Prepared Statement of Ranking Member Richard Burr

Infant Formula Crisis: Addressing the Shortage and Getting Formula on Shelves

May 26, 2022

Chair Murray, thank you for holding such a critical hearing today. It is time to hold the FDA accountable for its inaction.

There are millions of families that care for babies with the help of formula.

Babies with special needs, dietary restrictions, adopted families and foster families. Orphaned children. Children with mothers who are immune compromised or on lifesaving treatments. Women who can't breastfeed, and some cancer survivors.

I want to share a story with my colleagues about one of these millions of Americans:

A young woman called my office last week, after weeks of desperate searches to find a specific formula for her young child with special dietary needs.

She cares for and protects her baby with fierce love and devotion, and had done her research on the formula shortage.

When she called my office to demand accountability from her government, she was confused that the White House seemed to be blaming the formula manufacturer.

Abbott began flying formula to the U.S. from overseas in February, 11 million pounds since February, 50 flights a week, six to eight flights a day of 132,000 cans to 12 different airports around the country.

Abbott has been very transparent about what problems they've faced and what they were doing to fix the problem. Their CEO even published an editorial apologizing for their part in this crisis.

This month, CDC closed its investigation into the infection of four children, finding no direct link to the manufacturer's facility, but the FDA only just now has begun to use tools to increase the supply of formula.

And FDA still hasn't authorized the Abbott plant to resume manufacturing even though CDC determined the original contamination didn't come from Abbott's plant.

The question I could not answer for my constituent was, "what took the FDA so long?"

Why wasn't action taken when the warning signs of this crisis started last fall?

She asked if we knew what the FDA stands for.

Before we could reply, she said it stood for 'Formula Doesn't Arrive.'

Formula Doesn't Arrive.

My friends, the FDA failed to do its job. Plain and simple.

This isn't a story about funding.

Congress provides over $1 billion for the food center alone every year.

We even gave them $700 million in COVID money. $436 million is still available.

The House passed a bill to give an additional $28 million to the FDA. Ladies and gentlemen, that's called political cover. This money is a stunt, so people could go home and say they did something.

That's dishonest at best. And blatantly irresponsible at worst. The American people know better who's at fault here.

This also isn't a story about authority. The Food Drug and Cosmetic Act authorities are clear. The flexibility you have is real.

No, this is a story, a sad story, about the FDA's unwillingness or inability to do its job.

During the pandemic, the FDA apparently stopped its safety inspections. That seems like a bad decision. And when the FDA finally resumed inspections, they failed to act with speed.

Dr. Califf, you were confirmed in February when the nationwide formula shortage was at 26 percent.

There was a problem, and you and your agency failed to solve it.

I challenged you at your confirmation to learn lessons from the pandemic.

The FDA did a great job for those 18 months.

But what I cautioned against is already happening – FDA is slipping back in to its bureaucratic, bad old ways.

The FDA gets $6 billion from Congress each year. Over 18,000 staff.

Yet, you fail to prioritize the things that matter.

For the past two years, the food center ignored the formula crisis until it became a political liability for this Administration.

Instead, the center focused on reducing salt in foods, what kinds of salad dressing we can call "French dressing," and the ingredients that can be in yogurt.

You had time to decide what color additives can be added to make farmed salmon look more pink and work on consumer acceptance of grated parmesan cheese.

Infants, babies and toddlers are starving and parents are facing the reality that they can't feed their child in the United States of America and your food center is more interested in policing marketing claims about cheese than ensuring that American families have the formula to feed their babies.

When you finally took steps to help, the formula shortage had reached an alarming 43 percent.

The FDA has imperiled the health and safety of American families. You've created shortages and crisis. You've created panic and fear.

Yesterday in testimony to the House you tried to shift blame.

The mail room didn't deliver a whistleblower complaint.

It's *your* mail room. And FDA knew there were problems even before the whistleblower sent that letter. Strike one.

Yesterday you said you were new, but the President hired you and the Senate confirmed you because you had been there before. And your center director has been there almost a decade. Strike two.

Yesterday you said the FDA could have done better. That's painfully obvious, but where is the accountability?

Are we at strike three?

By the time Abbott resumes production, after finally getting approval from your agency which it still doesn't have, it will take about two months for their production to get back to capacity.

That will be a success of the private sector.

That you are acting only now, under pressure from outraged parents around the country and from Congress, deserves some serious soul searching.

When I begin my round of questions, I expect that you will answer my first questions in your opening statement. What did you know? When did you know it? Why did you fail to act for so long?

The Abbott CEO apologized for their mistakes, when will the FDA apologize?

I thank the Chair for her leadership on this issue. I thank her for her shared moral outrage at the failures of the FDA and I thank her for getting the current FDA commissioner to appear before our committee so quickly.