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INFANT FORMULA CRISIS: ADDRESSING THE SHORTAGE AND GETTING FORMULA ON SHELVES

HEARING

OF THE

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED SEVENTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING THE INFANT FORMULA CRISIS, FOCUSING ON ADDRESSING THE SHORTAGE AND GETTING FORMULA ON SHELVES

MAY 26, 2022

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C O N T E N T S

STATEMENTS

THURSDAY, MAY 26, 2022

INFANT FORMULA CRISIS: ADDRESSING THE SHORTAGE AND GETTING FORMULA ON SHELVES

Thursday, May 26, 2022

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The Committee met, pursuant to notice, at 10:32 a.m., in room 430, Dirksen Senate Office Building, Hon. Patty Murray, Chair of the Committee, presiding.

Present: Senators Murray [presiding], Sanders, Casey, Baldwin, Kaine, Hassan, Smith, Rosen, Lujàn, Hickenlooper, Burr, Paul, Collins, Cassidy, Braun, Marshall, Scott, Romney, and Tuberville.

OPENING STATEMENT OF SENATOR MURRAY

The CHAIR. The Senate, Health, Education, Labor, and Pensions Committee will please come to order. Today we are having a hearing on a nationwide infant formula shortage. I will have an opening statement followed by Ranking Member Burr, and then we will introduce our witness. After the witness gives his testimony, Senators will each have 5 minutes for a round of questions.

Again, while we were unable to have the hearing fully open to the public or media for in-person attendance, live video is available on our Committee website at *help.senate.gov*. And if you are in need of accommodation, including closed captioning, please reach out to the Committee or the Office of Congressional Accessibility Services.

Let me be clear, the fact that we even have to have this hearing, the fact that shelves are empty, the fact that babies across the country are going hungry and parents cannot find what they need to feed their infants is a massive, unacceptable failure.

I have said this before and I will say it again, the groups that families and caretakers depended on to help them in this moment, the FDA, infant formula manufacturers, all get an F in my book.

There were plenty of warning signs about this crisis, and it seems like the people who are responsible for safety and supply here just blew through each and every one of them. And now parents and babies are the ones dealing with the consequences.

Now, Dr. Califf, I get that the FDA needs more people and more funding, and I will keep pushing to get you the resources needed to support your work, but I still do not get why some of the steps

we are seeing now didn't happen a lot sooner. It is not like the FDA needed more warnings here.

It is not like the FDA didn't have any idea this could be a problem. As far back as last fall, last September, just as FDA was conducting an inspection at Abbott's formula manufacturing facility in Sturgis, Michigan, Abbott and FDA received the first report of an infant sickened by cronobacter bacteria after consuming infant formula. In October, an Abbott employee reportedly raised concerns with FDA about safety issues at that facility, which makes a huge amount of formula for U.S. families.

But it took weeks for FDA to take action on the whistleblower's complaints and months for the agency's senior leaders to see the report. A matter of life and death importance due to, "mailroom issues." Dr. Califf, that does not instill confidence. Nor does it explain away the many other warnings. In December, FDA and Abbott got a second report of a child infected by cronobacter. Sadly, that child passed away.

In January, a third report. And in February, a fourth complaint and a major formula recall from Abbott. Senator Casey and I sent a letter to Abbott promptly after the recall announcement way back in February when we first learned of these issues.

We pressed for information about why it took so long to respond to these reports and demanded assurances that Abbott was taking every effort to work with its state, Federal, and global partners to make this right and to make sure that it never happened again.

We asked Abbott for documents about these safety issues by March 10th. That deadline came and went. Since early March, my office has been speaking with Abbott and with FDA about the issues related to that recall, including the supply of infant formula. But still, action was slow, and information has not been forthcoming. Weeks after that conversation, FDA released the results of an inspection it started in January, an inspection which found contamination at the plant.

Later in April, reporting highlighted longstanding failures in the FDA's food program, years long delays, culture of inaction, decades of not prioritizing the food program, and it has all had a very real impact on families, including families who depend on formula. I will not allow the FDA to continue spinning its wheels on something as important as the food families feed their children.

That is why I quickly sent a letter demanding answers from you, Dr. Califf. In that letter, I detailed the delay in FDA investigating the reports of potential contamination of Abbott formula, and I demanded information on how you will reform and improve the FDA food program. I have not yet seen a plan.

Now, here we are, months after Senator Casey and I first pressed for answers from Abbott and from your agency, so I can't for the life of me understand why things have gotten so out of hand. Now the Administration has taken some important steps recently. President Biden invoked the Defense Production Act to make sure infant formula manufacturers are at the front of the line for the ingredients that they need.

Operation Fly Formula is now bringing millions of containers worth of formula director directly to our shores, including yesterday's badly needed shipment. FDA has announced steps to increase the supply of safe and nutritionally adequate infant formula by increasing flexibilities on importation, and it has announced alongside Abbott that the Sturgis facility can soon start to safely resume formula production. This is all helpful, but let me be crystal clear, it all happened way too late.

Back in 2021, when the first reports of potential contamination emerged, there should have been an immediate FDA response. And back in February, when Senator Casey and I recognized the need to get to the bottom of the formula recall, Abbott and the Federal Government should have been working together to make sure the shutdown of one plant did not explode into a crisis. Here we are.

Now, I know parents won't rest easy until there is formula back on the shelves or until they can feed their kids. I will not rest either. I am going to keep pushing for more steps here in Congress, from the Administration, and from the industry to fix this as soon as possible. Senator Casey and I led another letter to infant formula manufacturers calling on them to step up and produce more.

We also led a letter to President Biden making clear there needs to be a formula coordinator at the White House leading a national strategy, because we have witnessed now how multifaceted this problem is. We need a coordinated response to ensure better accountability from industry, stronger FDA response, and swift action from the Department of Agriculture to do everything it can give to give recipients the flexibility they need.

We also need to make sure that hospitals, NICUs, pediatricians, and state and local Governments have the information and access to formula necessary to get the right formula to babies and infants with the most critical needs.

We need to make sure retailers and suppliers are managing the supply in a way that is focused around families that need access to formula. We need to get parents clear information and direction on what products to use, which products are equivalent, and where those products can be found or will be coming soon.

It is incredibly frustrating to me we have yet to see a detailed plan for this and that parents are having to coordinate things themselves on Facebook because the Federal Government still doesn't have a point person on this.

I am going to keep pressing for answers for parents back in Washington State and across the country. Parents like Mac. He is a constituent of mine from Richland, Washington. He reached out to my office last week trying to find formula for his daughter and for other parents in the tri-cities area. Mac's daughter was born just 6 months into his wife's pregnancy.

She remained in the NICU for 4 months before going home and she needs a special kind of formula to help her grow and stay healthy. Because of this shortage, Mac has been searching high and low, day and night to try and find it, stop shopping at six different stores, getting donations from other parents on Facebook.

His dad even brought six cans from Milwaukee, nearly 2,000 miles away.

Mac is constantly worried about running out, and he has heard from parents across his community facing the same problem, parents who are driving to store after store, finding only empty shelves, who are searching online and finding price gougers who are trying to profit off the fact that babies are going hungry. Mac spoke with another mom who said when her baby was discharged from NICU, she was given a sample can, a specialty formula, and some ready mix bottles, enough to last maybe 4 days.

The Facebook group Mac started now has over 800 members just trying to connect parents in the tri-city areas to formula. As a mother and a grandmother, I know parents in Washington State won't just go as far to Milwaukee to get the kids—their kids the formula they need, they will go to the ends of the earth, but they should not have to. We should not, we cannot leave parents to fend for themselves.

We should be giving them the formula and the information they need as soon as we possibly can. People desperately want to know how soon can they get the formula their kids need to stay healthy, where should they go forward, especially for people who need specialty formulas like formula for preemies or for children with allergies, and what is the Administration doing to stop the price gouging, to end this shortage as soon as possible, and to ensure that this never happens again?

Parents need help. They need answers. Most importantly, they need formula now. I have been pressing HHS and the formula industry to help make sure we get families the formula they need. Believe me, I am not going to let up until parents like Mac can rest easy and don't have to call their Senators for help finding baby formula.

Dr. Califf, I hope to hear from you today about exactly what steps the Administration is taking to make this happen, as well as how FDA will address the pattern of delay and dysfunction we have seen throughout its food safety and nutrition efforts, not only its unacceptably slow response to complaints of contaminated formula, but also its stalled progress on other critical health, safety, and nutrition issues.

With that, I will turn it over to Ranking Member Burr for his opening statement.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Madam Chair, thank you for holding this hearing. It seems like you and I have been talking about plants a lot lately. I want to really thank the Members. The level of participation in this hearing outstrips anything we have seen, and I am appreciative for that. It is time that we hold the FDA accountable. There are millions of families that care for babies with the help of a formula.

Babies with special needs, dietary restrictions, adopted families and foster families, orphan families, children with mothers who are immune-compromised, or are on life saving treatments, women who

can't breastfeed and some cancer survivors. I want to share a story with my colleagues about one of those 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 United States from overseas in February 11 million pounds since February, 50 flights a week, 6 to 8 flights a day, 132,000 cans to 12 different airports across the country. There is something we haven't heard.

Abbott knew there was a shortage problem, but FDA seemed not to. Abbott has been very transparent about what problems they faced and what they are doing to fix the problems. Their CEO even published an op-ed 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 manufacturers' facility, but the FDA only just now began to use tools to increase the supply of formula. FDA still hasn't authorized the Abbott lab to resume manufacturing, even though CDC determined the original contamination did not come from Abbott's Sturgis plant.

The question I could not answer for my constituent is what took 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, formula doesn't arrive. Formula doesn't arrive, FDA. 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. This Congress even gave them an additional $700 million in COVID money, $436 million of it is still available. The House passed a bill to give an additional $28 million to the FDA. Ladies and gentlemen, that is called political cover.

This money is a stunt so people could go home and say they did something. That is dishonest at best and blatantly irresponsible at worst. The American people know better whose fault it is here. This 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 FDA's unwillingness and inability to do their job. During the pandemic, the FDA apparently stopped its safety inspections. That seems like a bad decision. 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. You and your agency failed to solve it. I challenged you at your confirmation hearing to learn lessons from the pandemic. The FDA did a great job for 18 months. But what I cautioned against is already happening. FDA is slipping back into its bureaucratic, bad old ways.

The FDA gets $6 billion from Congress each year, over 18,000 staff, yet you failed to prioritize the things that matter. For the

past 2 years, the Food Center ignored formula crisis until it became a political liability. Instead, the Center focused on reducing salt and food, what kinds of salad dressing we can call French dressing, and the ingredients that can be used 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 children in the United States of America, and your Food Center is more interested in policy marketing claims about cheese than ensuring American families have formula to feed their babies.

When you finally took steps, the formula shortage had reached an alarming 43 percent. The FDA has imperiled the health and safety of American families. You have created a shortage in crisis. You have created panic and fear.

Yesterday, in testimony to the House, you tried to shift the blame. The mailroom didn't deliver a whistleblower complaint. It is your mailroom. FDA knew there was a problem even before the whistleblower sent the letter, strike one. Yesterday, you said you were new, but the President hired you and the Senate confirmed you because you would been there before. Your Center Director has been there for almost a decade, strike two.

Yesterday, he said the FDA could have done a better job. That is painfully obvious, but where is the accountability? Maybe that is strike three. By the time Abbott resumes production after finally getting approval from your agency, which it still doesn't have, it will take 2 months for their production to go back to capacity. That will be a success for the private sector.

That you are acting only now under pressure from outraged parents around the country and from Congress deserves some serious 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. I wonder if the FDA apologized for their mistakes. I thank the Chair for her leadership on this issue. I thank her for her shared moral outrage at the failures of FDA.

I thank her for getting the current FDA Commissioner to appear so quickly before the Committee. I yield back.

The CHAIR. Thank you. Our witness today is Dr. Robert Califf, the Commissioner of the Food and Drug Administration. Thank you for joining us today to talk about this crisis. I know families in my state and across the country are following this very closely. So you may begin your testimony.

STATEMENT OF ROBERT M. CALIFF, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, SILVER SPRING, MD

Dr. CALIFF. Chair Murray, Ranking Member Burr, and Members of the Committee, thanks for inviting us to testify on the safety and supply of infant formula in the United States. I appreciate the 10-minute allocation.

Ensuring that infant formula is safe and nutritious is the solemn responsibility of the Food and Drug Administration, and we are working with our Government partners and industry that produces infant formula to stabilize the supply. We are fully aware that many parents and caregivers have been unable to access the infant formula products that they need.

Many of us are parents and grandparents, too, and we want to express our deepest empathy for parents and caregivers who are experiencing difficulty and stress as they attempt to find formula. I personally have been driven by memories of the month my daughter spent in the intensive care unit as an infant and the deep concern and anxiety of a parent driven to protect an innocent child.

We provided you with an extensive written testimony that describes a recent history of this problem and gives a detailed timeline. During this hearing, I welcome reference to this document. On September 20th, 2021, FDA learned of a cronobacter sakazakii infection in an infant who consumed formula produced at Abbott nutrition's facility at Sturgis, Michigan.

Our detailed written testimony and timeline specify the chain of events that culminated in a for-cause onsite inspection of the Sturgis facility on January 31st, 2022. While there are many stops along the way where different actions could speed up the sequence of events, to this date, I can find no evidence of intentional delay or malfeasance.

I believe we have the facts delineated at this point, and we have initiated an internal after action review so that we can make improvements to prevent delays like this in the future and improve our decisionmaking. I have asked Dr. Steven Solomon, Director of our Center for Veterinary Medicine, to lead this review.

Before leading the Center for Veterinary Medicine, Dr. Solomon served in the Office of Regulatory Affairs and has deep organizational knowledge of the processes in the food program, as well as compliance and enforcement. The FDA and CDC's investigation could not conclude, as you stated, that the egregiously unsanitary conditions in the Abbott facility caused the illnesses reported in our timeline.

We cannot rule it out either, as the confluence of events is highly unusual. There is no dispute that the facility was unacceptably unsanitary, as evidenced by the consent decree. Frankly, the inspection results were shocking.

Standing water, cracks in key equipment that present the potential for bacterial contamination to persist, particularly in the presence of moisture, leaks in the roof, a previous citation of inadequate handwashing, and current poor sanitation, bacteria growing from multiple sides, and many signs of a disappointing lack of attention to the culture of safety in this product that is so essential to the lives of our most precious people.

As a clinician, I have used lifesaving, clot busting drugs, diagnostic tests, and cardiovascular devices made by Abbott. This is so far removed from my previous experience with the company that I remain very concerned.

As soon as we received positive cronobacter results from environmental samples at the facility that we collected during the inspection, we contacted Abbott to ask the company to issue a voluntary recall. The need to take urgent action to protect the most vulnerable of all of our people, infants, presented a dilemma.

This was the largest plant of the dominant manufacturer, and it was the sole source of a number of metabolic formulas essential for viability of infants with no substitution possible because Abbott had no backup plan. We knew that ceasing plant operations would create supply problems, but we had no choice given the unsanitary conditions.

We took several critical steps within hours, including meeting with those who have been dealing with our supply chain throughout the pandemic. A memo was sent to relevant agencies signaling the supply chain risk. We acted early to ensure the specialty metabolic and amino acid products for which Abbott was the sole producer, were made available on a case by case basis, consulting with nutritionists, pediatricians, and safety experts.

We contacted companies in the industry to encourage increasing their production to supply the market. We asked retailers to place temporary limits on how much any one person could buy to minimize excessive buying. We remain in frequent communications with our Government and industry partners about the status and risks.

Because of the lack of diversification of this market and the absence of a central hub for integrating supply chains, we concluded early on that getting the Sturgis facility up and running safely was a top priority, but we had no confidence in the integrity of the Abbot quality program at this facility.

Accordingly, we initiated proceedings toward a consent decree which requires Abbott to undertake steps to assure safe production of formula, including hiring outside expertise with reporting to FDA. Our oversight is critical, but make no mistake about it, the return to normal will only occur when Abbott takes the steps to resume production in a safe manner.

As detailed in the charts included in your written testimony, we and our Federal partners have been monitoring the in shelf stocking of formula and the rates of infant formula consumption all along.

Through the efforts of other companies to step up their production, sales of infant formula have remained steady, and in fact, volume and quantity of formula purchased are 5 to 15 percent higher now than in the months before the recall, as demonstrated in charts included in the written testimony.

Despite the overall numbers showing diminished but steady supply, we knew that distribution was an issue. Some areas were experiencing significant shortages, but overall there was enough formula to go around. About a month ago, the reports of shortages on the shelf proliferated, although there was not a drop in production.

This increase in consumption most likely represents heightened concern of parents and caregivers about shortages, leading to understandable effort to purchase ahead to ensure adequate supply at

home. I want to emphasize again, this is not blaming the parents and caregivers. This is rational behavior based on the concerns that they had.

This type of cycle has happened with other products throughout the pandemic, and we realize that the only solution is to have adequate supply to make sure the shelves are stocked. To that end, we have employed a host of measures to increase supply. A consent decree was signed with Abbott Nutrition last Monday that will allow the starters plan to get back in production.

I met with the Abbott CEO the day before yesterday, and he assured me they will be ready to go in early June. They have now given a date of June 4th as when they will be back in production. We continue to work with current U.S. based manufacturers to increase the production and distribution from FDA inspected facilities, both domestically and abroad.

I commend them for their efforts in this regard as we have seen substantial increases. We are helping with the all the Government response, including Operation Fly Formula, encouragement and support of importation of product not currently in the U.S. market by using careful case by case easing of regulatory requirements to safely increase the number of manufacturers allowed to import formula, working with state health Commissioners to increase flexibility with WIC contracts to enable additional infant formula suppliers to enter the market, and to catch price gougers.

Throughout the time since the recall, a highly dedicated group of experts within and outside the FDA have worked to manage the complex issues encountered for those caring for infants with complex metabolic issues requiring very special formula. I will leave you with several thoughts.

First, FDA's timeliness of interviewing the whistleblower and getting into the facility for our for-cause inspection were too slow and some decisions in retrospect could have been more optimal. I did not return to FDA to preside over business as usual.

After years of working in multiple private and public parts of the industry, I believe that success follows proper attention to structure, function, leadership, and resources to support the work of employees. All of these issues need attention in the chronically underfunded food side of the FDA, and you will see changes in the near future. Our requests for funding and authority are essential in concert with improved operations and leadership.

Second, the return of the Sturgis plant to safe production of formula is critical. Abbott's enormous market share left it with a responsibility for producing safe infant formula that was not met. We will do everything in our power to work with Abbott to make that happen as quickly and as safely possible, but this timing is in Abbott's control.

Third, the all Government effort and the enormous goodwill of Government partners and companies within and outside the U.S. has been heartening. While we are waiting for Abbott to fulfill its responsibility, we will meet the essential needs of American families with supplies from a variety of sources.

Fourth, the supply of inadequacy did not happen overnight. Across the industries we regulate, we are seeing evidence that the just in time distribution system, market concentration, and sole source contracting are leading to shortages. Multiple reports to Congress call for improved supply chain management.

Until regulatory agencies have digital access to critical supply chain information and personnel to do the work, we will continue to react to supply chain disruptions rather than intervening to prevent them. I want to conclude by reiterating that we will not rest until our shelves are replete with safe and nutritious infant formula.

I am committed to improve the ability of the FDA to meet its mission to protect and promote the health of American people, particularly infants, our most vulnerable people. Thank you.

[The prepared statement of Dr. Califf follows:]

PREPARED STATEMENT OF ROBERT M. CALIFF

Introduction

Chair Murray, Ranking Member Burr, and Members of the Committee, thank you for inviting us here today to testify before you on supply disruptions in infant formula. We have all seen the images of empty store shelves and heard the stories of parents of kids unable to find the food their children need to survive. This situation is unacceptable. The staff at the U.S. Food and Drug Administration (FDA or the Agency) feel this not just as public servants whose job it is to ensure that these critical products are safe and nutritious, but also as parents and grandparents. Our top priority now is addressing the dire need for infant formula in the U.S. market, and our teams are working night and day to help make that happen.

At the same time, we have begun an after-action review to evaluate our own performance. We appreciate the opportunity to discuss conditions at the Abbott Nutrition facility in Sturgis, Michigan, which led to the recall that contributed to the current supply disruptions; our infant formula supply chain monitoring and mitigation efforts; and additional tools necessary if we are to prevent, monitor, and mitigate any future infant formula supply disruptions.

Inspection of Abbott Nutrition's Sturgis, Michigan, Facility

On September 20, 2021, FDA learned of a Cronobacter infection in an infant who reportedly consumed powdered infant formula produced at Abbott Nutrition's Sturgis, Michigan, facility. FDA immediately reported this case to Abbott Nutrition and immediately followed up on the complaint, including testing formula associated with this case complaint. No Cronobacter was recovered from the product after FDA testing.

On November 17, 2021, FDA received a complaint involving an infant with Salmonella infection. FDA and our partners at the Centers for Disease Control and Prevention (CDC) eventually determined this event was unrelated to the other cases.

FDA received the second complaint involving an infant with Cronobacter infection on December 1, 2021. We again collected intact samples of powdered formula; no Cronobacter was recovered. We also notified Abbott Nutrition about this case.

Because Cronobacter is not a nationally reportable disease, isolates of the pathogens had not routinely undergone genomic analyses, as would occur with pathogens like Salmonella. In 2021 there was no genetic evidence available for us to know if these two cases from 2021 were linked by whole genome sequencing.

But given the two case complaints and the potential severity of Cronobacter infections, along with a complaint from a former employee at the Sturgis facility, on December 6, 2021, FDA initiated inspectional planning for a for-cause inspection at the Sturgis facility with an anticipated inspection date in early January 2022. We notified Abbott Nutrition of the planned inspection on December 30, 2021. Abbott Nutrition responded by notifying FDA of approximately a dozen COVID–19-positive employees in its facility. Although we delayed our inspection temporarily because of these COVID–19 infections, FDA commenced our inspection on January 31, 2022.

FDA received a third report of an infant Cronobacter illness on January 11, 2022, while the facility's COVID–19 outbreak delayed FDA's inspection. Again, FDA tested product associated with this illness, found no Cronobacter, and notified Abbott Nutrition.

FDA learned of a fourth case of Cronobacter infection on February 17, 2022, the date on which Abbott Nutrition initiated a voluntary recall and FDA issued a consumer advisory.

Infants in all four cases were hospitalized, and Cronobacter may have contributed to deaths in two cases. All of the infants are reported to have consumed powdered infant formula produced at Abbott Nutrition's Sturgis facility. The Agency investigated each complaint and analyzed product from the consumers' homes when available. FDA also notified Abbott Nutrition after receiving each complaint.

The CDC receives reports on foodborne disease outbreaks from state, local, and territorial health departments. On average, CDC receives two to four Cronobacter case reports annually; however, because Cronobacter infection is not reportable in most states, the total number of cases that occur in the United States each year is not known. Thus, the four cases that came to our attention between September 20, 2021, and February 17, 2022, raised concerns. Despite this very unusual combination of events, we do not have definitive evidence proving that insanitary conditions of the Sturgis facility actually caused the Cronobacter illnesses of these infants.

We have included this timeline in Appendix A, and we have processes under review to develop better systems within FDA.

In sum, awareness of the four Cronobacter cases offered an evolving fact pattern, leading us to initiate a for-cause inspection, but our inspection dramatically altered the fact pattern.

Sanitary environmental conditions and well-maintained equipment are the most basic, minimal conditions needed for a manufacturer to produce dry powdered infant formula that is free of bacterial contamination. The FDA inspection team observed significant operational deficiencies in Abbott Nutrition's Sturgis facility during the January 2022 inspection. The totality of evidence obtained during our inspection caused FDA to conclude that infant formulas produced at this plant were produced under insanitary conditions and may be contaminated with Cronobacter. We based our conclusions on the following evidence:

- FDA investigators collected multiple samples from swabs in the facility's environment, which later tested positive for Cronobacter sakazakii.
- FDA investigators observed serious cracks in the firm's spray dryers, key pieces of equipment for producing powdered products and an issue that has been linked to at least one historical foodborne illness outbreak in powdered infant formula at a different facility.
- FDA investigators also found water leaks and condensation, which are risk factors for Cronobacter, in areas where dry powdered formula was produced.
- Employees in the facility lacked adequate handwashing technique.
- A review of the firm's internal records also indicated environmental contamination with Cronobacter sakazakii and the firm's destruction in 2019 and 2020, respectively, of two batches of finished product due to the presence of Cronobacter.
- FDA investigators noted that Abbott Nutrition did not establish a system of process controls covering all stages of processing designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.
- FDA also noted that Abbott Nutrition did not ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source.

FDA investigators collected numerous product and environmental samples during the inspection. Product samples FDA collected at Abbott Nutrition's Sturgis facility and analyzed for Cronobacter tested negative. It is well documented in the scientific literature, however, that end product testing is unlikely to detect low levels of contamination. In contrast, five environmental subsample surface swabs collected from the facility tested positive for Cronobacter sakazakii; four of these instances of contamination were detected by FDA-initiated testing, and one was detected through simultaneous firm-initiated testing. The positive Cronobacter sakazakii environmental samples collected at Abbott Nutrition's Sturgis facility have been analyzed

using whole genome sequencing, revealing five different strains of Cronobacter sakazakii. While none of these environmental samples matched the limited (two) clinical samples from infants ill with Cronobacter, these findings remain a serious concern, as environmental sources of Cronobacter in infant formula manufacturing plants have been identified as one of the most likely sources of contamination.

As soon as the Agency received these positive environmental sampling results in February 2022, we communicated with Abbott Nutrition about the need for the firm to issue a voluntary recall. Abbott Nutrition voluntarily ceased production at the Sturgis facility 2 days prior to the recall, and FDA supported this decision given the insanitary conditions at the facility. On February 17, 2022, we issued a public communication advising consumers not to use the affected products. Abbott Nutrition initiated a voluntary recall the same day.

Insanitary conditions of this kind are unacceptable in all food manufacturing facilities, but especially in areas producing dry powdered formulas that serve as the sole source of nutrition for infants. Finding pathogens in finished product during routine testing also generally indicates a potentially serious loss of sanitary process control during manufacturing. FDA would expect any manufacturer with a robust quality assurance program to identify and quickly take corrective action when such conditions are present.

FDA knew that restarting the Sturgis, Michigan, facility was critical, because it was one of three plants run by a company with the largest market share, and many of its specialty formula products cannot be quickly manufactured at other facilities. We also became aware that Abbott Nutrition lacked a contingency plan to produce its lines of specialty metabolic and amino acid formulas that serve as a sole source of nutrition for thousands of infants with metabolic disorders. We lost confidence that Abbott Nutrition had the appropriate safety and quality culture and commitment to fix these problems quickly. FDA was left with limited options. Given the market share that Abbott Nutrition had for regular and critically needed specialty metabolic and amino acid formulas, FDA decided to negotiate a consent decree with the company rather than seeking a court order of permanent injunction through a contested process. A consent decree was the best option, giving FDA more control over the outcome, and was more likely to result in a safe resumption of operations by Abbott Nutrition at the Sturgis facility.

With the urgent public health need in mind, FDA, along with the U.S. Attorney's Office for the Western District of Michigan, moved as quickly as possible through the negotiation process. In fact, the process here was shorter than it often is for obtaining a consent decree. FDA made clear its expectations for a safe reopening of the facility. Even still, because it was a negotiation process with a regulated firm, the U.S. Government did not completely control the timeline. Moreover, FDA's negotiations needed to be informed by our inspection of the Sturgis facility, which did not close until March 18, 2022, to ensure that the consent decree would fully address all observed violations.

FDA's and U.S. Government Actions to Increase the Supply of Specialty Metabolic Formulas

When we talk about the infant formula supply chain, we really need to consider multiple supply chains, including, but not limited to, the supply of infant formula for healthy infants, another for infants with allergies and/or medical conditions who need hypoallergenic amino acid formulas, and another for infants who have very serious medical conditions, such as inborn errors of metabolism, and require unique specialty metabolic formulas. Abbott Nutrition dominates the market for many of the amino acid-based and metabolic formulas. Unfortunately, the only site where Abbott Nutrition produces these critical products is the Sturgis plant. Thus, the Agency immediately had to consider the potential impact a recall of these specialty formulas could have on infant health.

FDA decided to exempt specialty metabolic products from the recall and required that the current stock of these formulas in storage would be subject to third-party review before release. Some of the infants who were using these non-recalled products could potentially be switched to comparable products, but transitioning is not always well tolerated or possible and thus requires clinical input from the child's health care provider. For this reason, we coordinated with groups such as the American Academy of Pediatrics, Genetic Metabolic Dietitians International, and the Society of Inherited Metabolic Disorders so providers would be prepared to advise their patients whether switching products was appropriate. We also coordinated with the U.S. Department of Agriculture's (USDA) Special Supplemental Nutrition Program for Women, Infants, and Children (WIC), and made them aware of the pending re-

call in advance of it occurring. To help support supply chains, our infant formula team had to determine for each of these products what comparable products might exist from other infant formula manufacturers and request that they increase production of these products as much as possible. These efforts included seeking available inventory outside of the domestic market.

FDA worked with Abbott Nutrition to identify and prioritize specialty and metabolic formulas and asked Abbott Nutrition to establish a process to provide these formulas to those in need on a case-by-case basis. After the third-party audit concluded, Abbott Nutrition began releasing these critical products on a case-by-case basis. In these circumstances, the benefit of allowing caregivers, in consultation with their healthcare providers, to access these products may outweigh the potential risk of bacterial infection. FDA determined that the case-by-case release of these priority products is the best solution prior to resuming production of them at Abbott Nutrition's Sturgis facility. Since Abbott Nutrition did not have a plan or any capability to produce these critical, lifesaving products at another of their facilities, case-by-case release was the only option. FDA continues to use all levers we have, including Operation Fly Formula, to be able to increase the supply of these formulas, which come from an even more limited set of manufacturers than general infant formula. The first airlifts of infant formula as part of Operation Fly Formula are amino acid and hypoallergenic hydrolyzed formulas that are most critically needed. We note that having access to good data on the availability of specialty and metabolic formulas is challenging; measures useful to assess the supply of general formula such as those from Information Resources Inc. (IRI) (discussed below), are not informative for these products, as they are not always sold in traditional retail settings.

FDA's Work with Partners to Increase the Broader Infant Formula Supply

The United States was facing infant formula supply chain stress even before the Abbott Nutrition recall began on February 17, 2022. Abbott Nutrition's voluntary recall and subsequent voluntary cessation of operations at its Sturgis plant in February further destabilized the infant formula supply chain. Prior to the voluntary recall of several infant formula products produced at the Abbott Nutrition facility, FDA was working to address supply chain issues associated with the pandemic, including those impacting the infant formula industry. Our efforts to help support an all-of-government supply chain response included regular engagement with the Infant Nutrition Council of America (INCA), and its members, to identify challenges they were facing. Beginning immediately after the recall in February, this work greatly intensified, and the Agency has been working extensively with Abbott Nutrition and other manufacturers to bring safe products to the U.S. market as quickly as possible.

FDA's intra-agency group includes experts from the Office of Food Policy and Response (OFPR) and the Center for Food Safety and Applied Nutrition (CFSAN). They began evaluating infant formula supply chain implications prior to the recall, met with USDA, and ensured that U.S. Government supply chain partners were engaged at the highest levels. FDA and USDA, as co-leads for Food and Agriculture Sector Risk Management, provided regular updates to the White House regarding overall supply chain concerns, including information about infant formula. Since the first day, FDA has worked tirelessly with U.S. Government partners to mitigate the supply chain disruption for both regular and specialty formulas.

It is important to understand that only facilities experienced in and already producing infant formula and specialty metabolic products are in a position to make products that would not pose significant health risks to consumers. Infant formulas for healthy, full-term infants are complex in terms of formulation, processing, and other considerations to achieve required levels of 30 different nutrients and to avoid excessive levels of 10 nutrients that can be toxic when levels are too high. Formulas for low birth weight or premature infants, or those with serious health conditions, are even more complex; for example, hypoallergenic formulas need to be manufactured to ensure cross-contact with other formulas made in a facility does not occur.

FDA continues taking key steps to help increase the supply of infant formula in the United States. FDA is leveraging all tools at our disposal to support the supply of infant formula products:

- Meeting regularly with major infant formula manufacturers to better understand and maximize their capacity to increase production of various types of infant formulas and essential medical foods. The infant formula industry is already working to maximize their production to meet new demands. Efforts already underway by several infant formula manufactur-

ers include optimizing processes and production schedules to increase product output, as well as prioritizing product lines that are of greatest need, particularly specialty formulas.

- Helping manufacturers bring safe product to the market by expediting review of notifications of manufacturing changes that will help increase supply, particularly in the case of the specialized formulas for medical needs.
- Monitoring the status of the infant formula supply by using the Agency's 21 Forward food supply chain continuity system, combined with external data. Originally designed to address the broader food supply during the pandemic, FDA has adapted 21 Forward to monitor and support infant formula supplies by adding additional data sets to provide more frequent and granular information about infant formula product availability and sales.
- Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.
- Implementing a new process to temporarily exercise enforcement discretion, on a case-by-case basis, for certain requirements that apply to infant formula. These flexibilities, applicable to both imported and domestically produced infant formula, will augment supply volume while meeting FDA's criteria for labeling, nutrition standards, and safety testing. Within a week, FDA informed two foreign manufacturers that they could use this pathway to import their infant formula, and we are evaluating multiple other promising requests.
- Expediting the necessary certificates to allow flexibility in the movement of already permitted products from abroad into the United States.
- Offering a streamlined import entry review process for certain products coming from foreign facilities with favorable inspection records.
- Exercising enforcement discretion on minor labeling issues to help increase volume of product available as quickly as possible.
- Continuing outreach to retailer stakeholder groups to request that their members consider placing purchase limits on some products to protect infant formula inventories for all consumers.

In broader whole-of-government efforts, agencies are working together to improve the supply of infant formula to American families by:

- Invoking the Defense Production Act, directing firms to prioritize and allocate the production of key infant formula inputs to help increase production and speed up supply chains.
- Launching Operation Fly Formula, coordinating the Department of Health and Human Services and U.S. Department of Agriculture (USDA) to leverage Department of Defense contracts with commercial air cargo lines to pick up overseas infant formula that meets U.S. health and safety standards, so it can get to store shelves faster. Bypassing regular air freighting routes will speed up the importation and distribution of formula and serve as an immediate support as manufacturers continue to ramp up production.
- Offering state health commissioners flexibilities through WIC to determine products that may be substituted for recalled products, allow families to purchase different container sizes and physical forms, allow purchase of noncontract brands, and waive retailer minimum stocking requirements to allow formula to transfer to where it is most needed. We thank Congress for passing the Access to Baby Formula Act of 2022 to expand access to baby formulas for certain American families during this supply chain disruption, but we know that still more remains to be done to ensure industry consolidation and sole-source purchasing contracts do not put future American families in this situation again.
- Addressing price gouging and unfair market practices by calling on retailers to issue purchasing limits, as well as engaging with state attorneys general to encourage them to user their power to monitor and act on price gouging and predatory behavior. In addition, the Administration has asked the Federal Trade Commission to use all of its available tools to monitor and investigate illegal and predatory conduct.

FDA has been working closely with all major infant formula manufacturers to mitigate supply disruption. All manufacturers already in the U.S. market have increased production to capacity. However, FDA lacks authority, resources, or dedicated staff to predict, detect, and respond to supply chain issues for infant formula and medical foods—although we have requested authority to do so since 2020, including in our fiscal year (FY) 2022 and fiscal year 2023 budget requests. FDA developed this legislative proposal because we were well aware that the U.S. infant formula supply chain was dominated by a small number of actors with only a handful of manufacturing facilities—making it at high risk for disruption by any single event or stressor. Even without the authorities to compel submission of supply chain data, FDA took numerous steps to request these data and shore up supply to the extent we received cooperation of firms.

Following FDA's efforts, the major infant formula manufacturers are producing at increased capacity and have been further optimizing their lines to produce more infant formula to meet current demand. In the month of April, consumers purchased more infant formula than they did in the 4-weeks prior to the recall, which is a good indication that powdered infant formula availability is headed in the right direction. Data from IRI show nearly 80 percent in-stock rates for the week ending May 15, 2022, (compared to 89 to 90 percent in-stock rates before the Abbott Nutrition recall; see figure 1). This means that if a local supermarket normally carries 50 different infant formula products, an 80 percent in-stock rate translates to 40 of those 50 product types being available. But we understand—as parents and grandparents ourselves—that many have been unable to access the products they need and that they are understandably frustrated and anxious.

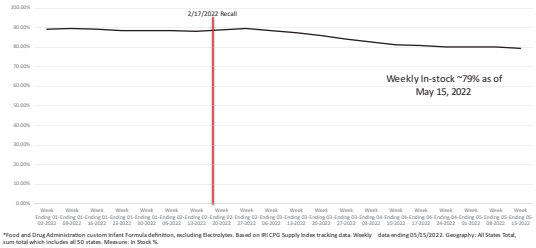

FIGURE 1: NATIONAL IN-STOCK RATE 2022 YEAR-TO-DATE: INFANT FORMULA

While in-stock rates have dropped gradually because of Abbott Nutrition's inability to resume production as quickly as we all would like, there are some positive trends because of FDA's call to action to the rest of the industry. National infant formula sales by volume for the most recent 4 weeks of data through May 8, 2022, increased 12 percent compared to the 4-weeks prior to the recall (see figure 2). And national infant formula sales by unit increased 5 percent for the most recent 4 weeks of data through May 8, 2022, compared to the 4-weeks prior to the recall (see figure 3).

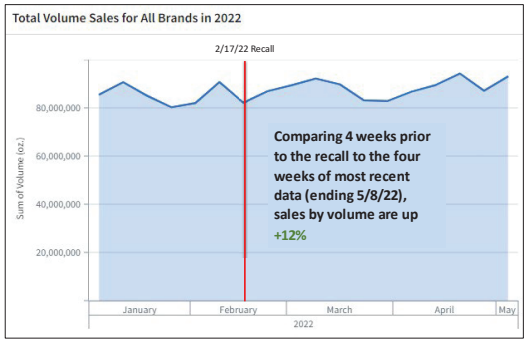

FIGURE 2: TOTAL NATIONAL VOLUME SALES INFANT FORMULA 2022 YEAR-TO-DATE

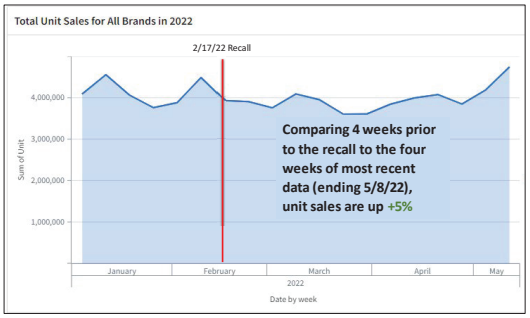

FIGURE 3: TOTAL NATIONAL UNIT SALES INFANT FORMULA 2022 YEAR-TO-DATE

Through our weekly intensive discussion with manufacturers, we also know that all producers that supply the U.S. market have already stepped up to the challenge and are telling us they are producing at an expanded capacity. For example, Nestle Gerber increased the amount of its infant formula available to consumers by approximately 50 percent in March and April, and Reckitt is supplying more than 30 percent more product so far this year.

What these data tell us collectively is that while there is more product being produced and sold, it is of less variety than prior to the recall. These metrics also indicate that we are on a positive trajectory. However, we know that one parent not being able to find the products they want is one parent too many, and we, also, have seen the photos of empty shelves and heard of the stressful stories of parents having to work extra hard to find product. This is unacceptable.

Importantly, we know that some data suppliers who use less standardized metrics have reported lower in-stock rates, and we believe those news reports, recited without validation, may have exacerbated the situation in recent weeks. Throughout the pandemic, retailers have experienced a new type of consumer behavior—which we can appreciate and understand—where consumers may purchase additional units to ensure they can stock their pantries, because of a loss in confidence that their desired products will be available during their next grocery shopping trip. And when it comes to ensuring their infants have access to a sole source of nutrition, this behavior is understandable.

As discussed above, data available to FDA show that volume sales of infant formula, as a category, are currently higher than they were before the Abbott Nutrition recall. However, there have been dramatic shifts in which products (e.g., brand, type, and size) are being sold, and the recent increases in consumption create empty shelves that require further ramp up of supply. In addition, there are significant concerns related to the availability of certain specialty formula products, such as amino acid-based products and formulas for individuals with inborn errors of metabolism—these are products on which FDA has been especially focused. Indeed, the availability of specialty and metabolic formulas remains a fluid and evolving situation.

The Agency's best current assessment is that with all of the current actions, and the potential for Abbott Nutrition's Sturgis facility to resume production safely in the near term, the supply of infant formula will continue to improve over the next several weeks. In the meantime, FDA is encouraged to see that as of early May, the amount of infant formula sold in the United States continues to rise.

On May 16, 2022, the U.S. District Court for the Western District of Michigan entered a consent decree of permanent injunction between FDA and Abbott Nutrition, as well as three Abbott Nutrition principals. Under the consent decree, Abbott Nutrition has agreed to take corrective actions following FDA's inspection of its Sturgis, Michigan, facility. The consent decree obligates Abbott Nutrition to take actions that are expected to ultimately result in an increase of infant formula prod-

ucts, while ensuring that the company undertakes certain actions that would ensure safe powdered infant formula is produced at the facility. When the company restarts production at this facility, it must conform with the provisions of the consent decree and meet FDA food safety standards. If contamination is identified, the company must notify FDA, identify the source of the problem, and conduct a root-cause investigation before resuming production.

Modernizing Infant Formula Safety and Supply Chain Security

We take seriously our duty to prevent and respond to foodborne illnesses and food contamination events. FDA will be conducting an evaluation of our response to this incident and determine what additional steps should be taken to ensure the maximum effectiveness of Agency programs and policies related to infant formula and medical food complaints, illnesses, and recalls.

More than 3.5 million babies are born in the United States each year, many of whom rely on formula at some point as their sole source of nutrition. FDA has nine staff devoted to reviewing infant formula premarket submissions for safety and nutrition. Even before the voluntary recall and production halt at Abbott Nutrition's Sturgis facility, FDA's infant formula staff faced increased workload due to COVID–19 supply chain issues and increased product innovation in the infant formula industry. Furthermore, the war in Ukraine has caused a disruption in the supply of sunflower oil, an ingredient in many formulas, which has further increased FDA's review responsibilities as manufacturers assess their supply chains and needs to reformulate product. Recent actions to increase imports will also increase FDA's workload, as the review team must review incoming applications and collaborate with the food safety team to ensure that these products are both safe and nutritionally adequate.

The wide-reaching impacts of a recall from a single infant formula manufacturing facility underscore the risks and vulnerabilities in the supply chain when production is consolidated among few major manufacturers utilizing few manufacturing facilities. Building resiliency across the infant formula supply chain will better enable the industry to withstand any future disruptions without a significant breakdown in supply. To this end, we are exploring additional mechanisms to incentivize flexibility and redundancy of the infant formula supply chain infrastructure to increase resiliency in the infant formula industry over the long term. Recommendations from the White House's 100-day supply chain review report [1] with regard to pharmaceutical and active pharmaceutical ingredient supply chain resiliency may prove insightful here. In partnership with other agencies across the U.S. Government, we also hope to initiate a broad dialog on how contracting models for these products could be enhanced to incentivize greater resiliency for infant formula supply, encourage new entrants into the market, and diversify the supply chain, without adversely impacting programmatic costs and the number of infants served by the WIC contract models.

While infant formulas—and particularly specialty and metabolic formulas—are regulated by FDA as food, they are in many ways comparable to life-saving medications. Viewing these products through the lens of how FDA addresses drug shortage monitoring and mitigation supports the need for a more responsive mechanism to monitor for and mitigate against potential supply chain disruptions. FDA's foods regulatory program has and can continue to benefit from the expertise and experience available within the Agency's medical product centers in this regard. The importance of a team with clinical, nutritional, and analytical expertise cannot be emphasized too much.

Strengthening data and technology tools at FDA and other agencies is also critical to enhancing infant formula supply chain resiliency. The industry has sophisticated supply chain data enabling modeling and predictive analytics for the individual manufacturers and suppliers, but there is no data system to combine the information into a composite picture that would enable an understanding of the resiliency of the entire system to stresses, disruptions, and changes in demand. We need a sustainable mechanism for infant formula supply chain monitoring to allow us to better identify and address existing and future potential supply chain disruptions. A dynamic, interconnected supply chain monitoring platform and robust data sets are necessary to enable the Agency to be most effective in monitoring food supply

[1] The White House, Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-based Growth: 100-day Reviews under Executive Order 14017, June 2021, available at *https://www.whitehouse.gov/wp-content/uploads/2021/06/100-day-supply—chain-review-report.pdf*.

chains, managing risks, and identifying and quickly addressing supply chain disruptions to reduce impacts on consumers.

One example of a beginning to this effort is FDA's 21 Forward platform, which has been essential to our infant formula supply chain efforts. Further development of the technology will allow us to integrate, analyze, and monitor multiple data sets—including data on consumer purchasing, in-stock product availability, food facility registration, and imports—in real time to inform our response and help us focus on the areas of greatest need.

In the President's fiscal year 2023 budget request, we have also identified legislative changes that would provide new tools to help FDA signal our partners who control supply chain dynamics to take action that would prevent or mitigate shortages of infant formula and essential medical foods. Our proposal would require firms to notify FDA of anticipated significant interruptions in the supply of infant formula or essential medical foods, similar to how drug manufacturers do today. These notifications would allow the Agency to receive relatively imprecise—but helpful—indicators about likely or confirmed shortages in the U.S. marketplace, better enabling us to alert the system and stimulate the industry and government partners to take steps that promote the continued availability of these important foods, which often are a sole source of nutrition.

Another component of this proposal would be requiring manufacturers to develop and implement risk management plans. These are routine in most industries and have been used in our drug shortages supply chain oversight. These plans would identify, evaluate, and manage risks to the supply of infant formula or essential medical food. These plans would serve supply chain resiliency within each manufacturer, but they would also be available to FDA for its real-time monitoring efforts of the way they fit together to produce a complete picture of resiliency and vulnerability of this vital supply chain.

None of these improvements would be as useful as a digital platform that monitors the supply chain constantly and in real time. This industry and most others have been resistant to efforts to develop such a system, but until such steps are taken, the American public will be vulnerable to threats from natural disasters and cyberattacks as well as the quality problem that created the current infant formula situation.

Another legislative change identified in the President's fiscal year 2023 budget request is access to records in lieu of or in advance of an inspection, or, in other words, the authority to conduct remote regulatory assessments. Presently, FDA has such authority for drug inspections, and the Agency often relies on voluntary participation for remote regulatory assessments of many non-drug establishments. However, reliance on voluntary requests is not sufficient to achieve effective and efficient oversight, as firms can refuse to provide records or other information in advance of or in lieu of an inspection or to participate in remote regulatory assessments. We are seeking to expand the explicit statutory authority in section 704(a)(4) of the Federal Food, Drug, and Cosmetic Act to require firms to provide records or other information pertaining to all FDA-regulated products. An expansion across the board, in advance of or in lieu of inspections, would significantly enhance FDA's ability to obtain access remotely to records and other information from facilities producing infant formulas and essential medical foods, and would help the Agency investigate emerging supply chain issues, promote regulatory compliance, and protect the public health.

Conclusion

Ensuring the availability of safe, sole-source nutrition products like infant formula is of the utmost importance to FDA. Our teams have been working tirelessly with all the responsible entities across government to address and alleviate supply issues while protecting safety, and we will continue doing everything within our authority to ensure the production of safe infant formula products.

Thank you, and we look forward to answering any questions you may have.

Appendix A: Timeline of Infant Formula Recall and Supply Chain Disruption

Summary

Below is the timeline associated with ongoing stressors on the infant formula supply chain and FDA's investigation and response to complaints associated with and conditions at Abbott Nutrition's Sturgis, Michigan, facility.

In this investigation, FDA received a total of five case complaints (four Cronobacter cases and one Salmonella case). Of these complaints, four were received prior to FDA's January 2022 inspection (three Cronobacter cases and one Salmonella case). FDA and CDC later determined the Salmonella case to be unrelated to the Abbott Nutrition facility. FDA had clinical isolates for only two of the Cronobacter cases. Investigating case complaints takes time—product samples are taken, interviews are conducted, records are collected, and pathogens are sequenced. In three of the Cronobacter case complaints, the product samples taken during the case investigations all tested negative for Cronobacter. However, as FDA received additional complaints and associated details over time, a pattern emerged that suggested a potential problem at the Sturgis facility. The timeline below sets forth the actions that FDA took to investigate these cases and Abbott Nutrition's Sturgis facility, as well as to obtain agreement from the company to cease production and enter into a consent decree containing a legally enforceable path forward to resume safe operations at the facility.

FDA has taken aggressive action to attempt to address the infant formula supply chain issues. Days after the World Health Organization declared COVID–19 a pandemic, FDA experts became concerned that a disruption at a single infant formula or medical foods facility could lead to a shortage of critical products—especially specialty metabolic and amino acid formulas. FDA developed and submitted to Congress a legislative proposal in March 2020 requesting supply chain authority. Despite not receiving such authority nor having dedicated resources, FDA stood up a system to monitor potential food supply chain disruptions, 21 Forward, which was funded by Acting Commissioner Janet Woodcock out of Office of the Commissioner's reserve funding.

Prior to Abbott Nutrition's voluntary recall, FDA began having supply chain discussions with our Federal partners and stakeholders, and these continued on a frequent basis. FDA ensured specialty metabolic formulas at Abbott Nutrition were excluded from the recall, held, and made available for those in critical need. Just after the recall, for example, FDA engaged with the relevant infant formula manufacturers to begin regular conversations about bolstering production and supply.

This timeline demonstrates areas where FDA can and must do better or be faster. A detailed internal review is ongoing to determine what process, policy, and authority changes can improve FDA's response to infant formula investigations and recalls. For example, the FDA investigator who performed the September 2021 inspection at the Abbott Nutrition facility followed standard process to search for associated case complaints days prior to inspection, and thus during the inspection was unaware of the first Cronobacter complaint that FDA received. If FDA had modernized IT systems that could have instantly linked the first Cronobacter complaint to the IT system the investigator was using during the inspection, it is likely FDA's timeline would look very different.

However, FDA's investigation was impacted by events not fully in the Agency's control, such as the emergence of the omicron variant that likely led to an outbreak of COVID–19 cases at the Sturgis plant that resulted in the delay of this inspection. Since Cronobacter is not a reportable pathogen, FDA is not able to know if clinical cases share the same pathogen, suggesting a point source, and there is not a robust data base of sequenced samples, which meant that FDA is not able to make rapid comparison of clinical, product, or environmental samples during an investigation to determine whether matches exist that can link a product or facility to an illness. There was also delay in the confidential complainant's availability to meet with FDA. And while FDA pursued the consent decree as quickly as possible, FDA does not have control over how quickly negotiations resolve.

FDA's path forward is informed by our experience. Even while responding to this supply chain crisis, we are working to improve our agency to make sure that we are protecting the most vulnerable members of our society. We are committed to coming back to this Committee after our review is complete to share more details on the ways we believe that FDA can improve our processes and programs, as well as any areas where we may need the Committee's support for additional authorities or resources.

The CHAIR. We will now begin a round of 5 minute questions. I ask my colleagues to keep track of the clock. Stay within those 5 minutes. Dr. Califf, parents and caregivers across the country rely on the FDA and the handful of dominant formula manufacturers

to make sure that formula that they feed their babies meets the highest standard of safety and nutrition.

But the companies and FDA let them down. I am ready and willing to work—to continue working with you and absolutely anyone to get this right and make sure we never are in this situation again. But I want to be clear about where we are in the current moment. Babies have gotten sick. Two have died after drinking formula from Abbott nutrition Michigan facility. It took months, months, in fact, you are telling us today it took 6 months for FDA to investigate.

During that time, Abbott continued to produce formula at the Michigan plant, and when FDA finally completed an onsite inspection, months after the first baby became ill, it found evidence of the cronobacter bacteria on surfaces where formula was being produced and a history of cronobacter in finished baby formula products.

That is incredibly alarming. So it makes sense the plant was shut down as Abbott and FDA tried to figure out why babies were getting sick and ensure inspectors uncovered substantial long term problems at the facility. What doesn't make sense, what I can't for the life of me figure out is why it took so long to investigate in the first place.

Why did so much time pass before the FDA took serious action to investigate this contamination in baby formula?

Dr. CALIFF. Well, Senator Murray, I appreciate the question. I think we all have a great degree of sorrow over the difficulties that you are describing. Many people at FDA are not sleeping at night, they are working weekends and trying to get this corrected. There is no question, it is not—it is just not a good——

The CHAIR. Well, I mean, I am asking the question, why did it take so much time?

Dr. CALIFF. Yes, I want to parse one issue with you. I have many more disagreements with Senator Burr about some things that were said. But from the very first case, there was investigation going on. It didn't take 6 months to start the investigation. That very first case, you have to collect samples——

The CHAIR. No, I am asking why it took 6 months to take serious action.

Dr. CALIFF. Because—the answer to that question is in our document, there are systemic issues at FDA and in our interactions with the industry and our authorities that need to be corrected. It is clearly——

The CHAIR. Do you have a plan to do that?

Dr. CALIFF. Yes.

The CHAIR. When can we see it?

Dr. CALIFF. When can you see the plan?

The CHAIR. To correct these problems, yes.

Dr. CALIFF. I mean, we have a plan, but a complete plan right now, we will have to get to you as soon as we can. I can't give you an exact date right now.

The CHAIR. Well, has Abbott told you why it kept producing formula when it knew it might be dangerous for babies?

Dr. CALIFF. They have not. I will remind you that we ended up in legal proceedings with Abbott. We could not get control of the quality in the plant without going through a consent decree process which has limited our ability to discuss it, because it is a serious legal proceeding, as you know. What I do know is that they now have good plans underway to correct it that we are overseeing every step of the way.

The CHAIR. For parents of preemies like Mac, my constituent in Richland, what is the clear message from FDA and HHS on how and where he is going to get Neosure or an equivalent formula for preemies?

Dr. CALIFF. For any infant requiring specialty formula, we have a committee and a whole host of pediatricians and specialists who are constantly in contact. The physician involved should be able to contact through the specialty societies access to the needed formula.

The CHAIR. What I am asking is exactly what should parents know? I want to be able to say to Mac that you, Secretary Becerra, are telling him directly where he can go to get the formula. He and many other parents.

Dr. CALIFF. A parent needing specialty formula should start with a pediatrician. If the pediatrician is not in the loop, one should go to the HHS website and call HHS, and we will intervene directly to help out. There is a committee in place to do that for each individual infant.

The CHAIR. Well, I—look, when this hearing is over, I expect you and the Secretary to do everything possible to make it very clear to parents like Mac across the country what they should know to be able to get—going to be able to do to keep their babies out of the hospital. Very clear, direct to parents across this country.

Dr. CALIFF. I understand.

The CHAIR. Senator Burr.

Senator BURR. Thank you, Madam Chair. Dr. Calif, Abbott submitted its paperwork for reopening Sturgis facility to the FDA on April the 8th. Seven weeks later, the facility is still closed. Do you have permanent inspectors every day in the Sturgis facility helping Abbott identify the contaminations that the inspectors found?

Dr. CALIFF. You have some incorrect information. Abbott did not submit adequate documentation on the date that you referred. That was only——

Senator BURR. Do you have inspectors today in the facility every day helping Abbott get the plant up and running?

Dr. CALIFF. We have inspectors working with Abbott every day——

Senator BURR. Not in the plant?

Dr. CALIFF. No, not in the plant.

Senator BURR. Why haven't you waived labeling requirements from trusted manufacturers in countries like the UK, Australia, or Canada? Couldn't manufacturers provide temporary labels on imported formula cans if the label is printed in a language other than English until U.S. manufacturing is restored? Some countries have

higher nutritional requirements. Why can't we provide a waiver for their products to come into the country?

Dr. CALIFF. We have waived many of the requirements, the ones that make sense. But the directions have to be clear to Americans in language that is understandable so that the formula can match up correctly. An error in mixing up the formula, for example, can lead to a very sick infant not getting the right nutrition.

Senator BURR. Dr. Califf, complacency is apparently the FDA's catch phrase when it comes to infant formula. In Fiscal Year 2021, the FDA received 42 submissions for new infant formulas. The agency was able to review only 15 of those submissions within 90 days. That is one-third. What happened to the other submissions?

Did you expedite the review of the new formula submissions when you took the helm at the FDA amidst a growing shortage? By law, by law, the FDA has 90 days to review new infant formula manufacturing submissions. What is the average number of days it actually takes for the FDA to review these?

Dr. CALIFF. Senator Burr, FDA employees are working around the clock, and they are hardworking people, so I somewhat resent the implication of part of that, but——

Senator BURR. Dr. Califf, there is no Member that has defended the FDA more than this one and there is no Member in Congress that has tried to fix areas when they are broken than this one. If you want to get into this with me, I am happy to do it. I got 28 years' worth of it.

Dr. CALIFF. I know you are quite capable of that. So let me just say, right from the start, any good application was expedited by the FDA since the shortage became evident.

Senator BURR. So 42 minus 15, the rest of them were not good for application.

Dr. CALIFF. Application like you were referring to 2019 or something, you said——

Senator BURR. No, it is Fiscal Year 2021.

Dr. CALIFF. Yes, I will have to get back on the details on that.

Senator BURR. Listen, the FDA Food Center, let's talk about it. It has a staff of 4,000 people, but according to your own budget documents, there are only 9 staff reviewing infant formula applications. Did you or other FDA leaders assign any staff to review infant formula as the shortage percentages rose sharply?

Dr. CALIFF. We pulled in people from all over the agency to help that short staffed group, which of course——

Senator BURR. To process applications.

Dr. CALIFF. I will have to go back and see exactly how they spent their time but looking at all of the activities of that group, they were supplemented by staff from across the agency, which of course means that other things didn't get done.

Senator BURR. Do you have the authority as Commissioner to move people around as needed?

Dr. CALIFF. Yes.

Senator BURR. Okay. Dr. Califf, I have looked at initial review of some of the activities of the Food Center, and I am concerned

with your prioritization of the activities with the staff you have since the voluntary recall.

Since the voluntary recall infant for infant formula, FDA Food Center spent time making changes to the definition of yogurt, opining on color additives in Antarctic krill meat, that is fish food, so farms can raise salmon that looks more pink, making announcements about the use of the term—of the definition healthy.

Since the first infant hospitalization, the same Center has issued a rule on the definition of French dressing and issued guidance on chocolate, cheese and chocolates that stray from the FDA's official definition. This is a pattern over the last decade.

The same Center has gone after salt, sprinkles, and even the definition of frozen cherry pie. So my question is simple, in conclusion, what are your priorities of the Food Center?

Dr. CALIFF. The Food Center has a broad set of mandates, as you well know, but there is nothing of higher priority than this particular issue that we are discussing today. It is the highest priority. We are assigning every resource that we can to work on this problem.

Senator BURR. Well, I hope that the Chair's request did not fall on deaf ears, that a detailed, comprehensive plan should be something that you could produce now, if, in fact, the agency is working at the expedited pace that you addressed. If it is not ready today, I hope it is in the very, very near future. Thank you, Madam Chair.

The CHAIR. Thank you.

Senator Sanders.

Senator SANDERS. Thank you, Madam Chair. Dr. Califf, concentration of ownership in our economy is a major, major problem in many sectors. It is true on Wall Street. It is true in energy. It is true in food production in general. It is certainly true in the production of infant formula, which is so terribly important to millions of parents with babies. Right now, we have three companies, Abbott, Mead, and Nestlè, who dominate the entire market.

We have recently been discussing contamination at an Abbott facility. Tomorrow it could be Nestlè. Are you concerned and what are you doing about broadening the number of companies who are producing infant formula?

Dr. CALIFF. I am very concerned, and as I said in my opening remarks, it is not unique to this industry that we are seeing concentration that puts everything at risk. I will remind you, as you well know, there is no requirement that companies show us their backup plans——

Senator SANDERS. Right, but all I am asking, I have got other questions, is what are you doing right now to aggressively make sure that more companies are producing infant formula so we will not see this problem regardless?

Dr. CALIFF. You know, and I am sorry, Senator, to interrupt, but yes, on a temporary measure, we have lowered some of the—reduced some of the paperwork so that many more foreign manufacturers can import. We have got 26 applications since we opened the portal just over a week ago. The largest producer, Nestlè, world-

wide, and hardly had any presence in the U.S., and they are going to help out quite a bit. They are very capable——

Senator SANDERS. I hope that you will focus on increasing the number of companies who are producing so we don't run into this problem again. Let me ask you this, on October 20th of last year, a whistleblower sent a 34 page report to the FDA describing in detail how the equipment in Abbott's manufacturing plant in Michigan, "was failing and in need of repair, and that the company knew that this was a problem for at least 5 years."

According to this report, Abbott falsified records to cover up deficiencies at its plant, improperly train employees, and successfully hid health and safety risks from FDA auditors in 2019. Even though this report was submitted to your agency last October, FDA did not interview the whistleblower until late December.

Now, my question is, during that same period of time, Abbott saw a $7 billion increase in its profits and its CEO, Mr. Ford, saw very substantial increases in his compensation packages. If a company lies to the FDA about its safety situation, at the same time it does massive stock buybacks, gives the CEO used compensation packages, are you going to fine them?

What are you going to do to make sure the industry understands that you simply cannot lie to a Government agency?

Dr. CALIFF. The whistleblower's complaint was received, and the usual staff reviewed it and did the interview. It was not escalated to the leaders of the FDA who were responsible, and that was an error that has now been rectified in terms of process. In terms of the status of the whistleblower complaint, I am not in a position to comment on whether they may be legal proceedings.

Senator SANDERS. What I am asking is—I am not even asking about the whistleblower complaint. If a major corporation lies to the FDA about something as terribly important, the safety of infant formula, what are you going to do? At the same time, they do billions in stock buybacks, huge compensation packages for its CEO.

Is the Government, is the agency going to say, sorry, it is more important to protect the babies of this country than to give huge compensation packages to your CEOs? Are you going to stand up to them?

Dr. CALIFF. Senator Sanders, we are standing out them. As I said, I am not in a position to say whether criminal proceedings are underway or not.

Senator SANDERS. Is that something in consideration?

Dr. CALIFF. I am just not in a position to comment.

Senator SANDERS. Well, I would hope that manufacturers of baby formula, which is so terribly important to parents and obviously the babies, understand they cannot lie to the Food and Drug Administration. I hope you are strong about that.

Dr. CALIFF. Senator, as you know, I have worked on all sides of this. I have been inspected. Everyone understands, when you lie to the FDA and you get caught, there is going to be big trouble.

Senator SANDERS. Well, I hope there will be. Thank you.

The CHAIR. Senator Collins.

Senator COLLINS. Thank you. Doctor, like many of my colleagues, I have heard from desperate parents all over the State of Maine, particularly those that need specialty hybrid allergenic formulas for their babies. One family from Sidney, Maine, for example, contacted my office after the mother had been spending 2 months making a round trip of 2 hours just to get formula for her baby from her baby's pediatric specialist.

That is just not sustainable. Why wasn't there better communication with parents right from the beginning? Why did it take so long for FDA to start being public about this very serious problem?

Dr. CALIFF. Well, I guess my best to answer that is that as we were monitoring the supply, up until about a month ago, there were issues, but they were manageable for the vast majority of people. Then things turned to empty shelves very quickly. That is when we really ramped up the public communication.

There were concerns if there was a lot of public communication before that, when things were manageable, that it would be understandable that families might purchase more than they needed to be safe. Which as I have already said, I am not blaming them. That would be a normal response that we have seen in other areas with the pandemic. And so that is really basically the situation.

Senator COLLINS. Well, I really think it would have been better if FDA had done what you said, which is put limits on how much could be purchased but been more forthright with the parents who are really desperate. I want to follow-up on press reports that indicate that the senior levels of FDA did not receive the alarming whistleblower's report due to, "mailroom issues."

You blamed COVID–19 staffing issues for preventing FDA leadership from receiving direct copies of the whistleblower report, despite the fact that FDA's district office in Detroit received a hard copy from a confidential informant way back in October of 26—October 26. Inexplicably, it took 4 months for that report to receive the attention and get to senior FDA leadership in mid-February.

Let's look ahead to happen. By that time, one infant had already died, two others were hospitalized, and the nationwide out-of-stock rate for infant formula had risen to 26 percent. I understand that the copy that was sent to then acting Commissioner Janet Woodcock still has not been located to this day.

What exactly do you mean by COVID staffing issues? Are you telling us that FDA still does not have people back to work in the mailing room and other portions of your agency?

Dr. CALIFF. Well, let me be clear about two things. The first is, the hard copies of the document didn't get to the leaders that should have gotten it for the reasons that you just gave. But there was a second issue, which is the escalation procedures, because the people on the staff did get it and they were dealing with it. And so there was not a procedure in place for them to inform the leaders who should have seen it.

Neither the Center Director nor the head of the Office of Policy and Response, nor the head of ORA. And so we now—I have dealt with this in hospitals and the quality systems where nurses were

not reporting surgeons errors, for example. We fixed it and we have essentially had to do the same thing at the FDA.

I am not blaming the mailroom, but there definitely are problems in the mailroom. This is not FDA staff. These are contractors hired by the FDA to handle the Federal Express.

Senator COLLINS. Well, are those contract employees and are the 18,000 FDA employees back to work?

Dr. CALIFF. Yes, they have always been at work. The productivity of the FDA staff is higher than it has ever been.

Senator COLLINS. But are they back—excuse me for interrupting, but are they back to work at their offices, in the mail rooms? I am not talking about remote work. Are they back to work?

Dr. CALIFF. For the jobs that require being onsite, they are onsite like the mailroom being one example. But for many of—remember, our inspectors are distributed all around the country. They are mostly on the road. And our reviewers are reviewing documents using computers. So they are actually very efficient doing what they are doing.

Senator COLLINS. But we need everybody to be back to where they would have been working pre-pandemic.

Dr. CALIFF. Well, I will look forward to discussing that with you later. I think, I came from Silicon Valley, where it is very clear that for many of these kinds of jobs, that you are much more efficient working in a hybrid situation where you are in the office some, but also at your computer for a longer period of time.

Senator COLLINS. Thank you.

The CHAIR. Senator Casey.

Senator CASEY. Dr. Califf, last Friday I was in Pittsburgh, Pennsylvania, at UPMC Children's Hospital and had a chance to listen directly to parents, in this case, two parents, talk about their experiences with this infant formula crisis. Just note one for the record, because this is the reality for so many families. The father, first name is Manuel, he has got three daughters. One of his three daughters has complex medical needs. Her name is Francesca. She depends on a combination of IV nutrition and formula for her nutrition.

Not having the right formula means two things, costly treatments and very high risk to her health. He said, "she is stable this week, but we live in fear—live in fear, not knowing if we will have enough of the right formula next week or every week."

He went on to describe the challenges they face. So you and everyone in this room has heard some version of those stories, especially for children that have complex medical needs, but all children who need formula. I don't think there is any question that when Senator Murray and others have pointed to that timeline between in your testimony September 20th, when the FDA learned of a cronobacter infection at the Sturgis plant, that time lag between September and then when the inspection was done and other actions were taken, there is—you haven't provided a good answer for that and the FDA needs to be held accountable for that, among other things, for that. But there is a lot of blame to go around here.

We, Senator Murray, made reference to the fact that on February 24th, she and I sent a letter to Robert B. Ford, Chairman of the Board and Chief Executive Officer of Abbott in Abbott Park, Illinois. This is a February 24th letter from the Chairman of a Senate Committee, the Health, Education, Labor, and Pensions Committee, Senator Murray, and we have not gotten the information that we asked for in that letter.

I know they have provided some, but it is totally in terms of a response, totally inadequate, especially, especially in light of the findings that you have in your testimony on page two about the evidence of contamination.

This is a contamination problem for sure. It is also a notification problem when it comes to what the FDA didn't do enough of in terms of notification, but also what the company didn't do. I have got legislation to impose obligations on both. One, is to require manufacturers to provide timely notification of circumstances that are known to the company that are likely to lead to a disruption in supply chain.

Companies got to do that, and they should be mandated to do that. But the FDA also needs to expand and accelerate these notification requirements. And the FDA has got to work with these companies to provide that notification. I also think you should have more authority to request records in advance of or in lieu of an in-person inspection.

My question is this, talk about those authorities that you would need to oversee the infant formula supply chain. What is the authority you have now? What are the blind spots or the defects that we should fix by way of legislation?

Dr. CALIFF. We have almost no authority now other than to review the products as they come in, as noted. When it comes to this sort of an issue, there is no requirement now that firms notify us when they have an impending shortage. There is no requirement that if they find a contaminant in a sample in their facility that has not yet been shipped out, that they need to let us know. That happened in this case.

There were cronobacter contaminants previously identified that they didn't notify us about. They are not required to have a backup plan, a contingency plan, which I thought was—in every industry I have been in, there is always a plan for what if the plant goes down? If that plant had been hit by a tornado instead of a quality problem, the same issue would be in front of us now.

You have reports, I think, three different reports to Congress now saying in a digital era, right now, what we have is every company has its own supply chain that is considered proprietary. There is no central switch. And so there is no way to look and see a distressed asset and ask the question, what would happen if a plant went out here? Is there somewhere else that could do it?

The idea that an individual company with 40 percent of the market share doesn't have a backup plan to me was inconceivable, especially since I have a history of feeling like Abbott was a reliable product maker for me in my profession. I was just very—it is up-

setting and disappointing. But we need authorities to have that kind of information.

When we have to ask and beg companies to give us the information about the supply chain and they don't have to give it, every little bit takes a long time.

Senator CASEY. Well, I would say in conclusion, doctor, there is no question that you should have that authority and companies should be responsive to you, just like they should be responsive to this Committee. But you have got to up your game and you can't allow that timeframe to—that lag of time from when that damn inspection is done so that you can act on it. Thank you, Madam Chair.

Dr. CALIFF. Yes, sir. You said we didn't have a good response. I think we have a thorough response. It is not good. It was too slow and there were errors made. I want to be clear that we acknowledge that.

Senator CASEY. Thank you.

The CHAIR. Senator Cassidy.

Senator CASSIDY. Hey, Dr. Califf. I am sorry we are having to have such a contentious hearing. I think this graph demonstrates better than the graphs in your paper the issue. The summer before this began, or a summer ago, there was an 8 percent increase in the shortage rate on shelves.

It actually was increasing prior to this latest episode, and this is when Abbott was closed. So it seems as if there was something happening here. Now there is a political—you can put that down, thank you—there is a political article from May 9th, and I will quote it, one of the takeaways was that a food—the food division has structural and leadership problems.

Aside from the lack of attention of food at the top, unique problems in the Center for Food Safety and Applied Nutrition, a deep seated culture of avoiding hard decisions and a near paralyzing fear of picking serious fights with food industry. Then it describes a power struggle between the top two officials, further strengthening the status quo of inaction.

Now to follow-up on Senator Collins' comment, Zoom can work if people are actually communicating. But if there is a silence between the two, maybe actually being in the office and rubbing shoulders is somewhat conducive to information being passed.

Now, so I am gathering from your answer that these two top leaders were probably Zooming, they were not in the office, and that their chief lieutenants were probably Zooming, and they were not in the office. Is all that correct?

Dr. CALIFF. They were in the office some. But in general, it is correct that most of them——

Senator CASSIDY. Some, as you and I know, I don't mean to be insulting, but some can be 1 day a year, 1 day a month or 1 day a week. Do you have a sense of what some is?

Dr. CALIFF. I would say it depends on the individual that you are talking about.

Senator CASSIDY. Now these two top who apparently their structural problems and the deep seated conflict between the two most likely is implicated here. How frequently were they in the office?

Dr. CALIFF. I don't have the data on that.

Senator CASSIDY. I understand that, but that would be useful to know. Now, it does make sense to me that if you have a dysfunctional mailroom and you have got a dysfunctional leadership and no one has actually seen each other, that it could take time for such a report to be done. I will just point that out, knowing that you as a leader will have to address that.

Second, what percent, going back to you mentioned how the inspectors are commonly in the field, but we know that HHS stayed shut down for far longer than the private sector. How many inspectors—hold this up once more. We had a problem a summer ago.

How many inspectors were actually not in the field working because of Coronavirus—I am not talking about the specific December function where there was COVID at the Abbott plant, but just in general, how many were Zooming their inspections as of—what percent of the workers, whatever, as opposed to actually showing up for work?

Dr. CALIFF. As you know, we have very limited authority to do inspections virtually. We actually need to have that as part of inspections. But the inspections were hands on, in the plants.

Senator CASSIDY. What percent of your inspectors were actually working as opposed to not being at work? Because HHS had a huge problem of people not showing up for work for 2 years.

Dr. CALIFF. I think from every piece of data I have seen, we have a very high rate of work. I might also mention, I was at a pretty highly functioning business called Alphabet, which has done pretty well where when you have——

Senator CASSIDY. I have limited time, I accept that, but inspecting onsite is different than what Alphabet does.

Dr. CALIFF. I agree.

Senator CASSIDY. I don't mean to be rude. Regarding importation and labels. Canada, New Zealand, U.K. all speak a form of English. Have we attempted to import from there from non-FDA inspected facilities knowing that getting FDA inspection can be prolonged, difficult, timely, etcetera, time consuming?

Have we attempted to alleviate by importing from English speaking countries with standards similar to ours?

Dr. CALIFF. The short answer is yes. We are open to all the applications. We have got 26 already.

Senator CASSIDY. But I am told that for that to occur, there is a 90 day wait—a 90 day lead in period for the FDA to accept.

Dr. CALIFF. That is not correct.

Senator CASSIDY. So if somebody from the U.K. said, I have got formula, it meets our standard, you can fly it in?

Dr. CALIFF. Yes. I mean, we can document most of what needs to be done without doing a hands on inspection ahead of time and we are doing that. I do want to address the Canadian situation——

Senator CASSIDY. Can I finish—one more thing. Are we actually importing from non-FDA inspected facilities in English speaking labeled countries who meet our standards intuitively?

Dr. CALIFF. We are looking at those applications and it is likely that we will where we have high degree of confidence in reciprocal inspections that are being done by others.

Senator CASSIDY. So we have not started yet. Do you have a timeline of when that might begin? Because applications pending is a kind of in an agency described as dysfunctional, could be months from now.

Dr. CALIFF. It will not be months, it will be days. Every day you will see a new—one come on board.

Senator CASSIDY. Okay. Thank you. I yield.

The CHAIR. Senator Hassan.

Senator HASSAN. Well, thank you, Madam Chair and Ranking Member Burr. Dr. Califf, like all of my colleagues here, I am hearing from my constituents. Granite Staters have shared with me their struggles to obtain formula for their infants. And as we all know, formula for many, if not most of these babies is a matter of life and death.

Their parents are desperate and terrified. I have called on the Administration to invoke the Defense Production Act and allow the importation of additional formulas. I am encouraged that the Administration has taken these actions.

But shortages continue and infants remain at risk. So what my constituents want to know is when can New Hampshire families expect the shortages to end? How quickly will they be able to walk into a store and be confident that they will find formula on the shelves?

Dr. CALIFF. Well, I am sure you know, Senator Hassan, I can't be exact about this, but I would—my expectation is that within 2 months, we should be beyond normal and with a plethora. And what you will see is, due to all these measures being taken, the shortage is going to be getting better and better.

You will also see the big focus is on these specialty formulas that all of you have mentioned. Back in the Abbott facility, that is the first thing to come off the line because they were such a dominant company in that regard, and they have been able to move their timeline up now to within a month they will have that specialty formula out.

Senator HASSAN. Thank you. So do you have a—does the FDA have a plan and a timeline that shows how you plan to get to that point 2 months from now?

Dr. CALIFF. This is across HHS, and it is a lot of data points. So as you said, is it a simple chart? The answer is no because there are many contingencies. But there is a committee that has all the data in hand. And if you would like something that is a little more specific about how the pieces fill in, I am sure we can produce it.

Senator HASSAN. I think it would be very helpful for us to get an actual plan, because without a plan, without goals, it is hard to know that you are actually going to meet them. It is also really

important for the public to be able to understand when they can expect to have a little bit more peace of mind as they search for formula.

Let me go to the issue of the specialty formula and the Operation Fly Formula that President Biden announced. He announced that we are now using Department of Defense planes to pick up overseas formula and deliver it to the areas in need.

At least two of these flights have arrived in the U.S. carrying several tons of formula. How is the Administration prioritizing the distribution of the imported formula to rural areas and other regions where families have few alternative purchasing options?

Dr. CALIFF. Each application also has to include a distribution plan, which is reviewed at the level of HHS to make sure that the most needy places are getting the formula. I can assure you there is hyper awareness of the problems in rural America right now with health in general and access to care. So that is one of the priority areas.

Senator HASSAN. Okay. Well, I would love to follow-up on that as well. I just want to turn to thinking through what we need to do once this current crisis is over. The FDA and other Federal agencies need to take steps to make sure, obviously, that this never happens again. Supply chain challenges exacerbated by the pandemic made clear the need to build out domestic capacity to manufacture critical goods quickly.

That goes for infant formula, as well as a number of other critical goods. What steps should FDA and other agencies take to prevent these shortages going forward? For instance, should the Administration work to build out extra manufacturing capacity, stockpile the ingredients needed to make formula, require manufacturers to produce a reserve of formula, or to have the capacity to make extra in short order to prevent situations like the ones we face now?

Dr. CALIFF. Well, we have a number of measures that are before you now in pending legislation, as you well know, and those are enumerated, and we will make sure you have a list of those. But you have mentioned a couple that are not yet decided where we do need to make a decision once we get on top of this crisis, and that has to do with stock—the word, stockpile.

There has been no stockpile of infant formula. It was not conceived of going back. I think it is something that we really need to consider. Of course, if we had diversification of the market, and some Federal agency, whether it is FDA or some other Federal agency, had insight into the supply chains and how they fit together, the likelihood we would need the stockpile would be quite low because we would have a vibrant system that was resilient to stress, but we don't have that now.

Between stockpiling and having a resilient system, we should be able to prevent this from happening again.

Senator HASSAN. Well, we certainly need to. Thank you very much. Thank you, Madam Chair.

The CHAIR. Senator Tuberville.

Senator TUBERVILLE. Thank you very much. Thank you, Dr. Califf, for being here today.

Dr. CALIFF. It is Califf by the way.

Senator TUBERVILLE. Califf—Califf. My name gets mispronounced——

Dr. CALIFF. I understand.

Senator TUBERVILLE. 18,000 staff members. How many of those are back working full time, not from home? You know, have a clue?

Dr. CALIFF. Well, that is the thing, they are all working full time.

Senator TUBERVILLE. But back in the office. Do you know?

Dr. CALIFF. It is may—I just, I don't know the exact percent, but it is not a large percentage.

Senator TUBERVILLE. It is not a large or it is large?

Dr. CALIFF. Not a large percentage.

Senator TUBERVILLE. I am just asking, you know. A lot of people are starting to work from home. Out of these 18,000 staff members, how many of these employees that you have been relieved of duty because of this, 18,000? Somebody has got to be fired, right.

Dr. CALIFF. You know, I have been involved in running a lot of successful organizations. Firing is not necessarily the solution to a problem like this. Correcting errors is——

Senator TUBERVILLE. Dr. Califf, people have died from this. Kids have died.

Dr. CALIFF. Kids have definitely died, but I don't believe there is a direct link between the plant and the sickness of these infants that has been proven.

Senator TUBERVILLE. So everybody in your office has done 100 percent right? They have been——

Dr. CALIFF. Absolutely not. And we are clear in the report that that is not the case, and that we are doing a review and putting systems in place and also reviewing individual decisions.

Senator TUBERVILLE. Okay. So let me ask you this, yesterday—last week, you suggested the shortage would be over in a few days. Yesterday, you said it might be weeks. Where are we at today with that?

Dr. CALIFF. As I just reviewed with Senator Hassan, it is going to be a gradual improvement up to probably somewhere around 2 months before the shelves are repleted again.

Senator TUBERVILLE. Two months? So you are in damage control here. What is the FDA going to do to restore public confidence, No. 1 in safety, and then the availability of the formula in the days ahead?

Dr. CALIFF. Well, I think one of the main lessons of the pandemic with cyclical shortages is that the only thing that will restore confidence is having adequate formula on the shelves. We are fully, fully aware of that. The safety, we are not letting unsafe products on the market.

Senator TUBERVILLE. I understand that. But how do we get that out to the consumer?

Dr. CALIFF. Constant communication. We are going to have to constantly communicate about——

Senator TUBERVILLE. Do you have a marketing department in the FDA? Is there anything that consists of that?

Dr. CALIFF. We have a very hard working external relations group and communications group.

Senator TUBERVILLE. Yes. Who is your direct person under you that is overseeing this? The No. 1 person you call every morning say, hey, what is going on? What do we need to do? Where we at?

Dr. CALIFF. It is actually twice a day. The person who is heading out the Incident Management Group as Frank Janis, who used to work at Wal-Mart and is an authority in the supply chain area. The person running the Center is Susan Mayne. We all meet together, along with our teams, twice a day to review what is happening and make sure we have got working orders for the day and also for the——

Senator TUBERVILLE. So the team of how many are working on this one specific, that you directly work with?

Dr. CALIFF. Dozens.

Senator TUBERVILLE. Dozens? You all work—and you meet every day, talk about it two or three times a day?

Dr. CALIFF. Yes. Each one has—if you just take the specialty metabolic formula that we discussed, this might be an effort with a hepatology problem where you got to have a liver specialist, a nutritionist, and a regulatory expert to make sure the infant gets the right formula. So it is a lot of people.

Senator TUBERVILLE. Okay. Thank you. Thank you, Madam Chair.

The CHAIR. Senator Smith.

Senator SMITH. Thank you, Madam Chair. Welcome, Dr. Califf. So the Minnesota Department of Health was the first to link the foodborne illness to the powdered infant formula manufactured at the Abbott nutrition facility in Sturgis, Michigan, in September 2021. And they informed the CDC and the FDA of that link in September. That infected Minnesota baby survived but was hospitalized for 22 days.

As we all know, the FDA did not initiate an inspection of the Sturgis facility until January 21st, which led to the voluntary recall and the shortages situation that we are experiencing now. So this is my question—my question is about how the FDA coordinates with state and local health departments on early detection of foodborne illnesses.

Is this process that happened with the Minnesota Department of Health, is that the standard process? Did something go wrong there? What can you tell us about what that link between state health departments and the FDA is and what it should be like?

Dr. CALIFF. Thanks for asking that question because it is really important. The minute that a report comes in, usually the CDC, because that is where the reports typically come in. There is an investigation launched and it is very intensive. You have to get to the site. You have to get the cultures, if they are available. You have

to interview everyone concerned. And often you need to review the medical records.

In this case, the Minnesota Health Department, from all the reports I have gotten, did a splendid job. The problem is it was one case, and it was chronobacter positive. But chronobacter, for example, is found in up to 15 percent of sponges in kitchens at home. It is a ubiquitous organism. It is not necessarily—so that case was very well documented.

Senator SMITH. Was it linked to the formula?

Dr. CALIFF. It was——

Senator SMITH. I mean, they suspected a link.

Dr. CALIFF. The infant had ingested that formula, so it was a matter of concern.

Senator SMITH. Yes.

Dr. CALIFF. I would also point out chronobacter is not a reportable organism. And so we have banks of now DNA sequencing that if we look at the peanut butter case that just occurred, that was solved within days because we had, we were able to link the genetics of the peanut butter and the sickness of the people, the genetics that were in the infections in those people, and the plant within days because we had the information. I think we need to do something about cronobacter because it is a well-known, although infrequent, cause of contaminant of infant formula.

Senator SMITH. So but are you saying that you think that the process—that the length of time that it took from when MDH, Minnesota Department of Health issued the, you know—provided this information and when the FDA ended up where the recall happened, is that like—is that as long as it should be according to the way your policies work? Could it be shorter? I am trying to understand if there is something in that that isn't working from the perspective——

Dr. CALIFF. I am sorry, I am trying to give a nuanced answer in a bit. I mean, the Minnesota Department of Health did its job and what it should have done. We had one case. You don't recall a product unless you have a direct link that proves that the product actually caused the problem. So usually we get a cluster as has happened in peanut butter where a bunch of people have it at the same time, then it is easy to make the case. In this case, we had the information and we had to wait and see what happened.

Now the time to the recall, as I have already said in my document, the more blunt answer, it was too long. You know, we are clear about that in our documentation, and we aim to fix it.

Senator SMITH. Okay. Let me ask you about something else. I want to—this is about coordination with USDA, which is responsible, as you know, for purchasing nearly half of the infant formula in this country through the WIC program.

My understanding is that the FDA didn't communicate with the USDA until around the time of the recall. I am wondering why you think that happened. Should the FDA be working more closely with the USDA sooner, and whether you see this as an area where there could be improvements?

Dr. CALIFF. Well, let me divide us into two tranches. Prior to the recall, there was a lot of communication between FDA and USDA on the general supply chain issues related to infant formula. There was not about this specific case, but as I have already told you, even the leaders in FDA didn't get the information until February 9th about what was going on.

That was an escalation error, as I have said, and we have documented that and are fixing that is a systemic quality problem within the FDA. And so it was shortly, as you said, the recall happened right after that.

We were then in the detailed discussion with USDA. So there has a been a supply chain group of supply chain committees for Government throughout the pandemic, and infant formula has been on the list. That has been covered by the relevant agencies, including USDA.

Senator SMITH. Dr. Califf, I understand that you have only been at the FDA for a short time, but I do think that you have a unique capacity, because you know the agency so well and because of your industry connections, to be a reformer at the FDA.

I am struck, as I listen to you today, about how you have been explaining what happened with regard to this supply issue as well as the health issues, rather than taking the posture of a reformer, which is what I think that we definitely need, and I do believe that you have a capacity, a unique capacity to be that reformer, I am—I believe that this infant formula crisis is a symptom of the broader, systemic structural problems with food safety in the food division that we have at the FDA. And so I urge you to adopt that reforming posture as we move forward.

Dr. CALIFF. Can I comment, with permission on that?

Senator SMITH. Yes, if——

Senator KAINE. Continue.

Dr. CALIFF. As we discussed in detail yesterday in the hearing, I do consider myself to be a reformer here. I knew coming in. I have gotten multiple phone calls. I was—I saw the problems in the food side of the FDA before. It has been massively underfunded. And what I am appearing to be maybe defensive about is I do not think castigating the FDA employees is the appropriate approach to reforming an organization.

What we got to do is to have a carefully thought out plan going forward and an after action review of all the decisions that were made with working with people to understand what is being done. If you take beleaguered employees and castigate them in an organization that is already under stress, I don't think that is a helpful way to fix an organization.

I have been involved in many such organizations, but I agree 100 percent with what you said. If I am not a reformer—I don't know, I mean I wasn't planning to come back to FDA, as you know. I would not have come back if I wasn't planning on changing it.

Senator KAINE. Senator Marshall.

Senator MARSHALL. Thank you, Chairman. I appreciate it. Dr. Califf, welcome. It took—takes a lot of guts to come here and face this situation. And we appreciate you being here in person. You

and I are both physicians. We both know that no matter what happens in the OR, the delivery room, or the E.R., that we are responsible for it, regardless of what the people beneath us did, their actions, their inactions, that we feel, that sense of responsibility. I am sure you do, too.

I want to start here by just reading a couple statements. This is a small sampling of what we have received. This is Stacy from Newton, Kansas. I have a 5-month old grandson and another on the way. The shelves are empty in Newton, Kansas and the surrounding areas. Please help. This should be top priority for all Americans. Next, Anna from Wichita. This is unacceptable in America. How we let this get to this point.

No parent should be worried about not having food available in stores to feed their child. The empty shelves is what I expect to find in Havana, Cuba, not Wichita, Kansas. Judy from Overland Park. The new press Secretary laughed today when a reporter asked her who the point person was for the formula shortage. She had no idea who the point person was. All I can say is, may God help the babies.

Jenny from Cimarron, Kansas. The shelves are—the stores are empty. How are we supposed to feed our babies? I believe the Government needs to step in and get answers to the public and get the formula shortage resolved. Next, Katie from Manhattan. There is no room for bureaucracy when it comes to our Nation's babies.

Last, Lisa from Seneca. I am an expectant mother due in June, and I am terrified I will not be able to find formula for my newborn. We already have to worry about gas prices, inflation, I don't need anything else to worry about. What would you suggest I tell these moms, grandmoms?

Dr. CALIFF. Well, first of all, we are physicians, and the physician in a hospital or a health care setting is a captain of the ship and takes accountability. So that is why I am here. I would tell them that we are sorry that we are in this situation, and we are working night and day to try to fix it at this point.

We know there is going to be further inconvenience and beyond inconvenience in terms of desperation that parents feel. But they also should contact us because we are dedicated when we hear about an individual case to fix it and make sure that everyone does get access to the formula that they need.

Senator MARSHALL. Thank you. I do want to submit for the record a letter that we sent to you. You haven't time to answer it yet. With some questions. I think it was signed by 21 Senators. So we will submit this for the record.

Senator KAINE. Without objection.

[The following information can be found on page 52 in Additional Material:]

Senator MARSHALL. Next, I just want to point out that from an action standpoint, what has the FDA, what is the White House done to correct this problem? We are kind of bragging about a shipment, I think of 78 million, was it pounds or ounces? Pounds of formula. Just to put some numbers to that, that is probably enough

formula to feed the babies in Kansas for three or 4 days and a fraction of what has been shipped in here.

How much of the of the problem could have been solved if people weren't working from home in the FDA, if they would have been willing to go examine, well, what was going on at the laboratory in in Michigan, or they could have possibly went over to Europe and certified some of the manufacturing plants in Europe that Abbott has.

You know, we were all expected to work—people had vaccinations. There was every reason, I think, to go in there sooner. But I am just afraid, and I guess the follow-up question is, is the FDA still working from home or are people engaged now?

Dr. CALIFF. Well, Senator, you are not just a doctor, you are an OB-GYN person, and that has special, special responsibilities, I know. But it is also the case in most of the jobs at FDA people are working 100 percent of the time or more. I will just remind you that I come from, in my last job, one of the most successful companies on the face of the earth, where people were working from home and more productive than ever.

I really don't agree with the contention that the work from home policies that FDA had anything to do with the outcome here. But I am also not saying the outcome was a good outcome. I don't want to be misinterpreted that way. We just have a disagreement. I think the right solution going forward is going to be a hybrid arrangement, as I said, as most of the industry is going to.

Which is if you have a job like in a lab that requires that you be there or in the mailroom you have got to be there. If you are reviewing documents or reviewing processes, you can do that from home. Just demonstrate that you are doing the work.

Senator MARSHALL. Thank you. Just a quick comment. I think this is a great opportunity for us to encourage breastfeeding. A great opportunity to encourage those moms who are thinking about weaning their babies today, tomorrow, and next week. This is one more reason to try to breastfeed a little more, a little extra. And by the way, it is healthier for your babies. Anything you can do to help us with that, I am all in.

Dr. CALIFF. I am totally in support of what you say there. I did want to remind you—I forgot what I was going to say. We do have a history on the importation front of very tragic outcomes with formula melamine, as you may remember, from imported formula not that many years ago. That is the reason we have got to be careful and make sure that we are reviewing these documents.

Senator MARSHALL. Safety first. Thanks, Senator.

Senator KAINE. Senator Lujàn.

Senator LUJÀN. Thank you, Mr. Kaine. I want to thank Chair Murray and Ranking Member Burr as well for holding this important hearing, and to Commissioner Califf for joining to share your insight and answer these tough questions. Sir, thank you for being here.

Now, I, like many of our colleagues, come from rural parts of America and that is where my question begins, sir, is in rural regions of New Mexico, picking up the formula needed to feed our in-

fants isn't as easy as going a few blocks to the closest grocery store. Many families have to drive hours to be able to take that trip to purchase infant formula.

When the supply chain fails and essentials are not available, it is not merely an inconvenience, but a crisis for those living in rural and underserved communities. Commissioner Califf, on May 10th, the FDA released a statement saying that the agency is, "compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go."

My question is this, is this system equipped to track the availability of formula in rural and tribal communities, some of which do not have access to broadband?

Dr. CALIFF. Thank you, Senator. It is good to see you back. Looking good, too. I—what I would say is the system is better than anything we had before. We asked for funding for a system to track this back at the early phase of the pandemic.

We got no funding. We took money from other things, which I want to emphasize again means that other things are not getting done. And we built a system which does give us some data, but not the data that we would really like to have down to the level of the individual location. You know, soon there will be broadband in every community, as you know, thanks to the good work that you all did to get the bills passed for that, but we don't have that now.

We are following at the granular level that we can. And as I have made the point before, the industry actually has very detailed data about where its products are going. We have no right to compel the industry to give it to us and no right to demand increase in production until the President put in place the Defense Production Act.

The answer would be, yes, we have a system. It is nowhere near what we need.

Senator LUJÀN. Well, I hope, Dr. Califf, that everyone is listening to that. The staff that you have here, we can work together to remedy that, make sure that the tools are in place for tracking, and then work with your staff to incorporate rural communities and tribal communities as well. I really appreciate that, and we have some work to do there as well, sir.

Dr. CALIFF. Yes, sir. I just might add. Over the last 5 years, I have written a number of academic papers about rural health. There is a disturbing drop in life expectancy in rural America compared to urban that we all need to pay a lot of attention to.

Senator LUJÀN. You are spot on, sir. I appreciate that reminder. Now, the shortage of infant formula comes as New Mexico is experiencing the largest wildfires in our state's history. On top of the loss of their homes, cars, and livelihood, some New Mexicans are now struggling to source the formula they need to meet the nutritional needs of children. How is the FDA taking the impact of this disaster into account as they advise the Federal Government on the distribution of formula?

Dr. CALIFF. Thank you for that question. Having lived in San Francisco the last 5 years, the wildfires are quite an astounding

thing. It is hard to appreciate unless you see the size of these fires that we are now experiencing. I just want to make the point that the supply chain part of what we do is HHS wide and involves all other part—it is an all of Government effort. I do want to commend colleagues around Government.

They are constantly getting reports of where the shortages are and directing product to those shortages, and any area experiencing a shortage due to wildfire where people can't get around, please get in contact with HHS to make sure that they are aware, but I am pretty sure they have got active feelers out to get this information.

Senator LUJÀN. Well, that is a good reminder to reach out to Secretary Becerra as well. And Dr. Califf, to everyone that will listen, I remind them that this fire was started by the U.S. Government. It was a controlled burn started by Federal employees, by the U.S. Forest Service. And so we just want to make sure that there is attention on this one. But that is an important reminder.

The other questions that I have, Mr. Chairman, I will submit them into the record. But I am hoping that we can do more in non-English language education and outreach, namely Spanish and Native American communities, where in most areas across the Federal Government we are still failing in that area, but especially with educating families to earn their trust back to say these are safe products, this is where you can get them, and this is how to do it. So that is one area I look forward to working with you on as well, sir.

Dr. CALIFF. Thank you. That is a good example, by the way, the labeling issues that we are facing as we import. So a lot of logistics here that have to be coordinated. Thank you.

Senator LUJÀN. Thank you. I yield back, thank you Chair.

The CHAIR. Thank you.

Senator Paul.

Senator PAUL. There have been some discussion about whether the Abbott plant was not closed soon enough or whether it was closed prematurely or whether it was closed too long. There is no definitive evidence that the children who died, the bacteria came from the formula.

Dr. CALIFF. That is correct.

Senator PAUL. Yes. I think it is important to know that. I mean, it is very sad that the children died. But as the investigation has gone on, the unopened samples from the household, which would be part of the same batch, did not have any of the bacterium.

The open bottle had bacterium, but cronobacter can come from the environment in when you manufacture it, but it also can come from the home environment. When they do their investigation, I know they go back to the plant and take swabs everywhere too. Do they also take swabs in the home environment?

Dr. CALIFF. In the home environment? I would have to check to see whether that happens every time. But is there suspicion about the home environment, they would.

Senator PAUL. I think it would be worth doing that because we are not—nobody is wanting—we want to know where it came from so we can prevent it happening from again. If you have other children in the house or you are having another child, it would be important, and it is nobody's fault, but it would be important to know if there was chronobacter found that matched the strain.

But what we do know is what was found in the plant when you do the DNA analysis did not match the bacteria that unfortunately killed the children. On the issue of formula, how is a European formula different than American formula? Why do we prohibited from coming into the U.S.?

Dr. CALIFF. We don't—we have never prohibited European formula from coming into the U.S., but we do have requirements that have arisen over time. There are 30 nutrients that need to be in a specified label and a specified amount, and 10 that if they are too high are dangerous.

We just need to make sure that the requirements are met. We have been importing, by the way. The American manufacturers that we talk about have plants in Europe and Mexico that have been importing all along.

Senator PAUL. Are we waiving any of the requirements to try to fix the shortage?

Dr. CALIFF. We are not waiving basic nutritional requirements or safety requirements. We are waiving some of the labeling requirements that are time consuming to get exactly right.

Senator PAUL. When you say that we don't prohibit it, you are right. It is not a law or an FDA edict saying you can't have it, but there are a lot of restrictions on it that do effectively prohibit it. Some of those are labeling. So we are waiving the labeling things. Do you think it might be a good idea to maybe permanently getting rid of some of these labeling requirements that are keeping European or Japanese formula out of our market?

Dr. CALIFF. Well, I disagree that that is what is keeping them out of the market, but we will continue to look at the labeling to make sure it is leading to safety. Remember that an error in mixing up the formula can be devastating to an infant.

Senator PAUL. Yes, but I think Europe has those same concerns too, so does Japan. I think this gets back to the basic question of whether we trust international standards on things or whether we don't. I think it is part of it. If you are loosening the labeling requirements now to get more in, then the labeling requirements obviously you believe are limiting it.

By loosening them, you are expecting that you will get more formula. Some of the differences, I think, would be and could be considered a matter of opinion. You know, how much iron is in the formula? I think we have more iron than in Europe has. Europe has more omega three fatty acids.

I don't think there are doctors over there consider or there is an outbreak of iron deficiency in Europe because their formula is less. I would say that there could be honest expert differences on exactly what formula should hold. Would you agree?

Dr. CALIFF. Yes, Dr. Paul. I mean, I am a huge advocate of global coordination for the basically the reason you gave. We are all human beings. The diseases we have don't know borders. And where the requirement is good, we should take it into account. And of course, the availability of cloud computing and internet makes it possible to do this in real time, but we are not there yet.

Senator PAUL. Right. But I will venture to say we are there. I mean, I think that part of what you are going to do is try to evade the rules that have restricted the flow of foreign formula in. It also would serve to have more competition. If you do have a problem, I am not so sure whether the Abbott plant should have been shut down for so long. But the thing is, we have more foreign formula flowing in.

I think that there is nothing wrong with a European formula. There is probably nothing wrong with the Japanese, there is nothing wrong with the New Zealand. So there does need to be more coordination. I don't think it's like, oh, we have got to wait until sometime in the future. I think it right now is completely safe and people ought to get the choice of where they buy it from.

We have proposed legislation that would get rid of tariffs also. There is a 17 percent tariff on it. I think the tariff, the agreement between Mexico and Canada in the United States, it was signed in the previous Administration, put an extra tariff on Canadian formula and Mexican formula. So those are economic barriers to it, and we have to look at the whole picture.

Closing down Abbott, I think, probably too long since there is no proof that the deaths actually were related to Abbott, and sort of I think the overreaction in some ways to the link and not really following the science has led to a lot of this. But I think also the economic barriers of tariffs, but also I think the overly zealous regulatory environment as far as what goes into it.

Nobody wants dangerous formula, but nobody also believes that the European Union is like delivering millions of babies in Europe dangerous formula. I think there does need to be more international acceptance of things.

I think you are doing some of that, and I commend you for doing it, but you are evading your own regulations right now, which is good, because I think some of your regulations don't make any sense.

I think we should, by legislation, address the needs of formula and see where there is a dispute. I will bet you we can bring in a whole panel of scientists that agree that the European formula is just as good as ours or better. And it would be a dispute and probably hundreds of papers written back and forth over what the level of ions should be.

I don't think there is any ironclad truth. It is another reason why we shouldn't have anyone dispensing what truth is, because truth is debatable, and people look back and forth and actually have opinions as to what the truth is. I think we need to be more open minded as far as this goes.

But I do commend you for trying to get outside the regulations to get more formula in. But I think we have to look at whether or

not it was an appropriate length of time that Abbott was closed down given that the evidence does not definitively say that the bacteria came from the plant. Thank you.

Dr. CALIFF. Madam Chair. Can I make two quick points on that?

The CHAIR. Yes.

Dr. CALIFF. No. 1, for those who argue that onshoring is the solution to all of our problems with our supply chains, this is a classic example of why that is not the case. This was almost all onshore material, and the industry couldn't produce what people needed.

The second, on the Abbott plant, Abbott will complete—now that Abbott is taking into account their own failings, I think they would agree completely with us, they are not ready to open. They have known for 3 months since they have been shut down that we were going to go through this court proceeding to gain control of their quality system.

They have been working on it all along and I do think they are doing a good job now. But they had to replace the roofs, replace the floors. They are still not done. And we went over with the CEO day before yesterday, the detail list of hundreds of things that they had to fix. And you just can't open a plant with bacteria growing in it.

I mean, would you go in a kitchen next door if there were bacteria growing all over the place and standing water and people tromping through with mud on their feet, which is essentially what the inspection showed. I do agree with some of the main points you made, Senator, but I just on those two, I wanted to make sure my feelings, at least, were known.

The CHAIR. Thank you.

Senator Hickenlooper.

Senator HICKENLOOPER. Yes. Thank you, Dr. Califf. It is great to have you back. I appreciate your willingness to come back and not just subject yourself to these questions, but for your service. I was going to try and catch Dr. Paul before he left, Senator Paul just because I thought it was unique, first time I heard him make a pun like that, where he was talking about the amount of iron in formula and getting to an iron clad solution, but somehow that got passed over.

Obviously, the grief that we feel on behalf of those kids is only compounded this week just after what has happened in the Uvalde. And these are circumstances and situations we wish we could repair.

But I think I do appreciate what you are trying to do to go back through the entire process and see where the mistakes were made, and then figure out how do you build back a better structure so that we catch—the next time we catch it sooner, or perhaps we even avoid it completely. I thought your comment about how to reform an agency made my heart sing because that is exactly what you have got to do, you have got to look at the culture.

You have got to make sure the culture can't—and they are beleaguered. Now, they have been underfunded. They are short staffed. They have got to believe in their future. I think that you are—you understand that and are going to move forward.

Now back to the supply chain management, we continue to react to supply chain interruptions rather than proactively plan ahead, which is, I think, your inclination to intervene so as to prevent them. Does the FDA have adequate access to the critical supply chain information that you need not only to address the current formula shortage, but also to help minimize the risk of similar shortages of other lifesaving and life sustaining products?

Dr. CALIFF. Short answer is no. If I could take just 30 seconds to just go on about this. I am a huge advocate of free enterprise and of the individual companies making their decisions that are in their interests. It has worked great for America. But what has happened is each company has its own supply chain, its own optimization, and when someone says, if company x gets in trouble, will we have a supply for that community.

On the drug side, we just got authority to require the companies notify us when there is a shortage. We had over 300 last year that we had to help with. And if you talk to hospitals and health systems around the country, they are every day dealing with significant shortages. I would refer you to 60 Minutes, the last Sunday.

Yet for food, we have no authority to compel companies to give us any information, and we even have to pay for it, very often, to get it, which just seems ridiculous. They have digital information. There is no reason it couldn't be transferred, and there is no reason for the Government to intervene except in the case where there is a public health need.

Senator HICKENLOOPER. That is something we might be able to help you with, I suspect. How can we, and this is just a continuation of that thought, at the Federal level support platforms like 21 forward, and analyze supply chain data.

Dr. CALIFF. I really appreciate that question. I have to be careful here because I came from the best computing environment in the world back into the Federal Government, which is—as I keep saying, I just want to say it over and over, very hardworking people, not people who are sitting at home, lounging around. These are hardworking people, but they are greatly impaired by legacy systems.

Anyone that has been involved in the technology industry knows that you have to update your systems. Companies have capital budgets. As you know, you run companies and you put it into capital equipment, and that is an expense that you take. We are woefully short. We are doing the best we can with gum and chicken wire to put things together. But ultimately, there is going to be a reckoning on this in the Federal Government.

I would also point that CMS is group that needs help. With them, we are doing a lot of work, but on the food side, we just need fundamental funding and technology to enable us to do our work. Imagine an FDA inspector armed with the kind of equipment I saw at Google, how much more efficient they would be in getting their job done because they are not hand entering data into an old computer.

Senator HICKENLOOPER. Exactly. Well, at some point we did an infrastructure bill this year in the Senate that was bipartisan, and

I think that they would be one of the next big things we should look at would be a technological infrastructure for Government, because we are in almost every agency decades behind, not just a few years out of date. I have got, maybe I will just lay this question out and you don't have to answer because I think I am out of time.

Based on the information you have, what do you see as potentially—maybe I will let you have 15 seconds to answer with the Chair's permission. What is the next supply chain crisis for critical foods or drugs under the purview of FDA? What do you see as looming problems?

Dr. CALIFF. Well, I mean, we already have one, which is contrast media, which is the opposite of the offshoring problem that we had here. We had a major manufacturers, GE, which had its only plant, I don't know all the details, making contrast media in Shanghai. And when the COVID problem hit there, they shut down.

All of a sudden we have had a number of medical illnesses in Congress lately. Someone with a stroke or heart attack wouldn't be able to get an angiogram. I mean, it is just unbelievable. But it is happening. I could give you a list of dozens where we are precariously—this is just in time, which is very efficient when things work well with very little inventory, that's the most efficient way to run a company.

But then when something goes wrong, if it is not a critical supply you need for health, Okay,so you don't have tennis shoes for a couple of weeks, knowing you make up for it. But when it is a critical thing, like——

The CHAIR. I am going to interrupt you. We do need to move on, thank you.

Senator Scott.

Senator SCOTT. Thank you, Chair. Thank you, Ranking Member, for holding such a really important hearing. One of the things, as I have watched this hearing all morning, frankly, I keep hearing, is who should be to blame for what didn't happen? The one thing I think Americans are really not very interested in is the watching each side point fingers at the other side. Some say it is the private sector, some say it is Government.

The fact of the matter is that the average person in this country is not as interested as we are in figuring out how to make a Republican responsible for what happened, or the Democrat to be responsible for what happens, or the private sector to be responsible for what happens.

This, frankly, seems to be an all hands on deck kind of problem. Everybody did something that they ought not have been doing or didn't do enough of what they should have been doing.

From my perspective, I am not sure of your opinion on that, but the truth of the matter is, it is pretty frustrating for the average person in our Country who sitting at home watching a crime wave that they haven't seen in decades, looking at the price of gas at the pump, and they are scratching their heads and they are digging into their pockets and they are coming up a little too short, a little too often, month in and month out, and then they see the absolute crisis of inflation that is weighing on their shoulders and their in-

ability to meet the needs that they were able to meet just 18 months ago.

Then finally, for mothers, fathers, new kids, they see this shortage of formula that seems to exasperate their situation in such a way that they simply can't imagine it happening here at home in America.

Dr. Califf, I hope that we spend less time pointing fingers at who is to blame and take responsibility for where we can make things better. You are a South Carolinian, born in Anderson, South Carolina. And as Senator Lujàn was talking about the rural aspects of his state, I will speak to the rural aspects of our state. You went to A.C. Flora High School. I went to Stall High School. And the fact of the matter is, we play ball against each other, different decades, but same schools.

The truth is that too many Americans and too many places and specifically at home are looking at the crises that befall them and they want solutions, not really the blame game. I hope that we spend a few minutes on, how do we make sure this doesn't happen again?

But before we get there, I just want to highlight the fact that in your home state, as I just suggested, in my hometown of Charleston, South Carolina, we have four babies in hospitals due to the shortage because they have had an allergic reaction to the generic forms, or they need a specialized formula.

What can we do to accelerate the path to those families having what they need? And how can we ensure that this doesn't happen again?

Dr. CALIFF. Well, to your first question on what can we do, for those specialty formulas, as I have reported, we have groups of FDA people, pediatricians, specialists and critical care who meet every day and talk about each case and try to get the right formula to the baby.

In the case of Abbott, which was the major manufacturer of these, for the hyper specialized formulas that had no substitutes, we actually have allowed on a case by case basis. The formula will be sent out after careful weighing of the risk and benefit since they were made in an unsanitary plant. For the next tranche that you are describing, it is right to try a different brand, which is considered to be interchangeable.

But we all know that when it comes to particular drugs, for example, sometimes what looks like the same thing doesn't sit well. And then what has to happen is trial and error. But there are specialists involved every day in helping to navigate these. You have great ones at MUSC. I know the institution well.

I am sorry that people, infants have to be in the hospital. But for that kind of critically dependent infant, it is probably the best place for them to be until we get everything back and running.

Senator SCOTT. Transitioning to the latter question as it relates to how do we ensure that this doesn't happen again? The safeguards, the whistles, the bells that should be going off when we are 11 percent shortage, 20 percent shortage, 30 percent shortage, 40

percent shortage. How do we look back and learn lessons that we use for the future?

Dr. CALIFF. Well, there is an old statement, there are lies, damn lies, and statistics. So Senator Casey and I have very different data. He showed the most extreme estimate. Our estimates are nowhere near what he showed. But having said that, we have a very specific list, some of which are in consideration in upcoming legislation that we are glad to share with you.

The big question that I think is going to have to be addressed is do we create a stockpile as a backup in case something doesn't work in the future. I do worry. What happens is that we are getting the Abbott plant back up there. Positive cultures would be one example. I think we are going to have to have a surplus. We are certainly planning on a surplus within a couple of months, as I have already told you.

Question is, should we maintain that surplus as a Government activity for the foreseeable future? That is a question we are all going to have to discuss together and make a decision about.

The CHAIR. Thank you.

Senator Baldwin.

Senator BALDWIN. Thank you. Thank you, Dr. Califf, for being here. I am aware of the resource constraints that the agency is under, but I want to make sure moving forward that the FDA has the resources it needs to keep all of us safe. But I am not sure that this crisis is solely due to a lack of resources.

As was indicated earlier, there was a sort of in-depth review in the Politico back in April of food safety not being a high enough priority, a big enough priority at FDA, and it is part of why we are here. So the failure to prioritize food safety has put infants at risk.

I know we are hearing examples of what is happening in our home state. I have heard from the Children's Hospital of Wisconsin, families coming to the E.R. because they couldn't find specialty formulas for their children.

There were babies who were hospitalized in Wisconsin because they did not have access and enough formula. This is not the first time that we have experienced a recall for a product made at Abbott's Sturgis facility, correct?

Dr. CALIFF. I think that is correct.

Senator BALDWIN. I am aware of a recall that occurred in 2010 and a citation that was issued to the facility in 2019. Was that a strike?

Dr. CALIFF. Yes.

Senator BALDWIN. Okay.

Dr. CALIFF. Yes, I have a—actually, I have a chart, but I have forgotten the exact date, I apologize.

Senator BALDWIN. Yes. So in the past decade, given those—that history, how many inspections did FDA conduct at the Sturgis plant, given a poor track record evidenced by the prior citation and recall?

Dr. CALIFF. There were a whole series of inspections, as you know, leading up to 2019, most of which did not show any major

problems. And then we had the most recent inspection, September 2021. I think I could get the exact date. You know what it is. It found five citations, including inadequate handwashing and standing water in the facility and several other infractions. That led to what is called a 483, which is a written citation. And then the company's responsibility is using its quality systems to fix it.

Senator BALDWIN. You are already anticipating my next question. But before we jump into the September 2021 inspection, would you agree that additional inspections and better oversight of this plant were warranted based on past performance, but especially because of knowing just how critical this plant is to our Nation's supply of infant formula?

Dr. CALIFF. Yes.

Senator BALDWIN. Okay. So in September 2021, FDA officials entered the Sturgis facility and as you indicate, found, pooled water. And they also discovered that the plant had found cronobacter in a finished powder formula lot from June 2020. But according to reports, the inspectors did not swab for the bacterium during this September 2021 visit. Is that true?

Dr. CALIFF. They sampled the product, but not the environment. I think the way you ask the question, you are correct.

Senator BALDWIN. Okay. So to be completely clear, we are talking about powdered infant formula being manufactured in a facility with a leaky roof, with cracked spray driers, with puddles on the floor, and this same manufacturer knowingly disposed of a contaminated product. And yet FDA inspectors did not swab for samples.

Dr. CALIFF. Well, at the time, the leaky roof was, I don't think it was known, but everything else was. So the intent of your question, you are correct.

Senator BALDWIN. Okay. Thank you, Madam Chair.

The CHAIR. Senator Braun.

Senator BRAUN. Thank you, Madam Chair. I am going to have two lines of questioning here. One is about the industry itself. I have been a proponent since I have been here because I come from the realm of full competition, price transparency, markets that have hundreds of players in them.

I know it is not your bailiwick, so to speak, but do you feel comfortable where you have three companies that control 98 percent of the supply of baby formula? And when it comes from the special—specialty formula, 75 percent by one company, Abbott. Is that a good place to be?

How much of that concentration is due to regulations and the involvement of FDA along the way? It is kind of a broad question, but——

Dr. CALIFF. Well, I will give two—I mean, there is a short answer to the first part of your question. No, I am not comfortable. It is not good for the country to have such an undiversified supply chain and manufacturing chain for a critical product like that that's used by so many people. I don't think FDA regulation is at the basis of that. We, anyone who meets the criteria within the U.S. or outside the U.S. that wants to import can bring formula

in—into that market. We don't restrict the market and we have absolutely no control over the market.

Senator BRAUN. I think that just—I want to be on record that that is not a free market. That is an oligopoly, minimally, it is a monopoly, very nearly. So, and that is not only the case in baby formula manufacturing. It is a case and a lot of our ag markets, our broader health care markets for sure.

Something has got to be done if we are not going to have issues like this, even if a company does pretty well most of the time. I have got a question about the WIC program. Is there a peculiarity where on anything that goes into it can only be gotten from one company or in that particular, which I think is about 50 percent of where baby formula goes—is that something that the FDA has directed or am I off base that that is even part of the way the system works?

Dr. CALIFF. The WIC program is run by the Department of Agriculture. So it is completely outside of the scope of the FDA.

Senator BRAUN. Okay. So well, I will deal with that with the Ag Department. Let's look at the timetable of when it looked like things were heading in the wrong direction. Of course, we shut down so much of the supply chain, I think, in a misguided way along the way. But there were cues a year ahead when it went up to 8 to 10 percent.

Senator Scott mentioned that it got up to where it was, close to 50 percent, not having the right amount of inventory on shelves. I think that part of that time when this all occurred, including the dustup with Abbott, Dr. Woodcock was in charge. Is that correct?

Dr. CALIFF. Yes, that is correct.

Senator BRAUN. Okay, then haven't you appointed Dr. Woodcock to now be the troubleshooter kind of on this, or is that—is she back in the program or working for the FDA?

Dr. CALIFF. She is a principal deputy. She is a career FDA employee who is——

Senator BRAUN. Well, I think that would beg the question, when you had somebody that was there, when most of the problem occurred about midway through, at least the Abbott issue, how it makes sense that she would be back in. But let's look at——

Dr. CALIFF. Senator, if I may, we did appoint someone else to oversee—look back at decisions that were made there. Steve Solomon, who is not working under Dr. Woodcock in this capacity.

Senator BRAUN. Let's get back to the incident itself. So roughly—first of all, Abbott was vindicated on the particulars, the merits of the issue. They had no contribution to those sicknesses, correct?

Dr. CALIFF. With all due respect, I wouldn't use the word vindicated. We can't say with certainty that the cause was there. But it is so rare to have four cases of cronobacter all from the same——

Senator BRAUN. But you haven't been able to connect the dots, and they may still be in that position to where there was culpability.

Dr. CALIFF. That is correct.

Senator BRAUN. Why did it take roughly 2 months after 9 to 10 months of the formula shortage saying that, hey, we better be on full alert to actually get through the particular issue itself? And then once you seemed to come up with a result—or an idea that there was not a connection, at least in the short run analysis, that took another couple of months. And at that time the shelves were empty. To get Abbott back in the business of doing what they were doing.

Dr. CALIFF. We saw the lack of quality in the system and the lack of accountability for the problems that were there, and so we had to invoke the Justice Department to negotiate a consent decree, which is essentially Abbott saying, yes, we had all these problems.

Here's exactly what we are going to do to fix them. For legal reasons, I can't discuss the exact details of the negotiation, but let's just say that it took a lot of arm wrestling to get to the point where the Justice Department got Abbott to sign the consent decree.

Senator BRAUN. Well, I think it is clear that we got too many eggs in one basket when it comes to producing this stuff. I think it is also clear that it got caught in a regulatory morass that took more time than what was necessary, and now we are dealing it with it after the fact.

Dr. CALIFF. We completely agree. It took too long, and I also want to agree with Senator Scott that we are not trying to blame everybody else. We have our own issues, which I think are clearly laid out in the documents that we have given you. And we will be accountable for fixing those going forward.

Senator BRAUN. Thank you.

The CHAIR. Thank you.

Senator Rosen.

Senator ROSEN. Thank you, Chair Murray and Ranking Member Burr for holding this hearing, Dr. Califf, for your participation and your clear answers for everyone. You know, my home State of Nevada has been hit especially hard by our current formula shortage. There is a reduction of at least half of available supply.

A recent report ranked Las Vegas as the metro area facing the worst shortage in the Nation. So our local community organizations in Nevada, we have three square babies Bounty, the Women and Children's Center of the Sierra, among so many others. They are really doing incredible work to get the formula to those who need it the most, but they are stretched so thin and so recent actions by the Administration are a start.

We—I know they have come too late. I know you have addressed some of that. But what I am concerned about here is, we talked a little bit about the forward 21 program, and that is a pilot program you are setting up to monitor and report on food supply chain disruption and vulnerabilities. So where is the status of that? Where are we at?

I really want an answer to—before I go to some other Nevada issues, is there a national phone number that parents can—who can't find formula, who can get help? Are families being—is there a place where they can do—find about homemade recipes? We don't

want people making dangerous things. So maybe if you could answer those.

Dr. CALIFF. Yes, HHS has a website, HHS. gov/formula and it has all the issues of the manufacturers. For example, you have an infant that has been using a particular kind of formula, you can call in. The hotlines are there. And if there's not an answer otherwise, there is a number you can call there for HHS to get help. So that would be the most immediate thing to do if there is a problem. You are asked about 21 forward. Would you like me to comment on that or—

Senator ROSEN. Yes, please. Because I think that would—if we can implement that, then that may help us out going forward with vulnerabilities and supply chain disruption.

Dr. CALIFF. As I said funding was asked for that. It wasn't given so we have borrowed from other FDA programs. We are not where we need to be. Just for example, there are 220,000 registered food facilities in the United States.

A system that is used for infant formula but also has more general applicability to the foods program, it has got to be a robust system. The kind I am used to working with in the private sector. We are making progress, but we are nowhere near where we need to be.

Senator ROSEN. Maybe we can help you with some funding there, but I want to follow-up on something Senator Hassan asked about, the distribution of the formula coming in for military flights. How is it being decided beyond existing supply chain routes? Are the areas that are hardest hit with the worst shortages like Las Vegas and other parts of Nevada, are they being prioritized?

Dr. CALIFF. Right now, those specialty formulas are the priority. So they are going to wherever babies are who need specialty formula, which could be anywhere. My expectation—I am not on the supply chain committee, which, as I think you know, is a Government wide committee that has been guiding us through the whole pandemic, I would say quite successfully, considering the problems that we had early on in the pandemic.

I would expect that they are going to send the more general formula to the places in greatest need at first, including I think a special problem has been alluded to. If you are in a rural area, you may be a small place, so you wouldn't show up in a general measure. I know that is going to be taken into account.

Senator ROSEN. Thank you. You mentioned that you weren't on the supply chain committee, but I do want to talk about staffing and FDA staffing, because according to the American Academy of Pediatrics, FDA has 13 staff members to regulate and monitor safe production of infant formula and no staff assigned to supply chain issues.

Is this currently still the case? Have you reassigned the staff to oversee the supply chain issues for baby formula with 21 forward? This formula is essential, and children can't—children can't wait. Like you said, it is the prepared gym shoes.

Dr. CALIFF. As I have already mentioned, we brought in staff from other areas of FDA, which means other things are not being

attended to that the public would expect. But this is the top priority, and you know that there is legislation pending that would fund additional people for this purpose. They are desperately needed.

We have really only nine because the other four, we just got the funding a couple of months ago and it is—it is going to take a little while to identify and hire the people. So we have had to bring in other people but from other programs.

Senator ROSEN. Thank you. I see my time is up, Madam Chair.

The CHAIR. Thank you.

Senator Burr.

Senator BURR. Thank you, Madam Chair. Let me just say this, Dr. Califf. I am not sure that there is a seated Member of Congress that has defended the FDA workforce more than the one sitting in front of you and in the role of the FDA. I got to admit, I was quite amused to see two doctors use the same data to come to two different conclusions. I was shocked that that would happen. I think it happens every day. But here is some of the real beefs. Will you provide for this Committee all the inspection reports on the Sturgis facility since 2019 and the deficiencies that were raised with the Sturgis facility?

Dr. CALIFF. I will commit to provide everything I legally possibly can. I don't know if there is anything that is enjoined because I have said I can't comment on——

Senator BURR. Let me put the end date of September 21st of 1921 so it doesn't get into the current time period that we are talking about.

Dr. CALIFF. I think it is—as long as it is legally permissible, I am committed to do that.

Senator BURR. It is my understanding that there wasn't even an inspection that was done in 2020. Do you know whether that is accurate?

Dr. CALIFF. That is accurate.

Senator BURR. It is accurate. You said Abbott didn't submit paperwork on April 30th. I just want to dig a little bit deeper. Did Abbott not respond on April 8th to the 483 that FDA issued where they detailed corrective action at the Sturgis facility?

Dr. CALIFF. That was their first take on corrective action, but——

Senator BURR. They submitted to FDA a detailed corrective action paper on April the 8th.

Dr. CALIFF. Not an adequate corrective action report.

Senator BURR. Okay.

Dr. CALIFF. I mean, Senator Burr, I have been on the other end of inspections in almost every industry. And usually when something has not gone right, the company has a particular perspective. It may be a little oriented toward the well-being of the company, not necessarily the needs that the FDA saw. So there is always adjudication back and forth that has to go on.

Senator BURR. It is my understanding that in every case that we have tried to fill a nutritional need that only Abbott made with for-

eign products, that Abbott has paid for those products. Is that an accurate statement?

Dr. CALIFF. I don't deal with the funding of those, but I do believe that Abbott has made a good faith effort to cover the costs. I just don't know the details.

Senator BURR. You said earlier that you weren't going to throw the mailroom under the bus. But yesterday, FDA statement basically did that. Square for me the last 24 hours as it relates to that.

Dr. CALIFF. First of all, let me just comment. I do believe that despite our contentiousness at times, you have supported the employees at the FDA. I don't want it to be taken that I don't believe that. I just believe it is my job to defend hardworking people. But as for yesterday, I just want to be clear, and I think we were yesterday, there are two issues here. One is that something went wrong in the mailroom.

The other is we didn't have an escalation policy that caused the employees who were dealing with the complaint to escalate it to the relevant leaders, including all three of the leaders who should have gotten it. I am not blaming this on the mailroom. Either one of those methods would have gotten the report to the proper people.

Senator BURR. So let me just read it for you because I found this sort of shocking. FDA leadership did not receive direct copies of the complaints due to an isolated failure in FDA's mailroom.

Dr. CALIFF. That is direct copies of the complaints. Specifically, FedEx sent the package that had five people addressed. There were five packages. There are two different facilities, one in White Oak. The food part of the FDA, as you may know, is up in a different part of Maryland. The direct copies didn't get to the people. They were actually sitting in the receiving dock. But that doesn't mean the employees——

Senator BURR. I was reading what was said yesterday. That it was——

Dr. CALIFF. But Senator Burr, that is one statement out of an entire report that goes through the other aspects of this about the escalation procedure.

Senator BURR. All right. Let's go to budgets, because you have been pretty across the board budgets. We don't have enough money. We don't have enough money. We don't have enough money. So you got $718 million in COVID emergency money. The omni, which it was in March, gave you $11 million for maternal and infant health and $10 million for inspections. That was 60 days ago. How many additional inspectors have we hired as of today?

Dr. CALIFF. I don't have that number in front of me, but I would be glad to get it to you.

Senator BURR. Provide it for us, if you will. Let me end on this, the Food Center's budget is $1.1 billion. I don't think that is gum and wire. You stated that you were putting together things with gum and wire earlier. I think it was to Senator Paul or somebody. I think $1.1 billion is a pretty substantial amount of money.

Now, the Chair and I—and I realize I am over my time, Chairman, but I will be brief. The Chair and I are negotiating the next

round of user fees and we are extremely close. FDA is sitting before us in the midst of a large failure as an agency since it was created. And once again asking for money with more authority, more money, less accountability.

I say to you and say to the Chair, I am going to go home, and I am going to try to think about this as to whether now is the time for us to move forward on finishing our user fee negotiations. It may be that finding all the answers to this question is increasingly more important than expediting something that really doesn't have a finality until the end of this year.

Madam Chair, I will work with you as aggressively as I can on this. But I also want to work with you as aggressively as I can to get the answers to the questions that are unanswered today on infant formula. I yield the floor.

The CHAIR. Thank you, Senator Burr. That will end our hearing today. But let me be clear, Dr. Califf, it will not end our focus on this. I am going to keep pushing to see that plan I mentioned earlier. I asked for it weeks ago, and I will not start pushing until I see it. This is life or death, and Dr. Califf, it simply should not have taken this long. I am going to keep pushing to get formula on shelves and to families and babies.

I am going to keep pushing to get answers for parents in Washington State like Mac, my constituent, about how they can get what they need. Because Mac did speak with his pediatrician weeks ago and they could not even find a sample can. And let me be clear, just asking parents to call HHS is not an answer.

Parents from the tri-cities, where he is, or anywhere else, should not be trying to figure out this for themselves on Facebook. This is a national crisis. It involves international supply chains, as well as nationwide distributors and retailers. It is unacceptable to leave families fending for themselves.

Parents like Mac need one simple place to find information they need and get help. We need one clear coordinating—coordinator managing this multifaceted problem and helping parents and hospitals and pediatricians and state officials and everyone get what they need to figure this out.

This should have happened days—this should have happened months ago. This shortage should never have gotten so out of control. And understand, I am ready to work with you or anyone else to fix this.

But I am not going to stop pushing everyone I can you, HHS, President Biden, Abbott, and other formula manufacturers to do everything you can to fix this as soon as possible and to make sure that this never happens again.

With that, for any Senators who wish to ask additional questions, questions for the record will be due in ten business days, June 10th at 5 p.m.

This Committee stands adjourned.

ADDITIONAL MATERIAL

HON. ROBERT CALIFF, M.D.,
COMMISSIONER,
FOOD AND DRUG ADMINISTRATION,
SILVER SPRING, MD 20993.
MAY 18, 2022

DEAR COMMISSIONER CALIFF:

Thank you for your efforts to ensure food safety at the Food and Drug Administration (FDA). For decades, the FDA has been the gold standard for approving and regulating medical products and food. Yet this year, the actions of the FDA's Center for Food Safety and Applied Nutrition (CFSAN) has raised questions regarding its ability to fulfill its core oversight responsibilities. The safety of, and access to, infant formula should be among CFSAN's highest priorities, as this food is vital for the growth and development of infants. To this end, we write to request a response from FDA on its activities that may have contributed to the exacerbated infant formula shortages and specific questions in the following paragraphs. It is our responsibility as U.S. Senators to do everything with our authority to hold the FDA accountable and legislate in areas that will enable the agency to meet the expectations of the American people.

Our hearts and prayers are with the parents and their families whose babies tragically died due to infant formula bacterial contamination. We understand and want to support the FDA in thoroughly evaluating all reported and potential infant formula contaminations. However, based on the timeline and where we are today, it is unclear as to why nearly 3 months have gone by and the FDA has failed to expeditiously conduct and conclude its investigation. On February 17, Abbott Nutrition initiated a proactive, voluntary recall of three of its powdered formulas manufactured at their facility in Michigan following four consumer complaints of potential Cronobacter bacteria contamination. [1]

The following day, FDA warned consumers not to use these products. [2] On April 15, the U.S. Centers for Disease Control and Prevention concluded the bacteria isolated from two of the sick infants and the Michigan facility had no connection. And as of last week, no connection has been found, yet the facility remains idle. [3, 4]

We are also concerned as to why FDA leadership failed to be proactive in mitigating the shortage crisis parents are now facing. The COVID–19 pandemic revealed many vulnerabilities across all

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[1] Abbott, Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant, February 17, 2022, *https://abbott.mediaroom.com/2022—02—17-Abbott-Voluntarily-Recalls-Powder-Formulas-Manufactured-at-One-Plant*. See also U.S. Food and Drug Administration, Company Announcement: Abbott Voluntarily Expands Recall of Powder Formulas Manufactured at One Plant, February 17, 2022, *https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily recalls-powder-formulas-manufactured-one-plant*.

[2] Kansas Department of Health and Environment, KDHE & FDA warn consumers not to use select Similac, Alimentum & EleCare powdered infant formula, February 18, 2022, *https://www.kdhe.ks.gov/CivicAlerts.aspx'AID=147*.

[3] Abbott, Press Release: Abbott Provides Infant Formula Update, May 11, 2022, *https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html*.

[4] U.S. Centers for Disease Control and Prevention, Cronobacter and Powdered Infant Formula Investigation, accessed May 12, 2022 (updated May 12, 2022), *https://www.cdc.gov/cronobacter/outbreaks/infant-formula.html*.

sectors of industry, and our food supply chain was woefully unprepared to handle challenges here and from foreign partners. Infant formula supplies at local grocery stores were relatively stable for the first half of 2021. The out-of-stock percentage started to climb steadily in the later half and continued to worsen throughout this year.[5] Abbott Nutrition's voluntary recall exacerbated the shortage, and yet no policies were taken to mitigate the sharp increases to the current out-of-stock 43 percent the Administration is now scrambling to address. It's also concerning that FDA and key officials in the Administration did not anticipate this crisis or take action within days following Abbott Nutrition's voluntary recall considering the company holds 48.1 percent of the U.S. market in infant formula.[6]

Families are getting to the brink of pursuing unsafe and potentially dangerous options to feed their infants including homemade infant formula. And physicians are, once again, running defense on misinformation due to a lack of Federal action to get the word out on safe alternatives.[7],[8],[9] In addition, the shortage will trickle into other Federal agencies, diverting and stretching resources from other crises like illicit fentanyl. In April, the U.S. Customers and Border Protection (CBP) seized $30,000 worth of unapproved infant formula across 17 shipments at the Philadelphia, Pennsylvania port of entry.[10]

Based on the timeline, it is unclear why Federal health agencies have not been able to complete this investigation in a more expeditious manner or plan ahead to mitigate this additional supply chain disruption. Therefore we respectfully request your responses to the following questions:

1. The manufacturing facility in Michigan is segmented where manufacturing designated areas are required to adhere to specific safety and infection control standards. The facility also maintains areas that are administrative and do not directly handle manufacturing or exposure of open products. Please describe the areas in which the FDA has taken samples and how many samples were taken that would empirically validate the results of the investigation. In your explanation, please also include the

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[5] Datasembly, Nation-wide Out-Of-Stock is now at 43 percent for the week ending May 8th, May 10, 2022, *https://datasembly.com/news/out-of-stock-rate-in-april-2022-copy/*.

[6] IBISWorld, Industry Report: Infant Formula Manufacturing, by Jack Curran, August 2020, *https://www.ibisworld.com/united-states/market-research-reports/infant-formula-manufacturing-industry/*.

[7] The New York Times, Why Doctors Don't Recommend Homemade Baby Formula, by Catherine Pearson, May 11, 2022, *https://www.nytimes.com/2022/05/11/well/homemade-baby-formula.html*.

[8] KAKE ABC, Homemade infant formula can be dangerous. Experts share how to feed your baby through the shortage, by Madeline Holcombe, May 11, 2022, *https://www.kake.com/story/46472922/homemade-infant-formula-can-be-dangerous-experts-share-how-to-feed-your-baby-through-the-shortage*.

[9] Bloomberg, Parents Are Trying Homemade Baby Formula. Doctors Say They Shouldn't, by Allison Nicole Smith and Kelsey Butler, May 12, 2022, *https://www.bloomberg.com/news/articles/2022–05–12/why-parents-making-homemade-infant-formula-should-beware-of-serious-health-risks*.

[10] U.S. Customs and Border Protection (CBP), Philadelphia CBP Seizes Nearly 600 Cases of Infant Formula Unapproved for Import to the United States, April 5, 2021, *https://www.cbp.gov/newsroom/local-media-release/philadelphia-cbp-seizes-nearly–600-cases-infant-formula-unapproved*.

expected timeline for each task and if CFSAN has met its obligations.

2. As noted in the paragraph above, the CDC concluded that the samples taken did not match the bacteria in the facility. How does the FDA partner with other agencies at the Federal, state, and/or local level to expedite investigations to forestall potential supply chain crises? To what extent do other agencies or organizations advance or hinder a timely investigation?

3. Why has it taken more than 3 months to complete the obligations required to finalize a safety inspection?

4. At what point did the FDA alert the White House of the bacteria and the product recall?

5. Did the FDA, along with the White House, have a strategic plan in place to mitigate formula shortages? If yes, please provide a brief description, date of implementation, actions the agency has taken, and expected timelines to enable manufacturers to produce, process and deliver food during supply chain disruptions.

6. Did or has the FDA made any recommendations to the White House about what actions the agency can take to prepare or handle the shortage?

7. The manufacturing facility in Sturgis, Michigan is the only Abbott plant to produce specialized formula for infants with metabolic disorders. How is the FDA going to work with Abbott and other formula manufacturers to ensure that the special medical needs of infants can be met?

8. Abbott Nutrition, along with other infant formula manufacturers, have registered domestic and foreign sites to manufacture infant formula for interstate commerce in the U.S. Abbott Nutrition's facility in Ireland is an FDA-registered facility. It also has several other facilities in the Netherlands, Spain, and France that manufacture infant formula. What steps has FDA taken to increase importation by accrediting more manufacturing facilities overseas?

9. At what point was the White House made aware that these importation options were available to ease the strain on domestic capacity?

10. Whose decision was it to ease these requirements on formula from foreign manufacturers?

11. In White House press briefings last week, the Press Secretary and others within the Biden Administration appeared to blame Abbott Nutrition for the deaths and shortages, despite the fact that the investigation is not

[11] The Hill, White House goes on defense on baby formula shortage, by Alex Gangitano, May 13, 2022, *https://thehill.com/news/administration/3487765-white-house-goes-on-defense-on-baby-formula-shortage/*.

concluded.[11],[12] Did the FDA state to the White House that Abbott Nutrition was responsible for the illnesses or deaths?

The shortage, felt by all families in need, is disproportionately impacting vulnerable populations. As you know, Medicaid is a major source of coverage for low-income vulnerable populations including pregnant women, infants, and children. In 2020, Medicaid covered 42 percent of births.[13] In addition,

49 percent of infants born in the U.S. participate in the Special Supplemental Nutrition Program for Women, Infants, and Children.[14] While breastfeeding has been on the rise, many infants rely on formula partially or as their sole source of food.

The FDA must do everything within its statutory authority to ensure it facilitates access to safe, quality foods. We would appreciate a reply no later than Wednesday, May 25, 2022. Thank you for your attention to this matter and please do not hesitate to reach

[12] The Hill, Buttigieg points blame at Abbott for baby formula shortage, by Monique Beals, May 15, 2022, *https://thehill.com/news/administration/3489439-buttigieg-points-blame-at-abbott-for-baby-formula-shortage/*.

[13] March of Dimes, Health Insurance/Income, *https://www.marchofdimes.org/peristats/data?reg=99&top=11&stop=154&lev=1&slev=1&obj=18*.

[14] National WIC Association, The state of WIC: Investing in the Next Generation, February 2022, page 40, *https://s3.amazonaws.com/aws.upl/nwica.org/state-of-wic—2022.pdf*

[1] The White House, Building Resilient Supply Chains, Revitalizing American Manufacturing, and Fostering Broad-based Growth: 100-day Reviews under Executive Order 14017, June 2021,

out to us or our staff should the agency require resources or cooperation from other agencies to fulfill its obligations.

Sincerely,

ROGER MARSHALL, M.D.,
U.S. Senator.

SHELLEY MOORE CAPITO,
U.S. Senator.

SUSAN M. COLLINS,
U.S. Senator.

MIKE BRAUN,
U.S. Senator.

JOHN BARRASSO, M.D.,
U.S. Senator.

KEVIN CRAMER,
U.S. Senator.

LISA MURKOWSKI,
U.S. Senator.

JERRY MORAN,
U.S. Senator.

MARSHA BLACKBURN,
U.S. Senator.

JOHN BOOZMAN,
U.S. Senator.

BILL CASSIDY, M.D.,
U.S. Senator.

DEB FISCHER,
U.S. Senator.

CYNTHIA LUMMIS,
U.S. Senator.

TIM SCOTT,
U.S. Senator.

THOM TILLIS,
U.S. Senator.

CINDY HYDE-SMITH,
U.S. Senator.

JOHN THUNE,
U.S. Senator.

JAMES LANKFORD,
U.S. Senator.

STEVE DAINES,
U.S. Senator.

TED CRUZ,
U.S. Senator.

ROY BLUNT,
U.S. Senator.

JOHN KENNEDY,
U.S. Senator.

[Whereupon, at 12:46 p.m., the hearing was adjourned.]

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