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June 29, 2026

The Honorable Bill Cassidy, M.D., Chairman
The Honorable Bernie Sanders, Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
428 Senate Dirksen Office Building
Washington, DC 20510

Re: Finish what the Senate started — botulism in infant formula, the shared milk and powdered-milk supply behind two outbreaks, and the case for hearings and parent testimony

Dear Chairman Cassidy, Ranking Member Sanders, and Members of the Committee:

For more than thirty years — since the 1993 Jack in the Box *E. coli* outbreak — I have represented children and families poisoned by food they trusted. I now represent the families of more than twenty-five infants paralyzed by botulism in the first months of their lives because of contaminated powdered infant formula. I wrote to this Committee's House counterpart last week in support of H.R. 7867, the Infant Formula Safety Modernization Act of 2026[1], and I am writing to you now because the Senate has already shown what this body can do on this issue — and because the work is not finished.

You have already led on this — and it mattered

Let me begin with credit, because you have earned it. On April 29, 2026, this Committee reported the Protect Infant Formula from Contamination Act, S. 272, favorably by a vote of 22 to 0, and the full Senate passed it the same day by unanimous consent.[2] Bipartisan legislation, introduced by Senators Gary Peters and John Hoeven, cleared this body without a single dissenting voice. That is not a small thing. In a Washington that agrees on almost nothing, the Senate agreed that parents

[1] William D. Marler, *Support for H.R. 7867, the Infant Formula Safety Modernization Act of 2026* (June 23, 2026) (letter to the House Committee on Energy and Commerce, with Appendix A — statements and photographs of affected ByHeart and Nara families), Marler Blog, marlerblog.com; full letter (PDF), HR_7867_Support_Letter_6_23_26_WDM_FINAL.pdf.

[2] Protect Infant Formula from Contamination Act, S. 272, 119th Cong. (2026), congress.gov/bill/119th-congress/senate-bill/272. Reported favorably by the Senate HELP Committee 22–0 and passed by the full Senate by unanimous consent on April 29, 2026. See Press Release, Sen. Gary Peters, *Senate Passes Peters' Bipartisan Legislation to Prevent Infant Formula Shortages* (Apr. 29, 2026), peters.senate.gov.

deserve to be told, within one business day, when the formula in their baby's bottle has tested positive for a deadly pathogen.

That achievement fits squarely within the food-safety agenda th Administration has championed under the banner of Making America Healthy Again. The MAHA movement has put the safety and integrity of what we feed our children at the center of the national conversation — Operation Stork Speed forced the first serious look at infant formula in a generation, and the FDA's April 2026 contaminant testing was the largest this country has ever conducted.[3] I have said publicly, and I will say it to you, that this work is long overdue and I am glad it is happening. The Senate's passage of S. 272 is of a piece with it. You closed a real gap, and you should be proud of it.

But S. 272 does not reach the pathogen that actually paralyzed these babies

Here is the hard part, and I say it as someone who supports what you did. S. 272 requires one-business-day notice only for the organisms already on the books — *Cronobacter* and *Salmonella*. It does not reach *Clostridium botulinum*, the spore-forming organism that produced the toxin that hospitalized 48 infants across 17 states in the ByHeart outbreak[4] and three more infants in California, Pennsylvania, and Washington in the Nara Organics outbreak.[5] Every one of those 51 babies was hospitalized. Many were placed on ventilators. Each was treated with BabyBIG antitoxin, which the State of California prices at $69,300 per dose.[6] Not one of them was harmed by the contaminants the April testing screened for. They were paralyzed by a spore that no federal regulation requires anyone to test powdered formula for, before or after it ships.

The hazard was not a surprise. On March 8, 2023 — two years before the first ByHeart baby fell ill — the FDA sent a Call-to-Action letter to the entire powdered infant formula industry, signed by the Commissioner of Food and Drugs and the Director of the Center for Food Safety and Applied Nutrition, naming *Clostridium botulinum* by genus and species and instructing manufacturers to account for it in the design of their controls.[7] The danger was foreseeable, it was named in writing by the government, and the rule still does not require the test. H.R. 7867 — led by Representative Rosa DeLauro and Representative Jeff Van Drew, and endorsed by the American Academy of Pediatrics, Consumer Reports, the Consumer Federation of America, the Center for Science in the Public Interest, STOP Foodborne Illness, and others — is the bill that names *botulism* on the testing list, mandates environmental monitoring inside the plant, and holds

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[3] FDA, *FDA Releases Results from Largest-Ever Testing of Infant Formula in the U.S.* (Apr. 29, 2026), fda.gov; see also FDA, *Operation Stork Speed*, fda.gov/food/infant-formula-homepage/operation-stork-speed.
[4] FDA, *Outbreak Investigation of Infant Botulism: Infant Formula (November 2025)* (ByHeart; 48 infants in 17 states, all hospitalized; whole-genome sequencing linking the organism across a clinical isolate, finished formula, and incoming organic whole milk powder dried at Dairy Farmers of America), fda.gov.
[5] FDA, *Outbreak Investigation of Infant Botulism: Powdered Infant Formula (June 2026)* (Nara Organics; three infants in California, Pennsylvania, and Washington, ages two to five months, treated with BabyBIG), fda.gov.
[6] California Dep't of Public Health, Infant Botulism Treatment & Prevention Program, BabyBIG® Fee Schedule — $69,300 per dose (eff. July 1, 2025), cdph.ca.gov.
[7] FDA, *FDA's Actions to Respond to Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula* (discussing the March 8, 2023 Call-to-Action letter to the powdered infant formula industry, signed by the Commissioner of Food and Drugs and the Director of CFSAN, naming *Clostridium botulinum*), fda.gov; letter text at fda.gov/media/166044/download.

foreign manufacturers to American standards.[8] The Senate did the narrower bill. The House has the broader one in front of it now.

My first ask is simple: I asked the House to move on H.R. 7867. I am asking the Senate to do the same. *Take up companion legislation, or your own measure, that closes the botulinum gap S. 272 left open — and finish what this Committee started on April 29.*

Why the system missed it twice — and why this Committee should hold hearings

The two outbreaks were not unrelated coincidences. They shared a supply chain. The FDA's own traceback has now confirmed that the Nara formula fed to the three sick infants was made with milk supplied by Organic West Milk and spray-dried by Dairy Farmers of America — the same two suppliers linked to the ByHeart outbreak.[9] One upstream source furnished the milk and the powdered milk behind both brands. The contamination did not strike two companies by chance; it traveled through one shared stream that the system missed the first time and then missed again.

During the 2025 ByHeart investigation, the FDA did exactly what the playbook calls for: it ran a trace-forward and asked Organic West who else it supplied, so the next brand could be found before the next baby got sick. According to the FDA's June 26, 2026 update, the customer list Organic West produced was incomplete — it did not include Nara — and Organic West has now admitted the list should have listed Nara. The trace-forward happened during the 2025 outbreak. The Nara babies were hospitalized in April and May 2026. A complete, accurate list could have put Nara on the FDA's radar months before a single infant showed a symptom. The one mechanism designed to prevent the second outbreak existed, the agency used it, and an incomplete supplier disclosure defeated it.

That is precisely the kind of failure congressional oversight exists to examine. The questions are concrete, and the answers belong on the record, under oath:

1. **Questions to the FDA:** When did the agency learn that Organic West and DFA supplied both ByHeart and Nara? Why did the 2025 trace-forward fail to surface Nara, what is the backstop when a supplier's customer list is incomplete, and why does federal regulation still require finished-powder testing only for *Salmonella* and *Cronobacter* — and nothing for *Clostridium botulinum*[10] — three years after the agency named the organism in its own letter to industry?

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[8] Infant Formula Safety Modernization Act of 2026, H.R. 7867, 119th Cong. (2026), congress.gov/bill/119th-congress/house-bill/7867. Sponsored by Rep. Rosa DeLauro and co-led by Rep. Jeff Van Drew; referred to the House Committee on Energy and Commerce, with a Subcommittee on Health hearing held April 29, 2026.

[9] FDA, *Outbreak Investigation of Infant Botulism: Powdered Infant Formula (June 2026)*, June 26, 2026 update (traceback finding that the implicated Nara lots were made with milk supplied by Organic West Milk and spray-dried by Dairy Farmers of America — the same suppliers behind the ByHeart outbreak — and that the customer list Organic West provided during the 2025 ByHeart investigation did not include Nara), fda.gov; see also William D. Marler, *FDA Confirms the Shared Suppliers — but Hasn't Linked them to the Nara Illnesses — Yet* (June 26, 2026), Marler Blog, marlerblog.com.

[10] 21 C.F.R. § 106.55 (microbiological testing of powdered infant formula limited to *Salmonella* and *Cronobacter*; no standard for *Clostridium botulinum*), ecfr.gov.

2. **Questions to Dairy Farmers of America:** What did you know about the risk of using powdered whole milk in infant formula? What did DFA know about the whole-milk-powder it dried for both brands; what testing did it perform for spore-forming organisms; and what did it disclose, and to whom, during the ByHeart trace-forward?
3. **Questions to Organic West Milk:** What did you know about the risk of using whole milk in infant formula? Why was Nara left off the customer list provided to the FDA in 2025? Who prepared that list, who reviewed it, and when did Organic West first know that the same milk supply had reached a second infant-formula brand?
4. **To Nara Organics:** What did you know about the risk of using whole milk in infant formula? When did Nara learn that its whole-milk-powder came through the same Organic West/DFA supply stream implicated in the ByHeart outbreak; what did it test for; and what did it tell regulators and parents — and when?

The common thread running through all four is a single question this Committee is uniquely positioned to ask in public: **why was the shared milk and powdered-milk supply not disclosed in 2025, when disclosure could have prevented the second outbreak entirely?**

I have spent a career watching companies answer that kind of question only when a courtroom compels them. Discovery and depositions will force a complete record in the litigation I am handling. But the public-policy record — the record that tells you whether the law needs to change — belongs to you. A hearing reaches witnesses, and asks questions, that no single plaintiff's case can.

My second ask: hold hearings. *Bring the FDA, Dairy Farmers of America, Organic West Milk, and Nara Organics before this Committee and put the disclosure failure of 2025 on the public record — so the next reform is built on what actually happened, not on what anyone is willing to volunteer.*

It is time for the parents to testify

There is one more thing, and to me it is the most important. Throughout this episode, the people with access to the rooms where decisions get made have been the companies and the agencies. The Secretary of Health and Human Services has met with formula-company chief executives more than once. The FDA has convened industry roundtables. The one group that has not been in the room — not in any room that counts — is the parents.

I represent those families. They followed every instruction on the label and watched a two-month-old go limp in their arms. They spent weeks in pediatric intensive care not knowing whether their child would breathe on his own again. One family was flown by medevac from Idaho to a children's hospital in Utah. Several of them have already written statements for Congress; I attached those statements, in their own words and with their own photographs, to my June 23, 2026 letter to the House Committee on Energy and Commerce. They are willing to do more than write. They are willing to come and testify.

When this Committee marks the human cost of a policy failure, no expert and no lawyer — myself included — can substitute for the parent who lived it. These mothers and fathers can tell you, better than any of us, what "safe" turned out to mean when the system tested for too little, too late, and told too few people when something went wrong.

My third ask: invite the parents to testify. *Give the families of the ByHeart and Nara infants a seat at the witness table before this Committee writes the next chapter of infant-formula safety law. They have earned it the hardest way there is.*

We have done this before

The Jack in the Box tragedy moved the USDA to declare *E. coli* O157:H7 an adulterant in ground beef in 1994 — a single decision that has kept countless children out of hospital beds in the decades since.[11] This Committee, and this Senate, have the same kind of window open right now. You proved on April 29 that the consensus exists. I am asking you to extend it the one further step these two outbreaks demand: pass a bill that reaches botulism, hold the hearings that put the 2025 disclosure failure on the record, and let the parents speak.

Thank you for your leadership on S. 272, and for your consideration of what I believe the moment now requires.

Very truly yours,

William D. Marler

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[11] USDA, Food Safety & Inspection Service (in August 1994 FSIS declared *E. coli* O157:H7 an adulterant in raw ground beef), fsis.usda.gov.