FDA OVERSIGHT PART II: RESPONSIBILITY FOR THE INFANT FORMULA SHORTAGE

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OF THE

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C O N T E N T S

WITNESSES

Written opening statements and statements for the witnesses are available on the U.S. House of Representatives Document Repository at: docs.house.gov.

INDEX OF DOCUMENTS

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FDA OVERSIGHT PART II: RESPONSIBILITY FOR THE INFANT FORMULA SHORTAGE

Thursday, May 11, 2023

HOUSE OF REPRESENTATIVES
COMMITTEE ON OVERSIGHT AND ACCOUNTABILITY
SUBCOMMITTEE ON HEALTH CARE AND FINANCIAL SERVICES
Washington, D.C.

The Subcommittee met, pursuant to notice, at 2:07 p.m., in room 2154, Rayburn House Office Building, Hon. Lisa McClain, [Chairwoman of the Subcommittee] presiding.

Present: Representatives McClain, Grothman, Langworthy, Porter, Balint, and Lee.

Mrs. MCCLAIN. The Subcommittee on Health Care and Financial Services will come to order. Welcome, everyone.

And without objection, the Chair may declare a recess at any time.

I recognize myself for the purpose of making an opening statement.

Thank you, again, for being here. I appreciate it. Six weeks ago, the Subcommittee held its first oversight hearing on last year's infant formula crisis. During that hearing, we heard from former Deputy Commissioner in charge of the Office of Food Policy and Response, Frank Yiannas. Mr. Yiannas' testimony highlighted many internal failures within the FDA that led to the crisis, including the FDA's poor efforts to carry out one of the most critical missions, which is food safety. His testimony also raised questions of why key facts about the crisis were omitted when Commissioner Califf and Dr. Mayne and Mr. Yiannas testified before the Energy and Commerce Committee last February and in the so-called independent Solomon Report.

Today's hearing will continue the long and overdue oversight of the Food and Drug Administration's response to the infant baby formula crisis. We hope to get answers on why the FDA has not been fully forthcoming with Congress and, really, the public. Today's hearing will examine why it took more than four months for inspectors to arrive at the Abbott facility plant in Sturgis, Michigan after babies started getting sick. We will determine why it took so long for the Biden Administration to take action to secure the infant baby formula supply after a recall left its shelves bare. Why was the FDA unprepared for the crisis? Why did they only inspect 3 of 23 infant formula manufacturing facilities in 2023 of 23? Why did they fail to investigate whistleblower warnings? Did the FDA

follow regulatory protocols? Did the FDA respond quickly enough? Was the FDA's so-called independent review truly independent or was it a cover up? Today, I will get answers to these questions to better understand exactly what happened, so it does not happen again.

American families must be confident that the FDA has the ability to prevent a crisis like this from ever happening again, and in our previous hearings, we learned a lot about how the crisis happened and how it could have been handled better from FDA officials. And here is what we know so far, just to kind of lay it out. The FDA ignored Abbott's employees' 38-page disclosure detailing concerns at the Sturgis plant. The FDA's telework policies and lax approach to oversight left it unprepared to address the supply chain shortages after the Sturgis facility was actually shut down, and the FDA had failed to prioritize food safety.

The FDA has not taken the action needed to prevent a similar crisis from happening again, and the American people paid the FDA $6.7 billion last year—$6.7 billion. And in next year's budget, the FDA wants over 10 percent more, totaling $7.2 billion. And I think the American people have a right to know that if you only took a look at 3 out of 23 and you were paid fully, now we had a crisis. We do not really have answers to the crisis, but yet you want more money. Listen, we all want everyone to be safe, and we all want to make sure we are safe, but I think we all also want to make sure that our money is going to do good work.

So, I think the American people deserve to know that if we are going to have these agencies and we are going to spend a lot of money on these agencies, these agencies need to make sure that they are doing their job as just opposed to throwing money at the problem. FDA field inspectors should have been doing the jobs, and there were not serious consequences. I am yet to hear what the consequence for the FDA is, other than "give me more money." They did not do their job, they sat at home, they still got their paychecks. They want more money, which may help, but what is going to change?

Now it is time for the current FDA leadership to really be held responsible, right? In business, their stockholders are held responsible, people get fired, they lose money, they lose profits. There is a consequence to the action. I have yet to hear who is responsible at the FDA and what is the consequence for their failure. I think we deserve that especially, for over $6 million worth of money. Here, we will discuss what failures within the FDA led to the crisis. We will discuss ways the FDA can improve its internal controls to get ahead of potential disruptions and prevent future supply chains. We will discuss why the FDA omitted key facts from the public.

We owe it to parents, caregivers, and infants to get to the bottom of what really happened, right, to fix it. We cannot fix a problem that we first cannot admit exists. As I said in our last hearing, the families of these babies that died from contaminated formula deserve answers on how this tragedy was allowed to occur in the first place and what we can do to prevent it from happening again.

So, thank you, Dr. Mayne, for being here today. Congratulations on your upcoming retirement, and we look forward to your testimony.

Now I yield to my Ranking Member, Ms. Porter, for her opening statement.

Ms. PORTER. Thank you very much, Madam Chairwoman. Today we are having the second part of our Subcommittee's hearing series on the 2022 infant formula shortage, and so far, I think the Chairwoman and I agree on something really important: an infant formula shortage could repeat itself, and that is a deadly serious problem.

Let us think back to a year ago today. Forty-three percent of formula products were out of stock across the country. A bacterial contamination in Abbott, which killed nine babies and made hundreds of others fall ill, prompted a recall that shocked our formula supply chain. That disruption, of course, interrupted our economy but, more critically, threatened the health, nutrition, and lives of our kids and the American people's confidence in government. Today we are saying on a bipartisan basis that it could happen again, and we have a duty to do something meaningful about it.

This hearing is called "Responsibility for the Infant Formula Shortage," and as I said last time, there is a lot of blame to go around. It is clear that, with today's witness selection, that Republicans want to blame the FDA, and I will level with you. I think some of that blame is well placed. We have had two subsequent infant formula recalls in 2023 already, and we are still seeing that the FDA can make further improvements on its internal processes, intervene in issues sooner, and follow through with more inspections to prevent further contamination.

Other lawmakers today will blame formula manufacturers for their negligence and failure to produce safe products, and that is true, too. Still others will blame Washington for allowing just three manufacturers to have monopolistic control over 90 percent of the formula market and for failing to invest the resources and authorities in the FDA that it needs to produce the results we demand. And I think those folks are correct too.

The thing about this issue, though, is it does not come down to the fault of one person or one agency, one company or one political party. We cannot fire or attack someone and expect formula contaminations and shortages to just go away. That is why today, I propose we go beyond the title of this hearing. We need to move beyond just assigning responsibility and toward delivering solutions that can prevent a shortage from happening again, and I want to thank the Chairwoman for her work with me on that.

We need to use these hearings to identify what are worthy proposals, worthy innovations, and then we need to transform them into legislation. If we do not do that, we are failing to solve the future problems. We risk just blaming and shaming rather than preventing and problem solving. If we work together, though, we can address the deficiencies and inefficiencies that risk the supply of safe, healthy infant formula. Luckily, we have an FDA expert before us who can help us with that. Look, Dr. Mayne can handle what we are going to throw at her. We should ask hard questions. We should push her on areas where we think the FDA can and

should do better, but we should also use Dr. Mayne's knowledge to figure out what Congress should be doing better.

Right now, the FDA is reorganizing its Human Foods Program to reduce fragmentation and approve coordination, but that is not going to solve all of the fundamental issues. Even with the best structure, leadership, and resources, the FDA is only as well-equipped and as accountable as Congress makes it be, so while we hold the FDA and others responsible, what can Congress be doing to help?

First, we have to provide the FDA with resources to increase its inspection and food safety capacity. You cannot expect an agency to do better when you are taking away the funding for the personnel and technology needed to make it happen. That is why I think the 22-percent cut to the FDA the Republicans have voted for would make this problem worse. Let's not go down that path. If we expect the FDA to do better, we need to set it up for success and then hold it accountable to deliver on a better outcome.

Whether we reach bipartisan consensus on proper funding or not, there are some no-cost reforms we should be able to agree on. We need better processes for reporting and tracking contaminations, whether that is making Cronobacter a nationally notifiable disease or making sure all contaminations in critical food factories are promptly and properly reported. If we use Dr. Mayne as a resource, we can find solutions we can all agree on to save kids and stop shortages. Let us come out of this hearing with next steps, not just complaints about missteps. I yield back.

Mrs. MCCLAIN. Thank you, Ms. Porter. And now I am pleased to introduce our witness, who is here to discuss the FDA's response to the 2022 Infant Baby Formula Shortage. Dr. Susan T. Mayne is the Director of the Center for Food Safety and Applied Nutrition at the Food and Drug Administration. She has been in this role since January 2015. Dr. Mayne has received a B.A. in chemistry from the University of Colorado. She has also earned a Ph.D. in nutritional sciences with Minors in biochemistry and toxicology from Cornell University.

And pursuant to Rule 9(g), the witness will please stand and raise her right hand.

Do you solemnly swear or affirm that the testimony that you are about to give is the truth, the whole truth, and nothing but the truth, so help you God?

Dr. MAYNE. I do.

Mrs. MCCLAIN. Thank you. Let the record show that the witness answered in the affirmative.

And now we appreciate you being here today. I really do look forward to your testimony, and let me remind the witness, that we have read her written statements. It will appear in full in the hearing record. Please limit your oral statements to five minutes. And as a reminder, please press the button on the microphone in front of you so that it is on, and the Members can hear you. When you begin to speak, the light in front of you will turn green. After four minutes, the light will be yellow. When the red light comes on, your five minutes has expired. We would ask that you please wrap up.

And for this, I recognize your opening statement, Ms. Mayne.

STATEMENT OF SUSAN T. MAYNE, PH.D., DIRECTOR
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION
U.S. FOOD AND DRUG ADMINISTRATION

Dr. MAYNE. Chairwoman McClain, Chair Comer, Ranking Members Porter and Raskin, and Members of the Subcommittee, thank you for inviting me to testify on the safety and supply of infant formula in the United States.

As a parent myself, I know nothing is more important than the health and safety of our children, and last year's infant formula recall and shortage put a strain on parents and caregivers across the U.S. When we saw the egregious conditions of Abbott's Sturgis facility, we knew a recall could stress an already unstable marketplace, but we had to put our children's safety first. FDA takes the situation extremely seriously and has applied many lessons learned, resulting in greater confidence in infant formula safety.

One of the most important lessons that we learned was that the Agency must do all that it can to ensure that no infant formula facility ever has the level of unsanitary conditions that were present at Abbott Sturgis in early 2022. We have made progress and are using the fullest extent of our authorities to address lessons learned. Preventing another shortage in the future will require a continued whole-of-government approach, increased industry accountability and cooperation, and help from Congress.

Today, I would like to talk about the future of infant formula safety and our vision for a modern regulatory approach.

First, the ultimate responsibility to produce safe products is on infant formula manufacturers. We need industry to comply with our requirements and to adopt enhanced food safety measures to deliver the safest possible infant formula. Two months ago, we issued a call to action to industry to take specific steps to improve food safety practices for the protection of infants.

Second, we have worked diligently to increase the supply of formula on the U.S. market. The in-stock rate for formula is near 90 percent, which is higher than pre-recall levels, and overall formula production exceeds sales week after week. Market consolidation is a serious concern and contributed significantly to shortages. There are currently only three major domestic producers of infant formula. This means that any disruption—a recall, international conflict, or natural disaster—could impact formula supply.

Our temporary exercise of enforcement discretion enabled safe products to enter the U.S. market, doubling the number of firms producing infant formula for the U.S. Almost all the manufacturers participating under the enforcement discretion policy are taking the necessary steps to stay in the U.S. market. Federal Agency partners also have an important role in helping to address market consolidation, and we will continue to work with them to encourage a stronger, diversified, and more resilient U.S. infant formula market.

Third, FDA and industry should be able to address product contamination in or near real time. Our inspections are currently a snapshot in time. More real-time oversight can transform infant formula regulation by ensuring firms promptly investigate product contamination and destroy adulterated product before it reaches consumers. To do this, we need modern authorities, including ex-

plicit authority to require industry to notify us when formula tests positive for Cronobacter, even if the product has not left the facility, and the ability to obtain records remotely from all food manufacturers.

Fourth, we continue to advance the science around Cronobacter, a very common pathogen in the environment, but one about which we have limited information. Cronobacter infection should be a nationally notifiable disease so local, state, and Federal public health partners can reliably collect information on all cases, and so we can rapidly link cases to potential sources of contamination.

Fifth, we are intent on delivering an empowered unified Human Foods Program and a world-class field force that will deliver modern, integrated oversight. As part of this will be creating an office of critical foods as required by the Food and Drug Omnibus Reform Act. We are also actively hiring for specialized infant formula inspection staff that will execute a modern preventive approach to infant formula inspections. Last, in the early days of COVID in 2020 and well before the Abbott recall and infant formula shortage, we recognized the critical need to better resource our infant formula program. We are grateful for the resources we have received, but our Human Foods Programs are still in dire need of additional investments and updates to meet current as well as future challenges.

As we emerge from the public health emergency, the food industry still has fragile supply chains. Preventing shortages will take continued cooperation among all the players and additional authorities and resources to modernize our programs. We look forward to working with you all to make this a reality. I welcome any questions you may have.

Mrs. MCCLAIN. Thank you, Dr. Mayne, and I now recognize Mr. Grothman.

Mr. GROTHMAN. Thank you. Dr. Mayne, are you familiar with the FDA's internal agency review led by Dr. Solomon?

Dr. MAYNE. Yes, I am.

Mr. GROTHMAN. Were you interviewed by Dr. Solomon during the course of the review?

Dr. MAYNE. No, I was interviewed by the same group of folks who were interviewing all the people who participated in the interviews. That information was consolidated and put together for Dr. Solomon.

Mr. GROTHMAN. Why don't you think you were interviewed?

Dr. MAYNE. I am sorry?

Mr. GROTHMAN. Why don't you think he interviewed you?

Dr. MAYNE. He did not interview any of the individuals. I think there were a large number of people who were interviewed. It was consistently done across all the interviewees.

Mr. GROTHMAN. OK. Apart from Dr. Solomon, did anyone else in the FDA or HHS author the report?

Dr. MAYNE. I am sorry? Did anyone——

Mr. GROTHMAN. Apart from Dr. Solomon, did anyone else at FDA or HHS author the report?

Dr. MAYNE. No, not to my knowledge.

Mr. GROTHMAN. OK. What was Principal Deputy Commissioner Janet Woodcock's role in the report?

Dr. MAYNE. I believe she was one of the individuals who called for the report so that we would look internally at our processes and see what changes could be made expeditiously in the spirit of continuous improvement.

Mr. GROTHMAN. OK. Was she involved in the report?

Dr. MAYNE. Other than asking that the report be executed, not to my knowledge.

Mr. GROTHMAN. OK. We have received witness testimony before this Subcommittee that implies that she was involved in it. I will give you another chance to answer. Did Dr. Woodcock influence the Solomon Report in any way?

Dr. MAYNE. She asked that the report be conducted. People were interviewed, the data was compiled, produced into a report. She asked that the report be conducted along with Commissioner Califf.

Mr. GROTHMAN. OK. The U.S. comptroller general, Gene Dodaro, stated in an April 26, 2023, House Oversight hearing that the FDA is "not doing enough to improve food security and food safety." Food Safety has been on the GAO's high-risk list since 2007. Dr. Mayne, do you think the FDA is doing enough to ensure food safety?

Dr. MAYNE. We can always do more to ensure food safety, and I am going to come here today with solutions on things we can do to ensure better food safety in infant formula manufacturing. Having said that, we worked very closely with the U.S. Department of Agriculture as we ensure the food safety for the U.S.

Mr. GROTHMAN. OK. Did the Reagan-Udall Foundation for the FDA conduct an operational valuation of FDA's Human Foods Program?

Dr. MAYNE. The Reagan-Udall Foundation did not conduct the evaluation, but they convened a group of independent experts that conducted that evaluation. So, it was not done by the Foundation, but by independent experts.

Mr. GROTHMAN. OK. And it describes their Food Division in a culture of constant turmoil. Do you agree with the Reagan-Udall Foundation's assessment?

Dr. MAYNE. My indication of their assessment was that the reporting and decision-making needed to be streamlined, which is something I agree with, that organizational changes could make a more efficient and effective program, which I also agree with. So, those were the primary recommendations coming out of the Reagan-Udall Foundation.

Mr. GROTHMAN. OK. COVID–19 was used as an excuse for FDA not receiving a whistleblower complaint about the Abbott plan. Commissioner Califf testified before Congress that the whistleblower report was not transmitted to key FDA food safety officials, like yourself, because of a COVID–19 mailroom issue. Do you believe the report was actually lost in the mail?

Dr. MAYNE. I cannot speak as to what happened to the report itself being lost in the mail, but what I can speak to is the report was received at FDA. It was received by our field inspectional force, and they worked on the report. They acknowledged that they received the report. They then went ahead and reviewed the report. There were some very serious allegations in the report, so they sought information from the Office of Criminal Investigations. And

so, they did act upon it. It is correct that senior leadership was not made aware of that, so it was not that FDA didn't act upon it, but that, simply, senior leadership was not aware of that.

Mr. GROTHMAN. So, everybody acted on it, but they did not tell the leadership?

Dr. MAYNE. That is correct. It was not escalated. There was no process within FDA to escalate this particular whistleblower complaint. FDA receives a large number of whistleblower complaints, so it was a failure of escalation. I do wish I had been made aware of this particular whistleblower complaint, but just to reiterate, the complaint was acted upon, but the leadership was not aware of that.

Mr. GROTHMAN. Did it surprise you?

Dr. MAYNE. Which, that the complaint itself or——

Mr. GROTHMAN. Yes.

Dr. MAYNE. The complaint was very lengthy and very deep. It had a lot of egregious claims in there, statements in there, allegations in there. There were very troubling things in there. What surprised me was language about data falsification and trying to hide information from Federal regulators. Given the nature of some of those allegations, that is why the inspector engaged the Office of Criminal Investigations with regard to that whistleblower complaint.

Mr. GROTHMAN. Thank you.

Mrs. MCCLAIN. Thank you, Mr. Grothman. The Chair now recognizes Ranking Member Porter.

Ms. PORTER. In our first infant formula hearing, I asked the Majority's witness a simple question, and the answer caused a little bit of bipartisan shock. I saw Chairwoman McClain's head shook upward, and so I even asked the same question again. So, I am going to start by asking it one more time, this time to you, Dr. Mayne. Let us say a major formula manufacturer finds bacteria in its supply today. Does the law require it to tell the FDA?

Dr. MAYNE. The answer is no.

Ms. PORTER. So, we all heard that correctly. The law puts no one at the FDA in charge or on notice if a major formula manufacturer finds bacteria in the supply. So, if we want to solve formula safety issues, someone needs to be monitoring real-time bacterial contaminations. Dr. Mayne, who can change the law to put someone in charge of this? Is it up to the FDA to change this rule, the manufacturers, or Congress?

Dr. MAYNE. We need Congress's help to modify that, and we have sought that from Congress.

Ms. PORTER. So, I think lawmakers can and must point some fingers at the FDA and manufacturers, but we need to also be willing to point the finger back at ourselves. The truth is we did not do enough in last year's omnibus. Yes, we gave the FDA some new authorities, and one was requiring manufacturers to notify the FDA of any interruption that would likely lead to a meaningful disruption in infant formula supply.

Dr. Mayne, I am wondering if you spot the same problem that I do. Let us think like parents here, like moms. If there is deadly bacteria in formula that your infant could eat, would you want the FDA to know about it only when it might cause a supply shortage,

or would you want the FDA to know any time your infant could get contaminated formula?

Dr. MAYNE. Just to be clear, what we really need is in the production, in the manufacturing facility, before it ever leaves that facility. That is what we are seeking, is the industry would notify us before it ever would leave the facility, so that we can make sure that the proper amount of formula is destroyed to protect infants.

Ms. PORTER. Yes. So, you would want to know if there was a bacterial contamination, whether it would cause a supply chain shortage or not. The FDA should know?

Dr. MAYNE. Correct, and by knowing in real time, that is a good way to prevent a supply chain shortage.

Ms. PORTER. Exactly, so we keep kids safe and we protect supply chain, but we just did not do enough in last year's omnibus. And look, this was a Democratic-controlled Congress last year. It is on us, I think, to lead the way here. Congress did not provide the authority for a full reporting process, and so now we have more work to do. In the meantime, this has real-world consequences. We have had two major infant formula recalls so far in 2023 from Reckitt and Gerber. Would either of these have been reportable to the FDA under the new provision of the law?

Dr. MAYNE. No. That was no. I am sorry.

Ms. PORTER. No. So, I am leading legislation that would establish a process for the FDA to be notified when manufacturer's critical food products test positive for foodborne pathogens. Dr. Mayne, it is no secret that the FDA has had some struggles in responding to instances of formula contamination, but the FDA has identified this legal change as something that it needs in order to do better. And I am ready to push Congress to deliver for you and expect you to deliver back to us, so I am ready to whip Republicans and Democrats to join together to act, but I want to think through the oversight piece of this.

Can you tell us a little bit about how required reporting of contamination would better equip the FDA to address contamination issues before the impact? You mentioned identifying the right amount of formula to be destroyed? Are there other features with regard to cleaning or other protocols?

Dr. MAYNE. Yes. So, by knowing in real time that there has been product contamination in the manufacturing facility, our experts, our food safety experts, our compliance experts can work with the manufacturers to determine to essentially bracket or scope the amount of product that needs to be destroyed. And that essentially means any product that was produced since the last sanitation break and before the next sanitation break. And that is where we have seen issues with recent recalls, where companies had destroyed product that they identified to be contaminated, but we didn't determine that they destroyed a sufficient amount between those sanitation breaks.

So, working in real time with the industry to make sure that proper amount of product is destroyed is critical to help support future supply chains and enhance food safety. It also allows industry to do a root cause analysis, working with FDA and our experts, to identify why did it get contaminated closer in time to when the actual contamination event occurred.

Ms. PORTER. Thank you very much. I know that Members on this Subcommittee care a lot about this issue, and I know that Subcommittee Chairwoman McClain does too. And I am excited about the potential to move this legislation forward on a bipartisan basis, and I just want to invite all of our colleagues on the Subcommittee and on the Oversight Committee to join in this legislation. We need to give the FDA the information it needs in real time to be able to both prevent supply shortages but, more importantly, to keep everybody safe. Together, we really can help solve this problem. I yield back.

Mrs. MCCLAIN. Thank you, Ms. Porter. I now recognize myself.

It is amazing to me, and it saddens me a little bit, that we actually have to legislate this, but if that is what it takes to keep people safe, I mean it is a shame that we have to legislate. If there is a problem, fix it. With that said, I think we also know that there is enough blame to go around. This is not a one specific, you know, I have the Lucky Star here and I will fix everything, but I have you in front of me today, so I want to focus my questions around the FDA.

I am concerned by the lack of inspections at the Abbott facility. I am not saying you are the only one to blame, but between the fall of 2019 and 2021, there was just not a lot of inspections going on. The FDA's May 2021 resiliency roadmap claimed that the Agency prioritized "mission critical inspections during the pandemic." And according to the FDA, the criteria for mission critical inspections is a product is used to treat a serious disease or medical condition and there is no substitute. Is that partially correct?

Dr. MAYNE. That is my understanding.

Mrs. MCCLAIN. So, a product with no substitute, to me, that sounds like baby formula, other than mother's breast milk, but some mothers cannot breastfeed for whatever reason. Inspections are also mission critical when there is an evidence of serious adverse events or outbreaks of a foodborne illness, and, again, that sounds to me like the Abbott plant.

Dr. MAYNE. At the time in 2020, there was no evidence of outbreaks or illnesses, at that time when the routine surveillance inspections were not in progress.

Mrs. MCCLAIN. So, can you just repeat that one more time? There was no evidence in 2021?

Dr. MAYNE. This was in 2020. I think when you were talking about the missed inspection in 2020, there was an inspection in 2021.

Mrs. MCCLAIN. In the fall of 2021?

Dr. MAYNE. Correct.

Mrs. MCCLAIN. Four months after, I believe?

Dr. MAYNE. The first complaint came in September 2021, which is when we were actually doing the inspection, so they were at the same time.

Mrs. MCCLAIN. I think from what I show, it was discovered in February, but there were no inspections done. In fact, despite this, 20 of the 23 infant formula production packing and distribution plants in the U.S. were not inspected for nearly two years. So, if you go back to critical, and I think we need to change what is crit-

ical, why is infant formula not considered mission critical to the FDA?

Dr. MAYNE. So, first of all, I do not oversee the inspectional branch of the Agency. The resiliency roadmap did come out of the inspectional branch. I can share with you what I know, but there may be things I need to take back. Essentially, the inspections in March 2020, the routine surveillance inspections were not executed during the early phases of COVID. They were reinstated in July 2020.

Mrs. MCCLAIN. So, let me stop you right there, and I think this is part of the concern, is we had inspectors not doing inspections because of COVID?

Dr. MAYNE. That is correct. During that brief interval at the beginning——

Mrs. MCCLAIN. Right. Were they getting paid during that period of time?

Dr. MAYNE. Well, let me be clear. That was routine surveillance. Mission critical inspections were conducted throughout the pandemic.

Mrs. MCCLAIN. I appreciate that.

Dr. MAYNE. Yes.

Mrs. MCCLAIN. Can you answer my question now? Were they paid so——

Dr. MAYNE. Yes.

Mrs. MCCLAIN. OK.

Dr. MAYNE. The inspectors continued to be paid. They were doing mission critical inspections and——

Mrs. MCCLAIN. But baby formula is not mission critical.

Dr. MAYNE. Baby formula manufacturers were inspected in 2020. My records indicate there were five infant formula inspections during 2020. Under FSMA, the Food Safety Modernization Act, we are supposed to inspect them once every three years. Our practice has been to inspect them annually.

Mrs. MCCLAIN. OK. But you did not inspect them annually, and I am going to ask my question again. Is baby formula critical? Deemed mission critical? Yes or no.

Dr. MAYNE. I would take that back to the Office of Regulatory Affairs because I do not know all of the criteria that determine mission criticality for an inspection.

Mrs. MCCLAIN. OK. OK. I just want to make sure that I have everything because I understand that it took until January 31, 2022, for the FDA to inspect the Abbott facility in Sturgis. Is that not correct?

Dr. MAYNE. No, we inspected in September 2021. At that inspection, we noted several violations for Abbott nutrition. We issued a 483, noting those violations. They came back to us with a 28-page report saying that they would investigate and correct those actions, committing to make those changes. When we went back in January 2022, they had not made those corrections. In fact, rather than correcting the deficiencies we identified in September 2021, the situation deteriorated, which is what led us to the situation leading to the recall.

Mrs. MCCLAIN. OK. With that, I am out of time, and I want to be respectful. So, the Chair now recognizes—one moment—Ms. Balint from Vermont.

Ms. BALINT. Thank you, Madam Chair. I am focused on the future, like my colleagues here, in preventing this from ever happening again. Now, our colleagues across the aisle have promised to collaborate with us to prevent a future infant formula shortage, and I appreciate that. However, at the height of the formula shortage, the crisis, 192 House Republicans voted against investing $28 million in funding to help the FDA conduct oversight and hold companies accountable. And in May 2022, Republicans chose not to join Democrats on this Committee in our investigation into Abbott's role in the infant formula shortage. Now with the House Republicans' Default on America Act, they are proposing massive cuts to nondefense discretionary spending, which to a layperson means all that other stuff that takes care of Americans. Dr. Mayne, how would a budget cut of approximately 22 percent affect the FDA's ability to employ inspectors and conduct inspections of formula manufacturing facilities?

Dr. MAYNE. Broadly across the FDA, I can say it would be devastating. That would translate into about a $790 million cut in our budget authority and broadly across the Agency. That means that, that could result in a loss of 32 percent of our domestic inspections and 22 percent of our foreign inspections, including in countries like India and China. In terms of the Foods Program, where I am, our budget is largely based upon budget authority. Ninety-seven percent of our budget is budget authority. We have very few user fees in the Human Foods Program, and so what that means is that cut would disproportionately impact the Human Foods Program.

It would also impact our ability to support innovation. Food industry needs a strong regulator as they are embarking on innovation. So, it would damage industry. It would damage us. What we constantly hear from industry, is they want strong regulators for predictability, for timeliness, and we do have a pre-market approval program as well. All of those would be adversely impacted, and we would be unable to do what I think American consumers expect us to do, given that they eat food every single day.

Ms. BALINT. Yes. Dr. Mayne, just to be clear, you said $790 million. Is that correct?

Dr. MAYNE. That is correct.

Ms. BALINT. Thank you. In January 2023, FDA Commissioner Califf began implementing the recommendations of internal and external reviews by announcing the restructuring of the Human Foods Program and by unifying several offices under a single new Deputy Commissioner. And so, I am wondering how would the budget cuts affect FDA's ability to implement those recommendations from its internal and external reviews to make sure that we have better oversight over infant formula, which is what we all want.

Dr. MAYNE. I think it would be devastating. We would not have the people. We would not have the necessary oversight. A cut of that magnitude in Human Foods Program, we would be back to the same number of FTEs that we have had at our lowest points in the last 40 years. Just as a point of reference, in CFSAN that I lead,

in 1978, we had 1,000 FTEs. Right now, we are at 1,100. So, if we took a 22-percent cut, given most of our budget is in payroll, we would be below the number of employees that we had in 1978, and, of course, our mandate has expanded dramatically since 1978.

Ms. BALINT. Sure. Dr. Mayne, let us talk about the bottom line. Who, in fact, will get hurt if FDA's Human Foods Program does not get the resources that it needs? Let us make it really clear for people.

Dr. MAYNE. I think the American consumers would be impacted adversely by that. All of our surveillance, all of the sampling, all the things we do, the interception through the international mail facilities, those all require resources and people, and that would be adversely impacted, but I also think it would adversely impact industry.

Ms. BALINT. Tell me about that.

Dr. MAYNE. Every time industry wants to put new innovation, whether it be cell-cultured meat, whether it be genetically engineered crops to support drought resistance, climate change, challenges into the future, our reviewers work to help bring these products to market safely and successfully. If there are concerns about food safety, these products will never be successful in the market. So, it is imperative that we are there to do that.

With regard to our Infant Formula Program, as you know, we run a notification program where we review new infant formulas before they come into the U.S. market. We had been doing that with nine infant formula reviewers. We saw an increasing complexity coming in. Applications that in the past would have been 30 pages long, are now 1,000 pages long. How would we have the capability to review those products appropriately before they come into the market as a sole source of nutrition for our infants?

Ms. BALINT. Thank you, Dr. Mayne. I yield back.

Mrs. MCCLAIN. Thank you. The Chair now recognizes Ms. Lee for five minutes.

Ms. LEE. Thank you, Madam Chair. The infant formula shortage has been horrible for all parents, but it has been even more devastating for low-income families who do not have the luxury of switching to more expensive brands or easy access to multiple stores to search for in-stock formula because they lived in food deserts. My district was hit particularly hard, with Pittsburgh among the top 10 areas with the worst shortages. I cannot imagine the stress and uncertainty that those families felt as they did everything they could to find food for their babies. We need to learn from this shortage and do better. The answer is, of course, not the 22 percent across-the-board cuts as passed by Republicans last month, a cut that would mean 1.7 million women, infants, and children would lose nutrition assistance, through WIC.

In March of this year, the FDA issued an immediate national strategy geared toward increasing the resilience in the infant formula supply chain. Dr. Mayne, how do the long-term and short-term plans ensure that both low-income and rural families get the formula supply they need in the future?

Dr. MAYNE. So, I think for the immediate future, we have been building up the supply chain. So, as you heard me say, the in-stock rates are now at 90 percent, which is better than they were before

the recall. Formula manufacturers are producing more than is being purchased week after week after week. So, the supply is building up and has been building up steadily, and that is really important. There are still challenges with distribution right now. And what we keep hearing is that it is not equitable across this country, that rural areas have harder challenges getting the formula they need and especially people who are served by private or independent grocers.

What we are doing is working with the National Grocers Association, to use whatever data they can give us to give to the infant formula manufacturers and say this is where the distribution is most challenging. We do not control that distribution, but we can certainly help provide information to make sure that areas—food deserts, rural areas, areas that are more challenged to getting access to product—can access that.

For the future, obviously, I think there are things looking at—you mentioned the USDA WIC Program. I know many Members of Congress are looking at that program to see how can that help support better resilience. As you know, for many of our lowest-income women, that is a critical source, the WIC program, to provide formula for those infants. So, gaining greater resiliency through WIC is another critical aspect, and I know Congress is interested in that. It is another thing we can do.

Ms. LEE. Thank you. That was my next question, so I will move to another. Reagan-Udall Foundation's independent evaluation suggests reorganization of the Human Foods Program. How will that improve how FDA operates and oversees infant formula safety and production?

Dr. MAYNE. Infant formula safety is one part of that, but the Reagan-Udall Foundation is looking at the overall Human Foods Program, and it is really taking a very deep dive at how we can do things more effectively. We have heard from so many of our employees—what would make your jobs easier, where are there inefficiencies, and how do we redesign a modern program to be more effective and efficient for the future.

With regard to infant formula, that is a special case that we are really very, very laser-focused in on how to do that better. So, we have, for example, made a commitment to have an inspectorate that is really dedicated to infant formula and increasing the numbers. So, these are inspectors who would only be doing or dedicated to infant formula manufacturers. The training, working through our scientific experts, we are committed to doing so much more, working with industry, making sure they understand all of our standards, how to produce infant formula in a very safe way.

So, there are a number of actions that we have identified in the national strategy on the steps that we can take to get to a better place in the future, and I think that is a good roadmap for the future.

Ms. LEE. Thank you. I understand that your Agency is considering asking Congress to give it the authority to require companies to submit positive results for contamination as we were discussing with Ranking Member Porter. How would granting that authority prevent another shortage in the future?

Dr. MAYNE. I think it is an important authority. So, that means we can be working with the manufacturers in real time to make sure no contaminated product enters the market. And as I noted earlier, to make sure that industry is trying to get to the root causes. We need to prevent contamination in the manufacturing facility in the first place. And doing that in real time is a heck of a lot easier than waiting until many months later when we may become aware of positive product contamination.

In addition to seeking that authority, we are also asking industry to do more environmental monitoring. That means sampling your food facility and finding that bacteria, and eradicating it, getting it out of the facility in the first place, and retaining the isolates. We rely on whole genome sequencing as a major scientific advance in food safety, but we need to get the bacterial isolates in order to utilize these new technologies for better food safety.

Ms. LEE. Thank you, and that is my time. I yield back.

Mrs. MCCLAIN. Thank you. The Chair now recognizes Mr. Grothman.

Mr. GROTHMAN. Thank you. In previous congressional testimony before the Energy and Commerce Committee in May 2022, you and Commissioner Califf provided an official document entitled, "Timeline of Infant Formula Related Activities," which is here, and I would like to ask unanimous consent to enter this document into the record.

Mrs. MCCLAIN. Without objection.

Mr. GROTHMAN. Thank you. Is this timeline complete according to the Agency's activities up to that point?

Dr. MAYNE. The timeline didn't entail every single activity we did because we were working round-the-clock day in and day out, but it is a synopsis of the major activities that the Agency conducted during the months leading up to and following the February 17 recall.

Mr. GROTHMAN. OK. In a document recently provided by HHS to the Committee, there appears to be more than two extra pages of information that have been added to this original timeline. Most of the additional information predates the May 2022 hearing. Why was this information omitted in the previous congressional testimony?

Dr. MAYNE. I do not know what the timing of those new informational events were. I have not seen that document. So, I would assume it is a more updated document, but I have not seen the document, so I cannot comment.

Mr. GROTHMAN. OK. One piece of information I found astounding is the FDA actually received a complaint about the conditions of the Abbott facility in Sturgis in February 2021, yet they did not take it seriously. Why do you feel this important fact was not shared with the American people at that time?

Dr. MAYNE. We were not aware that that complaint had been sent into the FDA. It was forwarded from OSHA into a mailbox at the FDA. I do not have firsthand knowledge of that particular mailbox, but my understanding is it was not processed and addressed promptly. And in fact, I was not aware of that complaint at all when we testified in May 2022.

Mr. GROTHMAN. Somebody should have told you. It has been also brought to our attention that the FDA had the opportunity to highlight the vulnerability of infant formula in USDA report on American supply chains in August 2021. Why did your office ultimately oppose the inclusion of infant formula in that report?

Dr. MAYNE. I have no information about that. I am not sure what report that was, but what I can say is that we work, FDA with USDA, on a Supply Chain Task Force. And we have been working with USDA throughout the pandemic on supply chain, including consideration of various commodities that were at risk, and USDA and FDA were both aware that infant formula was a potential commodity at risk. That is one of the reasons I came to the appropriators in 2021 seeking additional resources for infant formula, and we were grateful to receive those in 2022.

Mr. GROTHMAN. Are there remaining facts the FDA is withholding from Congress or the American people?

Dr. MAYNE. I am not aware that we withheld any facts from Congress or the American people. As I said, we did not know about the whistleblower complaint. That was not covered up. We had no information about that complaint.

Mr. GROTHMAN. OK. One final thing. Today, we are talking about the vulnerability of the infant formula supply chain. During the COVID–19 pandemic, FDA funded the 21 FORWARD Initiative to assess pandemic supply chain vulnerabilities. Why was this program or other supply chain analytics not utilized to evaluate in-stock rates of infant formula at the national level until it was too late?

Dr. MAYNE. Part of our Food, Drug and Cosmetic Act authorities are food safety and nutrition. We do not have authorities or resources to do supply chain monitoring. We did what we could with the information we had. So, we purchased through our budgets, without any resources received, publicly available data, such as the IRI data, to try to understand what was happening with regard to the supply chains. And that was an initiative we took on, out of concern for what could happen with the infant formula supply chain.

Mr. GROTHMAN. OK. It has been reported that a staff request was made in 2021 for funding from COVID–19 supplemental funds to further develop 21 FORWARD, a data analytical platform to monitor the food supply chain. However, then Acting Commissioner, Janet Woodcock, cut the food supply chain monitoring request, opting to fund a similar request for increased monitoring of drug supply chains. Why was the food supply monitoring request cut, yet one for the drug supply chain monitoring approved?

Dr. MAYNE. I cannot confirm anything about that. I have no information on that. I did not participate in any of that.

Mr. GROTHMAN. OK. Thank you.

Mrs. MCCLAIN. Thank you, Mr. Grothman. The Chair now recognizes Ms. Porter.

Ms. PORTER. To understand how the infant formula shortage happened, I want to take a look at a little more detail at Abbott Sturgis, Michigan production facility. Let us go back to 2021 and 2022 when, Dr. Mayne, you led the Center for Food Safety and Applied Nutrition. According to the FDA's timeline of the infant for-

mula shortage, FDA conducted an initial inspection of the Abbott manufacturing facility in Sturgis in September 2021. Is that correct?

Dr. MAYNE. That is correct.

Ms. PORTER. And that inspection revealed multiple unsanitary and improperly maintained working conditions, correct?

Dr. MAYNE. That is correct.

Ms. PORTER. The FDA then initiated a further inspection of the Sturgis, Michigan plant from January to March 2022, correct?

Dr. MAYNE. Yes.

Ms. PORTER. Dr. Mayne, what did those additional inspections in early 2022 reveal?

Dr. MAYNE. So, we noted many deficiencies in the plant, sanitation, plant conditions, in September 2021. Those were delivered to the company through a 483 and in regulatory meetings with their leadership. They committed to address our concerns in writing back to us through an investigation and a commitment to make those controls. When we got there in January 2022, those things had not happened, and, in fact, the plant's conditions had deteriorated. That led us to do our own environmental monitoring. Abbott also did environmental monitoring in the plant, given the conditions we saw. That is when we identified five different strains of Cronobacter in the manufacturing facilities. So, all of that information, along with the whistleblower complaint and the consumer complaints that we had received, led to the voluntary recall in February 2022.

Ms. PORTER. I would like, Madam Chairwoman, permission to enter into the record the March 2022 FDA inspection report and the timeline of infant formula-related activities from U.S. FDA.

Mrs. MCCLAIN. Without objection.

Ms. PORTER. This March 2022 FDA inspection report, which detailed the FDA's observation of these multiple unsanitary conditions that you just described, it says the FDA inspection team observed that Abbott "did not establish a system of process controls designed to ensure that infant formula does not become adulterated." The team also found that Abbott "did not ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source." The inspectors found employees, who worked directly with formula, failing to wear the necessary protective apparel and that Abbott's own self-investigation failed to conclude whether its operations were a health hazard.

It is unacceptable, and I think you agree based on how you described what you saw in September 2021 and what you saw in early 2022. It is unacceptable for a company that manufactures more than 40 percent of the infant formula sold in the United States and is a major recipient of government dollars via the WIC program to keep its facility in such poor conditions. It puts babies at risk and as a result of all of this, failure to follow the rules, failure to respond to regulators, despite promises to do, so we wound up with a recall in February 2020.

Dr. Mayne, what lessons learned from Abbott's failure to keep its plant in appropriate condition, commitments, but failure to follow through on those commitments to do better by 2020 to 2022? What

can we learn from this experience to make sure that the next time the FDA tells a formula manufacturer to clean up their plant, they do not arrive six months later and find that things have actually gotten worse?

Dr. MAYNE. Yes, and we agree, the conditions were egregious. And, in fact, that was why we took the exaggerated step of putting into place a consent decree where their resumption of manufacturing would be overseen by an independent expert and when working with our investigators and our subject matter experts to make sure they could resume safe production. That is an unusual step that we would take, but given the conditions we saw, we took it.

But what we have worked on is really trying to recalibrate the infant formula manufacturers broadly. That is the call to action we released in March of this year. We identified many deficiencies in the Abbott inspection. We identified certain deficiencies and other infant formula manufacturers as well, and so the call to action is for all infant formula manufacturers to do better. We have been engaging with them regularly. We have issued a prevention strategy. Our food safety experts are working directly with their food safety experts to explain what we expect for safe formula production. And so, we are on a path to be into a better food safety situation and not running into the situation we found ourselves in, in the Abbott plant situation in January 2022.

Ms. PORTER. Thank you. I yield back.

Mrs. MCCLAIN. Thank you, Ms. Porter. The Chair now recognizes Mr. Langworthy for five minutes.

Mr. LANGWORTHY. Thank you, Madam Chair. It seems like the more information that we get, the more questions that are created, and it really seems like there is a pattern of delay, delay, delay here. The Chairwoman already asked you why it took so long for the FDA to inspect the Sturgis plant. Why was there a three-month delay between the Abbott recall, and the closure of February 17, and the decision to waive FDA's strict formula labeling and importation requirements in May 2022, despite the national shortages?

Dr. MAYNE. So, I think if I heard your question, there are many questions embedded in there. So, let us take one at a time.

Mr. LANGWORTHY. Sure.

Dr. MAYNE. You mentioned labeling. We put in place an enforcement discretion policy to allow safe nutritious formula to come into this country to help make sure that parents could find product on store shelves during this period of this national shortage. We did have certain labeling requirements, and they are primarily for things like safety. For example, a baby that has a cow's milk allergy needs to know if a formula is based on cow's milk or soy, so there are certain label issues that are critically important for safety, like allergen information. Also, how to prepare a formula. Some formulas need to be diluted to different amounts than others. Over diluting risks having infants not get enough nutrition. Under diluting means the product will not flow through a bottle and babies will not get the desired nutrition.

Mr. LANGWORTHY. Dr. Mayne, I understand why we would have labeling, but why is there a delay from February 17 to three

months later when that labeling action took place? Why was there such a delay in the labeling?

Dr. MAYNE. The formula recall started on February 17. We then went through a series of steps to try to address shortages regarding infant formula, and given the market concentration in this country, that is not an easy step. There were a number of things we did. For example, we received product from across our borders from domestic manufacturers that have plants in other countries. We expedited the entry of those coming into the country. We worked with the infant formula manufacturers that were not at the Abbott plant, not the Sturgis plant, to increase their production. We did a number of different steps to get that into place.

We wanted to bring in safe product from abroad. We had to put out a guidance document, tell others, tell us if you want to bring product into this country, this is what we need to see from you. We need to know those products meet our nutritional criteria. We need to make sure those products have been tested for safety, the same way we expect our domestic products to be tested. We got applications and we started bringing those products into this country. In total, we issued, I think it was 20 letters, 36 different products, including specialty and medical products that were allowed to come into this country under enforcement discretion. And now we have doubled the number of infant formula manufacturers bringing product to this country, and that is through FDA's actions.

So, we jumped into action. We used what levers we had to try to address the formula shortage, but there are some levers we could not address, the market concentration, but as you have heard, we have taken steps to try to address those. More things are needed to prevent this into the future, and we are very willing to work with Congress and in an all of government response to make sure that we do not have this problem again in the future.

Mr. LANGWORTHY. A week before the formula recall on February 10, FDA leadership activated the coordinated outbreak response and evaluation network core. To your knowledge, were senior White House officials notified at that point?

Dr. MAYNE. I know that White House officials were notified on February 16. I do not know if they were notified on February 10, but I am aware that we did send a communication to the Supply Chain Task Force, which would include the White House on February 16, which was the day before the recall.

And just to be clear, the science was evolving on February 10. We did not have the information in place that we had had Cronobacter. That information was not available. We were doing the inspections. We had collected samples. The information about Cronobacter and the sequences actually came in on February 13. So, at that point, we had more information that this plant was contaminated on February 13. That led to the ask of Abbott to voluntarily recall. We notified the White House and others on February 16, prior to the recall occurring.

Mr. LANGWORTHY. If the White House was aware, why did it take three months for them to step in and help address the shortage of baby formula?

Dr. MAYNE. I cannot speak to what the White House, what their actions were, but what I can speak to is that we were working in

an all-of-government way throughout this process, including with regard to the enforcement discretion products. We worked very closely with Health and Human Services on Operation Fly Formula to bring those products to the U.S. market as quickly as possible, to help rectify the shortages that parents in this country were experiencing.

Mr. LANGWORTHY. And last, yes or no, did you talk to the White House about the possibility of a formula shortage? If so, when?

Dr. MAYNE. I am aware that we talked to them through a written memo on February 16. Whether there were previous conversations with the White House, I cannot say, but I can say that that information was shared to the White House before the recall occurred.

Mr. LANGWORTHY. Thank you, and I yield back, Madam Chair.

Mrs. MCCLAIN. Yes. Thank you. The Chair now recognizes Ms. Balint for five minutes.

Ms. BALINT. Thank you, Madam Chair. In September 2022, FDA issued an internal evaluation of the Agency's response to the infant formula shortage, and Dr. Steven Solomon, FDA's Director of the Center for Veterinary Medicine, drafted the report. Following the Subcommittee's March 2023 hearing, so just a few weeks ago, on the infant formula shortage, some of my Republican colleagues made some claims about how FDA conducted its internal review of the infant formula response. Dr. Mayne, to your knowledge, why didn't FDA tap you, Mr. Yiannas, or Ms. Woodcock to write the internal review and instead selected Dr. Solomon?

Dr. MAYNE. So, Dr. Solomon was not involved in any way in the infant formula response. Mr. Yiannas, myself, and Dr. Woodcock was the Acting Commissioner leading up to February 17, so all of us were involved in the response, and so having us evaluate ourselves is illogical.

Ms. BALINT. Got it. So, you needed somebody impartial. You cannot have the fox watching the henhouse, so to speak.

Dr. MAYNE. We asked for someone who knew the FDA well and knew the processes and procedures of the FDA well, so that someone would not have to translate all of the acronyms, everything as we discussed the processes, but he was not involved in the infant formula response in any way. And one other thing, is this was an internal response because we were very committed to improving our processes and our procedures as expeditiously as we could. There were a large number of recommendations that came out of that report. And we have been working hard every day every week to move further some of those recommendations, and we have made great progress in addressing many of the recommendations.

At the same time, there was also an external review of our program that was convened by the Reagan-Udall Foundation, and, as well, there is an OIG review as well. So, we are going to benefit from an internal review as well as two external reviews. We are always committed to continuous improvement to do better.

Ms. BALINT. So, just to follow up on that, can you just explain really quickly how did the FDA improved its consumer complaint and whistleblower complaint process?

Dr. MAYNE. Yes, the processes have been changed. So, for example, with regard to consumer complaints, we get a lot of consumer

complaints at the Agency, thousands of consumer complaints. But certain criteria, for example, if a consumer complaint comes in and it involves an infant, if it involves a death or hospitalization, anything like that, that is immediately escalated to the leadership, so I now see those.

So, there is an elevation process based upon criteria—vulnerable populations, hospitalizations, deaths, things like that—so those processes have been put in place, and the processes are important given the volume of work that we have. So, in the Foods Program, we address something like over 9,000 adverse event consumer complaints every year. We have a call center that responds to 25,000 calls every single year. We need strong processes and technology to manage that volume of workload as optimally as we can.

Ms. BALINT. I appreciate that. The internal review, as I understand it, also revealed that scientific gaps and understanding of the contamination spread and illness of Cronobacter also hindered FDA's response. What steps has FDA taken to remedy some of the knowledge gaps and to improve Cronobacter sampling and testing procedures so that we can prevent this from happening again?

Dr. MAYNE. Yes, we were truly in an information deficit here because Cronobacter is not a notifiable disease. And when we saw four consumer complaints and our physician complaints about Cronobacter, we did not know if that was unusual or not because we do not know what the denominator is. So, having a nationally notifiable disease would completely change the way we could have approached this particular situation. So, not much was known about the pathogen.

One of the things we did is, we convened the National Advisory Committee on Microbiological Criteria for Food to ask them a whole series of questions about Cronobacter. We have given them a charge. They are working on that right now. I am the vice-chair of that committee. The committee is meeting next week, to give us some progress on what they have learned about Cronobacter, so that is critically important. So, the work on national notifiability is critically important as is the work to understand this bacteria. What do we know about its prevalence? Where is it located? What are the sources of contamination? Our lack of information on whole genome sequencing for this pathogen has hindered us. We do not have anywhere near the tools that we have, like Listeria, Salmonella, or E. coli, but we really want to advance the science here. And we have made great progress already in the months since this has occurred.

Ms. BALINT. I really appreciate that. So, it is clear that FDA needs adequate resources to prevent this from happening again. And I just want to say, as a mom, who had to supplement my breastfeeding in order for my son to thrive, I know how important this issue is for parents all over this country, and this Committee, I know, is really focused on making sure this does not happen again. Thank you, Dr. Mayne.

Dr. MAYNE. Yes, thank you. We agree, and we appreciate that. We never want to have this happen again.

Mrs. MCCLAIN. Thank you. I now recognize myself. I am still confused, and I need you to help me connect the dots. Why did it take until January 31 for the FDA to inspect the Abbott facility in

Sturgis, Michigan? Not only did reports of Cronobacter infections start in September 2021, but we now know that OSHA transmitted a workplace complaint to FDA in February 2021, outlining the unsanitary conditions.

So, I just need some help on filling in the gaps. I mean, the FDA's 2021 investigations operation manual states, "All complaints involving either infant formula or baby food are to be thoroughly investigated on a high priority basis." I just think four months is a big delay. Can you help me fill in the timeline there?

Dr. MAYNE. Yes. So, typically, our goal is to inspect annually for infant formula manufacturers. Our normal high-risk food facilities are inspected once every three years, and non-high risk food facilities are inspected once every five years under the Food Safety Modernization Act that Congress gave us. But infant formula is a high priority, and that is why our goal is annually. But with regard to the Sturgis facility, we were in there in September. We found deficiencies. The industry committed to address those. We typically give time to industry to address those. They did not, but then we——

Mrs. MCCLAIN. When you went in there at the original September of 21, that was a normal regular-scheduled visit, so to speak, right?

Dr. MAYNE. Correct. Right.

Mrs. MCCLAIN. Then after that is when, unfortunately, some babies passed away and there were more complaints, right, between really that September and January. Why the four-month lag? I think that is what I need——

Dr. MAYNE. Yes, at a high level, and I am happy to address the timing. First of all, again, I am not head of the inspectorate, but I can tell you what I understand and what the dates are and what I know. So, we received that first consumer complaint at the same time the investigators were there. That was followed up on. We always try to interview the parents, obtain product, find medical records——

Mrs. MCCLAIN. But you did not know about Cronobacter on the 21st——

Dr. MAYNE. No.

Mrs. MCCLAIN [continuing]. In your normal, right? You got reports after that.

Dr. MAYNE. Correct.

Mrs. MCCLAIN. And that is when it——

Dr. MAYNE. The case report came in, but we would not have necessarily pulled the product, tested the product, seen what the evidence pattern was. That information did not come in until October, just to be clear.

Mrs. MCCLAIN. OK. I will give you October.

Dr. MAYNE. Right.

Mrs. MCCLAIN. We did not do anything until January. I mean——

Dr. MAYNE. Correct. So, that is the first step, and then in October, a whistleblower complaint came in. As I indicated, the staff received it, they acknowledged it, they reviewed it.

Mrs. MCCLAIN. It just did not get to you.

Dr. MAYNE. That is correct, but the staff were working on it, and then they attempted to interview the whistleblower, and as I think you know, the whistleblower, based upon timing on their end, was not available.

Mrs. MCCLAIN. But they had it since October, and they did not do anything from January.

Dr. MAYNE. Then they tried to schedule the inspection. In December, the inspection was attempted to be scheduled. Abbott declined to have the inspection done because they had a COVID outbreak in their facility, and then we finally got in there. But looking at that, we agree with you. Those timelines are less than ideal, and that is why we have put in place a whole series of processes based upon the lessons learned from this. Once we got in there and we saw the conditions, all of our timelines were met very expeditiously. But I agree with you, in the months leading up to that time, that those timelines could have been more ideal.

Mrs. MCCLAIN. Thank you. And then in my few minutes, I am still troubled by "during COVID." I mean, I think baby food is essential, especially in this day and age, and especially for underserved communities. I show that 20 of 23 of the infant formula production packing and distribution plants in the U.S. were not inspected for nearly two years. Why? Are we blaming that on COVID?

Dr. MAYNE. So, those numbers do not agree with what I have.

Mrs. MCCLAIN. We got those numbers from the FDA.

Dr. MAYNE. I think we should take that question back. Again, that would come from the data from our Office of Regulatory Affairs.

Mrs. MCCLAIN. What do you have as your numbers? Were the 23, were they all inspected in a timely fashion?

Dr. MAYNE. And again, some of it may be calendar years versus fiscal years. We should take the numbers and get back. But my understanding is that we did inspect, even in the early part of COVID, five different infant formula manufacturing facilities.

Mrs. MCCLAIN. But there are 23, so I am going to even give you on the five.

Dr. MAYNE. At that point in time, I think we had 21, but that is why we should take it back.

Mrs. MCCLAIN. OK. Let us even say with 5 of 21. Can we at least agree that is kind of a problem?

Dr. MAYNE. I am sorry. I did not hear the last thing you said.

Mrs. MCCLAIN. Can we agree even if it is 5 of 21 and your numbers are correct, 5 of 21? What was everyone doing?

Dr. MAYNE. Those——

Mrs. MCCLAIN. And I know it was COVID, but——

Dr. MAYNE. They were inspecting the prioritized inspections. There are many criteria——

Mrs. MCCLAIN. And baby formula is not prioritized, so maybe that is something else we need to change?

Dr. MAYNE. Certain manufacturers were. It was based upon their inspectional history, whether there had been complaints associated with products. So, if a formula manufacturer had a long history of no complaints, they might not have just been prioritized in that period of time in 2020.

Mrs. MCCLAIN. All right. Did Abbott have complaints?

Dr. MAYNE. Did Abbott have complaints? We asked Abbott when we go into the facilities. In fact, every time we——

Mrs. MCCLAIN. Did they have complaints?

Dr. MAYNE. I think you should ask Abbott that question, but——

Mrs. MCCLAIN. I am asking you. Do you know of any complaints from Abbott? You are the FDA. You are the inspection. You are the regulatory agency.

Dr. MAYNE. We get the consumer complaints. We——

Mrs. MCCLAIN. Did they have any?

Dr. MAYNE. We report them to Abbott. We tell Abbott if we get a consumer complaint, then——

Mrs. MCCLAIN. Did you get any?

Dr. MAYNE [continuing]. Then we talk. Yes, those are the ones that we talked about.

Mrs. MCCLAIN. OK. Thank you.

Dr. MAYNE. When we are in a plant, we asked Abbott if they had any similar complaint.

Mrs. MCCLAIN. But you had not done an inspection with Abbott, who had to had complaints for the prior two years? So, my time is up. I will yield back.

Voice. I think we are done. Questions?

Voice. Yes.

Mrs. MCCLAIN. I will now recognize Ms. Lee for closing statements. Thank you.

Ms. LEE. Thank you, Madam Chairwoman, for holding this hearing on such an important issue. Thank you, Dr. Mayne, for your testimony. Half of our Subcommittee hearings have been on this topic so far, and we have identified some necessary areas for improvement, but now we need to put this information into action.

First, we need to pass bipartisan legislation to create a process that makes FDA aware of bacterial contaminations in real time. Then the FDA will have no excuse but to take action on the contaminations immediately. Second, we need to continue working with the FDA and actually listen to them. The FDA should not be hampered by congressional inaction. We need to keep these lines of communication open to ensure the FDA can do its job. Third, we need to collect better data on Cronobacter, so that we can better stop its spread. While I appreciate the steps FDA has taken so far to increase our understanding of Cronobacter, this public health issue will not be solved with just one agency or one approach.

Finally, we have to put our money where our mouth is. If we want a stronger system, we need to fully fund the FDA to protect infants who use formula. Now is not the time for cuts to the FDA while expecting them to modernize and streamline their systems. That is definitely not going to happen with the 22 percent across the board cuts. A cut that would also mean 1.7 million women, infants, and children will lose nutrition assistance through WIC.

Look, I believe the Chairwoman and I, we all have the same goals here, avoiding an infant formula shortage repeat. There are things that should be easy for Members of both of our parties to agree to do now, and there are some things that will require longer conversations. But if we can find a path forward that saves kids'

lives and stops shortages, then it will all be worth it. Thank you, and I yield back.

Mrs. MCCLAIN. Thank you, Ms. Lee. I now recognize myself for a closing statement.

Today we have heard some excuses, excuses from the FDA's inability to do its job, excuses for the FDA's unwillingness to prioritize food safety, excuses from the FDA's lack of preparation to address the infant baby formula shortage the FDA prioritizes as critical. There is no excuse for these failures. I do recognize that the failures are not just one-sided, but I am talking to the FDA right now, and we need to first admit we have a problem before we can fix it.

There are just no excuses. The FDA has an important job, one that American people pay them to do and, more so importantly, trust them to do. If the FDA is not going to do their job, we have some serious decisions to make. The FDA is responsible for keeping Americans' food safe. We need to make sure we give that food safety enough responsibility, enough attention, right? Especially when it comes to baby formula.

Last year, the trust was broken, and families lost precious children as a result. Those lives can never be replaced, and we owe it to those families to demand answers, and I think that is what we are doing. The crisis exposed significant failures within the FDA's regulatory and oversight process, some of that which we are in the process of fixing. Others we need to fix. Frankly, I am still concerned that this has happened again, right? Can Congress do better? Yes. Can Abbott do better? Yes. Can the FDA do better? Yes. I think working together, we can all get to a better spot. The FDA has promised it can do better. Time will tell, and I hope it will. We will be closely following the FDA's effort to revamp its Human Food Program. I think that is critical.

As Dr. Mayne retires at the end of this month, there are a growing list of vacancies in the FDA's Food Safety Programs. These vacancies are concerning, but ultimately, there needs to be a culture change at the FDA. The FDA needs to reconsider what they deem critical and what the American people deem is critical. I think some of those changes will help bridge the gaps in those timelines. I am and will continue to be in communication with the FDA to monitor the process of hiring a new Deputy Commissioner of Human Foods, and oversight will continue.

In closing, I want to thank our panelist once again for your important testimony today. I appreciate it. I really hope that you enjoy your retirement. It is well deserved.

And without objection, the Members will have five legislative days to submit materials and to submit additional written questions for the witnesses, which will be forwarded to the witnesses for their response.

Mrs. MCCLAIN. If there is no further business, without objection, the Subcommittee stands adjourned. Thank you so much.

[Whereupon, at 3:25 p.m., the Subcommittee was adjourned.]