The Infant Formula Blame Game

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There's plenty of blame to go around over the infant formula shortage plaguing the United States. One might direct it toward the company where production was halted, the Food and Drug Administration (FDA) or Congress. It probably starts with the FDA for discouraging market competition and resiliency.

Nevertheless, let's begin with the company. By now, anyone making food should know that the first thing you need to do is keep your plant clean. FDA inspections found that the food contact surfaces at Abbott Laboratories' Michigan plant weren't clean. That doesn't mean the product harmed any babies, which is determined more scientifically. Apparently, the retained Abbott formula tested negative for both Cronobacter sakazakii and Salmonella newport.
Some Cronobacter sakazakii was found in the plant, though the genetic sequences were different than in the ill infants. There were other findings and accusations that will receive due attention.

But we need to pull back the lens and look at the FDA's Center for Food Safety and Applied Nutrition (CFSAN). FDA officials have at times tacitly admitted to a bad management structure. In the 1990s, Mike Taylor was brought in to run nutrition labeling rules from within the commissioner's office. Apparently, the commissioner didn't trust CFSAN's director to handle it. Taylor returned in 2010 as deputy commissioner for food policy and response, a new position in place ever since.

But what exactly is a director supposed to do if there is a similar role in the commissioner's office? In fact, when the FDA was supposed to be investigating Abbott, the current deputy commissioner for food policy and response, Frank Yiannis, complained that he didn't learn about the whistleblower report until four months later. Neither the CFSAN office employees nor the field inspectors report to him. Although having dual leaders is a problem, it's not the FDA's biggest one.

As I reported in "Fixing Food," when working on an FDA infant formula rule in the late 1980s, I asked a senior regulator why there were only six companies making formula. He said companies routinely asked what they needed to do to enter the formula market and comply with regulations.

They were apparently told, in some form, that the FDA preferred they didn't. Congress should ask for any such documentation.

With fewer companies, FDA inspectors had fewer plants to cover. That becomes a big problem when a company with some 40 percent of the market share is shuttered.

I found another problem back then: Our regulations didn't seem to fix the problems we were encountering and for which we already had sufficient authority. Instead, proposed rules added a lot of costly testing and recordkeeping. The costs of these requirements would naturally be passed on to consumers. And even parents who qualify for cost relief through the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) program don't necessarily get it. Only 49 to 56 percent actually enroll.

When prices increase, some people try to make formula last longer by adding more water to it. One study in Clinical Pediatrics found that 25 percent of food-insecure families admitted to considering ways to extend their formula. Adding too much water can result in too few calories, seizures due to lack of salt and nausea, vomiting and diarrhea.

I recently checked to see if anything had changed in 35 years, and again found only six U.S. formula companies. The FDA does not allow imports of formula, even from Canada. I was also somewhat amazed to see that during COVID-19, FDA food inspectors were working from home, among other things, evaluating records. Why, if plants were fully staffed to make food products (including formula), was it safe for workers but not FDA inspectors?

The agency justified the decision by saying, "[I]nspections are not what cause quality to happen. Safety and quality need to be owned by the industry and firms have the primary responsibility to reliably produce quality products." If that's true, why does the FDA hold to its old approaches and ask for more money for inspectors?

This brings us to the third leg of responsibility: Congress. Recently, the Cato Institute's William Yeatman noted:

"Agencies routinely submit nonsensical budget justifications meant to obfuscate administrative policymaking priorities, and lawmakers don't bat an eye. Where once agencies rushed to meet informational requests by committee leaders, agencies today dissemble in the face of questions from Congress, and lawmakers do nothing."

It's Congress' statutory duty to hold agencies accountable for results and yet every year, the FDA submits budget requests without much mention of actual successes or failures — such as making food safer. And despite budgets increasing over the years, food is no safer. Lawmakers who are outraged today didn't seem to notice.

It's an ugly blame game, but the least we can do is spread the blame around fairly.