



WASHINGTON STATE DEPARTMENT OF HEALTH

Provider Alert

Provider Alert: Infant Botulism Associated with ByHeart Infant Formula

Date: November 11, 2025

This is a Provider Alert from the Washington State Department of Health (WA DOH) regarding multiple cases of infant botulism after consuming ByHeart Whole Nutrition Infant Formula.

Current Situation

On November 8th, 2025, [the Centers for Disease Control and Prevention \(CDC\) announced an outbreak of infant botulism linked to infant formula](#). Since August 2025, at least 15 cases have been since identified in 12 states, including one case in an infant who resided in Washington at the time of exposure. Although infant botulism is potentially fatal, no deaths have been reported at this time; several cases remain hospitalized.

The [Food and Drug Administration \(FDA\) announced a recall of the formula](#), sold under the name **ByHeart Whole Nutrition Infant Formula**. Initially, only two lots of formula were involved in the recall; on November 11, 2025, the FDA announced that ALL lots of ByHeart Whole Nutrition Infant Formula sold in 24oz cans and 0.6oz "anywhere" single-serving packets are recalled.

Actions Requested

Providers in Washington are requested to do the following:

- **Be alert for infants presenting with [symptoms consistent with infant botulism](#).**
Symptoms can include:
 - Constipation
 - Poor feeding; Diminished suck and gag reflexes
 - Ptosis/Drooping eyelids; Altered/blunted facial expression
 - Decreased pupillary reaction or dilated pupils
 - Weak or altered cry
 - Poor head control
 - Hypotonia and generalized weakness
 - If left untreated: Symmetric, descending flaccid paralysis

- Providers who suspect an infant patient may have symptoms of botulism should **immediately** contact [the California Department of Public Health Infant Botulism Treatment and Prevention Program](#) (IBTPP) at **(510) 231-7600** for clinical consultation.
 - Consultation is available 24 hours a day, 7 days a week.
 - The IBTPP serves the entire country and provides clinical consultation as well as access to treatment for **infant botulism**.
 - The IBTPP provides access to treatment for Infant Botulism - **Botulism Immune Globulin Intravenous (Human) (BIG-IV), known as BabyBIG®**
 - For suspected cases of botulism in ADULTS, please call your [Local Health Jurisdiction](#) in Washington State.
- If clinical consultation supports infant botulism, **begin treatment with BabyBIG® as soon as possible**. Do not wait for laboratory confirmation.
 - Administering BabyBIG® will prevent progression of paralysis, but it will not reverse symptoms.
- **Infant botulism (as well as other types of botulism) is a [Notifiable Condition in Washington State](#).**
 - Report cases of suspected botulism to the [Local Health Jurisdiction](#) where the patient resides.
- **Clinical specimen testing for infant patients with suspected infant botulism is available via the WA DOH Public Health Laboratories.**
 - Testing can be arranged at WA DOH for infants that are being treated for suspected infant botulism.
 - Work with your [Local Health Jurisdiction](#) and WA DOH to arrange testing.
 - Collect a stool or enema specimen following [specimen collection and transport guidance from the Washington Public Health Laboratories](#).
- **Parents/guardians whose infants consumed the product should be advised of the following:**
 - Seek healthcare **immediately** if their infant develops symptoms of infant botulism.
 - Immediately stop using ByHeart Whole Nutrition Infant Formula, including unopened 24oz cans and 0.6oz single-serving packets.
 - **Discard opened and unopened formula.**
 - If possible, record (photograph or write down) the lot numbers of OPENED formula that their infant(s) have consumed before discarding.
 - **Wash items and surfaces that may have touched the recalled formula** using hot soapy water or a dishwasher.
 - Clinical testing of infants who have used this formula but are NOT symptomatic is not currently recommended; Instead, encourage parents to carefully watch their infants for symptoms.
 - Symptoms of infant botulism can take several weeks to develop, so **advise parents to remain vigilant for symptoms if their infant has consumed this formula.**

Background

Infant botulism is a novel form of human botulism in which ingested spores of the *Clostridium botulinum* bacteria colonize and grow in an infant's large intestine. *C. botulinum* produces a neurotoxin. The action of this toxin in the body produces constipation, weakness (notably of gag, cry, suck and swallow), and loss of muscle tone. If left untreated, symptoms will progress to a symmetric, descending flaccid paralysis, respiratory distress, and possibly death.

Affected infants have difficulty feeding, and often, breathing. However, in the absence of complications, patients recover completely from the disease.

Washington has an average of four cases of infant botulism annually. Most affected infants are six months or younger, although cases can occur until the first birthday. Spores are widely distributed in the environment and specific exposures are rarely identified. Since honey can contain the spores, it should not be given to infants.

Administering Botulism Immune Globulin Intravenous (Human) (BIG-IV), also known as BabyBIG[®] will prevent symptom progression but does not reverse existing symptoms of botulism toxin. Prompt administration of BabyBIG[®] can prevent intubation and avoid extended hospitalization. Additional treatment is supportive including nutritional and respiratory support as needed.

Resources

For more information about the outbreak and recall, please visit:

- [CDC Infant Botulism Outbreak Linked to Infant Formula, November 2025](#)
- [FDA Outbreak Investigation of Infant Botulism: Infant Formula \(November 2025\)](#)
- [CDPH Physical Examination for Infant Botulism](#)
- [CDPH Infant Botulism Treatment and Prevention Program](#)
- WA DOH Outbreak Page: [2025 Infant Botulism Outbreak Linked to Infant Formula](#)

Contact

For clinical consultation related to a suspected case of infant botulism, **immediately** contact the [California Department of Public Health Infant Botulism Treatment and Prevention Program](#) (IBTPP) at **(510) 231-7600**.

To report suspected cases, or for any other questions, please contact your [Local Health Jurisdiction](#).