MARLER CLARK
THE FOOD SAFETY LAW FIRM

MARLER CLARK INC., PS | 180 Olympic Dr S.E., Bainbridge Island, WA 98110
TEL 1.206.346.1888 | FAX 1.206.346.1898 | marler@marlerclark.com | www.marlerclark.com

WILLIAM D. MARLER, ESQ.
Writer's Direct Line:
(206) 346-1890
bmarler@marlerclark.com

August 28, 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: H.R. 7867 — the government confirmed on August 27, 2026 that the two infant botulism outbreaks were one contamination, and the bill that would have reached it is still sitting before this Committee

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

I wrote to you on June 23, 2026 in support of H.R. 7867, the Infant Formula Safety Modernization Act of 2026, and attached the statements and photographs of fourteen families whose infants were paralyzed by botulism in contaminated powdered formula.[1] I have had no reply. I am writing again because yesterday the federal government confirmed the central factual claim of that letter, and confirmed it with a laboratory result rather than an inference.

What the government confirmed yesterday

On August 27, 2026, the Centers for Disease Control and Prevention declared the Nara Organics outbreak over.[2] When I wrote to you in June the outbreak stood at three confirmed infants. The agencies added a fourth as the investigation continued, and four is the final count — in California, Pennsylvania and Washington, with illness onsets between April 20 and May 31, 2026. All four were hospitalized. CDC found that epidemiologic, traceback and laboratory data showed that Nara Organics Whole Milk Organic Infant Formula was contaminated with *Clostridium botulinum* and made infants sick. Its earlier update had said only that the formula *might* be contaminated.

Then the finding that should bring this bill back to your markup calendar. Whole genome sequencing linked a patient sample from the Nara outbreak to a patient sample, product samples

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

[2] Centers for Disease Control and Prevention, *Infant Botulism Outbreak Linked to Powdered Infant Formula, June 2026* (update of Aug. 27, 2026), cdc.gov. Investigation status reported as closed: four cases, four hospitalizations, no deaths, three states, with illness onsets April 20, May 17, May 20 and May 31, 2026.

and an ingredient sample collected during the investigation of the 2025 ByHeart outbreak.[3] The FDA describes the same result more specifically, reporting a match to a ByHeart clinical sample, a powdered infant formula base sample, and four samples of unopened cans of ByHeart formula.[4] CDC states that FDA's traceback determined that the infant formulas sold by *both* Nara Organics and ByHeart were made with milk supplied by Organic West Milk and spray dried by Dairy Farmers of America, and that the matching sequences indicate a common source of contamination for the two outbreaks.

In June I told this Committee that the contamination did not strike two unrelated companies by chance, and that it traveled through one shared supply stream the system missed twice. The support for that sentence was a traceback and a trade-press report. The support for it today is the government's own genome sequencing. The same organism has been found in an infant fed one brand and in the product and the ingredient of the other. A strain does not move between two babies who never consumed the same product by accident. It moves through the thing they shared.

One qualification, which you should hear from me rather than from a witness across the table. Neither agency has determined a root cause, and FDA says it cannot yet tell whether the milk was contaminated before it was dried or during the drying process. That question decides how responsibility is divided among the brands, the milk supplier and the processor. It does not touch whether the formula was contaminated, and it does not touch whether the formula paralyzed babies. CDC decided both of those yesterday.

The sequencing vindicates the specific provisions of your bill

H.R. 7867 is not a general expression of concern. It does six concrete things, and yesterday's result speaks directly to four of them.

The testing list. Federal regulation still requires finished-formula testing only for *Salmonella* and *Cronobacter* and says nothing about *Clostridium botulinum*.[5] The organism that has now been sequenced across two brands, two outbreaks and fifty-two hospitalized infants is the one organism nobody is required to look for. Section 1 of your bill names it.

---

[3] CDC, *Investigation Update on Infant Botulism Outbreak, June 2026* (Aug. 27, 2026), cdc.gov (whole genome sequencing analysis linking a patient sample from the Nara Organics outbreak to a patient sample, product samples and an ingredient sample collected during the 2025 ByHeart investigation; traceback finding that the infant formulas sold by both brands were made with milk supplied by Organic West Milk and spray dried by Dairy Farmers of America; and the statement that FDA does not have enough evidence to determine whether the milk was contaminated before or during drying).

[4] U.S. Food and Drug Administration, *Outbreak Investigation of Infant Botulism: Powdered Infant Formula (June 2026)* (update of Aug. 27, 2026), fda.gov. FDA describes the match set more specifically than CDC does, reporting a match to a ByHeart clinical sample, a powdered infant formula base sample, and four samples of unopened cans of ByHeart formula.

[5] FDA, *Post-Outbreak Response Activities: Clostridium botulinum Illnesses Associated with Consumption of Powdered Infant Formula*, fda.gov (trace-forward conducted during the 2025 ByHeart investigation; the customer list provided by Organic West Milk did not indicate that its milk was supplied to the manufacturers of Nara Organics infant formula; Organic West Milk subsequently informed FDA that the information should have included Nara Organics). Page stated as current as of July 13, 2026.

Environmental monitoring inside the plant. A single strain persisting through this ingredient stream across two manufacturers, a national recall, a federal investigation and a formal closeout is not an incidental event. It is a resident organism. Zone 2 and Zone 3 monitoring is how a resident organism is found, and it is how it would have been found before April 2026.

Foreign manufacturers held to American standards. The Nara formula was made abroad. Its milk came from an American supplier and was dried by an American processor, and the sequencing has now tied it to an American outbreak. The route your bill anticipated is the route the organism actually took.

Notice to Congress. Your bill requires notice to Congress of confirmed positives in finished formula and of any Official Action Indicated inspection finding. Consider what Congress would have known in 2025 had that provision been law, and how much of what I am reporting to you today you would already have had.

The trace-forward failure now has a measurable cost

During the 2025 ByHeart investigation the FDA did what the playbook calls for. It ran a trace-forward and asked Organic West Milk who else it supplied, so the next brand could be found before the next baby was hurt. The customer list did not include Nara Organics, and Organic West has since told the FDA that it should have.[6] ByHeart recalled all of its product on November 11, 2025. CDC declared that outbreak over on February 26, 2026. The first Nara infant became ill on April 20, 2026 — 160 days after the recall, and 53 days after the government told the country the first outbreak was finished. The one mechanism designed to prevent a second outbreak existed, the agency used it, and an incomplete answer defeated it. As of yesterday we know at the level of the genome exactly what got through.

Fifty-two infants hospitalized across the two outbreaks, many on ventilators, each treated with BabyBIG antitoxin that the State of California prices at $69,300 a dose.[7] The FDA named *Clostridium botulinum* by genus and species in a Call-to-Action letter to the entire powdered infant formula industry on March 8, 2023, three and a half years ago.[8] Since these outbreaks began the agency has written to industry, referred questions to international scientific bodies, and held a public meeting. That is the guidance approach, tried again, and it has now failed twice with a documented body count. The duty to test belongs in statute, where it is durable and enforceable, which is what your bill does.

---

[6] 21 C.F.R. § 106.55 (microbiological testing of powdered infant formula limited to *Salmonella* and *Cronobacter*; no standard for *Clostridium botulinum*), ecfr.gov.

[7] FDA, *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; instructing that historical associations between powdered infant formula and pathogens including *Cronobacter* spp., *Salmonella*, and *Clostridium botulinum* be considered when designing and implementing controls), fda.gov/media/166044/download.

[8] Infant Formula Safety Modernization Act of 2026, H.R. 7867, 119th Cong. (2026), congress.gov (sponsored by Rep. Rosa DeLauro and co-led by Rep. Jeff Van Drew; referred to this Committee, with a Subcommittee on Health legislative hearing held April 29, 2026); Protect Infant Formula from Contamination Act, S. 272, 119th Cong. (2026), congress.gov (reported by the Senate HELP Committee 22–0 and passed by the full Senate by unanimous consent on April 29, 2026; it amends 21 U.S.C. § 350a(e) to require one-business-day notification for the microorganisms already covered by 21 C.F.R. § 106.55(e) and does not reach *Clostridium botulinum*).

What I am asking of this Committee

First, mark up H.R. 7867 and report it favorably. The Subcommittee on Health held its legislative hearing on April 29, 2026. The next step is procedural and it is yours. In June I noted, with no small alarm, that the second outbreak arrived while this bill was already pending before you. That was two months ago. The bill is still pending, and the government has now proved that the second outbreak came through the same stream as the first.[9]

Second, hold the oversight hearing. This Committee authorizes and oversees the FDA. Bring the agency, Dairy Farmers of America, Organic West Milk, Nara Organics and ByHeart before you. The questions are sharper than they were in June because there is now a laboratory result to ask about. How long has this organism been in this ingredient stream? Who tested for it, by what method, and how often? Who prepared the 2025 customer list, who reviewed it, and when did each company learn that the same milk had reached a second infant formula brand?

Third, put the parents at the witness table. Appendix A to my June letter is fourteen families in their own words, with their children's photographs. They are willing to do more than write. 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.

Fourth, and this one is new: put a written question to the FDA, with a deadline. The agency's root cause investigation has been open since November 2025. Its own public page on this subject has not been updated since July 13, 2026 and still says there is not enough evidence to determine whether the shared suppliers are the source of the contamination — language its own sequencing has now overtaken. Ask the Commissioner what the root cause investigation has found; whether the agency intends to require testing or environmental monitoring for *Clostridium botulinum* by regulation; and if so, on what schedule. If the answer is that no rule is coming, that is the strongest argument for your bill that anyone could give you.

We have done this before

We turned the Jack in the Box tragedy into a rule that made hamburger safer for a generation of children. This Committee has the same window open for the food we feed newborns. The Senate passed the narrower bill in April by unanimous consent; I wrote to that Committee in June and again yesterday.[10] H.R. 7867 is the bill that names the organism, monitors the plant, and reaches manufacturers abroad. It has been before you since March. Two outbreaks, fifty-two hospitalized infants, and now a genome that ties them together say the cost of waiting is no longer hypothetical. It is arithmetic.

I would welcome the chance to answer any questions from the Committee or its staff, and to make the families available to you.

---

[9] 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. Case totals: 48 infants in 17 states in the ByHeart outbreak, CDC, *Investigation Update: Infant Botulism Outbreak* (Feb. 26, 2026), cdc.gov; four infants in the Nara Organics outbreak, CDC, supra note 11.

[10] William D. Marler, *Letter to the Committee on Health, Education, Labor, and Pensions* (June 29, 2026), Marler Blog, marlerblog.com. A follow-up letter was sent to that Committee on August 28, 2026.

Very truly yours,

William D. Marler

WDM:jd
Enclosure: Letter to this Committee of June 23, 2026, with Appendix A — statements and photographs of affected families