

HEALTH ALERT NETWORK | HEALTH ADVISORY | November 14, 2025

Nationwide Infant Botulism Outbreak Linked to Infant Formula

The North Dakota Department of Health and Human Services (HHS) is issuing this health advisory regarding an outbreak of infant botulism in multiple states. North Dakota clinicians are recommended to include infant botulism in the differential diagnosis for any ill infant who has compatible symptoms with infant botulism (e.g., constipation, difficulty feeding (sucking and swallowing), a weak and altered cry, and lack of head control), AND ask parents or caregivers about the use of ByHeart Whole Nutrition infant formula prior to illness onset.

Suspect botulism cases are a mandatory reportable condition in North Dakota. **Providers should contact the HHS Disease Control and Forensic Pathology Section immediately at 701-328-2378 if botulism is suspected in a patient.** Consultation with the California Infant Botulism Treatment and Prevention Program is available 24/7 at **510-231-7600** and will be initiated immediately after the suspect case is reported to ND HHS. If indicated, treatment with BabyBIG should be started as soon as possible after consultation. Treatment initiation should not wait for laboratory confirmation, which may take weeks.

Background

The Centers for Disease Control and Prevention (CDC) and public health officials in several states, the Infant Botulism Treatment and Prevention Program, and U.S. Food and Drug Administration (FDA) are investigating a multistate outbreak of infant botulism linked to **ByHeart Whole Nutrition infant formula**. At this time, North Dakota has reported no cases associated with this outbreak. Infant botulism occurs when an infant ingests *Clostridium botulinum* spores which colonize in an infant's large intestine and produce a toxin. Infant botulism symptoms often start with constipation followed by difficulty feeding (sucking and swallowing), hypotonia (floppy baby), a weak or altered cry, lack of head control, facial weakness, ptosis, and progressive, symmetric descending paralysis. Most infant botulism cases occur in infants under six months of age. With timely treatment, nearly all infants recover fully.

As of November 11, 2025, 15 infants with suspected or confirmed infant botulism have been reported from 12 states as part of this outbreak: Arizona, California (2), Illinois (2), Kentucky, Minnesota, North Carolina, New Jersey, Oregon, Pennsylvania, Rhode Island, Texas (2), and Washington. Laboratory confirmation for some cases is ongoing and cases report illness onset dates between mid-August and November 2025. All 15 infants were hospitalized and treated with BabyBIG. No deaths have been reported.

Following caregiver interviews, cases reported the infant consumed ByHeart Whole Nutrition infant formula prior to symptom onset. On November 8, 2025, ByHeart Inc. recalled two lots of Whole Nutrition Infant Formula. Parents and caregivers have reported feeding infants in this outbreak different lots of ByHeart infant formula that were not included in the initial recall. On November 11, 2025, ByHeart Inc. recalled all ByHeart Whole Nutrition infant formula products. ByHeart Whole Nutrition Infant Formula is available for sale online and at major retailers nationwide.

Providers should:

- Include botulism in the differential diagnosis for infants with [compatible symptoms](#), especially if the parent or caregiver has reported that the infant consumed ByHeart Whole Nutrition infant formula.
- **Providers should contact the HHS Disease Control and Forensic Pathology Section immediately at 701-328-2378 if botulism is suspected in a patient.**
- Consultation with the [Infant Botulism Treatment and Prevention Program](#) (IBTPP) is available for suspected cases. If you suspect your infant patient has botulism, **immediately call HHS and a joint consultation will take place.** Consultation with the IBTPP is available 24 hours a day, 7 days a week at **510-231-7600**.
- If clinical consultation supports infant botulism, begin treatment as soon as possible. **Do not wait for laboratory confirmation**
- HHS will facilitate testing the infant for botulism. **Do not send samples without consulting HHS prior.**
 - If testing is performed, the following samples should be collected:
 - Stool – collect raw stool in a sterile container
 - Serum – 3 ml collected prior to antitoxin treatment
 - Additional details on collecting and storing samples are available [here](#).
 - For questions about laboratory specimen collection, testing, and shipping call HHS Laboratory Services at 701-328-6272.
- Instruct parents and caregivers of the infant to stop using ByHeart Whole Nutrition infant formula. Additional parent and caregiver information can be found below.

Information for Parents and Caregivers:

Parents and caregivers are urged to **stop using any ByHeart Whole Nutrition infant formula immediately.** This includes formula in cans and single serve packets.

- **Do not use recalled infant formula.** Unopened formula can be thrown away or returned to where it was purchased.
- Leftover ByHeart powdered formula that an infant was fed should be kept for at least one month.
 - If possible, record the lot number and best by date.
 - Keep the container in a safe spot and label the product “Do Not Use.”
 - If the infant develops symptoms of infant botulism, the formula may be collected for testing.
 - If no symptoms appear after a month, throw the leftover formula away.
- **Wash items and surfaces** that may have touched the recalled formula using hot soapy water or a dishwasher.

- **Seek immediate medical care** if an 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
- Symptoms of infant botulism can take as long as several weeks to develop, so parents should remain vigilant if they used the recalled infant formula.

Additional Resources

- [CDC: Infant Botulism Outbreak Linked to Infant Formula, November 2025](#)
- [CDC: Clinical Overview of Infant Botulism](#)
- [California Infant Botulism Treatment and Prevention Program](#)
- [FDA: Outbreak Investigation of Infant Botulism: Infant Formula \(November 2025\)](#)
- [ND HHS: Botulism Information](#)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

HAN Message Types

- **Health Alert:** Conveys the highest level of importance about a public health incident.
- **Health Advisory:** Provides important information about a public health incident.
- **Health Update:** Provides updated information about a public health incident.

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This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations.

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