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 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: The genetic link confirmed on August 27, 2026 between the ByHeart and Nara Organics infant botulism outbreaks — and why the three requests in my June 29 letter now have an evidentiary answer

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

I wrote to you on June 29, 2026 about botulism in powdered infant formula.[1] I asked three things: that the Senate take up legislation reaching *Clostridium botulinum*, that this Committee hold hearings on how the same contaminated milk supply reached a second brand, and that the parents of the injured infants be given a seat at the witness table. I have had no reply. I am writing again because yesterday the federal government answered the question my June letter could only ask.

What the government said 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 on April 20, May 17, May 20 and May 31, 2026. All four were hospitalized. None died.

CDC did not close the file with a hedge. It 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. The agency dropped the qualifier.

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[1] William D. Marler, *Letter to the Committee on Health, Education, Labor, and Pensions* (June 29, 2026), 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.

Then came the finding that should bring this Committee back to the subject. Whole genome sequencing linked a patient sample from the Nara outbreak to a patient sample, product samples 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.

One qualification, which you should hear from me rather than from someone across a table. Neither agency has determined a root cause, and FDA says it does not yet have enough evidence to decide whether the milk was contaminated before it was dried or during the drying process. That open question governs which company bears what share of the responsibility. 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.

In June this was an inference. It is now a laboratory finding.

My June letter told you that the two outbreaks shared a supply chain and that the contamination did not strike two companies by chance. That was reasoning from a traceback. It is no longer reasoning. The same organism has now been found in an infant fed one brand and in the product and the ingredient of the other. A strain does not travel between two babies who never consumed the same product by accident. It travels through the thing they shared, and the only thing these two shared was an ingredient.

That is what turns the disclosure failure I described in June from a procedural lapse into a measurable one. During the 2025 ByHeart investigation the FDA ran the trace-forward the playbook calls for and asked Organic West Milk who else it supplied. The customer list did not include Nara Organics, and Organic West has since told the FDA that it should have.[5] 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. We now know, at the level of the genome, what got through.

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[3] CDC, *Investigation Update on Infant Botulism Outbreak, June 2026* (Aug. 27, 2026), cdc.gov (whole genome sequencing link to the 2025 ByHeart investigation; traceback finding that the 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.

[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; 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.

Fifty-two infants, and the regulation still does not name the organism

Forty-eight babies in the ByHeart outbreak. Four in the Nara Organics outbreak. Fifty-two infants hospitalized across the two outbreaks, many of them on ventilators, each treated with BabyBIG antitoxin that the State of California prices at $69,300 a dose.[6]

Nothing in the law has changed. Federal regulation still requires microbiological testing of powdered infant formula for *Salmonella* and *Cronobacter* and says nothing about *Clostridium botulinum*.[7] S. 272, which this Committee reported 22 to 0 and the full Senate passed by unanimous consent on April 29, requires one-business-day notice for the organisms already on that list — which does not include the one that paralyzed these fifty-two children.[8] 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.[9] Since these outbreaks began the agency has written to industry, referred questions to international scientific bodies, and held a public meeting. Letters and referrals are not a rule, and the sequencing result released yesterday is the strongest evidence yet that a rule is what this requires.

The three requests from June, renewed — and one more

First, pass a bill that reaches botulism. H.R. 7867, the Infant Formula Safety Modernization Act of 2026, names the organism on the testing list, requires environmental monitoring inside the plant, and holds foreign manufacturers to American standards. Take up a companion measure, or write your own. The gap S. 272 left open is now the only gap that has actually put babies in intensive care.

Second, hold hearings. Bring the FDA, Dairy Farmers of America, Organic West Milk, Nara Organics and ByHeart before this Committee. 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, with what method, and how often? What did each company know after November 2025, and what did each one do about it?

Third, invite the parents to testify. They followed every instruction on the label and watched an infant go limp in their arms. Several have already written statements for Congress. They are willing

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[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. Case totals: 48 infants in 17 states in the ByHeart outbreak, FDA, *Outbreak Investigation of Infant Botulism: Infant Formula (November 2025)*, fda.gov; four infants in the Nara Organics outbreak, CDC, supra note 11.

[7] 21 C.F.R. § 106.55 (microbiological testing of powdered infant formula limited to *Salmonella* and *Cronobacter*; no standard for *Clostridium botulinum*), ecfr.gov.

[8] 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.

[9] Protect Infant Formula from Contamination Act, S. 272, 119th Cong. (2026), congress.gov (reported favorably by this Committee 22–0 and passed by the full Senate by unanimous consent on April 29, 2026); 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 the House Committee on Energy and Commerce).

to come and say it in person. 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. A date certain would tell this Committee whether legislation is necessary or merely useful. The absence of one would tell you something too.

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 — one decision that has kept countless children out of hospital beds in the decades since.[10] You proved on April 29 that the consensus on infant formula exists in this body. Two months ago I asked you to extend it one step further. Yesterday the government supplied the evidence that the step is necessary. Fifty-two families already know what the sequencing means. They would like to know that the Senate does too.

Thank you for your leadership on S. 272, and for your consideration of what the record now shows.

Very truly yours,

William D. Marler

WDM:jd
Enclosure: Letter to this Committee of June 29, 2026

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