

***Update: IDPH urges halting use of ALL Byheart infant formula until further notice after two Illinois infants, 15 cases nationwide, show symptoms consistent with botulism***

### Summary and Action Items

1. Yesterday (November 11<sup>th</sup>) **all lots and sizes** of ByHeart Whole Nutrition infant formula were recalled after CDC and FDA investigation.
2. IDPH urges parents and guardians to avoid using all lots and sizes of ByHeart infant formula till further notice. No ByHeart products should remain for sale.
3. One of Illinois' two previously reported symptomatic cases has been confirmed by testing positive for infant botulism type A. Both Illinois cases had onset of symptoms consistent with botulism after consuming ByHeart powdered infant formula
4. Clinicians who suspect infant botulism should immediately call 510-231-7600 for case consultation (consultation is available 24/7), obtain information related to infant formula use and notify [their local health department](#) immediately. Clinical consultation is necessary to access treatment with BabyBIG and testing through the public health lab.

### Background

ByHeart infant formula has been linked to suspected cases of botulism in two Illinois infants. Nationwide, a total of 15 infants from 12 states have been linked to consumption of ByHeart formula. All have been hospitalized and treated with BabyBIG. No deaths have been reported as of November 11<sup>th</sup>. Illness onset information available for 14 of the 15 cases range from August 9 to November 10, 2025. Ages range from 16 to 157 days.

Botulism is an illness caused by a bacterial toxin, which can produce life-threatening symptoms. Botulism can be in foods that look and taste normal, which means consumers cannot inspect food on their own for botulism safety. Infant botulism happens when a baby swallows *Clostridium botulinum* spores that then grow in the gut and make 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.

Parents and caregivers have reported feeding infants in this outbreak lots of ByHeart infant formula included in the company's recall on November 8, 2025. On November 11, 2025, ByHeart Inc. expanded the recall to include all ByHeart Whole Nutrition infant formula products due to concern that other lots of ByHeart Whole Nutrition infant formula may be contaminated and are making infants sick with infant botulism.

Preliminary laboratory results reported by the California Department of Public Health suggest the presence of the bacteria that produce botulinum toxin in an open can of ByHeart infant formula (lot 206VABP/251131P2) that was fed to an infant with infant botulism. Additional product testing by Illinois, CDC, and FDA is ongoing with results expected in the coming weeks.

## Illinois Department of Public Health

## Symptoms of Infant Botulism

- Most infants with infant botulism will initially develop constipation, poor feeding, loss of head control, and difficulty swallowing.
- If untreated, infants with infant botulism experience a progressive, flaccid paralysis that can lead to breathing difficulties and require weeks of hospitalization.
- Treatment with BabyBIG® is recommended for all suspected cases of infant botulism.

## Guidance for Clinicians

### Diagnosis:

- Initial diagnosis of infant botulism is based on [clinical symptoms](#).
- If you suspect your infant patient has botulism, immediately call 510-231-7600 for case consultation. Consultation is available 24/7.
- You will reach the on-call physician at the [Infant Botulism Treatment and Prevention Program \(IBTPP\)](#) at the California Department of Public Health.
- The physician will provide a no-cost clinical consultation and release [BabyBIG](#) treatment if the patient's clinical findings indicate infant botulism.

### Treatment:

- If clinical consultation supports infant botulism, treatment should begin as soon as possible. Do not wait for laboratory confirmation.
- Infant botulism is treated with BabyBIG which is available through IBTPP.

### Laboratory Testing:

- Laboratory testing CANNOT be requested unless IBTPP has released BabyBIG for the infant. **Please do not directly contact the IDPH State Laboratory to inquire about testing.**
- Serum is generally not useful in the diagnosis of infant botulism but if collected, must be done prior to the administration of anti-toxin.
- A stool or enema specimen is required for definitive diagnosis of infant botulism. Enemas should be performed with sterile, non-bacteriostatic water. Guidance on performing and collecting and an enema specimen can be found [here](#). Stool and enema samples may be collected prior to or after the administration of anti-toxin. Testing is performed at the Ohio Department of Health. Guidance on specimen collection and shipment can be found [here](#). ALL specimens must be shipped through an IDPH Public Health Laboratory.
- This specialized testing often takes several days to complete and treatment should not be withheld pending suspected cases.
- Product testing is only performed on formula collected from infants that receive BabyBIG, the treatment for botulism, after a consultation with IBTPP.

### Notification:

- Report suspect cases to your [local health department](#) or IDPH immediately.

## Guidance for Parents/Guardians

- **Do not use recalled infant formula.** If you can safely retain the product, write DO NOT USE on the container and save it for 30 days. If you cannot safely store it and/or after the 30-day monitoring period has ended, dispose of the unused formula in the garbage with DO NOT USE promptly marked on the container. Be sure to document the lot number by writing it down or taking a photo before disposing of the product. You can also return the formula to the store where you bought it.

- **Wash items and surfaces** that may have touched the recalled formula using hot soapy water or in a dishwasher.
- Monitor your baby for 30 days from the last date they were fed ByHeart formula. Contact your physician if you have questions. Symptoms of infant botulism can take as long as several weeks to develop, so parents should remain vigilant if they used ByHeart Whole Nutrition infant formula.
- **Seek immediate health care** if your 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
- **Unfortunately, testing is not possible to screen infants for the disease nor is testing available of unused product unless infant botulism is suspected.**

### Guidance for Businesses

- **Do not sell or use recalled infant formula.**
- **Wash and sanitize items and surfaces** that may have touched recalled formula.

### Guidance for Local Health Departments

- Report any suspect cases to IDPH immediately.
- Working with IDPH Environmental Health, ensure ByHeart products are no longer being sold at retail sites.
- Provide guidance to providers and parents/guardians as detailed in this Health Alert.
- Provide additional guidance and communication to providers and residents as needed.

### Contact

Additional questions about this recall please contact the Communicable Disease Section at (217) 782-2016.

### Target Audience

Infectious Disease Physicians, Family Practice and Internal Medicine Physicians, Pediatricians, Nurse Practitioners, Physician Assistants, Hospital Emergency Departments, Infection Control Preventionists, Local Health Departments, Schools, and Daycares

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### Author

Communicable Disease Control Section