clinical-overview/infant-botulism.html) (<https://www.cdc.gov/botulism/hcp/clinical-overview/infant-botulism.html>)
- [MDH Botulism \(Clostridium botulinum toxin\)](https://www.health.state.mn.us/diseases/botulism/index.html) (<https://www.health.state.mn.us/diseases/botulism/index.html>)

A copy of this HAN is available at: [MDH Health Alert Network](http://www.health.state.mn.us/han) (<http://www.health.state.mn.us/han>)
The content of this message is intended for public health and health care personnel and response partners who have a need to know the information to perform their duties.