Baby botulism outbreak: FDA still doesn’t know cause—or how to prevent it

Still, the FDA could not determine where in the production chain the bacteria entered or how.

“Even though there are several hypotheses, investigational findings could not identify the source or root cause of contamination of the powdered infant formula,” the agency concluded.

Finger-pointing

Bill Marler, a lawyer specializing in food poisoning who is also representing 25 of the sickened infants in litigation, told Ars that the conclusion is “a little underwhelming to put it mildly.” The epilogue that the FDA posted this week, titled the “Post-Outbreak Response Activities,” provided a summary “without any real clear guidance for consumers or for the companies going forward.”

In the meantime, each of the three companies is shirking blame. ByHeart released a statement this week saying “FDA has shared that it did not identify any deficiencies in ByHeart’s facilities that could explain the root cause of this outbreak.”

Bill Van Ryn, an owner of Organic West Milk, previously stressed in media reports that “nothing has been proven about our milk yet.” Likewise, Dairy Farmers of America blamed Organic West, saying its processing met all required tests. “Manufacturers of end-use consumer products have a

responsibility to properly process ingredients to ensure product safety," Dairy Farmers of America said in a statement.

While Marler wants to see more investigation and action by the FDA to understand and prevent another outbreak from happening, the blame ultimately lies with ByHeart, he says. It's "not only an ingredient problem that happened to pass through ByHeart. That is ByHeart's product, in ByHeart's can, with ByHeart's name on it, fed to a baby," he wrote in a recent blog post. "Sourcing, verifying, and testing what goes into infant formula is the job."

Marler also noted that this is not the first time infant botulism has been linked to infant formula.

In its statement this week, ByHeart said it is working to resume infant formula production. The company is now working with a lab to develop more sensitive testing for *C. botulinum* in its products.

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