



TN Health Alert Network Communication:
Infant Botulism Illnesses Linked to Infant Formula
November 12, 2025

TO: Healthcare Providers, Hospitals, and Local Health Departments (LHDs)
FROM: Tennessee Department of Health (TDH)
Communicable and Environmental Diseases and Emergency Preparedness (CEDEP)

SUMMARY

The Tennessee Department of Health (TDH) is collaborating with the Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and multiple other states to investigate a rise in infant botulism cases among infants who consumed ByHeart powdered infant formula.

BACKGROUND

Since August 1st, 15 cases have been identified in 12 states, including Arizona, California, Illinois, Kentucky, Minnesota, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, and Washington. Cases range in age from 16-days-old to 5-months-old. No deaths have been reported. Nine of the cases have test-confirmed toxin type A infant botulism. Testing is pending on the remaining cases. No cases have been identified in Tennessee to date.

The FDA has issued a recall on **all** ByHeart Whole Nutrition Infant Formula products, including all unexpired lots of formula cans and single-serve “anywhere” sticks.

Infants should **not** be fed the recalled formula. Parents and caregivers should stop using and set aside any product immediately. If an infant develops symptoms, TDH may arrange for testing of the formula. TDH is asking clinicians to maintain heightened suspicion for infant botulism in any infant presenting with compatible symptoms who was fed ByHeart powdered infant formula. Additionally, providers should alert parents and caregivers to the ByHeart recall and ensure recalled formula is not used.

CLINICAL PRESENTATION

Infant botulism usually presents in children less than twelve-months-old, and includes constipation, poor feeding, difficulty swallowing, and loss of head control. This can progress to difficulty breathing and respiratory arrest. Infants under two-months-old are at the highest risk of progression to severe disease. Infection occurs after ingestion of *C. botulinum* spores, rather than preformed toxin. The time from ingestion to symptom presentation can be up to 30 days.

RECOMMENDATIONS FOR HEALTHCARE PROVIDERS

1. Maintain a high suspicion for botulism in infants who present with consistent signs and symptoms. If infant botulism is suspected, parents should be asked about feeding practices, including the brand of powdered formula used.
2. Contact the California [Infant Botulism Treatment & Prevention Program \(IBTPP\)](#) at 510-231-7600 (staffed 24/7) for consultation and possible release of infant antitoxin (Baby BIG).
3. Report suspected infant botulism illnesses to TDH at 615-741-7247.

FOR MORE INFORMATION

Additional information concerning reporting requirements, general information, and the FDA recall can be found at the below links.

- [TN Disease Reporting](#)
- [FDA Recall](#)
- [CDC Updates](#)