



This is an official  
MS Health Alert Network (HAN) - Advisory

**MESSAGE ID:** MSHAN-20251110-00606-ADV (Health Advisory)  
**RECIPIENTS:** All Physicians, Hospitals, ERs, ICPs, NPs, PAs, and Healthcare Providers –Statewide  
**Monday, November 10, 2025**  
**SUBJECT:** Recall of Infant Formula related to a Multistate Infant Botulism Outbreak

Dear Colleagues,

The Mississippi State Department of Health (MSDH) is alerting healthcare providers to a voluntary recall of ByHeart Whole Nutrition Infant Formula following reports of several infant botulism type A infections among infants who consumed the product between August 2025 to November 2025.

### Key Messages

- Infant botulism is an intestinal toxemia.
- As of November 8, 2025, 13 infant botulism illnesses have been reported to the Centers for Disease Control and Prevention (CDC) by 10 states (Arizona, California (2), Illinois (2), Minnesota, New Jersey, Oregon, Pennsylvania, Rhode Island, Texas (2), Washington).
- All 13 cases included in this outbreak are reported to have consumed ByHeart- brand powdered infant formula.
- No deaths have been reported at this time.
- FDA recommended a voluntary recall of ByHeart Whole Nutrition Infant formula.
- Officials in several states have collected leftover infant formula for testing. This testing is underway, and results are not yet available but expected in the coming weeks.
- Since July 2025, four cases of infant botulism have been reported to MSDH.
  - None have noted consumption of ByHeart- brand powdered infant formula.
  - At this time, no known commonalities have been identified in the reported Mississippi infant botulism cases.
  - All four Mississippi cases have survived.
- Mississippi physicians/clinicians must report any **suspected** cases of botulism to the Mississippi State Department of Health by phone within 24 hours of first knowledge or suspicion.
  - Reporting Hotline: 1-800-556-0003 (Monday – Friday, 8am – 5pm)
  - After-hours, weekends, holidays: 601-576-7400



## **Current Situation**

CDC and public health officials in several states, the Infant Botulism Treatment and Prevention Program, and FDA are investigating a multistate outbreak of 13 infant botulism cases from 10 states (Arizona, California (2), Illinois (2), Minnesota, New Jersey, Oregon, Pennsylvania, Rhode Island, Texas (2), Washington) linked to recalled infant formula. The infections occurred between August 2025 and November 2025. All 13 cases were hospitalized, and no deaths have been reported.

Epidemiologic data show that ByHeart Whole Nutrition infant formula might be contaminated with *Clostridium botulinum* and has made infants sick. Officials in several states have collected leftover infant formula for testing. This testing is underway, and results are not yet available but expected in the coming weeks.

On November 8, 2025, ByHeart Inc. recalled two lots of Whole Nutrition Infant Formula (Lot: 206VABP/251261P2 and Lot: 206VABP/251131P2) that were reported to have been consumed by the infants. FDA is continuing to work with the firm to ensure all potentially impacted product is removed from the market.

ByHeart Whole Nutrition Infant Formula is available for sale online and at major retailers nationwide. FDA reports that ByHeart Whole Nutrition Infant Formula makes up an estimated 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.

Since July 2025, four infant botulism cases have been reported to MSDH. To date, none have noted consumption of ByHeart- brand powdered infant formula, and no known commonalities have been identified. All four cases have survived.

## **Clinical Presentation and Treatment**

Infant botulism is an intestinal toxemia, primarily affects infants under 1 year of age, and is initially diagnosed based on clinical symptoms. It occurs after spores of the bacterium *Clostridium botulinum* or related species are swallowed. These spores temporarily colonize an infant's large intestine and produce botulinum neurotoxin.

Patients with infant botulism may present with some or all the following signs and symptoms: constipation, weaker suck or poor feeding, ptosis (drooping eyelid), sluggish pupils, flattened facial expression, diminished gag reflexes, weak and altered cry, weakness or decreased muscle tone, especially starting at the top of their body and limbs, and respiratory difficulty and possibly respiratory arrest. Infants may also experience bowel movement changes, like not pooping for days or even weeks at a time. It can take up to 30 days from the date of exposure to develop signs and symptoms. Treatment with BabyBIG® is recommended for all suspected cases of infant botulism.

## **Reporting Requirements, Specimen Collection, and Recommendations**

If you suspect your infant patient has infant botulism, perform the following:

- Immediately call the [Infant Botulism Treatment and Prevention Program](#) (IBTPP) on-call physician at 510-231-7600 for a no-cost 24/7 case consultation.
- The physician will release [BabyBIG](#) treatment if the patient's clinical findings indicate infant botulism.



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- If clinical consultation supports infant botulism, begin treatment with BabyBIG as soon as it is available. **Do not wait** for laboratory confirmation to begin treatment.
- Notify MSDH by phone **within 24 hours of first knowledge or suspicion** at 1-800-556-0003 (Monday – Friday, 8am – 5pm) and after-hours, weekends, holidays at 601-576-7400.

A stool or enema specimen is required for definitive diagnosis of infant botulism. Enemas should be performed with sterile, non-bacteriostatic water. Healthcare providers will need to coordinate with MSDH for sample submission for infant botulism testing.

Healthcare providers should remain vigilant for infant patients who present with symptoms consistent with infant botulism. If the infant's parents/guardians mention use of ByHeart Whole Nutrition Infant Formula, healthcare providers should recommend that the recalled formula not be used. Additionally, recommend that the infant's parents/guardians wash items and surfaces that may have touched the recalled formula using hot soapy water or a dishwasher.

**Additional Resources**

- Infant Botulism Outbreak Linked to Infant Formula, November 2025: <https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/index.html>
- 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>
- Clinical Overview of Infant Botulism: [https://www.cdc.gov/botulism/hcp/clinical-overview/infant-botulism.html#cdc\\_clinical\\_overview\\_clin\\_fea-signs-and-symptoms](https://www.cdc.gov/botulism/hcp/clinical-overview/infant-botulism.html#cdc_clinical_overview_clin_fea-signs-and-symptoms)

Regards,

Renia Dotson, MD FACS MPH MBA  
State Epidemiologist



### *Alerting Message Specification Settings*

**Originating Agency:** Mississippi State Department of  
**Health Alerting Program:** **MS Health Alert Network (MS HAN)**  
**Message Identifier:** MSHAN-20251110-00606-**ADV**  
**Program (HAN) Type:** **Health Alert Advisory**  
**Status (Type):** Actual ()  
**Message Type:** Advisory  
**Reference:** MSHAN-00606  
**Severity:** Unknown  
**Acknowledgement:** No  
**Sensitive:** Not Sensitive  
**Message Expiration:** Undetermined  
**Urgency:** Undetermined  
**Delivery Time:** 600 minutes

### *Definition of Alerting Vocabulary and Message Specification Settings*

**Originating Agency:** A unique identifier for the agency originating the alert.

**Alerting Program:** The program sending the alert or engaging in alerts and communications using PHIN Communication and Alerting (PCA) as a vehicle for their delivery.

**Message Identifier:** A unique alert identifier that is generated upon alert activation (MSHAN-yyymmdd-hhmm-TTT (**ALT=Health Alert**, **ADV=Health Advisory**, **UPD=Health Update**, **MSG/INFO=Message/Info Service**)).

**Program (HAN) Type:** Categories of Health Alert Messages.

**Health **Alert**:** Conveys the highest level of importance; warrants immediate action or attention.

**Health **Advisory**:** Provides important information for a specific incident or situation; may not require immediate action.

**Health **Update**:** Provides updated information regarding an incident or situation; unlikely to require immediate action.

**Health **Info Service**:** Provides Message / Notification of general public health information; unlikely to require immediate action.

**Status (Type):**

|           |                                                                                         |
|-----------|-----------------------------------------------------------------------------------------|
| Actual:   | Communication or alert refers to a live event                                           |
| Exercise: | Designated recipients must respond to the communication or alert                        |
| Test:     | Communication or alert is related to a technical, system test and should be disregarded |

**Message Type:**

|         |                                                          |
|---------|----------------------------------------------------------|
| Alert:  | Indicates an original Alert                              |
| Update: | Indicates prior alert has been Updated and/or superseded |

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**Reference:** For a communication or alert with a Message Type of “Update” or “Cancel”, this attribute contains the unique Message Identifier of the original communication or alert being updated or cancelled. “n/a” = Not Applicable.

**Severity:**

Extreme: Extraordinary threat to life or property  
Severe: Significant threat to life or property  
Moderate: Possible threat to life or property  
Minor: Minimal threat to life or property  
Unknown: Unknown threat to life or property

**Acknowledgement:** Indicates whether an acknowledgement on the part of the recipient is required to confirm that the alert was received, and the timeframe in which a response is required (Yes or No).

**Sensitive:**

Sensitive: Indicates the alert contains sensitive content  
Not Sensitive: Indicates non-sensitive content

**Message Expiration:** Undetermined.

**Urgency:** Undetermined. Responsive action should be taken immediately.

**Delivery Time:** Indicates the timeframe for delivery of the alert (15, 60, 1440, 4320 minutes (.25, 1, 24, 72 hours)).