

To: Vermont Health Care Providers, Health Care Facilities and Laboratories
Date: November 14, 2025
From: Laura Ann Nicolai, MPH, Deputy State Epidemiologist

Infant Botulism Outbreak Linked to Infant Formula

Summary

CDC, public health officials in several states, and the U.S. Food and Drug Administration are investigating a multistate outbreak of infant botulism linked to ByHeart Whole Nutrition infant formula. Infant botulism occurs when swallowed *Clostridium botulinum* spores germinate in an infant's large intestine and produce 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.

FDA has [recalled](#) all ByHeart Whole Nutrition Infant Formula products, including unexpired lots of formula cans and single-serve "anywhere" sticks. Parents and caregivers should discard all affected products immediately and, if a child has symptoms, should record the information from the bottom of the package before throwing it away.

The Health Department 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.

Requested Actions

- Consider infant botulism based on clinical symptoms: initial constipation followed by difficulty feeding (sucking and swallowing), a weak and altered cry, and lack of head control.
- Call the California Infant Botulism Treatment and Prevention Program immediately at 510-231-7600 for no-cost clinical consultation of suspect cases. Consultation is available 24/7.
- Begin treatment with BabyBIG® (obtained from California Department of Health) as soon as possible if clinical consultation supports infant botulism. Do not wait for laboratory confirmation.
- Report all suspect cases to the Vermont Department of Health by phone immediately at 802-863-7240, option 2 (available 24/7).

You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail address or fax number that you would like us to use, please contact your Health Alert Network (HAN) Coordinator at: ythan@vermont.gov.

- Contact the Health Department to get testing approval, then send clinical specimens directly to CDC for testing.
- Additionally, providers should ask which formula brand is fed to their infant patients, alert parents/guardians about the ByHeart recall, and ensure recalled formula is not used.

Background

As of November 10, 2025, 15 cases of infant botulism in infants who consumed ByHeart brand powdered infant formula have been reported to CDC from [12 states](#). All 15 infants were hospitalized and treated with BabyBIG®. So far, no deaths have been reported. Cases have been reported from August through the present, and the impacted infants range in age from 16 days to several months old. No cases have been identified in Vermont to date.

ByHeart is a small producer of powdered infant formula. Their product is distributed throughout the United States and is available for sale online and at major retailers nationwide. This company 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.

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.

Specimen Collection and Referral for Testing

If clinical consultation supports infant botulism, begin treatment with BabyBIG® as soon as possible. Do not wait for laboratory confirmation. While providing a definitive diagnosis, testing turnaround times can be as long as 12 weeks. Contact the Health Department at 802-863-7240, option 2 (available 24/7) for testing approval prior to sending clinical specimens directly to the CDC for testing.

You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail address or fax number that you would like us to use, please contact your Health Alert Network (HAN) Coordinator at: ythan@vermont.gov.

Raw Stool

- Stool is the preferred specimen for infants.
- Ideally, collect before treatment with BabyBIG or Botulism Antitoxin.
- Collect ≥ 10 g, if possible (a minimum of 0.5-1.0 g may be tested). Use a wide mouth, sterile leak-proof container. Store refrigerated at 2-8° C.
- Ship stool within two days of collection.

Enema Wash

- Enemas may be tested only if they are obtained using non-bacteriostatic water.
- Collect ≥ 5 mL. Use a wide mouth, sterile leak-proof container. Store refrigerated at 2-8° C.

Additional Resources

- [Infant Botulism Treatment and Prevention Program](#) - California Department of Public Health
- [Outbreak Investigation of Infant Botulism: Infant Formula](#) - FDA (November 2025)
- [Infant Botulism Outbreak Linked to Infant Formula](#) - CDC (November 2025)
- [Clinical Overview of Infant Botulism](#) - CDC
- [Clinical Guidelines for Diagnosis and Treatment of Botulism, 2021](#) - CDC MMWR
- [Specimen Submission Form and Guidance](#) - CDC

If you have any questions, please contact Laura Ann Nicolai at:
lauraann.nicolai@vermont.gov

To have your information updated please email the
Vermont HAN Coordinator at: ythan@vermont.gov.

HAN Message Type Definitions

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.

You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail address or fax number that you would like us to use, please contact your Health Alert Network (HAN) Coordinator at: ythan@vermont.gov.

Health Advisory
November 14, 2025

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

Info Service Message: Provides general correspondence from the Vermont Department of Health, which is not necessarily considered to be of an emergent nature.

You have received this message based upon the information contained within our emergency notification data base. If you have a different or additional e-mail address or fax number that you would like us to use, please contact your Health Alert Network (HAN) Coordinator at: ythan@vermont.gov.
