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In reply, please refer to:
File:

November 10, 2025

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

- Since August, 13 cases of infant botulism in infants who consumed ByHeart brand powdered infant formula have been reported to the Centers for Disease Control and Prevention (CDC) from 10 states. Six of the cases have been confirmed by testing that showed botulinum toxin type A.
- FDA issued communications about a recall of two lots of powdered infant formula. The link to the recall 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. Parents and caregivers should throw affected product away immediately and, if a child has symptoms, should record the information on the bottom of the package before throwing it away.
- **DOH is asking providers to maintain heightened suspicion for the possibility of infant botulism in any infant presenting with compatible symptoms who was fed ByHeart powdered 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 urgently report suspected botulism at time of initial evaluation to DOH Disease Reporting Line (808) 586-4586.

Dear Healthcare Provider:

Since August of 2025, 13 cases of infant botulism have been reported in infants from 10 states who consumed ByHeart brand powdered infant formula. States reporting cases include Arizona, California, Illinois, Minnesota, New Jersey, Oregon, Pennsylvania, Rhode Island, Texas, and Washington. Cases have been reported from August 2025 through the present and range in age from 16 days old to several months old. No deaths have been reported. Among cases with confirmatory testing, six have been confirmed as botulinum toxin type A. Testing is pending for the remaining cases. To date, no cases have been identified in Hawaii.

ByHeart is a small producer of powdered infant formula with products distributed throughout the United States. This firm has a low powdered infant formula 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.

FDA has issued communications about a recall of two lots of ByHeart powdered infant formula. The link to the recall is: https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025.
Currently identified affected lots are:

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

Infants should **not** be fed the recalled formula. If unused, parents and caregivers should throw affected product away immediately. If a child has symptoms, parents should be instructed to record the information on the bottom of the package, place the lid on the container of formula, place in a zip lock bag and store product in safe secure location in case further testing is needed. Parents should thoroughly wash all bottle, nipples, anything used prepare to formula, and surfaces that may have been in contact with recalled formula with soap and hot water.

DOH is asking providers to maintain heightened suspicion for the possibility of infant botulism in any infant presenting with compatible symptoms who was fed ByHeart powdered 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 and Management

Infant botulism is the most common type of botulism in the United States. Infants become infected by ingestion of C. botulinum spores that germinate in the colon, rather than ingestion of preformed toxin. Illness can take up to 30 days from exposure to develop. Symptoms usually present in children less than twelve months of age and may include constipation, loss of appetite, weakness, poor suck, ocular palsies, an altered cry, and a striking loss of head control. Severe cases can lead to respiratory failure. Symptoms are progressive and generally start with the muscles innervated by the cranial nerves, followed by those of the trunk, extremities, and diaphragm. Progression of symptoms is more severe in infants under two months of age.

Infants who were fed ByHeart Formula with clinical symptoms suggestive of botulism should be hospitalized for neurologic evaluation, careful monitoring of their respiratory status, and supportive care.

Botulism immune globulin intravenous antitoxin (BIG-IV or BabyBIG), is a safe and effective therapy for infant botulism and should be administered as early as possible. Administration of Botulism immune globulin antitoxin should not be delayed while awaiting the results of confirmatory tests.

Botulism IG anti-toxin access is coordinated by the California Department of Health infant Botulism Treatment and Prevention Program (www.infantbotulism.org/). DOH can help with coordination of anti-toxin as needed.

Reporting Cases of Botulism

Reporting of suspected or confirmed botulism is mandated by Hawaii Administrative Rules Title 11 Chapter 156, Communicable Diseases. Suspicion of infantile botulism warrants prompt action, and cases should be reported immediately to DOH upon initial suspicion.by calling the Disease Reporting Line listed below. DOH will work with the care team 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. If testing is approved, DOH will facilitate the collection and submission of specimens for testing in a timely manner.

If infant botulism is suspected, DOH will connect the care team to the California Department of Health for consultation and release of the infant antitoxin. The number (staffed 24 hours per day, 7 days per week) is 510-231-7600.

Specimen Collection and Referral for Testing

The specimen required for the definitive diagnosis of infant botulism is stool or enema.

Fecal specimens for infant botulism diagnostic testing can be collected before or after antitoxin administration. Botulism IG anti-toxin does not neutralize botulinum toxin present in the lumen of the intestine, nor does it kill or prevent the growth of *C. botulinum* or inhibit the formation of botulinum toxin in the infant's large intestine. Therefore, fecal specimen testing is valid, even after antitoxin administration.

Clinical laboratories should contact DOH before specimen collection and submission. Specimens must arrive at CDC at the correct temperature and be received within 3 days of collection; otherwise, they will be rejected. Due to Hawai'i's unique shipping limitations, collection and shipment timing are restricted. It is therefore essential to coordinate closely with DOH before specimen collection.

Promptly refrigerate specimen after collection. Do not freeze or store at room temperatures.

The best container in which to collect, store and submit fecal specimens is a sterile urine container with a tight, screw-capped lid. ***Do not use*** containers containing fixatives or preservatives. If spontaneously passed stool is difficult to obtain due to constipation, an attempt to collect stool in the rectal vault should be made by ***gentle*** digital examination. If no stool can be obtained digitally, do not wait for a spontaneous bowel movement. Instead, please follow the

enema collection procedure outlined here. **Important**: *Glycerin suppositories yield an unsatisfactory specimen and **should not be** used.*

Immediately report to DOH at the time infantile botulism is suspected. **DO NOT WAIT** for laboratory results. Infantile botulism is an URGENT CATEGORY NOTIFIABLE CONDITION and should be reported by calling:

Oahu (Disease Reporting Line) .....(808) 586-4586
Maui District Health Office .....(808) 984-8213
Kauai District Health Office .....(808) 241-3563
Hawai‘i District Health Office (Hilo) .....(808) 933-0912
Hawai‘i District Health Office (Kona) .....(808) 322-4877
After hours on Oahu .....(808) 600-3625
After hours on neighbor islands .....(800) 360-2575 (toll free)

We appreciate your assistance in protecting the health of Hawai‘i’s residents and visitors.

Sincerely,

Sarah Kemble

Sarah Kemble, MD
State Epidemiologist

References:
Infant Botulism Outbreak Linked to Infant Formula, November 2025 | Botulism | CDC: https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html
Outbreak Investigation of Infant Botulism: Infant Formula (November 2025) | FDA : https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-infant-botulism-infant-formula-november-2025
Clinical Overview of Botulism | Botulism | CDC: https://www.cdc.gov/botulism/hcp/clinical-overview/index.html
Botulism | Disease Outbreak Control Division: https://health.hawaii.gov/docd/disease_listing/botulism/
Hawaii State Laboratories Division infant botulism testing guidance: https://health.hawaii.gov/statelab/files/2013/05/sld-bacti-sr-infant-bot.pdf
Submit a Specimen for Testing | Botulism | CDC: https://www.cdc.gov/botulism/php/submit-specimen/index.html
Specimen Collection | Infant Botulism Treatment and Prevention Program, California Department of Public Health: https://www.infantbotulism.org/laboratorian/collection.php