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June 23, 2026

The Honorable Brett Guthrie, Chairman
The Honorable Frank Pallone, Jr., Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515

Re: Support for H.R. 7867, the Infant Formula Safety Modernization Act of 2026

Dear Chairman Guthrie, Ranking Member Pallone, and Members of the Committee:

I write in support of H.R. 7867, the Infant Formula Safety Modernization Act of 2026.

For more than thirty years — since the 1993 Jack in the Box *E. coli* outbreak — I have represented children and families sickened by food they trusted. I now represent babies who fell ill with botulism in the first few months of their lives because of tainted infant formula. The attachment to this letter contains their stories—of pain, survival, and preventable harm.

The hard arithmetic of my work is that reform rarely arrives until enough people are hurt to force it. The Jack in the Box tragedy[1] is what moved USDA to declare *E. coli* O157:H7 an adulterant in ground beef in 1994[2] — a single decision that has kept countless children out of hospital beds in the decades since.

This Committee has the same kind of window open right now to make infant formula safe, and this bill is the right response.

Two *botulism* outbreaks in seven months — and a longer pattern behind them

In November 2025, *Clostridium botulinum* in ByHeart Whole Nutrition Infant Formula — a whole-milk-powder product — was tied to an infant *botulism*[3] outbreak that ultimately sickened 48 infants across 17 states. Every infant was hospitalized. I represent more than twenty of those families. FDA's whole-genome sequencing matched the organism across a clinical isolate, a closed

[1] Over 600 sick, over 50 with acute kidney failure and four dead children.
[2] U.S. Dep't of Agriculture, Food Safety & Inspection Service, Risk Assessment of *E. coli* O157:H7 in Ground Beef ("In August 1994, FSIS declared E. coli an adulterant."), https://www.fsis.usda.gov/node/2003.
[3] Infant botulism is a rare but serious illness caused when spores of *Clostridium botulinum* grow in a baby's intestine and produce toxin that weakens muscles, https://www.cdph.ca.gov/Programs/cls/idld/ibtpp/Pages/InfantBotulism.aspx.

can of finished formula, and the incoming ingredient — organic whole milk powder. It also matched it to a Blendhouse facility tied to that supply chain that had already been flagged "Official Action Indicated," FDA's most serious inspection classification, before these babies were ever hurt.[4]

Seven months later it happened again. In June 2026, three more infants — in California, Pennsylvania, and Washington, all between two and five months old — were hospitalized with *botulism* and treated with BabyBIG antitoxin after consuming Nara Organics Whole Milk Organic Infant Formula, a product manufactured abroad and sold here through national retail.[5]

And these two outbreaks were not merely alike — they shared a common source. The whole milk behind the contaminated ByHeart formula and the whole milk behind the Nara formula came from the same supplier; one upstream source furnished both the fluid milk and the powdered milk that went into these products.[6] The contamination did not strike two unrelated companies by chance; it traveled through one shared supply stream that the system missed the first time and missed again — the clearest proof that the gap this bill closes sits upstream, at the milk and the plant, exactly where H.R. 7867 directs the testing.

A second *botulism* outbreak in the same year, in the same category of product, was foreseeable. We had just lived through the first and the system did nothing in between. The pattern is older still: we knew about *Cronobacter* bacteria for two decades before contamination at Abbott's Sturgis plant in 2022 took infant lives and triggered a national infant formula shortage.[7] The thread is not bad luck. It is a system that tests for too little, too late, and tells too few people when something goes wrong.

And these were not faraway statistics or someone else's constituents. The ByHeart outbreak reached infants in seventeen states — among them Arizona, California, Idaho, Illinois, Kentucky, Massachusetts, Michigan, Minnesota, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode

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[4] U.S. Food & Drug Admin., FDA's Actions to Respond to Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula (2026) (whole-genome sequencing linked the strain across the clinical isolate, finished formula, and the incoming whole milk powder), https://www.fda.gov/food/outbreaks-foodborne-illness/fdas-actions-respond-clostridium-botulinum-illnesses-associated-consumption-powdered-infant-formula. The case totals (48 infants in 17 states; 28 confirmed, 20 probable) and the "Official Action Indicated" designation — the agency's most serious inspection classification — are reflected in FDA's Outbreak Advisory and in the bill sponsor's summary, https://delauro.house.gov/media-center/press-releases/delauro-introduces-bipartisan-infant-formula-safety-modernization-act.

[5] U.S. Food & Drug Admin. & Centers for Disease Control & Prevention, investigation of infant botulism associated with Nara Organics Whole Milk Organic Infant Formula (June 2026); see also note 2, supra. Three infants in California, Pennsylvania, and Washington, ages two to five months, were hospitalized with type A botulism and treated with BabyBIG®.

[6] Helena Bottemiller Evich, *Federal Court Halts SNAP Restriction Pilots in Five States*, Food Fix (June 23, 2026) (reporting that the Nara Organics formula and the ByHeart formula shared the same whole milk supplier), https://foodfix.co/federal-court-halts-snap-restriction-pilots-in-five-states/.

[7] See Rep. Rosa DeLauro, DeLauro Introduces Bipartisan Infant Formula Safety Modernization Act (Mar. 2026) (Abbott Nutrition's Sturgis, Michigan facility, then responsible for roughly 40% of domestic formula production, shut down in 2022 following Cronobacter contamination, triggering a national shortage), https://delauro.house.gov/media-center/press-releases/delauro-introduces-bipartisan-infant-formula-safety-modernization-act.

Island, Texas, Virginia, Washington, and Wisconsin[8] — and the June 2026 Nara outbreak struck families in California, Pennsylvania, and Washington, each of them represented by a member of this Committee. The children paralyzed by contaminated infant formula are the children of the families you serve.

The hazard was on the government's own record — in writing — years in advance

On March 8, 2023 — two years before the first ByHeart baby became ill — the FDA sent a Call-to-Action letter to every manufacturer, packer, distributor, importer, and retailer of powdered infant formula in the country, signed by the Commissioner of Food and Drugs and the Director of the agency's food-safety center. It named the organism by genus and species, instructing the industry to account for the historical association between powdered infant formula and pathogens including *Cronobacter*, *Salmonella*, and *Clostridium botulinum* when designing safety controls[9].

In March 2025, under Operation Stork Speed,[10] FDA announced it would increase testing of formula and its ingredients for spore-forming contaminants — naming *C. botulinum* specifically — and by early 2026 it had opened a sampling assignment aimed at exactly the ingredients at issue: whole milk powder, nonfat dry milk, and whey.[11] The science is not obscure: *C. botulinum* is a spore-former whose spores survive ordinary pasteurization and spray-drying and live in soil and dust. That is precisely why the controls must start with the milk and the plant — upstream, where the spores enter — and cannot end with a reassuring number on a finished can.

Guidance has already been tried — and it failed twice.

The FDA named *botulism* in writing in 2023 and folded spore-forming pathogens into Operation Stork Speed in 2025, yet it never required anyone to test whole-milk-powder formula for *botulinum* before shipping it. Two outbreaks followed. The lesson is not that the agency needs another guidance letter or another voluntary initiative — either of which can be quietly shelved when budgets tighten or administrations change — but that the duty to test must be written into law, where it is durable and enforceable. Nor is the testing impractical: after these outbreaks,

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[8] The 48 infants in this outbreak were reported from 17 states: Arizona, California, Idaho, Illinois, Kentucky, Massachusetts, Michigan, Minnesota, New Jersey, North Carolina, Oregon, Pennsylvania, Rhode Island, Texas, Virginia, Washington, and Wisconsin. CDC, Investigation Update: Infant Botulism Outbreak (Feb. 26, 2026), https://www.cdc.gov/botulism/outbreaks-investigations/infant-formula-nov-2025/investigation.html.

[9] U.S. Food & Drug Admin., Letter to the Powdered Infant Formula Industry (Mar. 8, 2023) (signed by the Commissioner of Food and Drugs and the Director of the Center for Food Safety and Applied Nutrition; "Historical associations between powdered infant formula and pathogens such as Cronobacter spp., Salmonella, and Clostridium botulinum should be considered when designing and implementing controls"), https://www.fda.gov/media/166044/download; see also FDA, FDA Calls for Enhanced Safety Measures in Letter to Powdered Infant Formula Industry (Mar. 2023), https://www.fda.gov/food/hfp-constituent-updates/fda-calls-enhanced-safety-measures-letter-powdered-infant-formula-industry.

[10] U.S. Dep't of Health & Human Servs. & FDA, HHS, FDA Announce Operation Stork Speed (Mar. 18, 2025), https://www.fda.gov/news-events/press-announcements/hhs-fda-announce-operation-stork-speed-expand-options-safe-reliable-and-nutritious-infant-formula; see FDA, Operation Stork Speed, https://www.fda.gov/food/infant-formula-homepage/operation-stork-speed.

[11] U.S. Food & Drug Admin., FDA's Actions to Respond to Clostridium botulinum Illnesses… (note 2, supra) (FDA "initiated additional sampling of dairy-based ingredients, including whole milk powder, nonfat dry milk powder, and whey protein concentrate").

manufacturers began screening for spore-formers on their own. Nara itself quietly added "spore-forming organisms" to its published testing list after its recall. If industry can test for this hazard once babies are hurt, it can test for it before a single can ships. H.R. 7867 simply makes the timing mandatory rather than optional.

The economics favor this bill as strongly as the ethics do. A single dose of BabyBIG — the antitoxin that is the only treatment for infant botulism — costs $69,300[12] per dose (some need at least two) and every one of the 48 ByHeart and three Nara infants needed it. Add to that the intensive-care stays, the air-ambulance transports — one family in the appendix was flown by medevac from Idaho to a children's hospital in Utah — the months of feeding tubes and physical therapy, the nationwide recalls, the plant shutdowns, and the litigation that inevitably follows. Routine pathogen and environmental testing costs a small fraction of a single dose of the cure. This is the rare safety mandate that saves money — for families, for hospitals, for insurers, and for the public programs that ultimately absorb these costs.

What the bill does — Each fix mapped to a failure we have already seen

I have read every line of H.R. 7867.[13] It is sober, specific, and it closes the exact gaps that let these babies get hurt. It does six concrete things:

1. **Expands required pathogen testing.** Current rules effectively require finished-formula testing only for *Cronobacter* and *Salmonella*;[14] *C. botulinum* was not on the list — which is precisely how two botulism outbreaks slipped through. The bill directs FDA to build a real list and names *C. botulinum* on it.

2. **Mandates environmental testing inside the plant.** Standardized monitoring of Zones 2 and 3 catches contamination in the production environment before it ever reaches a can — standard practice elsewhere in food manufacturing but not required by law for the food we feed newborns.

3. **Sets consistent standards.** FDA, not each company, sets the testing frequency — so "we tested" means the same thing at every facility instead of each manufacturer grading its own work.

4. **Requires early notification — within one business day of a positive test, even before product leaves the building.** This is the provision that matters most in a *botulism* event. Today a company can get a positive result and sit on it while product lingers on shelves; mandatory

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[12] California Dep't of Public Health, Infant Botulism Treatment & Prevention Program, BabyBIG® Fee Schedule, $69,300 per dose (eff. July 1, 2025), https://www.cdph.ca.gov/Programs/OLS/CDPH%20Document%20Library/DPH-25-005-BabyBIG_Fee_FP.pdf; see Infant Botulism Treatment & Prevention Program, https://www.infantbotulism.org.

[13] Infant Formula Safety Modernization Act of 2026, H.R. 7867, 119th Cong. (2026), https://www.congress.gov/bill/119th-congress/house-bill/7867; bill text at https://delauro.house.gov/sites/evo-subsites/delauro.house.gov/files/evo-media-document/infant-formula-safety-modernization-act-of-2026.pdf.

[14] The current testing requirement reaches only Cronobacter spp. and Salmonella. See 21 C.F.R. § 106.55; 21 C.F.R. pts. 106–107 (infant-formula quality-control and testing requirements). The regulations do not require testing for Clostridium botulinum.

early notice shrinks the gap between when the company knows and when parents do — a gap measured in hospitalized infants.

5. **Holds foreign manufacturers to the same standards.** ByHeart's *botulinum* rode in on a home-grown ingredient. While the Nara formula behind the second outbreak was made abroad, for at least a period, it used a US-grown ingredient and same suppliers as ByHeart. Either way, if it is sold to an American baby, it should meet American testing requirements.

6. **Strengthens Congressional oversight.** The bill requires notice to Congress of any confirmed positive in finished formula and any "Official Action Indicated" inspection finding. That "Official Action Indicated" finding already existed in the ByHeart supply chain and went nowhere without Congressional oversight.

The bill also gives FDA 90 days to finalize the rules. We have waited long enough.

The bill will protect the formula supply, not threaten it. Some will warn that more testing means more recalls and another 2022-style shortage. The opposite is true. Contaminated formula is the supply crisis: it was a contaminated plant in Sturgis that emptied the nation's shelves in 2022, and it is undetected pathogens — not the tests that catch them — that force the largest recalls and the longest shutdowns. Catching contamination upstream, before a single can ships, is how this Committee keeps safe formula on the shelf. Safety and supply are not a trade-off; they are the same fight.

Bipartisan, broadly endorsed, and overdue. Protecting infants from contaminated formula is not a left-or-right question. H.R. 7867 is led by Representative Rosa DeLauro and joined by Representative Jeff Van Drew, and it is endorsed by the American Academy of Pediatrics, Consumer Reports, the Consumer Federation of America, the Center for Science in the Public Interest, the Environmental Working Group, STOP Foodborne Illness, the Association of Public Health Laboratories, and Prolacta.[15] That the American Academy of Pediatrics — the physicians who actually stand at these infants' bedsides — has put its name to this bill should carry particular weight: it is the considered judgment of the people who treat the disease. Every provision in this bill is something that, had it been law a year ago, might have meant fewer of the families in the appendix to this letter ever needing to suffer.

The Senate has already acted — now the House must finish the job. On April 29, 2026, the Senate passed the Protect Infant Formula from Contamination Act, S. 272, by unanimous consent — bipartisan legislation introduced by Senators Gary Peters and John Hoeven and reported out of the Health, Education, Labor, and Pensions Committee by a vote of 22 to 0.[16] That a measure to

[15] H.R. 7867 is sponsored by Rep. Rosa DeLauro (D-CT) and co-led by Rep. Jeff Van Drew (R-NJ); endorsing organizations are listed in the sponsor's release, https://delauro.house.gov/media-center/press-releases/delauro-introduces-bipartisan-infant-formula-safety-modernization-act. The bill was referred to this Committee and received a legislative hearing before the Subcommittee on Health on April 29, 2026.

[16] Protect Infant Formula from Contamination Act, S. 272, 119th Cong. (2026), https://www.congress.gov/bill/119th-congress/senate-bill/272. The Senate passed S. 272 by unanimous consent on April 29, 2026; the Senate Committee on Health, Education, Labor, and Pensions had earlier reported the bill favorably by a vote of 22–0. See Press Release, Sen. Gary Peters, Senate Passes Peters' Bipartisan Legislation to Prevent Infant Formula Shortages (Apr. 29, 2026), https://www.peters.senate.gov/newsroom/press-releases/senate-

close the infant-formula notification gap cleared the other chamber without a single dissenting voice is proof that this is neither a partisan question nor a close one. But S. 272 reaches only the contaminants already on the books — *Cronobacter* and *Salmonella* — and would not have caught the *Clostridium botulinum* that paralyzed the infants whose parents speak in the appendix to this letter. It is the narrower bill. H.R. 7867 is the one that names *botulism* on the testing list, mandates environmental monitoring inside the plant, and holds foreign manufacturers to American standards. The Senate has shown the consensus is there; this Committee can finish what the Senate started — and take the one further step these two outbreaks demand.

We have seen this turn out well before. We turned the Jack in the Box tragedy into a rule that made hamburger safer for a generation of children. This Committee can do the same for the formula we feed newborns. The Subcommittee on Health has already held its hearing on this bill; the next step is to act on it. I respectfully urge the Committee to markup H.R. 7867 and report it favorably.

I note, with no small alarm, that the second *botulism* outbreak arrived while this very bill was already pending before you: Nara's babies were hospitalized in the spring of 2026, after H.R. 7867 was introduced in March and after its April 29 hearing. The cost of waiting is no longer hypothetical.

The appendix that follows is the real heart of this letter. These are the infants harmed in the ByHeart and Nara outbreaks, in their parents' own words — statements many of these families wrote for Congress. I ask you to read them, and to keep these children in mind as you consider this bill.

Very truly yours,

William D. Marler

WDM:jd
Enclosure: Appendix A — Statements and photographs of affected families

passes-peters-bipartisan-legislation-to-prevent-infant-formula-shortages. S. 272 amends 21 U.S.C. § 350a(e) to require one-business-day notification of confirmed positive finished-product tests for the microorganisms already covered by 21 C.F.R. § 106.55(e) — *Cronobacter* and *Salmonella* — and does not reach *Clostridium botulinum*.

APPENDIX A

"From Botulism Babies and Parents"

Infants of the ByHeart and Nara outbreak — in their parents' own words

The statements below were written by the parents of children sickened in the 2025 ByHeart and 2026 Nara infant botulism outbreaks and several were first shared publicly in connection with testimony to Congress. Each is reproduced as the family wrote it. Photographs of the children accompany each statement, with the families' permission.

Baby 1 — *in the parents' words*

"When our six-month-old son was diagnosed with infant botulism, our world stopped. Watching our baby, who should have been learning, growing, and thriving – was suddenly facing a life-threatening condition, which is something no parent is prepared for. In the span of three days, our healthy baby boy exhibited failure to thrive, as he lost function of his motor skills, was unable to swallow, and his digestive tract was impacted. The fear and helplessness of seeing our child suffer and not knowing if he would recover or what long-term effects such as paralysis, respiratory issues, or even death that he might face, is a trauma that will stay with us forever.

What makes this experience even harder to accept is knowing it may have been prevented. Families should not have to endure this kind of trauma due to preventable risks or corporate negligence. Companies must be held accountable for their role in protecting the health and safety of the most vulnerable, especially infants who have no voice of their own.

We believe it is critical that Congress understands the real human cost behind cases like ours. We urge Congress to recognize these failures and to hold companies fully accountable for their role in protecting infants and families. Strong action can spare other families from enduring the fear, heartbreak, and lasting trauma that ours has endured. No parent should ever have to watch their child fight for their life because of failures that could have been avoided."

Baby 2 — *in the parents' words*

"It's been a nightmare." That's what I find myself saying to friends and acquaintances after sharing the story of what happened to my son over the last three months. What began as a slow, but noticeable weight loss and decreased feeds in late October quickly spiraled into a lengthy hospitalization with multiple readmissions for various setbacks and complications. Silent aspiration, oxygen levels in the low 80s, inability to feed from a bottle normally, the inability to hold his head up, and the inability to breath without oxygen. These are some of the complications he encountered.

The darkest day was the day he got air-flighted from Flagstaff to Phoenix Children's Hospital. That's when the realization hit that my previously perfect baby was very seriously ill. It was just two days after that when they told us our son had had three small strokes in the back of his brain. After finally getting treated with Baby BIG, the antitoxin for infant Botulism, we noticed dramatic improvements in our son's ability to hold his head up within just 2-3 days. We are thankful for this life-saving treatment. I understand the cost of Baby BIG is just over $69,000 for one dose. I can't help but wonder how different our lives would be, how different his life would be, if manufacturers were required to screen for microorganisms like Botulism and Cronobacter. The cost of screening is surely less than the antitoxin for Botulism, and with Botulism diagnoses on the rise something needs to be done to prevent another family from going through what we've endured.

The ripple effect has affected not just our son, but also his parents, his brother, his grandparents, aunts, uncle, friends and neighbors. It's taken an entire community who rallied together to get us to the place we are in today, which is a place of uncertainty, but also hope. He is still fed through an NG tube and any formula he eats by mouth has to be thickened so he doesn't aspirate it into his lungs. We are hopeful he will make a full recovery in time, but I still mourn all that's been lost in our new baby experience from this illness."

Baby 3 — *in the parents' words*

"As for a statement, this experience was the hardest thing my wife and I have ever been through. Our daughter changed so much overnight and kept getting worse. She had no energy, could barely move or open her eyes, couldn't hold her head up or eat or drink. We had to take her to the hospital 4 times before someone suspected botulism. We didn't know if she was going to survive.

She was in the hospital for 3 weeks but has required many follow up visits with her doctor and other specialists. She still hasn't fully recovered and will require more visits with doctors and physical therapists to get her development back on track. My wife and I have had to take a lot of time off from work and this situation has had a tremendous effect on our mental and emotional state. We will do whatever we have to in order for our daughter to recover, but it hasn't been easy."

Baby 4 — *in the parents' words*

"I am one of the many parents directly impacted by the ByHeart infant formula botulism contamination. As a parent, nothing prepares you for the fear and helplessness of realizing that something meant to nourish and protect your baby would instead cause them harm. This experience shattered our sense of safety at one of the most vulnerable moments in our lives, when our only focus should have been our child's healthy growth and development.

Like many families, we chose ByHeart because of the trust it cultivated—positioning itself as a transparent, science-backed, and parent-first brand. We relied on this formula as our baby's primary source of nutrition, believing it met the highest safety and quality standards; that trust was not given lightly. We depend on companies and regulators to ensure that what reaches store shelves is unquestionably safe. When that trust is broken, the consequences are not just emotional—they were physical and long-lasting.

This crisis underscores the urgent need for stronger oversight and a faster, more proactive FDA response to contamination risks in infant formula production. We urge Congress to ensure the FDA is empowered with the resources, authority, and accountability measures necessary to prevent failures like this from happening again. No parent should ever have to question whether feeding their baby could put their child's life at risk."

Baby 5 — *in the parents' words*

"This experience has changed our lives.

From feeling disgusted in myself when I eat; seeing that my son cannot enjoy a meal with me, and from having to be his life support and watch him relearn communication; I'm convinced at times that I am incompetent.

My son's strength gives me motivation to fight and speak up for him.

I never thought being so proud to be a mother; would come with my baby meeting fear at a defenseless age.

I have faith in all who goal to correct this situation.

No matter the mountain I'm going to climb it for my son, and I appreciate you for hearing our voices."

Baby 6 — *in the parents' words*

"We want to share our experience and the profound mental and emotional hardship our family has endured following our two-month-old infant's diagnosis with botulism. This experience has been deeply traumatic, and it has permanently altered what should have been a time of bonding, joy, and learning to care for our first child. We are grateful that this situation is now being thoroughly investigated and given the serious attention it deserves, so that stronger safety measures can be put in place to prevent other families from enduring the same ordeal.

It is devastating when new parents—already navigating the vulnerability and uncertainty of caring for a newborn—are forced to confront a life-threatening illness that was both unnecessary and preventable. From the earliest weeks, we knew something was wrong. For several weeks prior to her diagnosis, we repeatedly sought medical guidance to address significant feeding challenges. More than half of each bottle would drain from her mouth, leaving us fearful that she was not receiving the nutrition she desperately needed. In response, we fed her nearly twice the recommended amount, increased the frequency of feedings, and woke her throughout the night to ensure she was getting enough nourishment.

Despite our constant vigilance and growing concern, we had no explanation for her worsening condition. Watching our newborn slowly deteriorate—without answers—was emotionally unbearable. The fear, self-doubt, and helplessness we experienced during this time are difficult to put into words. It was not until we received an automated call from the retailer where we purchased ByHeart infant

formula that we finally began to understand the cause of what our child was suffering.

Seeing our two-month-old baby connected to feeding tubes and vital monitors was one of the most heartbreaking and traumatizing moments of our lives. The emotional toll of witnessing her in that state, combined with extreme sleep deprivation, overwhelming stress, lost work, and ongoing medical and recovery appointments, has had a lasting impact on our mental health and our family's well-being.

We sincerely hope no other family ever has to experience this kind of fear and trauma during what should be the most precious and formative time of their child's life. We are thankful that this incident is receiving the attention necessary to address and correct critical safety testing deficiencies, and we pray that meaningful changes are made to ensure the safety of infants and peace of mind for parents everywhere."

Baby 7 — *in the parents' words*

"Our son was hospitalized with infant botulism after consuming powdered infant formula—something we gave him believing it was safe and carefully regulated. In a matter of days, a healthy baby lost the ability to eat, move, and function normally. No parent should ever have to watch their child suffer this way from a product specifically designed for infants. This should not have happened, and the fact that it did points to serious failures that must be addressed.

What is often missing from policy discussions is the human reality behind these cases. We are not data points or rare anomalies—we are families whose lives have been permanently altered. The emotional trauma, financial strain, and long-term uncertainty do not end when a hospital stay ends. Action is urgent because babies are still being born, parents are still relying on these products, and families should not have to wait for another child to be harmed before safeguards are strengthened. Accountability and meaningful change are necessary to ensure infant safety is truly non-negotiable."

Baby 8 — *in the parents' words*

"We believe companies can correct mistakes only when there is real accountability. In this case, warnings about potential contamination were ignored, and infant safety failed. If there isn't real regulatory change that comes from this, the message to the industry will be that the risk to babies' lives can simply be priced in as a cost of doing

business. We're asking Congress to put child safety ahead of profit and ensure this never happens again."

Baby 9 — *in the parents' words*

"I want to be able to share my perspective and take as my daughter's mom, since she is unable to advocate for herself as she is only 9 months old. She was 6 months old when she was treated for Infant Botulism at Rady's Children Hospital in San Diego CA. As a working mom, and someone who was struggling to produce milk to feed my daughter, I trusted and used the Byheart formula for only 5 weeks. It is crazy how those 5 weeks were so impactful on our daughter, and how I saw the light and spirit of her change. I had no idea what was happening to her, only knowing something was not right, as my daughter who was always a happy, outgoing, smiley baby with no health issues, was fading and changing that last two weeks before we were aware that our daughter was impacted and needed treatment for Infant Botulism.

As parents, this experience has been absolutely heartbreaking and something we will carry with us forever. We have always been extremely cautious about what we put in her body and what we expose her to from the food she eats to the clothing she wears and the toys she plays with. We carefully research products and make decisions with her safety and well-being at the forefront. We truly believed we were making the best possible choice for our child when we purchased what we thought was a high-quality, safe, and trustworthy formula. It is devastating to know that what we believed was the best choice for her turned out to be anything but.

During her illness, we watched our daughter change in ways that were terrifying and deeply distressing. Her face became frozen, her expression disappeared, and tears would roll down her face while she was unable to cry out for help, her body was weak, and she wasn't being active and strong like she normally was. At the time, we did not fully understand that paralysis was slowly spreading through her body. Not knowing what was happening, how much she was suffering, or how far the paralysis might progress is something no parent should ever experience. As a school psychologist, I worry what this impact may have on her long term social emotional well-being.

She lost abilities she had already developed — her ability to vocalize, to cry, and to control her muscles. She could not communicate her needs or discomfort, and as her parents, we were left helpless, watching our child struggle without being able to comfort her or

understand what she was feeling. We now know that had she not received medical care when she did, we could have lost our child. Even with treatment, the risk of severe and lasting long-term impacts was very real.

After treatment, her recovery was not immediate. It took significant time for her mouth and feeding abilities to improve, and while there has been progress, we continue to live with uncertainty about the long-term effects. She now struggles with ongoing gastrointestinal issues and severe constipation that requires daily medication. Because she is still so young, she cannot tell us what she feels, if she is uncomfortable, or if something is wrong, and that uncertainty is incredibly painful as a parent.

This experience has changed our family forever. The fear, the helplessness, and the lasting uncertainty are things no family should have to endure. Our hope in sharing her story is that no other child or family has to go through this. If changes can be made to prevent this from happening again, then sharing our pain and experience may help protect other children and families from enduring the same trauma."

Baby 10 — *in the parents' words*

"I researched the ByHeart formula after being told I needed to start supplementing my baby's feeds due to him losing weight. I initially chose ByHeart due to it being labeled as organic, whole milk from grass-fed cows, close to breast milk, being awarded the Clean Label Project Purity award, made by us in the US with globally-sourced ingredients, and being clinically tested. I started feeding my baby ByHeart formula on September 18th of 2025. My baby first started to show signs of Infant Botulism on October 19th of 2025, while we were attending church. He began to be unable to support his neck and started to have a decrease in his appetite.

My baby's symptoms started to increase while in the middle of moving from Washington state to Tennessee. When we arrived in Idaho Falls on October 22nd, the symptoms reached their most concerning levels. My baby was unable to lift his head and limbs, was extremely lethargic, unable to open his eyes, not crying, refusing to eat, and could not close his mouth. He was rushed to the Mountain View Hospital emergency room around 8 pm. He was admitted to Mountain View Hospital, where he stayed from October 22nd to 24th of 2025. During his stay, he was put on a feeding tube along with oxygen. On the 24th of October, the doctors consulted Intermountain Health Primary Children's Hospital in Salt Lake City, Utah, where it

was discussed that Infant Botulism was an extreme possibility, and it was decided to have him medivac'd via plane to Salt Lake City.

My baby received BabyBIG on October 25th while still in the PICU. He received treatment even though, at the time, he was not diagnosed with Infant Botulism due to his symptoms being so concerning to hospital staff. My baby was then moved from the PICU to the long-term care unit on the 27th of October. Once moved, we contacted and were approved by the Ronald McDonald organization for long-term housing due to the cost of staying in hotels for an extensive amount of time. During the entire time of our stay in Salt Lake City, we also had to pay for the boarding of our family dog.

My baby had to receive physical therapy to be able to return to bottle feeding. During this time and to this day, he has a weakness in his ability to lift and control his neck and head. My baby struggles to roll over from "tummy time" to back. My baby is not able to sit up on his own and is barely able to with assistance. Having Infant Botulism has delayed my baby's developmental progress. My baby's attitude and personality has changed significantly. My baby now becomes easily frustrated and enraged with the simple milestones that he should be hitting for his age.

This whole experience was an emotional rollercoaster due to it taking 17 months and fertility treatment to conceive. Some days, we were told that my baby could have died. Other days, we were waiting for him to get better. This has resulted in me becoming overprotective with my baby and not wanting to leave the house due to fear of my baby getting sick again. My baby, my fiancé, and I experience sleep issues due to remaining stress from this experience."

Baby 11 — *in the parents' words*

"When my daughter was sick with botulism, I felt constant, overwhelming terror. In the 7 months between her illness and the recall, I blamed myself for what happened. Since hearing of the recall, I have been anxiously fighting for answers but feeling powerless. My daughter is 1 of the 48 infants impacted by this outbreak but she is not just a number. She is a sweet, playful, strong little person who survived a harrowing experience."

Baby 12 — *in the parents' words*

"There is nothing more heartbreaking than seeing your 2-month-old baby lying in a hospital bed, covered in monitor wires and connected to IVs. Yet that became our reality.

Our son had been a healthy, happy baby. Then, suddenly, something changed. He could no longer hold his head up the way he had before. His feedings decreased, and every feeding became a struggle. We knew in our hearts that something was terribly wrong, but nothing can prepare you for the fear of watching your infant decline before your eyes.

We are extremely fortunate that we live near the Children's Hospital of Philadelphia, where the doctors and staff recognized what was happening, knew how to care for our son, and were able to obtain the BabyBIG treatment he needed. I cannot begin to imagine how much worse his condition could have become if we had not had access to that level of care.

While our son was in the hospital, and even after he was discharged, we continued feeding him Nara Organics formula. This was a formula we had researched extensively. We trusted the company's representations about its ingredients, certifications, and testing. Like any parents, we believed we were giving our baby something safe — something that would nourish him, help him grow, and support his health.

To later learn that the very formula we were feeding our son — the product we trusted to help sustain him, may have been the thing poisoning him was devastating beyond words.

No baby should ever become a victim of infant botulism from the formula they consume. No parent should have to endure the terror of watching their infant weaken, the trauma of a weeks-long hospital stay, countless tests, emotional distress, and overwhelming medical bills. No sibling should have to ask whether their baby brother or sister is going to get better, or when they will finally come home.

This is not just about our family. This is about every family who places their trust in infant formula companies and assumes that the products on store shelves have been held to the highest possible safety standards.

In the past year, there have been two infant formula-related botulism outbreaks. That should alarm every parent, every lawmaker, and every person responsible for protecting the health and safety of children. What we have learned through this experience is that

without stronger safeguards, this is not a question of if another baby will be harmed — it is a question of when.

By passing the Infant Formula Safety Modernization Act, Congress has the opportunity to help ensure that no other family has to experience what ours did. This bill can help protect the most vulnerable among us: newborns and infants who depend entirely on adults, regulators, and manufacturers to keep their food safe.

When reviewing this bill, I ask you to think not only as lawmakers, but as parents, grandparents, aunts, uncles, and members of families who love children. Imagine your own future grandchildren, nieces, nephews, or loved ones depending on infant formula for nourishment. Imagine the peace of mind that would come from knowing stronger safety measures are in place to protect them.

Our family cannot undo what happened to our son. But Congress can act to help prevent it from happening to another child.

I respectfully urge you to support and pass the Infant Formula Safety Modernization Act."

Baby 13 — *in the parents' words*

"Faced with countless infant formula options for our newborn twins, we carefully researched what we believed to be one of the safest and highest-quality ones available - ByHeart. In May 2025, at just one month old, one of them contracted Infant Botulism. Watchful waiting as your newborn becomes more limp each day and undergoes constant medical testing is a trauma no parent should ever have to endure. She spent two weeks hospitalized and her entire first year of life attending numerous Doctors appointments. This experience not only took a significant physical, emotional and financial toll on our family, but deprived us of irreplaceable time bonding with our other daughter. No parent should have to question whether the formula they trust to nourish their baby is safe; This must be treated as an urgent public health priority."

Baby 14 — *in the parents' words*

"In the early weeks of our son's life, we primarily breastfed but supplemented with infant formula out of necessity. After hours of research, we chose ByHeart infant formula based on the Organic ingredients and the claim that it was 'the closest thing to breastmilk'. We trusted that the formula we purchased had been rigorously tested and was safe for consumption. That trust was shattered when our 7-week-old became critically ill with infant botulism in October 2025.

The following weeks were spent in the hospital watching our precious boy fight for survival while being fed through an NG tube and once stable, moved to a Rehabilitation Hospital to work with therapists while he re-learned how to suck, swallow, and lift his head. Weeks that should have been spent at home bonding as a family were spent in fear and uncertainty, separated from each other and from our baby at times while he received the care he desperately needed and we took turns staying with him at the hospital. The toll that this experience has taken on our family has been enormous and we are still unpacking it months later.

The one thing that we are certain of is that stronger regulatory oversight and accountability within the infant formula industry is urgently needed to prevent other families from living the nightmare that we did."