NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Michelle Morse, MD, MPH
Acting Commissioner

2025 Health Advisory #23: Recall of Infant Formula Related to Botulism Type A Outbreak

Please distribute to all emergency medicine, infectious disease, internal medicine, family medicine, and pediatric medicine staff in your facility.

November 12, 2025

- See below for a New York State Department of Health (NYSDOH) advisory regarding a recent recall of ByHeart brand powdered infant formula related to infant botulism.
  - Providers should advise families to not use any infant formula from this brand while the investigation is ongoing.
- In New York City, providers should immediately call the NYC Health Department's Provider Access Line at 866-692-3641 with any suspected cases of infant botulism.
  - NYC Health Department staff will provide clinical consultation and arrange clinical botulism testing with the NYC Public Health Laboratory, as appropriate.
  - Environmental botulism testing (i.e., testing samples of formula) will be referred to NYSDOH.

KATHY HOCHUL
Governor

JAMES V. McDONALD, MD, MPH
Commissioner

JOHANNE E. MORNE, MS
Executive Deputy Commissioner

November 11, 2025

TO: **Healthcare Providers, Hospitals, and Local Health Departments (LHDs)**

FROM: **New York State Department of Health (NYSDOH)**
Bureau of Communicable Disease Control (BCDC) and Bureau of Community Environmental Health and Food Protection (BCEHFP)

UPDATED HEALTH ADVISORY: RECALL OF INFANT FORMULA RELATED TO BOTULISM TYPE A OUTBREAK

Please distribute to the Infection Control Department, Emergency Department, Infectious Disease Department, Obstetrics/Gynecology (including Nurse Practitioners and Midwives), Family Medicine, Pediatrics, Director of Nursing, Medical Director, Laboratory Service, Pharmacy, and all patient care areas.

SUMMARY

- **Update: ALL lots of infant formula from ByHeart, in all sizes of cannisters and pouches, have been recalled.**
- Since August, 15 cases of infant botulism in infants who consumed ByHeart brand infant formula have been reported to the Centers for Disease Control and Prevention (CDC) from 12 states. Nine of the cases have been confirmed by testing that showed botulinum toxin type A.
- FDA issued communications about a recall of all lots of infant formula from ByHeart, in all sizes of cannisters and pouches. The link to the recall, which includes photos of products, is: https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025.
- Infants should **not** be fed the recalled formula. If parents and caregivers still have ByHeart product, they should:
  - take a photo or record the information on the bottom of the package.
  - keep the container in a safe spot and be sure to label that product as DO NOT USE.
  - If the child develops symptoms, the product might be needed for testing. If the child does not develop symptoms after 30 days, they should throw the containers out.
- **NYSDOH is asking providers to maintain heightened suspicion for the possibility of infant botulism in any infant presenting with compatible symptoms who was fed ByHeart infant formula.**
- **Additionally, 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.**
- Providers should report suspect botulism cases to the local health department of the patient's county of residence immediately.

BACKGROUND

Since August, 15 cases of infant botulism in infants who consumed ByHeart brand infant formula have been reported to CDC from 12 states. States reporting cases include Arizona, California, Illinois, Kentucky, Minnesota, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, and Washington. Cases range in age from 16 days old to several months old. So far, no deaths have been reported. Cases have been reported from August through the present. Among cases with confirmatory testing, 9 have been confirmed with testing showing botulinum toxin type A. Testing is pending for the remaining cases. No cases have been identified in NYS to date.

ByHeart is a small producer of infant formula. Their product is distributed throughout the United States. This firm has a low market share compared to other manufacturers. The high number of infant botulism cases reporting use of this brand is highly unusual and represents a significant epidemiological signal. Preliminary test results have detected *C. botulinum* spores in ByHeart powdered formula.

FDA has issued communications about a recall of all lots of ByHeart infant formula. The link to the recall, which includes photos of products, is: https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025.

Infants should **not** be fed the recalled formula. If parents and caregivers still have ByHeart product, they should:

- take a photo or record the information on the bottom of the package.

- keep the container in a safe spot and be sure to label that product as DO NOT USE.
- If the child develops symptoms, the product might be needed for testing. If the child does not develop symptoms after 30 days, they should throw the containers out.

NYSDOH is asking providers to maintain heightened suspicion for the possibility of infant botulism in any infant presenting with compatible symptoms who was fed ByHeart infant formula. Additionally, 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: https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html.

CLINICAL PRESENTATION

Infant botulism is the most common type of botulism in the United States. Symptoms usually present in children less than twelve months of age and include constipation, loss of appetite, weakness, poor suck, ocular palsies, an altered cry, and a striking loss of head control. Progression of symptoms is more severe in infants under two months of age. Infants become infected by ingestion of *C. botulinum* spores that germinate in the colon, rather than ingestion of preformed toxin. It can take up to 30 days from the date of exposure to develop signs and symptoms.

REPORTING CASES OF BOTULISM

Reporting of suspected or confirmed botulism is mandated under the New York State Sanitary Code (10NYCRR 2.10 and 2.14). All physicians, nurses, laboratory directors, infection control practitioners, health care facilities, state institutions, and schools should report to the local health department where the patient resides. The diagnosis of botulism warrants prompt action, and cases should be reported immediately to the appropriate local health department.

The local health department should immediately call the NYSDOH Regional Epidemiologist, or the NYSDOH Central Office Bureau of Communicable Disease Control if the NYSDOH Regional Epidemiologist is unavailable, to report any suspect case of botulism. The local health department will ensure that the attending physician of the case patient participates on a joint call with NYSDOH, and possibly CDC, to discuss the patient's clinical progression, testing requested, and testing results.

Information learned from the call will be used to determine whether botulism is high on the differential diagnosis, if testing will be approved at Wadsworth Center, and whether antitoxin will be released. If testing is approved at Wadsworth Center, the local health department will facilitate the collection and submission of specimens in a timely manner to the laboratory.

If infant botulism is suspected, the local health department should immediately provide the attending physician with the number of the California Department of Health for consultation and possible release of the infant antitoxin. The number (staffed 24 hours per day, 7 days per week) is 510-231-7600.

Provider reporting requirements also apply to patients who are diagnosed and treated based solely or in part on clinical presentation and history.

SPECIMEN COLLECTION AND REFERRAL FOR TESTING

Wadsworth Center's specimen collection and shipping guidelines are provided in the table below:

Wadsworth Center Specimen Collection & Shipping Guidelines: Botulism				
Population	**Infant**		**Adult**	
Specimen	Rectal swab	Enema wash	Stool	Serum
Amount	1-2 swabs	≥ 5 ml	≥ 10 grams, unpreserved	≥ 5 ml
Test Type	PCR, culture, and MALDI-TOF MS		PCR, culture, and MALDI-TOF MS	MALDI-TOF MS
Collection Instructions	Place swab into a sterile container. Store refrigerated at 2-8ºC.	Use a wide mouth, sterile leak-proof container. Store refrigerated at 2-8ºC.		Collect blood in a red top/SST or equivalent tube. Allow specimens to clot at room temperature, centrifuge and transfer serum into plastic tube(s). Store refrigerated at 2-8ºC.
Shipping Guidelines	Ship on freezer packs. Specimens must be shipped "Priority Overnight" and received within 24 hours via chosen carrier.			
Performing Lab	Biodefense			
Special Requirements	If botulism is suspected, STOP work, and immediately retain and secure all specimens and derivatives. Testing requires prior WC Laboratory approval.			

If you have any questions regarding this information, please contact your LHD or the NYSDOH Bureau of Communicable Disease Control at (518) 473-4439 or via email at bcdc@health.ny.gov. Contact information for LHDs is available at Contact Your County Health Office - NYSACHO