

Hot Tips: Public Health Advisory #150 Date: 11/14/2025

Please copy and distribute to ALL physicians at your location.

Multistate Outbreak of Infant Botulism Linked to ByHeart Infant Formula

Key Messages

- The California Department of Public Health (CDPH) has issued a [health advisory](#) to inform healthcare providers about a multistate outbreak of infant botulism linked to infant formula.
- A total of 23 cases of infant botulism have been identified and linked to this outbreak across 13 states, including California.
- All cases reported consumption of ByHeart Whole Nutrition infant formula prior to their illness, and laboratory testing has confirmed the presence of *C. Botulinum* Type A spores in a sample of the powdered infant formula.
- On November 11, 2025, ByHeart, Inc. expanded their initial voluntary recall to include all ByHeart formula sold nationwide.
- Providers should inquire about the use of ByHeart Whole Nutrition infant formula in any suspected cases of infant botulism. **If infant botulism is suspected, providers are urged to consult with the CDPH Infant Botulism and Prevention Program (IBTPP) immediately by calling 510-231-7600. Consultation is available 24/7. Suspected cases of infant botulism must also be reported immediately to Ventura County Public Health by calling 805-981-5201.**

Situation

The California Department of Health, in collaboration with the CDC and FDA, is investigating a multistate outbreak of infant botulism associated with ByHeart Whole Nutrition infant formula. As of November 14, 2025, 23 cases have been reported across 13 states, including 3 in California. All cases were hospitalized and treated with BabyBIG®. Illness onset dates range from mid-August to present, with patient ages ranging from 2 weeks to 6 months old.

All affected infants reported use of ByHeart formula prior to their illness. The product is sold online and at major retailers nationwide. Following an initial recall of specific lots, ByHeart, Inc. expanded its voluntary recall to include all batches of product sold by their company, to include cans as well as single serve packets of infant formula. Federal, state, and local agency officials are partnering to ensure that all potentially impacted products are removed from the market nationwide. Our local Environmental Health Division contacted market retailers in our county as soon as the alert came out, to make sure they have removed the item.

Parents and caregivers are urged to immediately discontinue use of any ByHeart formula, and to monitor their children closely for signs/symptoms of illness for 30 days after they last drank ByHeart formula. Medical care should be sought immediately if an infant consumed ByHeart formula within the past 30 days and develops

any of the following: constipation, poor feeding, difficulty swallowing, weaker facial expressions, or loss of head control.

Background

Infant botulism is considered an intestinal toxemia, which is caused by ingestion of *Clostridium botulinum* spores that temporarily colonize the large intestine and produce botulinum neurotoxin. This can result in bulbar palsies, hypotonia, or symmetric, descending, flaccid paralysis. The following signs or symptoms may be present in patients with infant botulism:

- Constipation
- Poor feeding
- Ptosis
- Sluggish pupils
- Flattened facial expression
- Diminished suck and gag reflexes
- Weak and altered cry
- Respiratory difficulty and possibly respiratory arrest

What providers should know:

- Maintain a high index of suspicion for infant botulism and ask parents or caregivers of suspected cases about potential use of ByHeart Whole Nutrition infant formula.
 - o Parents and caregivers should also be urged to immediately discontinue use of the formula and discard any unopened product, while retaining any open containers along with lot numbers and expiration dates of any infant formula that was consumed by their child.
- If infant botulism is suspected, providers should consult with experts at the CDPH Infant Botulism Treatment and Prevention Program (IBTPP) immediately at 510-231-7600. Consultation is available 24/7.
 - o Experts at the IBTPP will provide guidance to determine whether a diagnosis of infant botulism is supported, and details on how to secure immediate treatment with BabyBIG®.
 - o Treatment should not be delayed while awaiting laboratory confirmation.
 - o Testing guidance would be provided by IBTPP staff as indicated and would be coordinated in conjunction with Ventura County Public Health once approval has been obtained from the state.
- All suspected cases of infant botulism should also be reported immediately to Ventura County Public Health by calling 805-981-5201.

Resources

- [CDPH Infant Botulism Treatment and Prevention Program](#)
- [Infant Botulism Outbreak Linked to Infant Formula, November 2025 | Botulism | CDC](#)
- [Outbreak Investigation of Infant Botulism: Infant Formula \(November 2025\) | FDA](#)
- [Clinical Overview of Infant Botulism | Botulism | CDC](#)

This bulletin is intended to improve the public health in our county by keeping physicians and nurses informed of noteworthy diagnoses, disease trends, and other events of medical interest. Another goal of a public health department is to educate. We hope that you will use this information to increase your awareness. Please allow us to continue in our role of speaking to the press so that we may maximize the educational message to the benefit of all citizens of Ventura County.