Committee on Energy and Commerce

Opening Statement as Prepared for Delivery
of
Subcommittee on Oversight and Investigations Chair Diana DeGette

Hearing on "Formula Safety and Supply: Protecting the Health of America's Babies"

May 25, 2022

Today, the Subcommittee seeks answers on how families across the country have faced empty shelves during this nationwide infant formula shortage. We expect answers from FDA, Abbott, and the other two leading formula manufacturers on why caregivers are scrambling to find the necessary nutrition for their babies and children.

And, most importantly, we will discuss solutions to prevent this from ever happening again in the future.

The current formula shortage has real consequences. Babies and children are suffering. I've heard stories from pediatricians who are seeing malnourished children; I've spoken directly to desperate parents who are tired after driving from store to store trying to find formula; and I've heard from children's hospitals who are seeing an increase in patients whose caregivers haven't been able to secure the formula their infants need.

Unfortunately, we know that this crisis has had a disproportionate impact on low-income families and on those infants and children who rely on specialty formula for nutrients and their health.

These children and parents are our top priority as we proceed with today's hearing. Their tragic situation is unacceptable, and worse, was preventable.

There were growing strains on the domestic supply of formula in the months leading up to the reported infant illness and the subsequent recall of Abbott products, but the recall itself turned the U.S. formula supply into a tailspin.

Let's be clear: Abbott is not blameless. The company appears to have neglected essential manufacturing and cleaning processes that are in place to guarantee the safety and reliability of products intended for our most vulnerable population.

To date, the exact batch of contaminated infant formula that sickened four infants, resulting in two of their deaths, remains unknown. The bacterial strain of the samples taken from two of the four infants who fell ill were not found in environmental samples taken from Abbott's Sturgis, Michigan production facility.

Alarmingly, however, its facility has too long a record of deficiencies—including evidence of the same potentially fatal bacteria on site and in batches of its formula in 2019 and

leading up to the 2021 inspection. Fortunately, those batches were caught before the product was released for distribution, but this presents a disturbing pattern of negligence.

Yet, one company alone does not bear the entire burden for landing us in this the current crisis.

There are too many questions surrounding the timeline of FDA's investigation and response. From a four-month lapse before returning to inspect the Sturgis facility, delayed connection with a former Abbott employee whistleblower, and slow communication to the American people, there is much more to learn about FDA's actions.

Today we seek clarity on what the Agency was doing behind the scenes during this critical time period and what lessons have been learned from this situation.

I am pleased that FDA and the Administration have already been focused on solutions—announcing a range of actions across the Federal government to increase the supply of formula for families in greatest need.

And, that manufacturers are in the mix of these discussions and expediting their production efforts to meet the urgency of the moment.

In fact, we are also joined today by the other two major manufacturers of infant formula in the United States: Gerber and Reckitt.

These companies, along with Abbott, have been partnering with the Biden administration to ramp-up production and bring safe infant formula into the country to fill the current supply gaps.

The Biden Administration's efforts to coordinate this response to get families out of the immediate crisis have been extensive, but we cannot ignore the need for longer-term solutions.

The bottom line is that FDA needs the resources to make sure that the "Food" part of the "Food and Drug Administration" is not an after-thought. Just as FDA works to ensure that lifesaving medicines are safe and effective, the Agency must have the resources to ensure that the food Americans consume is safe and reliable.

Yet FDA's food safety oversight is resourced at only half the amount of Drugs and Biologics. FDA's food safety activities have been under resourced for far too long.

I am glad that the House passed supplemental funding last week to help address this current emergency, but this critical one-time fix is not enough to build a more resilient food safety system for the future.

We must work together to bolster our food safety and supply chain system not just today, but for our children's tomorrows. The empty shelves are inexcusable and the stories of caregivers scrambling to find the nutrients that their children need are heart-wrenching. I stand

with my colleagues and with our witnesses today in committing to finding solutions to prevent such heartache and health treats in the future.