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FORMULA SAFETY AND SUPPLY:

PROTECTING THE HEALTH OF AMERICA'S BABIES

WEDNESDAY, MAY 25, 2022

House of Representatives,

Subcommittee on Oversight and Investigations,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 11:07 a.m., in the John D. Dingell Room, 2123 Rayburn House Office Building, Hon. Diana DeGette, [chairwoman of the subcommittee] presiding.

Present: Representatives DeGette, Kuster, Rice, Schakowsky, Tonko, Ruiz, Peters, Schrier, Trahan, O'Halleran, Pallone (ex officio); Griffith, Burgess, McKinley, Long, Palmer, Dunn, Joyce, Palmer, and Rodgers (ex officio).

Also present: Representatives Barragan, Bilirakis, Blunt Rochester, Bucshon, Carter, Castor, Dingell, Soto,

Upton, and Walberg.

Staff Present: Jesseca Boyer, Professional Staff Member; Austin Flack, Policy Analyst; Waverly Gordon, Deputy Staff Director and General Counsel; Tiffany Guarascio, Staff Director; Perry Hamilton, Clerk; Xiaoyi Huang, GAO Detailee; Fabrizio Herrera, Staff Assistant; Mackenzie Kuhl, Digital Assistant; Will McAuliffe, Counsel; Kaitlyn Peel, Digital Director; Kylea Rogers, Policy Analyst; Harry Samuels, Professional Staff Member; Andrew Souvall, Director of Communications, Outreach, and Member Services; C.J. Young, Deputy Communications Director; Sarah Burke, Minority Deputy Staff Director; Marissa Gervasi, Minority Counsel, O&I; Grace Graham, Minority Chief Counsel, Health; Brittany Havens, Minority Professional Staff Member, O&I; Nate Hodson, Minority Staff Director; Peter Kielty, Minority General Counsel; Emily King, Minority Member Services Director; Bijan Koohmaraie, Minority Chief Counsel, O&I Chief Counsel; Clare Paoletta, Minority Policy Analyst, Health; Kristin Seum, Minority Counsel, Health; Olivia Shields, Minority Communications Director; Alan Slobodin, Minority Chief Investigative Counsel, O&I; and Michael Taggart, Minority Policy Director.

*Ms. DeGette. The Subcommittee on Oversight and Investigations hearing will now come to order.

Today the committee is holding a hearing entitled, "Formula Safety and Supply: Protecting the Health of America's Babies.'' Today's hearing will examine the nation's infant formula product recall, shortage, steps needed to take == increase supply, and what further action we need to do to make sure families access -- have access to safe formula across the country.

Due to the COVID-19 public health emergency, members can participate in today's hearing either in person or remotely, via online video conferencing. For the members participating remotely, your microphones will be set on mute for the purpose of eliminating inadvertent background noise. Members participating remotely will need to unmute your microphone each time you wish to speak. Please note that, once you unmute your microphone, anything that is said in Webex will be heard over the loudspeakers, in the committee room, and subject to be heard by the livestream and C-SPAN.

Now, because members are participating from different locations at today's hearing, all recognition of members such as for questions will be in order of subcommittee seniority.

Documents for the record can be sent to Austin Flack at the email address we have provided to staff, and all documents will be entered into the record at the conclusion

of the hearing.

The chair will now recognize herself for an opening statement.

Today the subcommittee seeks answers on how families across the country have faced empty shelves during this nationwide infant formula shortage. We expect answers from the FDA, Abbott, and the other two leading formula manufacturers on why caregivers are scrambling to find the necessary nutrition that they need to sustain their babies and children. And most importantly, we will discuss solutions to prevent this from ever happening again in the future.

The current formula shortage has real consequences. Babies and children are suffering. Parents are nervous wrecks, trying to get this. I have heard stories from pediatricians who have seen malnourished children. I have spoken directly to desperate parents who have been driving for hours from store to store to find formula. And I have heard from children's hospitals who are seeing an increase in patients whose caregivers haven't been able to secure the formula that their infants need.

Unfortunately, we know that this crisis has had a disproportionate impact on low-income families and families who rely on specialty formulas for children with special needs. These children and their parents are our top

priorities in today's hearing. The tragic situation is unacceptable. And worse, it was totally preventable.

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

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

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

But alarmingly, however, the facility has two long of a record of deficiencies, including evidence of the same potentially fatal bacteria on site and in batches of its formula in 2019, and leading up to the 2021 inspection. Fortunately, those batches were caught before the product was released for distribution. But this prevents -- presents a disturbing pattern of negligence.

But one company alone does not bear the entire burden for landing us in this current situations. There are also questions surrounding the timeline of FDA's investigation and response from a four-month lapse before returning to inspect the Sturgis facility, delayed connection with a former Abbott employee whistleblower, and slow communication to the American people. There is much more to learn about FDA's actions.

Today we seek clarity on what the agency was doing behind the scenes during this critical time period, and what lessons have been learned from the situation. Now, I am pleased that FDA and the Administration have already been focused on solutions, announcing a range of actions across the Federal Government to increase formula for companies in the most special need, and that manufacturers are in the mix of these discussions and expediting their production efforts to meet the urgency of the moment.

In fact, as well as Abbott, we are also joined today by the other two major manufacturers of infant formula in the U.S.: Gerber and Reckitt. These companies, along with Abbott, have been partnering with the Biden Administration to ramp up production and bring safe infant formula into the country to fill the current supply gaps.

The Biden Administration's efforts to coordinate this response to get families out of the immediate crisis have

been extensive, and I think we will see them working soon. But we cannot ignore the need for longer-term solutions.

The bottom line is that the Food and Drug Administration needs the resources to make sure that the food part of Food and Drug Administration is not an afterthought. Just as FDA works to ensure that lifesaving medicines are safe and effective, the agency must have the resources and the staffing to ensure that the food consumers consume is safe and reliable.

But FDA's food safety oversight is resourced at only half of the amount of drugs and biologics. And as a member of this subcommittee for decades, I will tell you this is not a new problem. It has been under-resourced for far too long.

Now, I am pleased that the House passed supplemental funding last week to help address the current emergency. But a one-time fix is not enough to build a more resilient food safety system for the future. We have to work together to bolster the food safety and the supply chain system, not just today, but for our children's tomorrows.

The empty shelves are inexcusable, and the stories of caregivers scrambling to find the nutrients that their children want and need are totally heart wrenching. I stand with our colleagues and our witnesses today in committing to finding solutions, permanent solutions, for the American public.

[The prepared statement of Ms. DeGette follows:]

**********COMMITTEE INSERT**********

*Ms. DeGette. And now, at this time, I hope I can see him -- I am proud to recognize the ranking member of the subcommittee, Mr. Griffith, for five minutes for an opening statement.

Mr. Griffith?

*Mr. Griffith. Thank you very much. Thank you, Chair DeGette, for holding this critically important hearing.

I also want to thank Commissioner Califf personally for coming to this hearing, and responding to my invitation last week in a phone call that the FDA arranged.

At the House Appropriations Committee hearing also last week, Commissioner Califf told Chairwoman DeLauro that he would be prepared to go into much more detail today at our oversight hearing. I look forward to learning those details.

Many infants in the U.S. rely on infant formula for their nutrition, and parents all over the nation are experiencing anxiety as the country faces an infant formula shortage. No parent should have to worry about how they are going to feed their baby, period. I have heard from folks from all over southwest Virginia who are having issues providing the most basic need for their infants.

The big question I have today is why did the Biden Administration let the shortage become so dire before acting with any urgency? I anticipate that we will hear different excuses today. And frankly, I am not interested in debating

in-stock rates or whether babies can switch from one brand to another depending on their health needs. I am looking for answers and for a long-term plan moving forward so this doesn't happen again.

So how did we get here, and when did this infant shortage -- infant formula shortage begin?

On one hand, the FDA says the shortage issue has been on their radar since March 2020. Furthermore, HHS Secretary Becerra said the FDA has been keeping him apprised of the situation since last year.

On the other hand, when asked if more could have been done sooner, then-White House Press Secretary Jen Psaki said, "Hindsight is always 2020.'' And in response to criticism that the White House was too slow to respond, President Biden told reporters, "If we had been better mind readers, I guess we could have. But we moved as quickly as the problem became apparent to us.''

So which is it? Was the Administration aware that an infant formula shortage was developing for over two years and failed to take sufficient action to prevent the shortage from getting worse? Or were they caught flat footed? Or, as I believe, both?

No matter the reason, it is not acceptable.

Suffice it to say I have a lot of questions for our FDA witnesses. With all of the stresses on infant formula,

including COVID-19 disruptions in the supply chain and consumer stockpiling during the lockdowns, the availability of formula on shelves was already strained before Abbott closed their Sturgis, Michigan facility on February 17. Where was the Biden Administration plan to deal with what should have been a foreseeable event?

We did not see a plan on February 17th or 18th or March 1st, or even in April. In fact, the FDA did not even conclude its follow-up inspection of the Sturgis plant until March 18, and it wasn't apparent until mid-May that the FDA and the Biden Administration took this issue seriously and began to act. Why did it take an onslaught of national media attention for the Biden Administration to act with the sense of urgency that is required to adequately address an infant formula shortage?

Abbott submitted their response and corrective action plan following FDA's inspection on April 8, but not until May 16 did the FDA, working with the Department of Justice, issue a consent decree. I don't understand how the FDA can justify three months to respond to this crisis. I expect to learn why the FDA did not move heaven and earth in an attempt to get the Sturgis plant back up and running as soon as possible.

And folks, February to June is not acceptable to the American families. And American parents don't consider that

working as soon as possible.

I also have questions for the infant formula manufacturers, because they do have a role in this -- in addressing this crisis, as well, including what can be done in the short term to increase supply, and what will be done in the long term to prevent something like this from ever happening again.

I have questions for Abbott about the events that led to the shutting down of the Sturgis plant. I hope to hear from Abbott about the status of the plant and Abbott's ongoing efforts to safely reopen the plant.

Being a parent brings an incredible amount of joy, excitement, and love. But it can also be an incredibly stressful time for parents. And parents should not have to worry about how or if they are going to be able to feed their baby. The mental health challenges associated with the inability to provide nutrition for a young infant cannot be ignored. More must be done to address the current shortage and prevent future shortages.

In closing, statements like the ones we have heard from the President and his staff, statements like, "If we had better -- been better mind readers, we could have acted more quickly,'' those statements, backed up by a lack of action, do not inspire confidence. The American people deserve answers. I look forward to today's discussion and learning

more about how to best address this ongoing crisis.

I thank the witnesses for being here today on this tough issue, and for being a part of this important discussion.

[The prepared statement of Mr. Griffith follows:]

**********COMMITTEE INSERT**********

*Mr. Griffith. I yield back.

*Ms. DeGette. I thank the gentleman. The chair now recognizes the chairman of the full committee, Mr. Pallone, for five minutes.

*The Chairman. Thank you, Chairwoman DeGette, for convening this important hearing, and I know you always move quickly on anything that involves the Oversight and Investigation Subcommittee.

Today, because of a shortage of baby formula, parents and caregivers are seeing empty store shelves, astronomical prices online, or having to drive hours for the formula they need to feed their children. And this is simply unacceptable. And this hearing will explore how this dire situation occurred, the steps taken to address it, and crucially, how we can prevent it from ever happening again.

And our solutions will undoubtedly include legislation. The Energy and Commerce Committee has jurisdiction over the FDA, and will initiate any authorizing legislation.

The data on the extent of the shortage varies based on where a family lives, or whether a child needs a specialty formula or a specific type or brand. So some regions have been hit harder by the shortages than others. And disturbingly, low-income women and children who rely on the WIC program for their infant formula have been particularly impacted by the shortage.

Now, the shortage rates began to rise in late 2021 due to pandemic-related strains on the supply chain. But there is no question that the February recall of Abbott products and the shutdown of Sturgis -- of their Sturgis, Michigan plant is responsible for the supply crash that we face today. The impact from just one infant formula plant closing in the United States shows the power one single manufacturer has to influence the nation's supply of formula, when just three companies control roughly 95 percent of the market.

We are too reliant on too few companies to do the right thing. And when just one of those companies cuts corners, we spiral into an emergency. So there needs to be more competition so that these few manufacturers don't have a monopoly. And I stress that.

This committee will examine the circumstances surrounding the recall and shutdown. We will ask questions about the FDA's investigation of the foodborne illnesses that sickened four infants and led to two of their deaths. We also will ask about issues at Abbott's Sturgis facility, and the questionably slow timeline of action to address safety risks. And at the same time, we have to address the current shortages and prevent future supply strains by hearing from the FDA, Abbott, and other manufacturers about the supply shortages that they face and the challenges and the steps they are taking to increase the availability of safe infant

formula.

The FDA officials and executives of the manufacturers need to answer some tough questions. Babies' lives are at stake, and this committee, Congress, and the American people demand answers and solutions.

Fortunately, the Biden Administration has taken important, responsive actions to increase the supply of formula for American families. It worked with manufacturers to increase production at other facilities and encouraged importation of safe infant formula. The President also invoked the Defense Production Act and launched Operation Fly Formula to increase domestic production and bring safe imported formula to store shelves. The FDA has also caused -- or eased, I should say -- import restrictions for 180 days to allow international manufacturers to help address the shortage, while ensuring the formula meets our national safety and nutrition standards.

Now Congress has already taken swift action, passing legislation which the President signed, I believe, on Saturday into law that grants flexibility to the WIC program to increase the supply of formula available to families. And the House also passed the Infant Formula Supplemental Appropriation Act, providing FDA with immediate resources to resolve the current baby formula shortage and lay the foundation to ensure this never happens again.

But we have to do more. My colleagues, I said for years that FDA's food safety efforts have been chronically under-funded, under-resourced, and under-staffed. Last week this committee took a step to help address that by advancing an FDA user fee bill that will strengthen FDA's ability to recruit and retain highly qualified staff across the agency, including in areas overseeing infant formula and baby foods. And that bill will head to the floor in the coming weeks. But additional legislation will be necessary to improve transparency and reporting requirements, and to empower FDA to set limits more quickly on contamination.

Industry must also do its part to ensure robust internal controls are in place and are being followed to prevent contaminated products from ever reaching a single child.

So put simply, Madam Chair, it shouldn't take the direct intervention of FDA and the President to keep infant formula on the shelves. The manufacturers have to take responsibility. And now we must all work together to guarantee the safety and supply of baby formula to ensure the health of our nation's children.

And let me just say the Energy and Commerce Committee will act, as always, on a bipartisan basis to enact the necessary authorizing legislation. So this committee hearing is important, but it will lay the groundwork for what we have to do legislatively. And I do want to emphasize that, and

our role in all of this.

[The prepared statement of The Chairman follows:]

**********COMMITTEE INSERT**********

*The Chairman. Thank you, Madam Chair, and thank you for doing so many things of an oversight nature with this subcommittee. I do appreciate it. I yield back.

*Ms. DeGette. Thank you, Mr. Chairman. The chair now is pleased to recognize the ranking member of the full committee, Mrs. McMorris Rodgers, for five minutes.

*Mrs. Rodgers. Thank you, Madam Chair.

Before I begin I want to address the school shooting in Texas. As a mom, I kissed my children this morning and sent them off to school. And I thought about the possibility of it being the last time that I would see them.

Schools are where our children should be safe, and learning, and thriving, making friends, and being kids. And I know we are all anxious to get all the information. We all want answers as to what would put someone in a place to take a young -- the young, innocent lives.

And there is an overwhelming sense that people are struggling. Crime and violence is going up. There is a mental health crisis. These are the courageous conversations that we must have together. And I hope that we will, to help end this despair and bring hope to our communities again.

Now, regarding today's hearing and the crisis point we have hit on baby formula shortages, parents shouldn't have to drive hours, paying record-high gas prices, visiting multiple stores to find some formula after midnight to finally feed

their children just two or three days more. That is the reality of the crisis in America today. It is putting newborns and babies in the hospital.

There are parents who are unsure if tomorrow they will be able to feed their baby. They need support and immediate, meaningful action to increase supply. They also deserve answers. There are several reasons for this shortage, including failure by FDA and the Administration to act early enough to address supply shortages and the Abbott shutdown that made it worse.

The Biden Administration says it did not anticipate the formula shortage. But it should have. As a part of its pandemic response, FDA had a data and analytics tool to monitor the supply chains of various products, including infant formula. The FDA's Food Safety Center was in contact with the infant formula industry to monitor ingredients and other components for production, and to maintain a healthy and safe supply.

A January Wall Street Journal article, a month before the Abbott plant closed, reported problems of hard-to-find formula. The FDA didn't have to "read minds,’‘ as the President dismissively suggested. They just had to read their own data and listen to parents. With Abbott being a major supplier, and given the information at its disposal, the FDA should have known the plant closure would make the

shortage even worse.

This is not the first time FDA has been confronted with a looming supply crisis. In 2004 the U.S. flu vaccine supply was provided by -- with only two manufacturers. One of the two manufacturers, a British company called Chiron, shut down after FDA inspectors found safety problems. That meant, just before the flu season, half of the U.S. flu supply -- the vaccine supply -- was gone, and the Administration immediately took action to secure doses of other manufacturers and encourage foreign manufacturers to seek licensure from the FDA.

When Abbott's Sturgis plant closed in February, the Biden Administration should have likewise acted with urgency to increase supply on day one. Instead, the FDA didn't act decisively until parents and the media coverage moved -- forced them to move publicly. FDA failed to react promptly to the warning signs it was getting about the Abbott nutrition plant.

In September of 2021 FDA conducted an inspection, and issued a 39-page report that found hazardous food safety practices, and that product could have been contaminated. Around the same time, FDA received four complaints of cronobacter infections in infants. Tragically, two of the babies died. All had been -- reportedly consumed Abbott nutrition product, though a link has yet to be established.

In October of 2021 the FDA received a 34-page complaint about the Sturgis plant from an Abbott ex-employee who alleged data falsification and release of untested product. There was a life-and-death crisis in front of FDA, but they failed to see the severity of the situation. FDA reportedly did not interview the whistleblower until months later, and did not re-inspect the plant until January of 2022. FDA did not even form an incident management group on infant formula until April 1st of 2022, more than 6 months after it found issues.

This hearing is an opportunity to ensure parents are certain that the FDA does not repeat mistakes that led to these shortages, and I am leading on legislation to increase and restock empty shelves, and it also requires more oversight and accountability to ensure the FDA is doing its job, acting quickly. We must solve the immediate issue, and also ensure that we are taking actions so this situation never happens again.

[The prepared statement of Mrs. Rodgers follows:]

**********COMMITTEE INSERT**********

*Mrs. Rodgers. I thank you and yield back.

*Ms. DeGette. I thank the gentlelady.

The chair now asks unanimous consent that members' written opening statements be made part of the record.

And without objection, so ordered.

I now want to introduce our first panel of witnesses for today's hearing.

Dr. Robert Califf, the commissioner of the Food and Drug Administration, welcome.

Frank Yiannas, the deputy commissioner for food policy and response of the Food and Drug Administration.

And Dr. Susan Mayne, the director of the Center for Food Safety and Applied Nutrition of the Food and Drug Administration.

I want to thank all of you for appearing in front of our committee today.

And I know you are aware the committee is holding an investigative hearing. And when we do so, we have the practice of taking our testimony under oath. Does any of you have any objection to testifying under oath today?

*Dr. Califf. No objection.

*Ms. DeGette. Let the record reflect the witnesses responded no.

So the chair now will advise you that, under the rules of the House and the rules of the Committee, you are entitled

to be accompanied by counsel. Do any of you wish to be accompanied by counsel?

*Dr. Califf. No.

*Ms. DeGette. Let the record reflect the witnesses have responded no.

So please raise your right hands so you may be sworn in.

[Witnesses sworn.]

*Ms. DeGette. Let the record reflect the witnesses have responded affirmatively, and you are now under oath and subject to the penalty set forth in title 18, section 1001 of the U.S. Code.

And at this time the chair is very pleased to recognize Commissioner Califf for a 10-minute opening statement on behalf of all three of our FDA witnesses.

Now, Dr. Califf, I want to note there is a timer on the screen -- you can see it -- that counts down your remaining time. You are a pro with this now, I think, just like all of the rest of us. So I want to thank you for appearing, and recognize you for 10 minutes.

TESTIMONY OF HON. ROBERT M. CALIFF, M.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION; FRANK YIANNAS, M.P.H., DEPUTY COMMISSIONER, FOOD POLICY AND RESPONSE, FOOD AND DRUG ADMINISTRATION; AND SUSAN MAYNE, PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION

TESTIMONY OF ROBERT M. CALIFF

*Dr. Califf. Thank you, Chairwoman. Chair DeGette, Ranking Member Griffith, and members of the subcommittee, thank you for inviting us to testify on the safety and supply of infant formula in the United States.

Ensuring that infant formula is safe and nutritious is a solemn responsibility of the Food and Drug Administration. And we are working with our government partners and the 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 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 parents driven to protect an innocent child.

We have provided you with an extensive written testimony that describes the 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 in 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 steps along the way where different actions could have sped 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 to improve our decision-making. 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 Foods program, as well as compliance and

enforcement.

The FDA and CDC's investigation could not conclude that the egregiously unsanitary conditions in the Abbot facility caused the illnesses reported in our timeline. However, we cannot rule it out, either, as a 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 the key equipment that present the potential for bacterial contamination to persist, particularly in the presence of moisture; leaks in the roof; a previous citation for inadequate handwashing; and current poor foot sanitation; bacteria growing from multiple sites; 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 am very concerned.

As soon as we received positive cronobacter results from environmental samples we collected during the inspection, we contacted Abbott to ask the company to issue a voluntary recall. The need to make urgent action to protect the most

vulnerable of all of our people, infants, presented a dilemma. This was the largest plan of the dominant manufacturer, and it was the sole source of a number of metabolic formulas essential for the viability of infants, and 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. And a memo was sent to the relevant agencies signaling the supply chain risk. We acted early to ensure the specialty metabolic and amino acid products for which Abbott was a 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 excess buying. We remain in frequent communication with our government and industry partners about the status and risks.

Because of the lack of the 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 an outside expert 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 month 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, while there was not a drop in production. This increase in consumption most likely represents heightened concern of

parents and caregivers about shortages, leading to an understandable effort to purchase ahead to ensure adequate supply at home. 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 shelves are stocked.

To that end, we've employed a host of measures to increase supply. A consent decree was signed with Abbott Nutrition last Monday that will allow the Sturgis plant to get back in production mode. I met with the Abbott CEO yesterday, and he assured me they will be ready to go in early June.

We continue to work with current U.S.-based manufacturers to increase their production and distribution from FDA-inspected facilities, both domestically and abroad. I commend them for their efforts in this regard, and we have seen substantial increases. We are helping with the all-of-government response, including Operation Fly Formula encouragement and support of importation and -- 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 to enable additional infant formula suppliers to enter the market, and 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 a 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. As many of you know, I was enjoying a pretty good life in the private sector when asked to come back.

After years of working in multiple private and public parts of industry, I believe that success follows proper attention to structure, function, leadership, and resources to report -- support the work of employees. All of these issues need attention in the chronically under-funded 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 the responsibility for producing safe infant formula that was not met. We will do everything in

our power to work with Abbott to make this happen as quickly as safely possible. But this timing is in Abbott's control.

Third, the all-of-government effort and the enormous goodwill of government partners and companies within and outside the U.S. has been heartening. And 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, this supply inadequacy did not happen overnight. Across the industry 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. And I am committed to improve the ability of FDA to meet its mission to protect and promote the health of the American people, particularly infants, our most vulnerable people. Thank you.

[The prepared statement of Dr. Califf follows:]

**********COMMITTEE INSERT**********

*Ms. DeGette. Thank you so much, Commissioner Califf, and I appreciate your recognition of the challenges facing the agencies and your -- also your commitment to trying to fix it.

But I want to make sure that we are all on the same page. And I just want to go through the timeline that was presented in your written testimony -- and you referred to it, too.

From September 20th through the 24th on 2021, FDA did a routine inspection of the Sturgis facility. And then, coincidentally, on the same day, September 20th, FDA got news of a complaint about an infant that -- who had become ill due to the cronobacter after consuming infant formula produced at that Sturgis facility.

But then a month -- about a month later, FDA got a complaint from a whistleblower about the lax cleaning and testing facilities at Sturgis, as well as alleged falsification of records and deception of FDA inspectors. But that person was not interviewed until two months later, in December.

Then, between December and February 2022, FDA received three more consumer complaints regarding cronobacter cases, two of which, sadly, resulted in death. But then, despite all of this, FDA didn't return to inspect the Sturgis facility until January 31st.

Then, according to your testimony, there was a six-week inspection and there were fundamental sanitation, building, and equipment issues.

But then, February, Abbott closed down the plant at Sturgis and ceased production.

Then two days later, finally Abbott voluntarily recalled the products.

Well, so then, on March 18, FDA closed the inspection and issued its inspection observations to Abbott.

But then, finally, on May 16th, FDA and Abbott signed a consent decree providing numerous steps that Abbott needs to undertake. You referred to that. So that was May 16th.

But now Abbott is telling me it is going to take two weeks to clean the plant, then it is going to take up to six to eight weeks more to get back to full production.

And so, Commissioner, this is what I am concerned about. I went through this whole timeline because, by my account, it took about four months from when the agency first became aware of these reported cases of cronobacter to inspect the Sturgis plant. Then it took two more weeks for Abbott to stop production, and then it took three months more for FDA and Abbott to enter into a consent decree.

Does that sound about right to you, in terms of the timeframe?

*Dr. Califf. I think you have got it right.

*Ms. DeGette. Doctor?

*Dr. Califf. And as you know --

*Ms. DeGette. Okay.

*Dr. Califf. -- it is all documented in your -- in the testimony in great detail.

*Ms. DeGette. Now -- yes. So what all of us are really concerned about, obviously -- and the parents of America are concerned about -- it could be up to a year between the first inspection in September last year and full production at this plant. And at the same time, there -- the vulnerable infants and children are not getting their formula.

So I guess you referred to this, that you have somebody looking into it. Do you have any idea why it took so long from the report to the inspection and recall?

And what is the plan to shorten the time in the future?

*Dr. Califf. Well, first of all, let me say you are right to be concerned, and the public should be concerned. As I have said already, it was too slow, and there were decisions that were suboptimal along the way.

And I am sure you also know that, as I was going through confirmation, I got many calls from people concerned about the food side of the FDA because of the lack of resources and concerns about the organizational structure.

My basic plan has been to get through this crisis, and then we will be looking at the overall food program from the

perspective of reforming it, but not waiting to deal with the specifics of this case. This is where Dr. Solomon, who is a truth teller in the FDA and well known by everyone, will lead an effort to help us get the processes corrected.

I could --

*Ms. DeGette. Yes.

*Dr. Califf. You mentioned many items, and I could go through each one if you wish, but --

*Ms. DeGette. Well, I -- we don't have time, unfortunately.

But what I do want to say is that I have been on this subcommittee for several decades now, and the food program at the FDA has -- it crops up time to time. We had the peanut butter crisis. We have had many, many crises over the years. And we always rush to make that plant safe, clean it up.

But ultimately, what we have to do is we work to -- have to work together -- and I think you agree with this -- to put food back into Food and Drug Administration. We have to not just throw money at it. We have to figure out what we need to do to make these inspections robust, and then to shorten the time. Would you agree with that?

*Dr. Califf. I 100 percent agree, and applaud you for what you did with 21st Century Cures on the medical product side. We need the equivalent on the food side. I think the medical product side is doing really well at this point. The

food side needs a similar shot in the arm.

*Ms. DeGette. Okay. Well, we will work on it. Thank you so much.

I am now pleased to recognize the ranking member, Mr. Griffith, for five minutes.

*Mr. Griffith. Thank you very much. I appreciate it. Thank you, Chair DeGette.

And Dr. Califf, thank you so much for being here. This is not going to be an easy hearing, and I respect you for showing up to take the tough questions on. And that means a lot to me.

That being said, I know it is not what you intended to say, but I think some could take the impression that, in part at least, you were blaming moms and dads who were scared that their children couldn't be fed, and that they were over-buying. And the answer is not that moms and dads are responsible for this problem. It is the manufacturers of the infant formula and the FDA. So I think that is important.

Let me go to some follow-up questions. And this is the kind of stuff that drives you crazy.

So Ms. DeGette went through a timeline and, according to your written testimony, it was December 6 when your team finally got together. And I know you weren't there yet, but the FDA team got together to say, "Hey, we ought to probably have a plan to go in and inspect the Sturgis plant.'' But

the timeline that isn't attached to your testimony, your written testimony, says that the first time they got together to start planning the Sturgis plant inspection was October 21st.

Now, you have said it was too slow, and that is where I was going to go with that. And I think it is pretty clear, whether it was September that they started meeting or December, when you have a problem that is identified in September -- I am glad that you have already agreed that getting to do an inspection on January 31st is too late. And you stand by that, that you -- you agree that was too slow.

*Dr. Califf. Yes.

*Mr. Griffith. Yes or no?

*Dr. Califf. Yes.

*Mr. Griffith. And I am curious, too, about the fact that your testimony states the FDA began to first have concerns about infant formula production in March of 2020. The situation was going to get worse with the Abbott Sturgis facility -- which my calculations say made about 11 or 12 percent of the total U.S. production -- when they shut that facility down.

Did the FDA have a detailed action plan to deal with one of the food manufacturers, one of the infant formula manufacturers shutting down, and what we were going to do when the kids didn't have enough formula? Did we have a

detailed plan on what action we would take?

*Dr. Califf. We had several committees that were meeting regularly and doing the things that I have mentioned, which was contacting all the other producers, as has already been detailed. There are not that many other producers, and they did ramp up right away to the extent that they could. And, you know, I enumerated other actions that were taken to try to deal with this --

*Mr. Griffith. Well, why did it take -- I mean, the question is, when you have -- particularly your WIC recipients have, you know, one source in most states that they can purchase, and a lot of times that is Abbott, why did it take nearly three months to say, okay, we are going to have a relaxation on some of these regulations related to WIC, we are going to have a relaxation on some of the products coming in from Europe?

I mean, where was the request for legislation from us? Where was the action planned by the Administration to start flying formula in from overseas?

I mean, why wasn't that happening in March, instead of mid-May?

*Dr. Califf. Mr. -- Madam and Mr. Chairman, can I refer to my other colleagues here, or would you prefer that I answer the questions?

*Mr. Griffith. Well, I like you answering them, but if

somebody else --

*Ms. DeGette. They can --

*Mr. Griffith. -- has got an answer, I would love to hear it.

*Ms. DeGette. They can refer to it, if they have the answer.

*Mr. Griffith. Yes.

*Dr. Califf. Well, I will ask Mr. Yiannas to comment, but we were monitoring this, and we -- the system seemed to be keeping up with demand until fairly recently, although there were spot shortages that we were responding to one at a time. And at the same time we were trying to get the Abbott plant up as quickly as we could.

But Mr. Yiannas, who is an expert in this area, may have a comment.

*Mr. Griffith. Because my time is running out, let me move to another question, and that is I know you are trying -- you say you are trying to get the plant up as quickly as possible. And I believe that you believe that.

The problem is, when you have an emergency situation like this -- and I know you did some special things for the metabolic, and the kids that need special formulas, you tried to move on that a little quicker. But when you have 11 to 12 percent of your total production going down, I am wondering why it is taking so long just to get where we are at. Why

weren't we working at breakneck speed?

I mean, I am reminded of the Battle of Midway, when, after being damaged at Coral Sea, Yorktown pulls into Pearl. And General Nimitz says -- or Admiral Nimitz says, "Get it done. We need to get this ship out.'' And that ship is sailing in two days. Forty-eight hours later, that ship is sailing because the American soldier got in there and got it done. I don't expect that you could get Sturgis open in two days, but why is it going to take four or five months to get it open? And why weren't we moving on all of these things in March, and moving towards getting this plant reopened then?

*Dr. Califf. I know we are out of time. Am I allowed to respond?

*Ms. DeGette. You can answer briefly, if you [inaudible], if you know.

*Dr. Califf. Yes, I would just point out that, with regard to the Sturgis plant specifically, as I say, we didn't have confidence that they would produce safe formula until we got control of the plant through the consent decree.

And a consent decree is a legal agreement involving the Department of Justice and the plant -- and the manufacturer that has to be negotiated.

And the number -- and I will also add Abbott actually did start remediating the plant, but it was so bad -- we met with them yesterday. There were so many steps in this. Even

though they had been working at it -- on it since day one, they are still not ready to go, but they will be in the next several weeks.

*Ms. DeGette. Thank you. The gentleman's time has expired. The chair now recognizes Chairman Pallone for five minutes.

*The Chairman. Thank you, Chairwoman DeGette.

Commissioner, I want to use half of your time to talk about the current crisis and half on what we can do in the future, particularly legislatively, since we are the authorizing committee.

And I love the ranking member's war mentality, because that is how I feel right now, you know, this has got to be like a general in the field.

So first question for two minutes, the President has invoked the Defense Production Act. He has launched Operation Fly Formula. You are taking actions with Abbott. How is this going to complement each other? Will it be effective in getting this formula out quickly? Are talking two weeks, three weeks, whatever, to get this shortage over with?

And then, as part of that, how will you get information distributed so we can tell our constituents how they get this formula, you know, how they have access to it so they can get it?

That is two minutes.

*Dr. Califf. Sure. First of all, let me just say this is a war mentality. It is a crisis. We are fully aware of it. Families should not be searching for formula, but they have to do it now until we fill in.

So if we set our expectation at several weeks out, we will have a surplus of formula. When I say "several,'' I can't say exactly how many weeks. Until then we have to fill it in with all these measures. The other producers have stepped up. We are now importing, we are flying military planes and other planes to pick it up and bring it in. And we just have to keep filling in until we get to the point that the production is up.

The good news with Abbott --

*The Chairman. All right, now --

*Dr. Califf. I am sorry?

*The Chairman. How about getting it out, so that our constituents know how to get this formula?

I am very concerned that you do all this, and they won't know how to access it, and still have a problem, particularly low-income people, people that don't have access to information easily.

*Dr. Califf. Yes, I think it is really important for people to go to the HHS website, HHS.gov/formula. There you will find the hotlines for all the manufacturers, and helpful

information about where to go.

The distribution is being handled by real professionals at supply chain who have been working throughout the pandemic with a variety of products. So as soon as it comes in, we'll get it out to the places that are in the greatest need.

But you're right, the public is going to have to stay attuned, hopefully, through that website to get information that they need.

*The Chairman. All right. And think of other ways, too, because not everybody has a computer, so let's think of other ways to get that information out as this formula becomes available -- hopefully, in the next couple of weeks.

Now, my second question. We are the authorizing committee. I am concerned about a future crisis, because I -- we need to have a mechanism, in my opinion, where the manufacturers tell us, or there is some kind of trigger or alarm bell with the FDA if they are experiencing shortages for whatever reason.

So what I am told is, you know, that maybe we need to have some kind of transparency legislation through shortage reporting requirements that would require manufacturers to alert FDA of potential shortages so they can shift production, or we can go into overload.

And also something to empower the FDA to act more quickly with regard to contamination, because that process is

so bogged down in long and cumbersome regulatory ways.

So a minute-and-a-half, what can we do to have a better reporting?

What can we do so that you don't get bogged down in this long process when there is potential contamination?

Or anything else you think -- other tools you need?

You have about a minute.

*Dr. Califf. We've asked for a number of authorities, and we have consistently all -- just to remind the group of what's in the document you have, a month into the pandemic we requested authorities to deal specifically with the potential for infant formula shortages, and we were unsuccessful in getting those acted upon. Yet we did a number of things at FDA to try to deal with it, with the resources that we cobbled together.

But you mentioned a couple of things that are absolutely critical. Right now we have no ability to -- there is no requirement that manufacturers alert us if they are running short.

Secondly, just for example, Abbott had cultured cronobacter in samples going back a ways, but since they had not shipped them out, they had no requirement to either keep the samples or alert us that that had happened. We discovered it on inspection, but it may surprise people to know that.

The consent decree process we could have a long discussion about, but they -- and, you know, for me, I worked at Google for five years before coming back. You would be surprised to know there is no just-in-time system where all the FDA employees can see what is going on.

What we really need is access to the information that the manufacturers have about each of their individual supply chains. They each have their individual supply chains, but there is no national system to make sure the supply is getting where it needs to go.

And then finally I will mention this is not unique to this problem. This is our most special problem. But right now we have a shortage of contrast media for people having strokes and heart attacks. 60 Minutes ran a show that I would recommend for you. Generic drug shortages are happening every day in hospitals. We have to do something about our supply chain issues.

*The Chairman. Thank you.

Thank you, Madam Chair.

*Ms. DeGette. I thank the gentleman. The chair now recognizes the ranking member, Mrs. McMorris Rodgers, for five minutes.

*Mrs. Rodgers. Thank you, Madam Chair. I kind of want to pick up where the chairman left.

As a part of the pandemic response, did FDA not have a

data and analytics tool to monitor the supply chains of various products, including infant formula?

*Dr. Califf. We requested funding for a tool and, because we didn't get the funding, we cobbled it together. It is a start, but it is nowhere near -- you know, again, I was at Google for five years. The technology at FDA and in many Federal agencies is outmoded, and needs an upfit. There is just no question about it.

*Mrs. Rodgers. Okay. Well, I guess I would like to understand more about that, because, as a part of the pandemic response, Congress had authorized funding for a data analytics tool to monitor the supply chains for various products, including infant formula. And the FDA's Food Safety Center was in contact with the infant formula industry to monitor ingredients and other components for production and to maintain a healthy and safe supply.

The slow response by FDA to the infant formula crisis has created a desperate situation for parents. Months without any action has only contributed further to this life-and-death situation. It is suspected that two babies now have died, and two others are critically ill from contaminated baby formula.

But on top of that, with the Abbott plant shut down and a possible safety problem, it is presenting another public health crisis, and that is the lack of access to baby

formula. Just a few days ago, we have learned that there is at least four babies hospitalized in South Carolina because of complications arising from baby formula shortage. So we have an additional public health crisis because people cannot get -- parents cannot get baby formula.

How many reports does FDA have of babies who got sick or worse related to the shortage of baby formula?

*Dr. Califf. Let me give a general answer to that. It is not a large number, but each one is highly significant. And we have a committee of people, including outside experts, to look at every single case to make sure we get formula to those people.

I would like to refer this question to Dr. Mayne, who has spent countless hours working with experts on this issue.

*Dr. Mayne. Thank you. And one thing I would like to point out is we have been in discussion with the infant formula manufacturers throughout COVID, but discussion is not the same thing as data. And we do not have the authorities to demand data from the companies to get necessarily all the information that you would want to have to really monitor these supply chains --

*Mrs. Rodgers. Okay.

*Dr. Mayne. -- as Dr. Califf indicated.

*Mrs. Rodgers. Okay, thank you. I am going to quickly run out of time. I do want to know more about the data

analytics tool that I was -- that Congress authorized to FDA, so -- to help with this specific situation.

Did FDA conduct an assessment of the public health impact of a baby formula shortage, if the Abbott plant had to close? And what were the findings?

*Dr. Califf. What I would say -- I was not here when that decision was made, so I don't know all the details. So I will refer again probably to Dr. Mayne.

But I would say, based on everything I have looked at, there was intense discussion about the consequences of this, and there are memos that will adequately document the thought that went into it. But we simply could not allow a plant that was unsafe to be shipping formula.

Dr. Mayne, would you comment quickly?

*Dr. Mayne. We've certainly anticipated that this would have significant impact in the general formula, but even more so in the specialty and metabolic products. And that is why we made the decisions we did, not to have those products be recalled, because the concerns for the health of these infants were greater had we recalled those products.

With regard to the general infant formula supply, what we heard from other manufacturers is they had capacity to increase production, and they have. They have stepped up, they have increased production. And that was the kind of scenario planning.

At the same time, we also invoked all kinds of mitigation steps that we could, things like mitigation to reduce regulatory -- you know, add those flexibilities, things like asking the retailers to limit purchases. We did a whole number of steps, right from the get-go, to try to reduce the impact.

But at the same time, we were in a tough place, where we did not want to allow this unsafe formula prepared under insanitary conditions --

*Mrs. Rodgers. Okay.

*Dr. Mayne. -- to be served to infants in this country.

*Mrs. Rodgers. Thank you. Thank you, I appreciate that.

I feel like I am getting kind of -- you know, on one hand we are being told now that the Abbott plant is going to be up and running in a couple of weeks. I know that you testified last week, Commissioner, that -- concerning the whistleblower complaint -- that the integrity of the organization was compromised.

So I am kind of, on one hand, I am like, how do you believe that organizational integrity can be restored in just two weeks for the expected reopening of the plant, if there is these significant concerns?

*Dr. Califf. May I have 30 seconds or so to --

*Ms. DeGette. Yes, go ahead.

*Dr. Califf. -- answer that?

*Ms. DeGette. Go ahead.

*Dr. Califf. The only way I would have -- and again, I have a long history with Abbott in my previous life, as a doctor. It has been a great company. But given what we saw, the only way we could have confidence was through a consent decree where we literally have oversight of every single step.

When we met with the CEO yesterday, there were hundreds of steps that they went through that they are having to do, many of which have already been done. So it is only if we have direct oversight over it that I would have confidence.

But I do have confidence that we are seeing every single step, both physically, in person, and also through following the documentation and the outside expert. So many --

*Ms. DeGette. I thank the gentleman. The gentlelady's time has expired. The chair is now going to go to Miss Rice for five minutes.

Miss Rice, you are recognized.

*Miss Rice. Thank you, Madam Chairwoman. You know, I just think we have to dig a little deeper on how we can, you know, avoid the current disastrous situation in the future. And we have to understand the missed opportunities that led to the formula recall and empty store shelves, and apply those lessons going forward.

I mean, you would think after the pandemic and the -- what we didn't have enough of would have enabled us to look at these critical products that everyday Americans need just to survive, and make sure that this wouldn't happen.

I mean, it is clear to me that the delay between the FDA's annual inspection of the Sturgis plant in September of 2021 and the FDA inspector's return in late January of 2022, more than four months later, as the chairwoman pointed out, which was also after three reported illnesses, was a missed opportunity, to say the least.

You know, Commissioner, understanding that you were not yet in the position that you are in now at that time, but as the head of the agency today, what steps have you taken to ensure that we are not going to see, God forbid, something like this in the future, where it is going to take four months after notification of first illness before the FDA initiates an investigation into whether it is Abbott's facility or any other facility?

*Dr. Califf. Well, there are a number of steps.

I mean, the most important one, I think, is the escalation requirement. That is, notifying the leaders. And it is documented in our report that Mr. Yiannas, Dr. Mayne, and Ms. McMeekin, the head of our Office of Regulatory Affairs, were not notified until February that all this was going on.

And, you know, that is -- you know, we have to have standards. I used to work in hospital quality systems. You remember when medical errors were not being reported, and nurses were empowered to, if a surgeon made a mistake, to report it, not as a punitive matter, but to make the system better. So we are putting systems like that in place.

But I must tell you that, you know, we still have vulnerabilities. We have a very tired, over-worked workforce that, in the midst of a pandemic which is still ongoing, and an under-funded segment -- and, you know, whenever -- I have worked in corporations and health systems with the best of facilities and people, and it is very different than when you have really good people -- who could do other things for a living, let me point out -- who are really straining to use human labor to do things that computers could do automatically.

So that is a list of some of the things.

*Miss Rice. Oh, okay.

Dr. Mayne, according to FDA testimony, after becoming aware of the first infant illness complaint on September 20th of 2021, the agency immediately notified Abbott. It is my understanding, however, that the FDA inspectors who were on site conducting a routine inspection of Abbott's Sturgis plant on September 20th through the 24th of 2021 were not told about the reported complaint of illness at the time of

the inspection.

If that is accurate, Dr. Mayne, why were the FDA inspectors not informed of the complaint? And do you believe more timely communication with them about the reported illness could have better informed their assessment and facility classification?

*Dr. Mayne. Thank you, Congresswoman. Two things to note is, once the agency receives a complaint like this, we then have to follow up on that complaint. And every one of these complaints was followed up on. That means reaching out to who made the complaint. That means trying to obtain samples of the product for testing. That means getting the medical information with regard to the complaint. And that process does take time.

In this case, product was obtained. It underwent microbiological testing. The final testing results were not available until October 6. It does take time to get these results.

So, had we known that there had been a complaint, we wouldn't have known the details of what that complaint involved, how that could potentially impact the inspection, what they may need to look forward to.

So in the real world, we would have loved to have all that information the moment the complaint was made. But that is not what happened.

And I will reiterate: on every one of these four complaints the FDA did follow up with those exact procedures to follow up, get as much information about the complaint. And that is critical to inform what you might look for in a plant.

*Miss Rice. My time is about to expire, but also, you know, the fact that there is three companies who manufacture such an essential product that we need to keep children alive, we maybe should look at, you know, increasing domestic production on that front.

Madam Chairwoman, thank you so much. I want to thank the witnesses, and I yield back the balance of my time.

*Ms. DeGette. I thank the gentlelady.

Mr. Burgess, you are now recognized for five minutes, but you need to go on camera.

[Pause.]

*Ms. DeGette. Oh, I guess I am going to go to Mr. McKinley.

Mr. McKinley, you are on camera, so I am going to recognize you for five minutes.

*Mr. McKinley. Thank you, Madam Chairman, and thank you for this testimony, holding this hearing, because this is just -- the Abbott plant is just one example of what happens when government agencies and the private sector companies do not get out in front and disclose safety issues that impact

public health.

Through his Twitter account just last week, a TV producer put on social media that there were multiple -- this is a quote -- "multiple inspections showed no issues at the Abbott plant,'' and that the FDA bill that we passed last week was unnecessary. I emphasize this statement was just sent out last week all across the country.

So documentation of these violations, we have heard it all through the testimony today, they were reported during the last several FDA inspections at the plant, firmly established there were serious problems at the plant that led to a recall and a plant closing. Problems have escalated into a public health crisis. Yet both the FDA and the Abbott company have remained curiously silent.

I remind you this statement that was put out on Twitter, on social media, was sent just last week saying the government was wrong, there were no problems there.

And so I wonder -- there are consequences when this type of misinformation is not rebutted, and the public continues to lose confidence in the governmental process, in government. So -- and we in Congress did not hear about the scope of this issue until early May, and the Administration seems clearly to be caught off guard.

So Commissioner, a couple of questions to you, if you could, please. Why did you not -- and maybe you have

answered this, but I want to hear it again -- why did you not inform the public in January or February or earlier of the problems at the Abbott plant?

*Dr. Califf. We -- with all due respect, we did. When the recall was made, there was a public announcement both by Abbott and by the FDA about the problem with the product, and the general reason it needed to be recalled.

I'd also have to point out that, in the midst of a consent decree negotiation, it is very difficult to talk about the specifics --

*Mr. McKinley. Yes.

*Dr. Califf. -- of the problem until that is completed, because of the legal prohibitions.

*Mr. McKinley. I have got a couple other questions. So what are you doing to combat this type of social media providing incorrect public health information? How would you respond to that?

*Dr. Califf. I am only smiling not because I think it is funny, but because it is so critical right now that we get the misinformation situation under control. And, you know, I -- remember, I worked at Google for five years, and so I saw the good and the bad of access to information.

FDA is going to have to change its outward-facing strategy to be much more proactive and preemptive. I would point to the American strategy with Russia in the Ukraine as

one of the best examples in history of always being one day ahead of the misinformation.

*Mr. McKinley. Okay.

*Dr. Califf. This is a big change for FDA, so we are going to have to --

*Mr. McKinley. Reclaiming my time to -- I have got two more questions.

How will the passage of last week's FDA bill increase the production of baby formula?

*Dr. Califf. Well, the production is increasing --

*Mr. McKinley. Yes, but [inaudible] criticism, that it -- they said on these various tweets -- it was not just one, it was several -- they said it was unnecessary. So I want to know, how do we increase -- how we get back to production. How did putting, what, $28 million, how did that -- how is that going to increase production?

*Dr. Califf. Well, remember, the Abbott plant needs to get up and running. We got to oversee it every step of the way in micro detail to make sure that it is done correctly.

And as we bring in supply from other countries -- remember, we already have overseas plants that we import from on a regular basis, almost double digits. So, as we bring that product in, we've got to inspect it, and make sure it is of the quality that we expect in America of formula.

And we need to upgrade our information systems, as I

have already said, to make sure that, as all this goes on, we can keep track of it, and make sure that we are coordinated.

*Mr. McKinley. Commissioner, did the FDA have a mitigation plan in place before the plant was shut down?

*Dr. Califf. Yes, as Dr. Mayne, I think, recounted in some detail, we had a number of steps that we were taking to keep production up, and it actually did increase on a national basis. But the purchasing, obviously, outstripped the production, as you well know.

*Mr. McKinley. Thank you.

Madam Chairman, my time has expired, so thank you, and I yield back.

*Ms. DeGette. I thank the gentleman. The chair now recognizes Ms. Schakowsky for five minutes.

*Ms. Schakowsky. Thank you, Madam Chair. You know, I was beginning -- going to begin by saying I am extremely concerned. A lot of us had talked about concern. But I have to tell you, it is really more than that. I am actually pretty furious about the FDA's lack of food safety leadership, communication, and action.

And I just also want to ask unanimous consent to begin by putting into the record a in-depth report that was done by Politico called the "FDA Food Failures,'' and it is based on 50 interviews, and it really goes into detail. It was done in April of 2022. And I ask unanimous consent.

*Ms. DeGette. If the gentlelady will submit it to committee staff, we will do all of those unanimous consent requests at the end of the hearing.

*Ms. Schakowsky. Thank you very much. You know, food safety over the decades -- this is not a new story -- has been a real problem. I have been following this not only throughout my career, but even before I became part of the House of Representatives.

And, you know, there is a kind of ongoing joke that -- it is not really a joke -- that I have heard that says that -- and it is said by FDA employees -- that says that the F in FDA is silent. We have not seen this as being a priority in the Food and Drug Administration. And now here we are, you know, and I can't tolerate, really, any excuses and delays.

I have just one question about timing, although I think my colleagues have done a great job in talking about the various delays that there were.

So according to FDA testimony, staff received the whistleblower report in October of 2021, and senior food staff officials did not respond to that report until four months later, in February. How does that happen? How can that possibly happen?

And I want to ask you that of the administrator.

[Pause.]

*Ms. Schakowsky. I am -- can you hear me?

[Pause.]

*Ms. Schakowsky. Hello?

*Dr. Califf. I got muted there, I apologize.

*Ms. Schakowsky. Oh, I see, okay.

*Dr. Califf. I -- first of all, let me just point out that the complaint was received. It was logged in right away. The ORA employees did their usual review. It went to OCI, the criminal investigations unit, because there were concerns.

The decision was made then that the informant needed to be questioned and brought in to go over things. There were some medical illness issues that delayed it. I can't go into details, because they are personal, related to that.

So a number of things happened. I'm -- we are on record as saying it took too long.

And then, on top of all that, as I have already said, the lack of escalation --

*Ms. Schakowsky. So --

*Dr. Califf. -- meant that senior officials were not aware until February 10th or February 9th.

*Ms. Schakowsky. Well, I mean, we -- so much has been said today that needs to change the focus. I know that you are rather new to this position right now, but you have a long history with the Food and Drug Administration on the food side. So we really are calling you to change the focus,

the emphasis, to really put food up front. We are tired of seeing all -- you know, one after another of these kinds of situations.

I also just wanted to alert you. I have introduced legislation that deals with chemicals that are in our food that are toxic. They are known toxic chemicals. I have legislation that would require research and, ultimately, removal of those from our foods. I hope that you will definitely consider that.

But we don't want to hear any more about this without prompt, swift, effective response from the Food and Drug Administration. Let's put food back into the Food and Drug Administration.

And thank you, and I yield back.

*Mr. Peters. [Presiding] The chairman's audio -- the chair's audio is out, so we are going to go next to Dr. Burgess if he is on camera. If not, it is Mr. Long.

I don't see Dr. Burgess. Are you on?

[No response.]

*Mr. Peters. We will go to Mr. Long for five minutes.

*Mr. Long. Thank you, Mr. Chairman.

And Commissioner Califf, I am going to have you rate your performance at the FDA and this situation on a scale of 1 to 10. How would you rate your personal performance?

*Dr. Califf. Well, I would say, because of the outcome,

I would give it, at best, a four or a five.

*Mr. Long. I also would like to have you rate the urgency with which your agency has taken up this matter of no baby formula on the shelves. How would you rate the urgency that has been within your administration from 1 to 10?

*Dr. Califf. Well, when I look at the employees, it is 9.5 out of 10. People have been up days, nights, weekends working on this. I would totally stand behind their effort.

The result, as I say, is not what we would have wanted. So I cannot give it a high rating.

*Mr. Long. I mean, I am from Missouri. You have got to show me. I mean, that doesn't -- you can't say that you got a 9/10 urgency, but yet it is failed. So how do you account for that?

*Dr. Califf. It is a complex system, where the people working on the ground are working their tails off, speaking of being from Missouri, working as hard as they possibly can with inadequate systems, inadequate funding, and we didn't meet the needs. So that is why the overall rating is low, but the rating for the hardworking employees is very high.

*Mr. Long. And so it is systematic? It is money? It is people? What is it, again? I am a little confused.

*Dr. Califf. As I said in my opening statement, it is a combination of leadership, people, money, and technology.

I am so acutely aware of the technology gap, having come

from the best technology in the world now to technology which is completely outmoded, that I think it is a combination of all of the above.

I have said that I knew before coming in that the food side, just as your predecessor just said, the food needs to be brought back in the FDA. It is a major issue. There will be everything looked at. But the day that I was confirmed was the day that the recall made the news. And we've been engrossed in that, trying to take care of this problem, for the first three months of my time.

*Mr. Long. I don't know of anyone in this hearing today that is not furious with the FDA and with the situation with the baby formula. I don't know any American that is not furious, for the record.

Commissioner Califf, the HHS Secretary Becerra claims that the FDA has been briefing him about the baby formula situation for months, going back to last year. Is that an accurate statement?

*Dr. Califf. We've been communicating with HHS and having communications with the Secretary for -- you know, throughout the pandemic about baby formula.

*Mr. Long. Was it the FDA's understanding that the Secretary would brief the White House, Secretary Becerra would brief the White House on the shortage?

And if you -- if so, do you have any idea when that

briefing occurred?

*Dr. Califf. I don't know if there was a -- I do not know the answer to that question.

But we do have other communications with the White House that are regular, they are part of the supply chain effort, which has guiding us -- guided us through the whole pandemic.

*Mr. Long. [Inaudible] try and find out an answer to that question for me about whether there was a briefing and, if so, when it occurred?

*Dr. Califf. We would be glad to do our best with that.

*Mr. Long. And also, sticking with you on the questions here, HHS Secretary Becerra, has he provided any guidance or support to the FDA?

If so, what guidance or support has he provided?

*Dr. Califf. He has been tremendously helpful as we've gotten into the Operation Fly Formula, and the enforcement discretion enabling foreign suppliers to send in. And he has gotten on the phone and called CEOs to encourage them to increase their production, among many other efforts to support. Even in the last week, when people know he was sequestered in Germany with COVID, he was on the phone putting in good work.

*Mr. Long. Like I say, I don't know of anyone on this -- in this hearing today that is not absolutely furious with what we have been going through, and what parents, more

importantly, have been going through, freaking out, trying to -- I saw that someone -- I am not sure, I should have looked it up before the hearing, I guess, but someone in the Administration said the best suggestion was to go to your pediatrician and see if they had some samples for you. And being the father of a pediatrician, I can assure you that she doesn't have cases of baby formula sitting around in the back room of her office.

I yield back.

*Ms. DeGette. [Presiding] I thank the gentleman. I also want to thank Mr. Peters for subbing in. I am having some audio trouble with my computer, so if -- so he is on deck.

And I appreciate it, Scott.

Next I would like to recognize Mr. Tonko for five minutes.

[Pause.]

*Mr. Tonko. Thank you, Madam Chair.

Can you hear me?

*Dr. Califf. Yes.

*Mr. Tonko. Okay. As we have learned over the past two years when it comes to public health guidance, clear communication with the American people is vital. Uncertainty without information breeds fear and panic.

And it is fear following the Abbott product recalls

that, in some instances, led families to stockpile formula or even turn to unregulated and risky solutions to feed their children, which makes me wonder why there was so little communication to the public from FDA during the months leading up to the February Abbott product voluntary recalls.

In fact, the FDA did not warn the public about the potential risk of consuming infant formula products manufactured at Abbott Nutrition's Sturgis, Michigan plant until February 17th, following Abbott's announcement that the company was voluntarily recalling these products.

So Mr. Yiannas, with -- you know, there have been discussions about the delay and all, but with the benefit of hindsight, and knowing now the impacts that product recalls would have on formula supply, do you think FDA could have provided more public guidance, not just on the safety of infant formula, but its supply, actual supply opportunities in the U.S.?

*Mr. Yiannas. Well, thank you for that question, Mr. Tonko.

You know, when I think about it, it has the safety issues and then the supply chain issues. And when it came to the safety issues, as soon as I became aware and started working with the coordinated team here at FDA, we worked pretty quickly to pull that product off of the shelves.

As soon as we had information that we believed that

product was unsafe, that message was quickly communicated to the American consumer. It was actionable information, and we wanted them to avoid consuming those Abbott recalled products. Early at that time, I don't think there was anything actionable to communicate to the American public. In hindsight, I am a strong believer of transparency. Maybe we could have done more talking about the current state of supply chains.

But I do think some type of alert or warning that there might be supply chain shortages coming could have led to, you know, some type of panic buying. So I think we did the right thing on the public health portion, the safety, communicated it as quickly as we could, and we told the American public that they should avoid these products. And we pulled it off the shelf. And then, as information started becoming known about the supply chain challenges, we tried to share as much as we could.

*Mr. Tonko. I thank you for that.

Commissioner Califf, would you please help shed some light on how the agency's food safety leadership is coordinated?

With respect to the Abbott investigations, for instance, how were the reports of infant illness complaints distributed by FDA, and was the information shared amongst all key food personnel within FDA in a timely manner?

*Dr. Califf. As I have already said, if you are referring to the complaints associated with the infant formula, not the complaints associated with the metabolic formulas now -- those are two different things. But if we go back to the beginning, as noted in our timeline, there was a failure to escalate, which was a system failure, so that neither Mr. Yiannas nor Dr. Mayne nor Ms. McMeekin, the head of the Office of Regulatory Affairs, knew of it until, as Mr. Yiannas said, until early February.

*Mr. Tonko. And I was particularly alarmed to learn, Commissioner, that, according to FDA's testimony, that while infant formula and medical food staff received the former Abbott employee whistleblower report in October of 2021, Dr. Mayne, the director of CFSAN, did not receive the report for another four months, which by that time had been under review by the Office of Regulatory Affairs review, and discussed with FDA's Office of Criminal Investigations.

So yes or no, is this, at best, a lack of coordination and, at worst, a breakdown amongst the leadership?

*Dr. Califf. It was a lack of coordination, for sure.

*Mr. Tonko. And understanding this transpired before your new tenure, moving forward in your leadership of FDA, Commissioner Califf, how, if at all, do you plan to address such food safety leadership breakdowns within the agency as we go forward?

*Dr. Califf. Well, when we think about food safety, it is -- as one of your colleagues already noted, it is very broad. It includes things like chemicals in the food, and the sort of outbreaks that we are talking about here.

I knew coming in we were going to need to make changes. But they are across the board, it is not just structural. It is also the people. And it is the resources, and it is the technology. All those need to be addressed. You can't do that overnight. You need to really plan --

*Mr. Tonko. Well, let --

*Dr. Califf. And as you well know, Congress needs to approve any such major changes.

[Pause.]

*Ms. DeGette. Thank you, Mr. Tonko. The chair now recognizes Mr. Palmer for five minutes.

*Mr. Palmer. Thank you, Madam Chairman. I commend my colleagues on the committee for the thoroughness of their questions.

I want to bring up an article that was in this morning's Washington Post that, frankly, has some stunning revelations. And I want to talk to Mr. Yiannas.

You are the deputy commissioner for food policy and response, yet neither of the FDA's food policy divisions report to you, nor do the food safety inspectors. Is that true?

*Mr. Yiannas. That is true.

*Mr. Palmer. Before Commissioner Califf was appointed, food safety problems were reported to the principal deputy commissioner, Janet Woodcock, who is a medical doctor who was acting commissioner when the whistleblower complaint arrived.

When you did -- when did you get access to that report?

*Mr. Yiannas. The whistleblower report, I believe, I got access to it around February 10th, thereabout.

*Mr. Palmer. But the whistleblower report had been out for months. Is that correct?

*Mr. Yiannas. Yes.

*Mr. Palmer. Why is it, then, if you are the deputy commissioner for food policy, you didn't get the report?

How is it that it got tied up in the bureaucracy, and it didn't get to the person who arguably should be responsible for responding to it?

*Mr. Yiannas. Yes. I am not sure why the report wasn't shared with me, and how it didn't get escalated. As you have heard the Commissioner state, I know that there is going to be a review, and we are going to try to get to the bottom of it.

*Mr. Palmer. Madam Chairman, I think we need to get an answer to this question.

*Mr. Yiannas. I certainly --

*Mr. Palmer. I know Commissioner Califf was not there

when this occurred, but this is stunning to me.

I mean, Commissioner Califf, is this typical of how whistleblower reports are handled, that you don't get them to the right people?

*Dr. Califf. Well, of course, I haven't been involved in whistleblower reports until just the last three months, but we've already done a pretty extensive review of it. There were five whistleblower reports --

*Mr. Palmer. That is not my question sir, that is not my question.

My question is you have the deputy commissioner for food policy and response, who basically was shut out of the process. And you know, the old saying in management that personnel is policy, and -- but it is also management structure.

Mr. Yiannas, I understand you were working on unifying the food program at the FDA to ensure that failures such as that have led to the baby formula supply crisis wouldn't occur again. Have you been aided or impeded in that effort?

[No response.]

*Mr. Palmer. Mr. Yiannas?

*Mr. Yiannas. Well, we've had a collaborative effort -- yeah, hopefully you can hear me. Thank you. We've had a collaborative effort.

We knew that responding to outbreaks fast and being

right was critical [inaudible] --

*Mr. Palmer. Yes, but what I am asking you is --

*Mr. Yiannas. -- last year our --

*Mr. Palmer. What I am trying to find out is that, according to the Washington Post, you were told to stand down in that effort to reorganize this so that you could actually do your job, and have the FDA organize in such a manner that -- and this is my opinion, this is not the Post. But in my opinion, the FDA focuses more on medical issues than they do food issues. And that is what Ms. -- Representative Schakowsky brought up.

Were you impeded in that effort?

*Mr. Yiannas. I could answer the reference to the Washington Post, because that was very unethical and egregious behavior. I was called on my FDA personal mobile. The person identified themselves as Kim, somebody who I work with regularly, similar voice, asked a question and I answered it. They didn't identify themselves as a reporter.

*Mr. Palmer. Okay --

*Mr. Yiannas. But no, what that article referenced was that the investigation is going to be led at that time by Principal Deputy Commissioner Janet Woodcock. And as you heard today, Steve Solomon is going to now be leading it.

*Mr. Palmer. What I think -- and I am not speaking for the entire committee, but I believe it would be a consensus,

that we want the FDA structured in such a way that, when these issues arise -- and we know that, for two years, the FDA did not do inspections, even though they knew there were problems at Sturgis. And when they did the inspections, the report didn't -- that they issued -- didn't mention them. That is unacceptable.

And, Madam Chairman, I will yield back, but I hope that the committee will continue to pursue this to ensure that in the future we have the right structure at the FDA to make sure this doesn't happen again. With that, Madam Chairman, I yield back.

*Ms. DeGette. Mr. Palmer, this is exactly what I said in my opening statement, and I agree totally with you about that.

The chair now will recognize the vice chair of the subcommittee, Mr. Peters, for five minutes.

[Pause.]

*Ms. DeGette. Please unmute, Mr. Peters.

Or he can't -- he has no -- Ms. Schrier, are you ready?

*Ms. Schrier. Yes, I can be ready.

*Ms. DeGette. Then you are recognized for five minutes.

*Ms. Schrier. Thank you, Madam Chair.

You know, this is a really distressing time for parents with infants and parents to be. Most babies, even if they are breastfed, will at some point rely on formula to survive.

And baby formula to these infants is essentially medicine. Because for kids under four months -- and I mean, really, even under six months -- this is essentially their only source of nutrition. And there are some babies with allergies or metabolic conditions that require them to take a very specific type of formula that they just can't live without.

So I am really glad to be able to have this conversation today, Dr. Califf, as we try to sort of figure out what happened. I think it is also really important to look ahead, as my colleagues have pointed out, to what can be done to make sure this never happens again.

You know, when I was practicing as a pediatrician, we would regularly get notifications that we were running short on certain medications. There is an online list of shortages. I checked it this morning. Right now, for example, you mentioned the shortage of technetium, Lidocaine, Propofol. Like, this is really important for doctors to know, because it lets us make informed decisions about which antibiotic to use, or which sedative to use during an operation, and whether there are alternatives.

And since formula is kind of like medicine for babies, like there is nothing else, and it keeps them alive, I am wondering if that kind of warning system would make sense. And so I just want to know, first, is there any early warning

system for products like baby formula, not just the ingredients, but for formula itself, where a manufacturer would let you know if they are running short or anticipate a shortage.

*Dr. Califf. The short answer is no.

First of all, let me thank you for being a pediatrician. I sometimes call the Academy of Pediatrics just for the positive vibes that you all exude as a profession.

But no, there is not such a warning system. We've repeatedly asked for that authority, and have not been granted it. The industry, by and large, has opposed it.

*Ms. Schrier. And would that authority, for example, come from Congress? Is that something that we can do and work to make sure it happens?

*Dr. Califf. That is what I am referring to, it would require congressional authorization for that to happen.

I just want to go further to say I was at Google, I know what digital technology could do. There is no reason that we don't put together a national system to enable us to do stress testing on the supply chain for critical products like this, just like we have for banks.

*Ms. Schrier. Thank you, I appreciate that. And I also understand that there has been weird buying behavior. Toilet paper, formula, you know, people get nervous about Omicron, they start buying baby formula. And that did exacerbate

this. But there is other underlying issues, as you have heard from my colleagues.

There is another thing I really want to touch on here, because we are talking a lot about these efforts to open -- reopen the Sturgis plant. Let's get it up and running in two weeks. And, you know, you made some pretty damning comments about the conditions in that plant that were found in the 2021 inspection. And then I read the whistleblower report. And, my gosh, that makes me really worried. And you have said that, you know, you have put in hundreds of requirements that they need to fulfill before that can be opened safely.

But I have got to tell you, when I read about falsification of records, swabbing empty cans, not really reporting on differing weights in cans, like, it feels like there is just corruption from the top down in that plant. Are you insisting on a full change of staff, management, employees, and how are you going to oversee this so that we feel confident, when this opens, that we are getting clean, safe formula?

*Dr. Califf. Well, you sort of alluded to it, but I mean, you know well I am not in a position to either confirm or refute that there may be criminal proceedings.

So, you know, but with regard to the specifics of what you said, every step of the way we will be there until we are comfortable, not just that the plant is physically okay, but

that the systems and people are the right people to be in place to make sure -- you know that we can't inspect every batch of every element or every plant every month. So --

*Ms. Schrier. Right, right.

*Dr. Califf. -- we have to depend on quality systems.

*Ms. Schrier. I appreciate that. And you have to trust the information you are getting.

I just have one other question, because some of this was found coincidentally, right? Like, you happened to find this in an inspection. We didn't hear about it back in September, when that -- when all of these problems were found. I am just wondering. Now it raises questions about all the other formula companies. Like, how sterile are their conditions? How much can we trust them?

And, you know, what can you say to parents out there right now who are worried?

*Dr. Califf. What I would say is that we are inspecting formula plants. The standard is once a year. We did fall a bit short during the peak of the pandemic, but we are up and going, and the plants will be inspected once a year with a very diligent inspection. So we are on top of it.

*Ms. Schrier. And to date they have been safe?

*Dr. Califf. Yes. The formula that is on sale now is safe.

*Ms. Schrier. Thank you. I yield back. Apologies.

*Ms. DeGette. Thank you so much.

Mr. Joyce, you are now recognized for five minutes.

*Mr. Joyce. Thank you for yielding, Madam Chair. Just this morning, after visiting a local supermarket, I reached out to the head of a major supermarket chain to hear what the concerns were about the supply for baby formula.

Commissioner Califf, can you please elaborate and describe the plan for distribution of baby formula that is being currently imported from foreign countries, and that -- and how that formula will reach rural parts of our country, rural parts that I represent in Pennsylvania?

*Dr. Califf. First, let me say I greatly appreciate your bringing up rural America. I published a number of research papers over the last five years about the decline in life expectancy in rural America, and the disadvantages that accrue to the people that you represent compared to urban areas. So we are acutely aware of that.

Right now the batches coming in, though, are going to wherever infants are who are dependent upon this critically special formula, who have critical medical problems, no matter where they may be. And pediatricians around the country are aware there are -- HHS has a website, and each of the producers has a number you can call if you have a person, an infant who requires a special formula.

That is a --

*Mr. Joyce. So I know my time is limited --

*Dr. Califf. As the -- yes, go ahead.

*Mr. Joyce. I don't mean to interrupt, but I know my time is limited.

So your recommendation is the pediatricians, the physicians, the family doctors reach out to HHS and let them know about the concerns and the patients that they are worried about. Correct?

*Dr. Califf. I am talking here about the special infants with metabolic disturbances who could die --

*Mr. Joyce. Exactly.

*Dr. Califf. -- if they don't get formula right away. Yes, and the American Academy of Pediatrics is very involved. We are talking with the pediatric subspecialties daily to have a network of communication about this.

So a rural physician -- and also recognize there is a great shortage of rural physicians -- a rural physician should be able to reach out and get help. And if that doesn't happen, call HHS. Get on the website. We will be responsive.

*Mr. Joyce. Thank you. We will reach out to you from the rural parts of America to do that.

We understand -- and this is for Director Mayne -- we understand that the FDA identified cronobacter at the Sturgis plant. However, it found that the samples collected did not

genetically match the strains that were collected via samples from the sick children. Is that correct?

*Dr. Mayne. That is correct. There were four children who we had reports -- the complaints of cronobacter. Two of them had isolates of the pathogens available for genetic sequencing. So for two of those children, we had no genetic material available. When the sequencing was compared between the cases and what we found in the environment in the Sturgis plant, they were not the same sequences. So they were not the same.

*Mr. Joyce. So when did the FDA collect the samples of cronobacter from the Sturgis facility that it used to conduct these genetic sequence testing?

*Dr. Mayne. Those were conducted as part of the inspection in January, where there was extensive environmental sampling done. This was a for-cause inspection. When we have a for-cause inspection, we collect a lot of information. We send those samples to our labs, we wait for those results.

And while we are waiting for those results, we started to prepare for if those results would come up positive, what would we do. And so we had been really --

*Mr. Joyce. So is it relevant that the testing did not show the strains to be identical? And if so, how?

*Dr. Mayne. What the data show is we can't rule in or

rule out whether or not those infants, their cronobacter, was caused by this plant. The data just simply can't be used to inform it. The --

*Mr. Joyce. But by the genetic testing you did -- allow me -- by the genetic testing that you did, it does not match from the plant, correct?

*Dr. Mayne. That is correct. But what we did not have is any sampling done at the same time that the product was manufactured that was consumed by the individuals who got sick. So we didn't have that --

*Mr. Joyce. Thank you, Director Mayne.

Now, Commissioner Califf, there has been some suggestion in the press that the FDA should have called the White House chief of staff back in February, when the Abbott plant closed. And the implication is that the FDA did not reach out to the White House. When did the FDA alert the White House about the closure of the Abbott plant, and who was alerted?

*Dr. Califf. In early, early February there were communications up and down the chain. I don't think we -- I mean, I was not here, but I know we did not -- I am pretty sure we didn't talk to the chief of staff. But there was communication with White House staff as a regular event, and there are memos that are -- that were produced that I think give a very elegant description of the issues and the

concerns.

*Mr. Joyce. What agencies are involved in interagency process that White House Economic Advisor Deese referenced in a recent interview?

*Dr. Califf. Well, as you know, there are multiple agencies. The CDC, for example, is involved, and the Agriculture Department is an enormous participant in this, because the WIC program is such a large part of the infant formula enterprise. So there are multiple agencies that are involved in these considerations because there is so many complicated aspects to the supply chain.

*Mr. Joyce. I see my time has expired. Thank you, Madam Chair, and I yield.

*Ms. DeGette. Thank you so much. The chair now recognizes Mr. Ruiz for five minutes.

*Mr. Ruiz. Thank you.

From a public health perspective, this is appalling. And as a father, this is heartbreaking. My wife and I are parents of twins, and we relied on formula in addition to breast milk to meet our daughters' nutritional needs. I can only imagine the anxiety parents are feeling as they desperately search for formula, and the anger they feel for the insane prices they are paying online. This would be terrifying and infuriating for any parent, but even more so for those without the means to pursue alternatives if they go

to the store and find empty shelves.

According to the NBC News report this week, prices for baby formula from online sellers such as eBay, Craigslist, and Amazon predatory sellers are taking advantage of the shortage, price gouging customers by charging up to 300 percent or more for baby formula. I don't know about the rest of you, but many of my constituents couldn't pay that much, even if they wanted to.

So once again, we are facing a huge disparity in our country in terms of who has access to basic necessity and who doesn't.

I am grateful for the expertise of our witnesses today, and want to use my time to ask them what the American people can do to secure safe infant formula for their children, and particularly thinking about the families that have been disproportionately impacted by the shortage, such as low-income Americans, caregivers living in rural areas, and those families with infants and children who rely on specialty formula.

So Commissioner Califf, FDA has recently announced multiple actions to increase the availability of infant formula. Though I am pleased by the news that Abbott has agreed to the consent decree, and its Sturgis facility may be operational in a matter of weeks, American families need formula for their children today. So what can American

families who are searching for formula and those most disproportionately impacted by the Abbott product recall and overall shortage, what can they do to get the products they need to feed their children?

*Dr. Califf. Well, the problem you describe is gut wrenching, and, you know, it does refer me back to my days as a parent.

So we don't have an answer that people -- that is a great answer. We are bringing in all the supplies we can, and getting them distributed as fast as we can. In the meanwhile, the -- I would refer people to the HHS website and the hotlines from the companies, and you will find on the HHS website a really good description of community resources, which are absolutely critical for the populations that you just described.

A great thing about America is the communities have come together and are making supply available at a local level. And so all those measures are going to be needed --

*Mr. Ruiz. Thank you.

*Dr. Califf. -- until we get back online.

*Mr. Ruiz. Thank you. Unfortunately, I have heard alarming reports that, in their desperation to feed their babies, some Americans are turning to riskier options, such as homemade formula, and falling prey to online scams and counterfeit products.

Dr. Mayne, what do parents need to know about these potentially harmful options, and what recommendations do you have for them to consider, and how is FDA [inaudible] this to the households of the families most affected?

*Dr. Mayne. Thank you. I missed a little bit of your audio, but I think I understood the question.

In terms of these counterfeit formulas, what we have advised consumers is to avoid single purchases coming in from abroad that have not been through an FDA-approved facility. So we urge consumers to be cautious about that.

We also urge consumers not to make your own formula at home, because we have seen problems with that, as well, and also not to dilute formula, because that means those babies would not necessarily be getting the nutrition that they need.

We are looking at the borders. We are surveying to make sure that these counterfeit formulas do not come into the country. That is an important priority for us, and that is some of the resources that are in the supplemental for infant formula.

*Mr. Ruiz. Thank you.

You know, I appreciate that the Administration is working around the clock to address these issues. Because the President invoked the Defense Production Act, manufacturers are able to get the supplies that they need

more quickly to increase formula production. And thanks to Operation Fly Formula, we have been able to cut transportation times from Europe from weeks to just a few days.

But we must continue this all-hands-on-deck approach to make sure that no child goes hungry, regardless of where they live or how much their parents make. And with that, I yield back.

*Ms. DeGette. I thank the gentleman. The chair now recognizes Ms. Kuster for five minutes.

*Ms. Kuster. Thank you, Madam Chair, and thank you for holding this incredibly important hearing. I apologize that I have had some complications today, but I was picking up my husband from the hospital, so I didn't mean to give anybody a fright when I was driving on -- in the car. I am settled at home now, and delighted to be with you.

Granite Staters and families all across the country are scrambling for formula, driving miles across state lines, forming local donation pools, and even falling victim to scams and counterfeit products out of desperation. And while Abbott bears responsibility for why its product recall was necessary at all -- and I am shocked by the conditions -- it was ultimately the safe thing to do to ensure the health of our infants. However, it is going to take industry-wide dedication to increase production so that retailers can keep

their shelves stocked.

Mr. Fitz, your testimony states that Gerber recognizes -- oh, I apologize. I believe I am on the wrong panel. I am sorry. I am going to have to pass, and come back. I apologize for the complication. So sorry.

[Pause.]

*Ms. DeGette. Mr. Peters, is your sound fixed now? Are you ready to go?

*Mr. Peters. I am, Madam --

*Ms. DeGette. Okay.

*Mr. Peters. -- Chair, thank --

*Ms. DeGette. You are recognized for five minutes.

*Mr. Peters. Thank you very much.

*Ms. DeGette. Thank you.

*Mr. Peters. Thank you. I want to say thank you for holding this hearing.

I also get the sense that there is a real bipartisan concern about this policy. I think there is a bipartisan interest in addressing it. I can't get out of my mind that the context of this hearing is what happened in Texas. And I would love to see the same interest in preventing our children from being massacred in their elementary schools. I would love us to get beyond politics on that, as well.

Commissioner Califf, FDA has announced numerous agency actions to address the ongoing formula shortage, making it

easier for -- to import safe and nutritious products, and expediting reviews of manufacturing changes that can increase supply. Can you tell me how the FDA has coordinated its actions with other agencies in the government to alleviate the shortage?

[Pause.]

*Ms. DeGette. Commissioner, you need to unmute.

*Dr. Califf. Sorry about that. First time today. I thought I was doing so well.

I -- in response to your question, we coordinate with all of the relevant HHS and government agencies, including CDC, the Agriculture Department, economic advisers, and supply chain committees that have been in place throughout the pandemic.

And I also want to say I have been amazed by -- they have also not been sleeping and working on weekends and nights to pitch in in the all-of-government response.

Furthermore, I think the industry has actually responded quite well, with pretty -- with substantial increases in production, which in normal commerce times they wouldn't have to do, but they have risen to the occasion -- and the amazing support of the global industry, which, for reasons that you have alluded to already, has largely not been involved in importation into the United States.

So I really feel that people are pitching in. We are

not there yet, but the effort is really being made.

*Mr. Peters. You know, the shortage is exacerbated, as we have discussed, by the voluntary recall of the products because of the cronobacter infection.

In the U.S. today, 3 major companies comprise about 95 percent of the market. They also distribute about half of their products to WIC agencies, Women, Infant, Children. We know that the burden of this shortage has fallen disproportionately on low-income families and families with special dietary needs. We have 4,000 families in my district alone who receive WIC benefits.

For Mr. Calamari, one of the main causes for the nation's formula shortage is the condition of the Michigan facility. You know, you testified that you have invested "billions of dollars'' in things like growing production, and creating new specialized formulas, and enhancing safety and quality. How much of the resources --

*Dr. Califf. Congressman --

*Mr. Peters. -- either as a percentage --

*Dr. Califf. I am sorry, Mr. Peters, you may be on the wrong question there. Mr. Calamari, I think, is tomorrow.

*Mr. Peters. Oh, gosh. I am sorry. I had the same problem as -- I am sorry about that. I will -- let me ask, then, Mr. --

*Dr. Califf. It was a good question, though.

*Mr. Peters. -- Mr. Califf a little bit more -- how are you -- what -- I said how are you coordinating. I know you are coordinating. What is the way you are reaching out to manufacturers, retailers, consumers to alleviate the formula shortage?

*Dr. Califf. Well, the manufacturers we are in daily conversations, and I have personally spoken with most -- almost all the CEOs around the world who could contribute to this, but also our team at the working level.

As you know, CEOs have conversations. It is the people who are actually working that get it done. And so we are in constant communication going back and forth, because each of these efforts -- for example, importation -- requires multiple different people to work together in ways they haven't done before.

*Mr. Peters. Great, thank you.

And Madam Chair, I yield back.

*Ms. DeGette. I thank the gentleman.

Ms. Kuster, I believe you are now ready. So you are recognized for five minutes.

*Ms. Kuster. Thank you very much, Madam Chair. I apologize again.

I was pleased by the timeliness of the consent decree agreement reached between FDA and Abbott filed just nine days ago. This agreement sets in motion the critical process of

Abbott retaining expert assistance to bring the Sturgis facility into compliance so you [sic] can safely restart production of infant formula.

Clearly, the FDA's oversight of Abbott's actions will be critical to ensuring the consent decree is properly implemented and maintained. Commissioner Califf, what updates can you share with us about Abbott's implementation of the consent decree in the days since its filing?

*Dr. Califf. As I mentioned yesterday, we met with Abbott's leadership -- I am sorry, earlier. We met with Abbott's leadership yesterday. They reviewed hundreds of steps that they've taken, many of which are done.

As I would expect from the industry that I know well, there are very detailed charts and graphs that are recording every step of the way what is happening, and how close to complete they are. And I do believe that they are making substantial progress, and I feel optimistic about it.

In fact, you know, they were originally quoted as saying two months to get product out on the shelves. That has now been cut to one month due to decisions that have been made about the type of product that will be put first on the line. That special product for people that have -- for infants that have allergies to milk will be first on the line.

So I think it is going well. But, as I say, I would --

*Ms. Kuster. What changes do you think Abbott needs to

make to improve safety, and particularly sanitation of the facility, for the FDA to be confident that it can safely begin production of infant formula that American consumers can rely on to safely feed their babies?

*Dr. Califf. Well, thank you for that question. And I was about to say I have a really good history with Abbott in my past, as a doctor. But this was beyond the pale. And so we are watching every step.

Just as an example, before they will open production, they will completely cleanse the whole production area and take samples, look at those samples, and then do that twice more. So that will happen three times before they open the production area. They have completely redone the roof. They have completely redone the floor, so that there is not drainage on the floor. And they have expanded the area of -- in which people must exert sterile precautions, which was too small in our inspection. And it is now expanded out.

There are dozens of others that I could name.

*Ms. Kuster. And what, if any, contingency plans does the FDA have in place to ensure the adequate availability of infant formula in the months to come, should it take Abbott longer than the estimated several weeks to get the Sturgis plant operational again?

*Dr. Califf. That is a great question. And what I would say is that we are not going to stop with our

importation plans and our increasing our production by the other manufacturers until we are comfortable that we are back to a normal level. And I would predict we are going to have a surplus a few months from now, because we want to have excess for all the reasons that your committee has said.

There is actually substantial global capability of producing infant formula. The largest manufacturer, Nestle, for example, has a small presence in the U.S., but they are the number one in the world. And so I am very optimistic that, over time, we will have plenty of formula. But that doesn't -- I don't want to make light of the fact there -- it is going to be days to weeks until we get there.

*Ms. Kuster. Well, our constituents are struggling right now. And as parents, many of us on this committee, mothers and fathers that have dealt with feeding young babies, and also I -- my heart goes out to the people with work schedules that they have to worry about, that they are spending so much time in this, trying to get safe formula for their babies, and the cost.

I have one last line of questioning, if I could. I know that in this part of the country -- I am in New Hampshire -- we have milk banks of mothers' breast milk. And I am wondering, what is the regulation by the FDA, and can we assure our constituents that breast milk from a milk bank is safe and is thoroughly vetted by the FDA?

*Dr. Califf. You are asking some very good questions. I am going to refer this to Dr. Mayne, who probably would have the best answer.

*Dr. Mayne. Thank you --

*Ms. Kuster. Thank you --

*Dr. Mayne. Thank you, Congresswoman. So human breast milk is regulated as a food. And so that is reassuring. And they have to have proper screening protocols and things like that in place to make sure that the donors that are donating the milk, that that is critical for human food safety. So that is how I would respond. Thank you.

*Ms. Kuster. My time is up, but I will submit further questions for the record.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. Kuster. Thank you, Madam Chair, and thank you for your indulgence, and I appreciate --

*Ms. DeGette. I thank the gentlelady. I know you have been dealing with a lot, so our best wishes go out to your husband today.

*Ms. Kuster. Thank you.

*Ms. DeGette. Mrs. Trahan, you are recognized for five minutes.

*Mrs. Trahan. Thank you, Madam Chair.

So, as many of us have known, and many became more recently aware, infant formula is more regulated than most food products in the United States, reflecting the vulnerability of its consumers, infants and children. Robust regulation not only ensures product safety, but it also helps consumers trust that the product they feed to their children is of a high quality and will meet their baby's nutritional needs.

Dr. Mayne, in light of the search for solutions to the nation's current formula supply shortage, some lawmakers have called for deregulating infant formula production. Can you share just a bit about the nature of the regulatory standards manufacturers of infant formula must adhere to, and why they are so vital to ensuring the high quality and safety of infant formula in the U.S.?

*Dr. Mayne. Thank you, Congresswoman. I would be happy

to do that.

The requirements under statute are that we need to make sure that these products have appropriate nutrition as the sole source of nutrition. That means they have to have the right amounts of 30 different constituents: vitamins, minerals, things like that. And they can't be too high and they can't be too low. So that is the nutritional side of it.

They also need to demonstrate appropriate growth. There is growth monitoring data that are required as a critical source of nutrition for our babies.

At the same time, there are safety data. And so when we review infant formulas, we also work with our Office of Food Safety to make sure that the production is done in a way that the product is safe. So that is what the regulations require.

What we did announced recently is regulatory flexibility while assuring safety, and while assuring nutritional adequacy, and that is really important. So things, for example, where we are looking for flexibility -- certain labeling requirements that aren't critical for safety, we would provide regulatory flexibility. But labeling is critical for things like allergens. We don't want babies to have an allergenic reaction because allergens in the product are not properly labeled.

Also, the preparation instructions are critically important. If consumers don't know how to prepare the product, then you could get the wrong ratios and you again don't get the nutrition you need. So the regulations are there to protect all those infants.

I am a mother, I am reassured that we have those regulations in place. But at the same time we recognize the challenge we are in, and we are applying regulatory flexibilities while protecting nutrition and safety.

*Mrs. Trahan. I appreciate that. And as manufacturers currently expedite efforts to ramp up production of infant formula, and Abbott's facility completes corrective actions and restarts operations, what is FDA doing to ensure that the available formulas remain safe and nutritious for our nation's infants?

[Pause.]

*Dr. Califf. Dr. Mayne, do you want to take that?

*Dr. Mayne. I mean, everything that is coming into the market through our flexibilities is appropriate for nutrition, and it is safe. So that is clear.

And I will comment as Operation Fly Forward -- Fly Formula, one of the things that we note is we've got new product that is coming in. It hasn't been in the U.S. market before. This is coming from UK. This is the Kendamil product that we announced very recently. That is two million

cans of general infant formula, not the specialty formulas, but general infant formula.

We looked at the data that were required to be submitted as part of our flexibility to assure that that product meets our nutrition and our food safety standards. That includes information on microbiological testing that the companies have done along with the production. So we are making sure these are comparable to the U.S. market with regard to nutrition and safety.

*Mrs. Trahan. Thank you. That is reassuring.

Commissioner Califf, conducting oversight of these regulations is not without significant costs. Yet, as has been discussed already today, FDA's food safety activities have been chronically under-resourced. We understand that you are conducting an internal investigation also regarding FDA's response.

Could you please just describe the scope of that investigation, and whether it will include recommendations on how to improve FDA's future responses, and whether the findings will be made public?

*Dr. Califf. Well, let's divide it into two segments. On the one hand, we have the specific response, the after-action review that Dr. Solomon is leading. That'll go through great detail. The interviews are already well underway of the people who are involved. And I want to

stress again, to my knowledge, there is no malfeasance here. These were people working very hard, but we had systems that were failing, and decisions that could have been better. And those findings will be made public, no question about it.

But there will also be a review of the entire food program, which is vast and includes things that you all have discussed, including chemicals and nutrition [inaudible] all the things that are involved. That is what some of the discussion has been about over the last three months. That is going to take longer, because we need congressional approval to make major changes in a program like this.

*Mrs. Trahan. Well, we are eager to get those results and eager to get those -- the formula back on store shelves that is safe.

Thank you, Madam Chair. I yield back.

*Ms. DeGette. Thank you so much.

Mr. Burgess, great to see you on screen, and you are recognized for five minutes.

*Mr. Burgess. Yes, I am trying to unmute. It won't let me.

*Ms. DeGette. You are unmuted. You are unmuted.

*Mr. Burgess. Oh --

[Pause.]

*Mr. Griffith. You were. Dr. Burgess, you are muted again.

*Mr. Burgess. Okay.

*Ms. DeGette. There --

*Mr. Burgess. How is that?

Dr. Califf, very good to see you again, and I apologize for the technical difficulties. But listening to all of the other questioners, it is -- I mean, it is a terrible problem. And, of course, you have come on board just a couple of months ago, and this problem has landed at your feet. I appreciate the efforts that you are making.

It strikes me, though, that this is a very propitious time to have someone who has spent time at the FDA in the past, and has spent time in the digital world in the interim, and is now back at the FDA. Several members have mentioned our food safety efforts, even going back to 2005, 2006. And during that time I remember it kept coming up that the modernization of the information systems at the FDA was a critical missing piece of this. And it just strikes me that it is -- this is an excellent time to have you there, because you are the one who can -- you can be the architect of that FDA modernization, that FDA digital transformation that clearly has been lacking, and is so critically necessary.

[Pause.]

*Dr. Califf. Are you still there?

*Mr. Burgess. Yes.

*Dr. Califf. Well, you want me to respond to that?

*Mr. Burgess. I wish you would.

*Dr. Califf. Yes. As I have already mentioned, I was enjoying a nice life in the private sector, living under the Golden Gate Bridge. And when the call came, this is one of the things that I just thought was so critical. I hadn't expected to be asked to come back. So I did jump at the opportunity.

I know that Mr. Yiannas and Dr. Mayne have a keen interest in the technology. I have lived my whole career at the interface of technology, information technology, and health outcomes, and so I would say I am not the architect, but I am maybe the boss of the architects, because these -- this is a very --

*Mr. Burgess. Well, you referenced -- yes, you referenced that you were going to need authorization and help from Congress. So you have come to the right place. This is the committee, this is the authorizing committee that -- where we need to work together.

And I certainly look forward to hearing from you beyond this hearing as to just what the tools are that you need to be able to implement that digital transformation. Because, gosh, it has been painful, listening as -- to the timeline: October 19th from the whistleblower letter -- good for the FDA that they caught on that there was a problem in September. But then the whole thing kind of fell apart, that

there wasn't an inspection until February. And we are where we are now with the lack of supplies.

But I am encouraged by what you said about your efforts to remedy the problems at the Sturgis plant. I just wish they could have begun in October.

*Dr. Califf. Yes, sir. It was too slow --

*Ms. DeGette. Mr. -- go ahead.

*Dr. Califf. If I could just add one more thing, I would like -- I hope I can get Congress to imagine the life of an FDA investigator living in a digital world which is modernized, how much more efficient and effective and productive and happy those employees will be.

I am 100 percent confident that, if we get the right technology -- you see, it is not just one thing. The technology and the people interfacing is really what is --

*Mr. Burgess. Sure.

*Dr. Califf. -- so critical here.

*Mr. Burgess. Well, and that -- obviously, that was the missing link between September, October, February, and where we are today.

But I guess the good news in all of that is you have a structured program of remedy that you are implementing at the Sturgis plant. Just give us an inkling as to the timeframe over which those types of tasks can be accomplished and Sturgis can be up and running and producing for the American

people again.

*Dr. Califf. Yes, sir. The Sturgis plant, as I say, we met with the CEO and his team yesterday. We would expect by June 4th production will be underway, and within a month from now, according to Abbott's own projections, we should be having formula rolling off the production line.

Now, I have already mentioned that there are hundreds of steps along the way. So if any one of those goes wrong, you know, that will cause a further delay. But we are talking every single day, and I really do believe they are making best efforts at this point to make this work with all hands on deck.

*Mr. Burgess. Well, let me just ask you a question, and I think it was brought up by Dr. Joyce, on the dissimilarity between the genetic makeup of the bug that caused the illnesses and deaths and what you recovered from the plant. Do we need to be concerned that there are some missing pieces here, and perhaps there is part of this story that is yet to be shown to us?

*Dr. Califf. There definitely are missing pieces, but I am not confident they will be filled in for the reasons that Dr. Mayne already said. We don't have samples that are simultaneous in the infants and their surrounding environments and the plant.

I would also just point out -- this is a little geeky,

but you are a doctor -- whole genome sequencing is actually taking images, much like facial recognition on your computer. And there are errors in whole genome sequencing, or variations that can occur, where you get a conclusion that -- something like we are not sure it matches, but we are not sure it doesn't match. And so all those kinds of things can happen, which I think will leave us being inconclusive about the -- those links. But we will continue to learn more.

One final thing just to get in, cronobacter is not currently a reportable bacterium.

*Mr. Burgess. Right.

*Dr. Califf. If you compare that to what just happened with peanut butter, within days we had genotypes that completely linked things, and we were able to act. We need to make cronobacter, in my view, a reportable bacterium, so we can build a genetic database.

*Ms. DeGette. Thank you.

*Mr. Burgess. Very good, thank you.

*Ms. DeGette. Mr. O'Halleran, you are recognized for five minutes.

*Mr. O'Halleran. Thank you, Madam Chair, Ranking Member, for putting this meeting together today.

You know, I am incredibly frustrated that we are here today at all. As a father and -- of three, and a grandfather of four, the thought that any of anybody's children or

grandchildren at any time in their lives were going hungry during this critical development phase of their lives is unbearable.

While there clearly, clearly are issues that must be addressed by Abbott regarding the plant, I want to hone in on the FDA's failures between, well, actually, October and May, and when the shortage of baby formula became a full-blown crisis. And actually, it goes back -- oh, let's go back to the 1990s. And -- because we have to be able to address things in an orderly fashion throughout time. And there were problems with this plant back then, and they have not been consistently brought to bear time and time again.

Part of my previous life I was in long-range planning, and redundancy issues, and so understanding that this is not the first time this has occurred -- I am off script here, because of what I have heard today. But this is the -- this is not the first time that there has been conditions at the plant that were problematic, and the -- that -- this is a sole provider of some of the food for our children in this country. The Abbott plant has -- or what I heard today -- has no back-up plan?

I come from a business that, if you are down for a second, you are down. And, you know, so that is why you put in redundancy across the board to make sure on something this critical is addressed, and so our citizens do not have to

have this problem. And the New York Times had an article just this weekend on the long history of problems in this plant.

So I don't know what the protocols is -- are at the Food and Drug Administration. But whatever they are, they need to be reviewed, going back in time, taking a look at other facilities, identifying clearly how not to have this happen again, and being aggressive about it.

And it is sad when I hear Dr. Burgess say that the information systems in 2005 are still not up to the level they should be. We, as a Congress, have to look at that, too.

But it is obvious also that administration after administration after administration have been lacking on addressing this important issue.

I -- whether it is the roof leaking -- we don't allow these at our plants that address food to our people, our citizens in this country, and especially to those most vulnerable.

And when we go and look at what occurred there, I don't understand -- you know, I fully understand that, you know, that we had had an agreement. But people can work on parallel tracks. And why this wasn't -- I haven't seen where this has been worked on in a parallel track across the process, so that we anticipate that this consent agreement

was going to occur, and that we were working long before the consent agreement to be able to address these issues.

I -- the ranking member clearly identified the timeline here. In the world I come from, if you have a timeline like that, you have a big problem. And that should never have happened. And once that timeline was -- that clock should have started ticking then, and never stopped until this was addressed.

But I am going to give you some time to talk about those issues, but I just had to make those comments. Thank you, Commissioner.

*Dr. Califf. Well, I couldn't agree with you more about your general sentiment. You would think that a critical industry like this would have resilience plans, redundancy. But we don't even have legal authority right now to require that the firms have a plan for potential failures and resilience. That is something we've asked Congress for every year for a while, and we are asking for it again. So I hope that it happens this time.

I would also add that this is not unique to this industry. We are seeing this across the entire device and medical supply industry with frequent failures, as exemplified by the 60 Minutes show and the contrast medium problem that I talked about. We have gone to just-in-time, large, single-source contracts that lead to a lack of

diversification in the industry, and the industry has fought us tooth and nail on requiring that there be insight into their supply chains so that the sum of all of the industries leads to the avoidance, the preemption.

We would like to be able to stress test and prevent these things from happening, rather than waiting until they happen and then scrambling.

And then, finally, I would just add again --

*Mr. O'Halleran. Thank you, sir. I know the chair wants to move on, we have other members. I just -- if we are talking about a whole-of-government and how great we are doing, we should also talk about whole-of-planning, and working on a continual basis to get things right.

*Ms. DeGette. We --

*Mr. O'Halleran. Thank you --

*Dr. Califf. Thank you --

*Ms. DeGette. I thank the gentleman. We still have a second panel, so we are going to move on. And we now have a number of members of the full committee who have waived onto our subcommittee.

We welcome you, as always, and we will recognize you for five minutes. First I am going to recognize Representative Dingell for five minutes.

*Mrs. Dingell. Thank you, Madam Chair and Ranking Member Griffith, for convening today's critical hearing. I

share the outrage of all of my colleagues, and I guess there are times that I want to say to everybody involved here as we get into these trite conversations about whether this form of the bacteria or this -- this plant was contaminated, an infant formula was being made and delivered in a contaminated plant. But we will talk about that in the next one.

While FDA is charged with the authority to ensure the safety of the nation's food supply, coordination with other agencies, particularly the CDC, is crucial in times of foodborne illness outbreaks. This recent crisis has demonstrated just how vital this interagency coordination is, not just for public health, but for the broader supply implications for a product millions of American families rely on for the safety and nutrition of their children.

Dr. Mayne, following initial reports of illnesses linked to the consumption of powdered infant formula, how did the Center for Food Safety and Applied Nutrition coordinate its investigation with CDC and state departments of health?

*Dr. Mayne. Thank you, Congresswoman Dingell.

In any foodborne outbreak investigation or any consumer complaint investigation like this one, we coordinate very closely with the states, as well as with the Centers for Disease Control and Prevention. And in this setting, some of the genetic sequence data and some of the product samples, that was actually done at the states. But we work in

partnership with our states to get the information we need to help inform these investigations. So close coordination throughout.

As you heard our commissioner say, there is an issue. The cronobacter is not a reportable disease. That is not FDA's to own, but that is something we really should be looking at because the tools that we have been using to link cases together based upon the molecular signature of the pathogen that made them sick, we did not have those tools here. What we had were two case complaints that came in at the early part. At the time we had no idea if they were linked by a point source. We had no genetic information available. All we knew is that they had consumed powdered infant formula from Sturgis.

But we also know Sturgis is a big part of the infant formula market. So we had that concern, but we need data and we need science. And with the idea that we could potentially warn parents, it -- had we warned parents without strong scientific justification for that, we could have potentially contributed to these shortages that we are seeing today without evidence, in fact, that there was a contamination problem in the plant.

So we had that evidence with the for-cause inspection. We found the bacteria. We found multiple strains of bacteria. We inspect infant formula manufacturers around the

country. Our experts said this plant had very, very seriously concerning conditions, unlike things that they have seen in other plants in the U.S.

*Mrs. Dingell. So let me build on that a little, and I am going to give you a two-part question here.

So clearly, I think all of us are going to come out of this hearing saying we need to look at what we need to do to be able to get at cronobacter faster. But were there processes filed for the infant formula investigation?

Were they the same as for other foodborne illness investigations, or were there factors unique to the cronobacter bacteria or to infant formula?

And Dr. Mayne, with the benefit of hindsight, in what ways could the Center or FDA coordination with CDC and other state or Federal agencies be improved?

*Dr. Mayne. And I would say the processed we followed here were exactly the same as what we would use in an outbreak investigation. We use our coordinated outbreak response team, and that is a dedicated team of individuals, and that is their job: to investigate foodborne outbreak investigations and these clinical illnesses.

One of the things that was a little different in this particular infant formula situation is you don't have the challenges with traceback or traceability that you do when we are doing leafy green investigations. Rather, the parents

could tell us what specific products were fed to these infants. So we used the same processes, but the data and the information that we had available were different in this particular investigation.

In terms of improving coordination, we work hand in hand with CDC on all foodborne outbreak investigations, including this particular situation, daily contact with CDC on these types of investigations.

*Mrs. Dingell. Would there be changes you would recommend today, so that we might have prevented some of what happened?

*Dr. Mayne. In terms of prevention, there are some authorities that we think could potentially be helpful in the future to prevent these types of things from happening.

So, for example, we could consider new authorities around what industry would need to do with regard to their own testing. We have learned the importance of testing the environment of the food production facility. So there are things that industry could do. If they found the bacteria, they could be required to provide sequences to the FDA to build the database of information to help solve any future situations.

*Mrs. Dingell. Thank you, Madam Chair. I yield back.

*Ms. DeGette. Thank you --

*Mrs. Dingell. More questions, but yield back.

*Ms. DeGette. Thank you so much.

Mr. Upton, you are recognized for five minutes, and welcome.

*Mr. Upton. Well, thank you, Madam Chair, for allowing me to waive on. I know we all have a good number of questions. There really isn't a bigger issue for many families than this one for us to resolve.

And as you know, for me, as the former chairman of the Oversight Subcommittee, and you now as the current chair, we have learned from a lot of masters that have gone before us, and this subcommittee has been very important to investigate over the years what goes wrong, identify it, and then come back with legislation to fix it so it does not happen again.

I am actually in Sturgis, Michigan right now. I spent much of the morning here. For a couple of hours I was actually at the closed Sturgis Abbott facility, talking with the vice president of nutrition and supply chain and a number of the employees that have been there -- actually, some that had been there for generations of families working there, some for as long as 40 years at that facility. It is actually the tallest facility in St. Joe County, and I have been there a number of times over the last number of years.

A couple of questions. But because I was there, I have been unable to hear the witnesses' testimony, or really have a -- listen to some of the answers to the many questions that

were -- been posed by both sides of the aisle on this very important topic.

I will say this, and I appreciate Dr. Califf's input. He is a recent leader, of course, at the FDA, just recently being confirmed by the Senate.

I know, as I understand it, you responded to our colleague Billy Long saying that you thought on a scale of 1 to 10 your performance, you thought, was about a 4. You and I talked a couple of weeks ago, as this facility remains closed, and one of the things that you told me was that, frankly, the FDA needs more resources to make sure that these food safety operations are safe.

Now, when Chair DeGette and I worked on 21st Century Cures, we gave the FDA a lot more responsibility. If we were going to approve these drugs in devices on an expedited basis, the FDA needed more resources, and we did that. Last week, of course, the House passed $28 million in additional resources for the FDA. I would imagine that the Senate may take that up at some point soon, whether it be this week or the first week that we are back.

And my question, Dr. Califf, is if that money is approved, ultimately signed by the President, can you tell us how you are going to use that $28 million?

*Dr. Califf. Sure. First of all, we really appreciate what the House has done, also appreciate what the two of you

did, and your colleagues, for 21st Century Cures. It has made a dramatic difference on the medical products side.

On the $28 million, it is obvious from all the discussions that we've had that we need more people who can assure the quality of the imported infant formula, who can review the applications and get them done, and inspectors to -- investigators to assess and do the testing that is needed to make sure that this surge in infant formula that is going to occur happens in a safe way.

Now, as we have said before, we will scrape together and do it somehow without the money, but something else will really suffer. And we need the dedicated funding to really make this happen.

We've also talked about the information technology. The money allocated is a drop in the bucket compared to the ultimate need, as you know. But it will at least allow us to patch it together to get the job done acutely.

*Mr. Upton. You know, as I sat down with a number of the management levels in Abbott this morning -- I would like to share this with my colleagues -- it does appear as though -- well, first of all, it has been, of course, shut down since February. They have made massive changes inside the facility in a number of different ways. They have shared that, of course, with the FDA. But they also have a third-party group to, in essence, certify that they are going to

comply with the demands that the FDA has made. And they intend to have the facility, as you indicated, I think -- to Congressman -- our colleague -- O'Halleran, that it will be up June 4th.

But if they don't meet the test, it will be later than that. They are going to make sure that they are 100 percent before that plant is open. And their sense is that they will, if they do start on the 4th, that they will be able to have product, and they are going to prioritize the product so that it is the folks with the biggest need -- and they are working very closely with the FDA and the White House to make sure that some of those allergens are taken care of. But they intend to see that that supply chain be fully committed and on the shelf as early as the end of June, probably the 20th or 22nd of June, assuming that they start out on the 4th.

So again, I would be glad to share my -- I guess last quick question, Mr. -- Dr. Califf. Would you be willing to come back? Once this plant is up and running, would you be willing to come back and actually walk the floor with me to make sure that, in fact, it meets the test that all of us want to see it make?

*Dr. Califf. Absolutely. I love to visit facilities, and would be glad to make a home visit with you.

I mean, it is a great thing about America that the way

it works is you are there on the spot. This is your district. And the fact that you can be there in person, I think, is really a critical part of the overall effort.

*Mr. Upton. Well --

*Ms. DeGette. Thank you. Doctor, we need to move on, and I want to thank Mr. Upton.

Ms. Barragan, I understand you are in the committee room.

*Ms. Barragan. Yes, thank you, Madam Chair.

*Ms. DeGette. You are recognized for five minutes.

*Ms. Barragan. Thank you, Madam Chair, for holding this important hearing.

I have gotten a number of calls from constituents and folks who have had a problem getting access to infant formula. As we have heard, people who are on WIC have been heavily impacted in my district, which is a very working-class -- 70, 90 -- almost 90 percent Latino, African American, and many parents on WIC are really feeling this impact. So they appreciate this hearing, and the responses, and they want to know what happened.

Dr. Califf, we have heard today some of the deficiencies at FDA, a combination of -- my understanding is people, leadership, lack of money, lack of state-of-the-art technology, just to name a few.

I want to talk about the position of a deputy

commissioner for foods at the FDA. My understanding is that during the Obama Administration there -- established the role of a deputy commissioner for foods at FDA, and that was in 2010, and that in 2018, under the prior Administration, that position was effectively eliminated.

And Dr. Califf, you are an accomplished cardiologist and a researcher with expertise on drug and medical policy. I am concerned maybe there is a lack of a similarly accomplished individual leading the FDA on food, safety, and the food program, which may have also led to this shortage. Do you think that we need a deputy commissioner for food to be reinstated at FDA to ensure another infant formula shortage doesn't happen?

*Dr. Califf. I appreciate that question. I know a lot of people are asking it, and I would respond like this.

I did -- when I came through in 2016 as commissioner, I had Steve Ostroff, who had been acting commissioner and was a food expert, who then moved into that seat, and it was reassuring.

Then changes were made by Dr. Gottlieb. And, you know, I have talked with him quite a bit about why those changes were made.

Now I have come back again. And as I have tried to make the point, there were deputy commissioners, and these problems that we are describing are systemic, and they

weren't fixed. And I don't think it is because those were bad people who were deputy commissioner. But my point is there is more to it than just having a person in that particular job.

And what I am trying to do over the next few months, I had planned to do this at about six to nine months into my administration. We will move it up now because of all that has happened, once we get through this crisis. What I plan to do is look at the whole thing, and whatever the right structure is.

You also know we have had multiple commissioners in between, which changes things on and off. I would like to put in place a structure that will last that people have confidence in.

In general, I agree you definitely need a stronger team at the higher levels on the food side as part of the revamping of the entire food program.

*Ms. Barragan. Okay. And we have heard some of the deficiencies at FDA, and kind of generally you have heard about some of these. Is there anything specific that you think Congress should be doing to prevent this from happening again?

I think there is a lot of things that went wrong here, and it seems that sometimes we get these solutions in general -- in generalities instead of specifics.

*Dr. Califf. We have a long list of specifics. We've gone over a number of them today, but we will be glad to compile those into a list, and make sure that they are right on hand.

They -- you know, we are in this period where the user fee Act that is going through -- and a number of them are included in that legislation as a possibility.

*Ms. Barragan. Okay, thank you. My next question is about the structure. Who would you say is in charge of food safety at FDA?

*Dr. Califf. You know, I have been a part of many organizations, health systems, academic centers, businesses, and almost all of them in modern times are matrices, which means you have a mix of people with specific responsibilities. In this case, Dr. Mayne is the world's authority in nutrition, how organizations work, and scientific management. Mr. Yiannas is the world's authority in supply chain, how the industry works, and fully knows that. They have their specific responsibilities --

*Ms. Barragan. Thank you. Thank you, Doctor.

*Dr. Califf. Thank --

*Ms. Barragan. So let me go to Dr. Mayne, since you just mentioned that.

Dr. Mayne, would you say you are in charge of food policy and safety at FDA?

*Dr. Mayne. So my role is that I direct the Center for Food Safety and Applied Nutrition. So I lead that initiative. That includes all of the scientific operations within the Center.

There are other components, as you heard in our matrix organization. We work very closely with Deputy Commissioner Yiannas in the Office of Food Policy and Response, who has oversight for the outbreak and response part of the portfolio, as well as other high-priority areas such as the New Era of Smarter Food Safety. And we work with the associate commissioner for regulatory affairs, Dr. Judith McMeekin, who oversees --

*Ms. Barragan. Okay, thank you.

*Dr. Mayne. -- [inaudible].

*Ms. Barragan. Thank you, Doctor. My time has expired, and I think just the responses show I don't think there is one person that is responsible, which I think just goes to show, I think, that there needs to be restructuring, and it needs to be more clear who is ultimately responsible.

Thank you, I yield back.

*Ms. DeGette. I thank the gentlelady. The chair understands Mr. Bucshon is also in the committee room.

And so, Mr. Bucshon, you are recognized for five minutes.

*Mr. Bucshon. Thank you, Madam Chairwoman. I

appreciate it.

And Dr. Califf, I just wanted to say thank you for your professionalism in coming and answering the tough questions in front of this subcommittee today. I very much appreciate that.

I am disappointed that the -- it appears the leadership at the Sturgis plant doesn't appear to have an employee-driven health and safety program in place, or they just didn't listen. Food manufacturing facilities that I visited in my district and my state have these types of programs in place. Problems are addressed quickly if a climate and culture of collaboration is in place.

And why did it take a whistleblower to identify that standing water in a food manufacturing facility was a problem?

The FDA also clearly needs to be more nimble, and may need some operational restructuring.

In addition, the non-competitive, inflexible marketplace in infant formula needs to be thoroughly evaluated.

With -- Dr. Califf, with respect to additional resources and staffing, according to a recent letter sent by House Appropriations Chair DeLauro and Representative Bishop during fiscal year 2019, Congress funded 2,179 full-time equivalent positions for ORA, or Office of Regulatory Affairs. But ORA allocated only 785 positions for food safety, compliance, and

inspection staff. At the end of the 2019 calendar year -- and this may have changed, that is what I am asking -- over 100 of those positions were vacant.

So again, why are additional resources needed, at least for staffing, if the FDA hasn't filled the positions it already has funding for?

*Dr. Califf. I think you are asking a good question. I will have to get back with you on the details of the updates of exactly where you are.

And I would emphasize this is a place -- in 21st Century Cures, on the medical side, we got authority to do the hiring for these very technical scientific jobs, which are very difficult to recruit for. It takes us much longer to fill the jobs on the food side, because we don't have the same hiring authorities or the same ability to pay. So we very much need that in order to fill these jobs.

But your question about the specifics of the intersection of the requests we currently have [inaudible].

*Mr. Bucshon. Yes, I appreciate that. I mean, it is very clear that many Federal agencies need to update their technology. I mean, I understand that. And maybe that is where additional resources should be allocated. I just think, from a congressional standpoint, just blanketing the FDA with more money without specific line-item things that need to be addressed is the wrong approach.

The FDA's testimony notes that hard copies of the whistleblower complaint, which were sent to three FDA officials, including Dr. Mayne and Dr. Woodcock, were not forwarded from the FDA mailroom. Literally, we are blaming the mailroom, which could be the case. But we are in the -- we are in 2022 here.

Despite the mailroom issues, according to the FDA's testimony and the timeline, some FDA officials did receive the whistleblower complaint in October 2021, whether it be via email or FedEx. And still Dr. Mayne and Dr. Woodcock did not receive copies of the whistleblower complaint until February 2022 via email.

Again, I think you have answered this, but again, why would it take four months for Dr. Mayne and Dr. Woodcock to receive copies of the whistleblower complaint, when others within the FDA already -- were already in receipt of the complaint? It seems like, to me, this is a process problem here, and not necessarily a funding problem in this area.

*Dr. Califf. This particular issue, as I have stated before, is a significant process issue of escalation criteria within the organization, which we have now fixed. The people did -- were working on the complaint, and they didn't escalate it to the three leaders that you have discussed, who really should have heard about this earlier.

Again, I am not blaming the people, because it was not

standard [inaudible] procedure at the time to do so. But in retrospect, it would have been much better to do it.

There was also --

*Mr. Bucshon. Yes, I mean --

*Dr. Califf. -- [inaudible] in the hard copy area that will be publicly addressed. But it is a technical issue, and we are fixing the mailroom as we go.

*Mr. Bucshon. Is the reason we are waiting for hard copies, is it a privacy issue as it relates to emails that -- or that type of thing? Because in medicine, you know, with HIPAA, a lot of hospitals, a lot of times, won't -- they want you to still fax stuff, because you -- it doesn't go into the -- you know, into the cloud. It is -- and it is gone. Is there a substantial issue there also?

*Dr. Califf. I really don't believe that is the issue in this case. It was just the --

*Mr. Bucshon. Okay.

*Dr. Califf. -- standard procedure was not to escalate. People were working on it, they just didn't let the leaders know.

*Mr. Bucshon. Okay, I appreciate that. And again, I want to say I appreciate you coming to the committee today, and being professional about it, knowing that you were kind of dropped into this situation only a few months ago.

I yield back.

*Dr. Califf. Thank you.

*Ms. DeGette. Thank you. I thank the gentleman. The chair now recognizes Ms. Blunt Rochester for five minutes.

*Ms. Blunt Rochester. Thank you, Madam Chairwoman, for holding this important and timely hearing. And thank you to the panelists for helping us better understand this crisis, specifically what happened, what is being done about it, and how do we prevent this from ever happening again.

My state, Delaware, is among the hardest hit states in this national infant formula shortage, and protecting the health of our nation's children is a responsibility that I take very seriously. As families find empty shelves at the grocery stores -- like Dr. Ruiz, I am particularly concerned about reports indicating that scammers and counterfeiters are trying to take advantage of parents and caregivers' desperation, further putting the health of babies at risk.

Dr. Mayne recognized that FDA is aware of these scams, and gave practical advice on how parents can recognize and avoid counterfeit products.

Commissioner Califf, is FDA coordinating with other agencies, such as the Department of Justice, to end these scams and hold scammers responsible?

*Dr. Califf. We are, yes, as much as we can. But we have very limited resources. And as you correctly note, we don't have our own capability of enforcement. The Justice

Department has to take on the case.

So it is an area -- it is another area perhaps for another day to spend more time on. But with the increasing availability of the internet, this is a big concern. And right now it is especially a concern because you have a history -- melamine from China, for example, historically, that caused a lot of problems. So parents have to be careful.

*Ms. Blunt Rochester. You know, you preempted my next question, which was does the FDA have the resources it needs to effectively coordinate with other Federal and state agencies to combat these scammers and remove the counterfeit formula products from the market?

And even additionally to that, you know, from the resources, do you have the authorities and flexibilities?

And it sounds like something that you would probably have to get back to us on. But specifically, we are looking at what resources do you need to coordinate with these agencies, what funding authorities or flexibilities that would be helpful.

*Dr. Califf. I really appreciate it, and we will get back with you.

I wish everyone could go with me to the mailroom at JFK, for example, to see what comes in that Americans are buying internationally that is quite dangerous.

And we have very limited capabilities right now. We are doing all we can with it.

*Ms. Blunt Rochester. We would love to follow up with you on that.

And also in your testimony you note that "the wide ranging impacts of a recall from a single infant formula manufacturing facility underscores the risks and vulnerabilities in the supply chain when production is consolidated among few major manufacturers utilizing few manufacturing facilities.''

The bipartisan supply chain resilience subtitle of the America COMPETES Act that I am leading would incentivize businesses to diversify their supply chains and prioritizing investments in small and medium-sized manufacturers. How could incentivizing businesses to diversify the infant formula supply chain and increase reliance on small and medium-sized manufacturers enable the industry to better withstand any future disruptions?

*Dr. Califf. As I think you know, I love this question because it is so critical and essential to the future of America.

With digital technologies now there is no reason we can't keep track of supply chain, no matter where they are. And in a world with climate changes and with cyber warfare ongoing all the time, it needs to be the case that, if you

had a critical plant in Michigan, you would have a second plant or a third plant at a distant site, and you would have digital connections among them so the second one could be activated when needed, or might have adjustment of production according to needs.

The case we have in front of us also emphasizes the importance of international supply chain management, because -- and I think it exemplifies that just saying "bring it to America,'' that is not going to fix everything. It is an important part of what we need to do, bring it to America, but we need to have digital control of supply chains on an international basis.

*Ms. Blunt Rochester. Well, I want to thank you for your testimony, and also for the answers that you gave to all of us. You can see this is something that cuts across every -- our parties, every state. It is for the future of our country, and I really appreciate it.

And I am also glad that you bring your private-sector experience to solving these problems, as well. So thank you so much for your testimony.

And Madam Chairwoman, I yield back.

*Ms. DeGette. I thank the gentlelady. The chair now recognizes Mr. Carter for five minutes.

*Mr. Carter. Thank you, Madam Chair, and thank you for allowing me to waive on to this committee, this subcommittee,

and thank all of the panelists for being here, as well.

You know, Commissioner Califf, I am a pharmacist, a health care professional. But even more importantly, I am a father and a grandfather. And we have six grandchildren. They are all over the country in Charlottesville, Virginia; New Orleans; Atlanta. And this really -- this hits home, literally.

I mean, my youngest granddaughter is six months old, and she is on infant formula. We have a family text chain that we send around. And my wife had sent a picture of the infant formula to everyone all across the country, "If you see any of this, buy it, we need it. We need it for Mary Emma.'' That is how real this is, and I know you recognize that. But I just want to drive home the point that this is impacting all of us.

And you know, it just appears that the Administration really didn't pay any attention to this until it hit the media. I mean, this is -- granted that what happened in Michigan with the plant was crippling, but at the same time this has been building up for a while. So I am disappointed in the lag in the time that it took to respond to this.

Now, having said that, I will say that I have always believed that it is never too late to do the right thing. And when the President did invoke the Defense Production Act, that was a good thing. As I understand it, that is going to

speed up the manufacturing of U.S.-made infant formula, and it would require the suppliers to send the necessary resources to the infant formula suppliers before other customers who have requested those.

What specifically -- do you identify those resources, Commissioner, or -- in the Defense Production Act, are those certain resources identified in order to make sure that we have that capacity, and make sure that they are getting to where we need them to be?

[No response.]

*Mr. Carter. You are muted.

*Dr. Califf. Sorry about that. I don't know why it mutes and unmute when I don't touch it.

But anyway, I was going to say you are from Georgia, I am from South Carolina. I appreciate the accent and the chance to wear a seersucker suit coming up in the summer.

But having said that, you are also a pharmacist. You know the complexity of the -- you know, in a formula there are 30 constituents that have to be there in the right amount. So there is constant communication with the manufacturers about what they need.

I would like to ask Dr. Mayne to make a comment about the special issues related to Ukraine, which is an example of the kind of thing that we are having to deal with with infant formula.

*Dr. Mayne. Thank you.

And yes, Congressman Carter, what we've seen is, first, the strain of the COVID-19 pandemic, then the strain of the recall, and now we've got the Russia-Ukraine conflict. And one of the things that we know is the Ukraine region is one of the world's biggest exporters of products like sunflower oil. Sunflower oil is used as an ingredient in many food products, including infant formula.

And so we have been working with the manufacturers, should they be unable to maintain their supply of sunflower oil, what they would replace it with, and make sure that that would meet the nutritional requirements for infant formula. So it has been a constant dialogue with the manufacturers. What do they need, and how can we help make sure that they get what they need to make these products as the utmost priority?

*Mr. Carter. Well, I appreciate knowing that. That is a great explanation, and I accept that explanation. And hopefully, it is going to result in more U.S.-made product as soon as possible because, as I say, this is an immediate problem.

Let me ask you this now. We are not going to inadvertently impact other areas or other production of things that are needed with these products by invoking this Defense Production Act, are we?

*Dr. Califf. Well, I am going to ask Dr. Mayne to also comment again.

But first, let me just say it is entirely possible, which is why it is critical for everyone to realize the complexity of the supply chain group that has been working across government ever since the start of the pandemic. It is what you call the cheap suit phenomenon: you fix one thing, and then the other thing gets out of whack. That has to be looked at.

Dr. Mayne, is there anything that comes to mind about that?

*Dr. Mayne. Yes. And we've considered that. Things like sunflower oil provides essential fatty acids that we need in infant formulas, and we want it to go -- prioritize it there. It is also used in other products like snack foods, as an example, where they could replace other oils that would work, from a technical functional point, but are not there as a sole source of nutrition. So the prioritization is done based upon the nutritional priority of these products.

*Mr. Carter. Okay. Well, thank you very much for your efforts in this.

Madam Chair, again, thank you for allowing me to waive on, and I will yield back.

*Ms. DeGette. Thank you so much, Mr. Carter.

And Mr. Soto, welcome, and thank you for joining us. You are recognized for five minutes.

*Mr. Soto. Thank you so much, Madam Chair. And I apologize about my delay. We are in graduation season back in Florida's 9th congressional district.

The pandemic has wreaked havoc on our supply chains, including infant formula. Consolidation of industries to three or four major formula manufacturers has made our nation vulnerable. Add a recall and closure at Abbott's massive Sturgis plant, and we see a major infant formula shortage in America.

Congress's greatest responsibility is to the health and welfare of our children and families. They are literally the future of our great nation. Congress is responding with action. We passed a law to boost WIC, the program to help source more formula for low-income families. I am thanking -- I thank President Biden for invoking the Defense Production Act to airlift a major shipment of infant formula, multiple shipments, to the United States.

And I appreciate the Republicans' outrage at the hearing today. But where were you when we voted on the 28 million in emergency FDA funding? Thanks to Representative Upton and Representative McKinley for your bipartisan vote to help on our infant formula shortage. The rest of you, sadly, voted no.

We want to all make sure the Sturgis plant is reopened quickly, and that takes more resources. That is why that vote is so critical. The FDA is short-staffed, and this is causing further delay. It is time to work on this in a bipartisan manner, and solve this crisis. And this hearing goes a long way to doing that.

Commissioner Califf, the House just voted on a $28 million emergency FDA funding package. Is the FDA short-staffed in the food safety area, and would this help us along in reopening the Sturgis plant?

*Dr. Califf. The short answer is yes.

And I just want to take this chance also to make a statement about the hardworking employees that have been working on this night and day, weekends, getting very little sleep. Very talented, but there are just not enough of them. And we really do need to increase the staffing.

*Mr. Soto. Well, Commissioner, we are going to put our money where our mouth is. We are going to make sure to work with the Senate to get you additional funding, to make sure that we have that -- those extra resources to get that plan up and running again safely and efficiently.

We are also going into a conference on the America COMPETES Act, where we are looking at a whole host of items that are critical to national security and helping with our supply chain, boosting domestic production of critical goods

for our national security, for our families. Medicines are part of that negotiation. Would diversifying our infant formula manufacturing through the America COMPETES Act help prevent shortages like this in the future?

*Dr. Califf. Absolutely. I am privileged to be a member of the National Academy of Medicine, and served on the Supply Chain Resilience Committee. I had to resign when I was nominated for commissioner. That report, if you read it, gives every bit of the case that you need that we must diversify, not just in the U.S., but also in our international efforts. And we need to link it with digital technology to make sure that we can get the right products to the right place at the right time.

*Mr. Soto. And would this additional funding help with that modernization that you are talking about?

*Dr. Califf. Absolutely. Yes, sir.

*Mr. Soto. Thank you so much, Commissioner Califf.

And I yield back.

*Ms. DeGette. I thank the gentleman. Now the questioning has ended for this panel, but I would defer to the ranking member if he has a last question or so.

I don't know if you have any, Morgan.

*Mr. Griffith. Yes, ma'am, I do. I just --

*Ms. DeGette. You are recognized.

*Mr. Griffith. -- a comment. Thank you.

It was interesting that my colleague, Mr. Soto, just referenced that some of us did not vote for the money last week to send to the FDA, and the FDA has indicated today they need money. But Chairwoman of Appropriations DeLauro also has sent a letter saying that, while Congress funded 2,179 food -- full-time equivalent positions for ORA, the ORA only allocated 785 positions for food safety, compliance, and inspection staff. So I think it is a discussion we need to have. I am not saying I am totally against it, but I would just remind everybody that sometimes it is good to have these hearings so we can figure out what we do need. But what we don't need is just automatically saying there is a problem, let's throw money at it. And that would be my position.

Now, that being said, I would like to ask Commissioner Califf. We know that there is one infant formula product that you all have approved and enforcement discretion on so that we can bring it in from the UK, a foreign product, infant formula. How many other enforcement discretion requests are there for infant formula currently pending with the FDA?

*Dr. Califf. This has been a tremendous response. So I will turn to Dr. Mayne, who I think has the latest data.

*Dr. Mayne. Yes, thank you. Since we announced the flexibilities, the regulatory flexibilities, we also held a webinar with industry. Over 700 attended our webinar, where

we explained the data and the information that we were seeking, and we asked for people to apply if they had product available that they thought would meet our safety and nutritional standards. As of last night, we have 26 different people who have applied through our portal. As you heard yesterday, one of those was approved.

*Mr. Griffith. Thank you.

And I yield back, Madam Chair.

*Ms. DeGette. I thank the gentleman. I just have one final question. And Dr. Califf or Dr. Mayne, you might be able to answer this.

But what -- everybody talked about this issue, about the bacterial strains that were found in the infants that were sick and the ones that died didn't necessarily match the strains that were found in the two inspections of the Abbott facility. But I want to make sure that we don't leave anybody with the impression that that makes -- that that means that there was no contamination at the facility, or that there is no problem.

Can you talk again, Dr. Califf or whoever, about the problems that were found, and why it was necessary to take the actions the FDA did?

*Dr. Califf. Sure. First, as we said before, the absence of being able to prove that there was a connection doesn't mean that there was no connection. We just can't

rule it in, nor can we rule it out. And of course, when you make a conclusion there is a connection, that is a major thing, and you have to have the evidence, and we don't. But that is totally -- that clued us in to what needed to be done, and we went to the plant.

I mean, I have thought about it. Let's say you had a next door neighbor who had leaks in the roof. They didn't wash their hands. They had bacteria growing all over the kitchen. You walked in, and there was standing water on the counters and the floor, and the kids were walking through with mud on their shoes, and no one cleaning it up. You probably wouldn't want your infant eating in that kitchen. And that is, in essence, what the inspection showed.

I want to emphasize, again, I think Abbott is on the way. I think they are working very hard. This is not emblematic of the Abbott that I have known as a cardiologist. So I am optimistic, as Mr. Upton said, that we are going to get over this. The people who work in that plant I know are hardworking people, and we are not meaning to castigate them. But these are just the facts that we saw.

*Ms. DeGette. Thank you. Thank you so much, Commissioner. Thanks to you and your team, to all the members. We appreciate it.

We do have a second panel today. And so the chair will announce that we are going to take a very short break for 10

minutes, and we will reconvene at 2:05 p.m. Eastern Time. Thank you very much.

[Recess.]

*Ms. DeGette. The chair calls the committee back to order, and welcomes our next panel.

I would now like to introduce the members of the next panel for today's hearing: Christopher Calamari, president, U.S. and Canada nutrition, and senior vice president of Abbott; Scott Fitz, vice president, technical and production, Gerber Products Company; Robert Cleveland, senior vice president, nutrition, North America and Europe, of Reckitt.

I want to thank you all again for appearing in our hearing today.

And I know you are all under -- aware that the committee is holding an investigative hearing. And when we do so, we have a practice of taking testimony under oath. Do you have any objections to testifying under oath?

Let the record reflect that the witnesses have responded no.

The chair then advises you that, under the rules of the House and rules of the Committee, you are entitled to be accompanied by counsel. Do you desire to be accompanied by counsel during your testimony today?

Let the record reflect that the witnesses have responded no.

So if you can, gentlemen, please raise your right hand so you may be sworn in.

[Witnesses sworn.]

*Ms. DeGette. Let the record reflect the witnesses have responded affirmatively.

And now you are all under oath, and subject to the penalties that are set forth in title 18, section 1001 of the U.S. Code.

At this time, the chair will recognize each of our witnesses for five minutes to provide their opening statement.

Before you begin, I would like you to be aware, in case you have never done Webex before, which I find hard to believe, but there is a timer on your screen that will count down your remaining time.

And so I will now recognize you. Mr. Calamari, you are recognized for five minutes.

TESTIMONY OF CHRISTOPHER J. CALAMARI, PRESIDENT, U.S. AND CANADA NUTRITION, SENIOR VICE PRESIDENT, ABBOTT; SCOTT FITZ, VICE PRESIDENT, TECHNICAL AND PRODUCTION, GERBER PRODUCTS COMPANY; AND ROBERT CLEVELAND, SENIOR VICE PRESIDENT, NUTRITION, NORTH AMERICA AND EUROPE, RECKITT

TESTIMONY OF CHRISTOPHER J. CALAMARI

*Mr. Calamari. Thank you, Chairs DeGette and Pallone, Ranking Members Griffith and McMorris Rodgers, members of the subcommittee. My name is Chris Calamari, and I lead Abbott's U.S. nutrition business.

The current infant formula shortage is heartbreaking. On behalf of everyone at Abbott, I want to express our extraordinary disappointment about the shortage. We are deeply, deeply sorry, and we are committed to ensuring that this never happens again. Safety comes first, and the recall and shutdown were necessary steps to ensure that our formula supply was safe. But both steps have worsened the current shortage. It will take more time, but we want to assure you that we are doing everything we can to get more supply onto shelves for families.

Since issuing the recall and shutting down Sturgis, we've taken aggressive action to boost supply.

First, we have reworked our global network to create

additional capacity in the U.S. market. We've airlifted millions of cans of infant formula powder into the U.S. from our FDA-registered facility in Ireland. We are now up to nearly 50 flights per week coming in to 12 major airports across the country. Those flights will continue as long as necessary.

Second, we have converted other Abbott liquid manufacturing lines to make Similac liquid that is ready to feed.

Third, we are running our other U.S. manufacturing facilities in Ohio, Arizona, and Virginia 24/7 to help replenish supply in the market.

Fourth, we've been working with USDA and WIC agencies to ensure that WIC participants will continue to be able to obtain formula free of charge.

And fifth, for babies with specialized needs, we are releasing metabolic formulas previously on hold, and working with other manufacturers to address demand.

We are also taking steps to address the issues arising from shortages of EleCare, a specialized formula for children that cannot digest other formulas and milk. We are in the process of releasing an additional 300,000 cans of EleCare to individuals needing urgent, life-sustaining supplies.

We are also establishing a $5 million fund to help families in need with medical and living expenses. By the

end of June, we expect we will be supplying more formula to Americans than we were in January, before the recall.

As we do the hard work to increase supply, we've been truly inspired by our employees across the country who have done everything they can to get formulas into parents' hands. Employees like sales representatives Kathy, Tolanda, and Alex, who each made long drives to deliver formula to those in need, or Director of Customer Service Operations Lee, who arranged to have formula delivered same day to Alaska so that it could be air-shipped to families of active duty service members in remote parts of the state.

But at Abbott we know that this is not about us, it is about you. You either don't have the product you need or are having trouble getting it. We understand the difficult position you are in. We know we let you down. And we are going to do everything we can to re-earn your trust.

We are also working closely with our regulators to restart production at Sturgis, which will further increase our manufacturing capacity by 40 percent.

As I said earlier, safety comes first. At Sturgis we regularly take samples across our operations to ensure the facility and the product we produce is safe. And we regularly test our formula before, during, and after the production process, exceeding regulatory requirements.

We will also continue to look for new ways to improve,

because operating a clean and safe plant is a job that requires constant vigilance.

We plan to start production at Sturgis the first week of June. We will begin with the production of EleCare before turning to the production of other formulas and Similac. From restart we estimate that it will take six to eight weeks before product is available on shelves.

We are also going to learn from this. Current supply chains are simply not resilient enough. We have been a leader supplying food to families for over 50 years, and we are determined to make sure that this never happens again. This means we will expand both capacity and redundancy.

In closing, I want to assure you that we will not rest until we can fully meet the needs of the millions of families that depend on our products.

Thank you, and I look forward to your questions.

[The prepared statement of Mr. Calamari follows:]

**********COMMITTEE INSERT**********

*Ms. DeGette. Thank you, Mr. Calamari.

Mr. Fitz, you are now recognized for five minutes.

TESTIMONY OF SCOTT FITZ

*Mr. Fitz. Thank you. Chairwoman DeGette, Ranking Member Griffith, Chairman Pallone, Ranking Member McMorris Rodgers, and the distinguished members of the subcommittee, thank you for the opportunity to testify before you today.

Since 2018 I have served as vice president of technical and production at Gerber Products Company, and I appreciate the opportunity to discuss Gerber's efforts to address the current infant formula shortage.

At Gerber our mission is anything for baby, and that promise has driven our business for generations. As a father, I can only imagine the anxiety felt by parents who need formula for their children right now. While Gerber is a small manufacturer in the U.S. infant formula market at about an eight percent market share, we are working tirelessly to help parents and caregivers get the formula that they need.

For 90 years the quality and safety of our products and the well-being of infants and young children have always been top priorities for Gerber. We have stringent controls in place at all levels of production, and our infant formulas undergo hundreds of quality and safety checks. Our standards are among the strictest in the world, and many of our measures exceed FDA requirements.

Like most industries, the infant formula industry is not

immune to global supply chain challenges related to the COVID-19 pandemic. Given our high safety and quality standards, the highly-regulated nature of this industry, adding new suppliers or changing ingredients or changing packaging materials is a rigorous and time-intensive process.

We have also faced constraints related to availability of labor and transportation for product distribution. These challenges were exacerbated by the recent recall in the infant formula space.

We recognize the gravity of the current shortage, and have taken decisive actions to respond.

First, we have increased production of infant formula. Our factories run 24/7 to produce formula as efficiently as possible, while maintaining our high safety standards. We are prioritizing the manufacture of products that are most in demand, as well as specialty formulas that have been in critically short supply.

Second, we have significantly increased formula available to consumers and hospitals. We have accelerated e-commerce availability, we are air freighting product produced in other countries, and we are releasing our reserve inventory to get more product to consumers. As a result, we increased availability of our infant formula in the market by roughly 50 percent in March and April.

We know more must be done. We believe the steps Gerber

has taken over the past several months have made a real difference. In the past week we partnered with the Biden Administration on Operation Fly Formula, which will expedite the import of the equivalent of 1.5 million bottles of our specialty hypoallergenic formulas. The first of these shipments arrived in Indiana on Sunday, and is being distributed to hospitals. The second shipment arrived in the U.S. today, and is being transported to Allentown, Pennsylvania.

Third, we are providing essential information about infant formula to parents and caregivers. Our Parent Resource Center has baby-feeding experts available 24/7 to address questions and concerns.

Finally, we are working with our WIC state partners to help ensure sufficient supply. While Gerber is a small player in this space, we are proud to serve our WIC states.

Although we have taken many important steps, more work remains to be done.

We appreciate the efforts taken by the FDA to date. We welcome the temporary flexibility regarding the import of certain infant formulas, and we are actively pursuing opportunities to import more formula. As of today we have filed two requests with the FDA to import formula produced at our facilities outside the U.S.

We believe FDA should also have the authority to provide

greater transparency on the anticipated impact of a recall when critical products are involved, so that companies like Gerber can respond more quickly to help fill the gaps.

And the FDA must also have appropriate resources to review routine notifications from manufacturers.

For the past 90 years, our mission has been anything for baby. And we look forward to continuing to work with all necessary parties to ensure that all families are able to feed their little ones.

Thank you, and I look forward to your questions.

[The prepared statement of Mr. Fitz follows:]

**********COMMITTEE INSERT**********

*Ms. DeGette. Thank you, Mr. Fitz.

And Mr. Cleveland, you are now recognized for five minutes.

TESTIMONY OF ROBERT CLEVELAND

*Mr. Cleveland. Chair DeGette, Ranking Member Griffith, and distinguished members of the subcommittee, thank you for the invitation to appear before you. It is an honor to be here to discuss our efforts to address the urgent infant formula shortage in the United States today.

My name is Robert Cleveland, and I am the senior vice president for the nutrition business unit covering North America and Europe at Mead Johnson Nutrition.

Mead Johnson was founded in the United States in 1905 as a premiere producer of pediatric nutrition, and we now produce infant and specialty formulas under well-known brands such as Enfamil and Nutramigen. Our major manufacturing facilities are in northern Michigan and southern Indiana, where we employ over 1,200 people.

At Mead Johnson we recognize that the formula shortage is a very serious issue. And as a father, I understand that nothing is more important than the ability to feed and nurture one's children. That is why we are working around the clock and coordinating closely with the Federal Government to do whatever is possible to address the shortage. I am immensely proud of the extraordinary people at my team whose efforts have succeeded in increasing Mead Johnson's supply of infant formula by more than 30 percent

compared to this time last year.

In response to the shortage, we have all hands on deck working around the clock to get products to families who need it. The steps we are taking include the following.

We have added shifts and unlocked unlimited overtime in our plants to run 24/7.

We have cut our time to market almost in half by having trucks ready to load the minute we roll products out of our facilities.

And we are working with our retail partners to ensure that when those trucks arrive, they are the first at the distribution centers to ensure that the product gets to shelf quickly. Because it is not just about more, it is about how fast can we get it to shelf.

And we are simplifying our supply chain by reducing the number of different products we make, focusing on those sizes and formats that allow us to get the most products out in the fastest time.

We are taking all of these measures while keeping a close eye on quality and safety to ensure that we always meet the near pharmaceutical grade safety requirements that apply to infant formula production. We will take no shortcuts.

We have also been working closely with the Federal Government to take every step we can to end this shortage as quickly as possible. Earlier this month Mead Johnson and

other infant formula manufacturers met with President Biden, after which the Administration invoked the Defense Production Act to help address manufacturing supply shortages, and implemented Operation Fly Formula, which directs the use of military aircraft to import formula from overseas.

We are also working with the FDA to explore ways to expedite review and approval of some of our infant formulas manufactured at our facility in Delicias, Mexico. And we are working with the FDA on imports from our facility in Singapore.

And finally, we are working with the Department of Agriculture to make regulatory and administrative adjustments to the Women, Infant, and Children, or WIC, program, which will better position that program to provide WIC participants the nutrition they need, and to ensure that WIC mothers do not bear the brunt of this shortage.

We also applaud the efforts of Congress to consider a variety of legislative changes to prevent such a shortage from ever happening again. We will be happy to work with you in all of those efforts.

In conclusion, thank you to the subcommittee for the opportunity to speak with you today about how we can best meet the needs of families who rely on formula to feed our children. We are intensely focused on resolving the shortage as quickly and safely as possible. Thank you.

[The prepared statement of Mr. Cleveland follows:]

**********COMMITTEE INSERT**********

*Ms. DeGette. Thank you so much, Mr. Cleveland.

It is now time for members to ask questions, and I will remind everybody to mute yourself if you are not asking questions to prevent feedback. And the chair will now recognize herself for five minutes.

Mr. Calamari, I want to say that I appreciate that Abbott has taken ownership of the role that the company's -- the company -- or that the company played in parents being unable to find the nutrition that their babies need. And I do also appreciate you saying that you are doing everything you can to get this facility back up and going, and to get production going.

But what struck me when Commissioner Califf was testifying, Abbott does have a great reputation among Members of Congress and the Administration, particularly in the drug and device arena. I just can't understand why this factory in Michigan had such substandard health conditions when it was inspected in January. And I am wondering if -- as well as all of the things you talked about that the company is doing to try to get formula out for families, what new provisions have -- and protocols has the company put into effect to ensure that we don't get into a situation like this again, where a major production facility has to be closed down?

*Mr. Calamari. Chair DeGette, thank you for the

question.

I was at Sturgis last week, and I can tell you the staff there, the team there, they make formula as if it were for their own families. And they -- after the FDA identified observations where we needed to improve, and we are -- we needed to address, the teams have been actively working on taking steps to address those issues.

*Ms. DeGette. Mr. Calamari, maybe you don't understand what I am asking. I know you are trying to clean it up and get it back open, but what additional protocols are you putting in place so that we don't have this happen again?

*Mr. Calamari. Absolutely. So for the 483, it did identify clear observations which we needed to address. So some of those key areas that we are improving are including in the installation of non-porous flooring; where information of -- improvements across different processes and traffic patterns within the plant; additional training of employees to address some of the observations that were identified.

So our improvements range from the physical to the process, and all throughout the facility.

*Ms. DeGette. And are you institutionalizing that for the future, not just to remedy these deficiencies?

*Mr. Calamari. Yes, I --

*Ms. DeGette. Okay.

*Mr. Calamari. Chair DeGette, yes, we are.

*Ms. DeGette. Okay, great. Maybe you can supplement your answer on that.

I want to ask you, Mr. Fitz, in your testimony you said, "More needs to be done. Much more needs to be done to ensure every baby can get the formula he or she needs now and in the future.'' And obviously, we all agree with that. So what steps can Gerber take to be a part of the future solution to make sure that we never have something like this happen again if, say, one of the manufacturers shuts down a key plant?

*Mr. Fitz. Yes, thank you for the question, Chairwoman. Certainly, again, we are a small player in the U.S. market, so an eight percent market share. So our ability to respond to a gap in the marketplace like this is pretty limited.

But we appreciate the steps the FDA is taking for temporary flexibility in importing products so that we can tap into Nestle's global network and global capacity. We appreciate the steps that we are going through with Operation Fly Formula, where we are importing quickly supplies of the desperately-needed specialty products that we manufacture outside the United States.

*Ms. DeGette. Okay, and Mr. Cleveland, I guess I am going to ask you the same thing, but what is your company doing to make sure that we can more nimbly respond to any crisis in the future?

*Mr. Cleveland. Well prior to this -- it is a great

question, and it is a very legitimate concern.

And so prior, just prior to the recall, we had already filed to bring our Delicias, Mexico facility under the oversight of the FDA, so that it can produce a product sustainably for the United States market, as well. And we are working with the FDA now to address that more urgently to create that backup, or that additional supply for the U.S. market.

And then, of course, we will be learning from this experience, and building contingency plans with our other facilities so, should an event like this ever happen again, we can respond even more quickly and better than we are today.

*Ms. DeGette. Thank you. I will just say, gentlemen, I appreciate your commitment to rectifying this as quickly as possible, because it is small solace to my constituents, who are driving around for three or four hours to try to find formula. The quicker we can get that to those babies, the better it is going to be.

With that, I am pleased to recognize the ranking member for five minutes.

*Mr. Griffith. Thank you, Madam Chair, and thank all the witnesses for being here.

Mr. Calamari, I think you are a good guy in a bad spot, but I am going to ask you some tough questions.

So here is the deal. I think you got more than a porous floor problem, or a roof problem at Sturgis. When you look at the FDA reports over the years, and you see similar problems occurring, and then you read the whistleblower report, which says that members of your team at Sturgis were hiding information from your office, from the home office, that could lead to some of the problems that the FDA has mentioned in their testimony and that you know about, it seems to me that you have a culture problem.

What steps are you taking to change that culture, and have any heads rolled?

*Mr. Calamari. So, Representative, thank you for the questions. I think there are a couple pieces there.

First, on the culture problem, I don't think it is a problem. I think -- we were there last week. And I saw generations of employees who worked -- who work in Sturgis with pride, who feed their own families. And they are committed to making steps to improve. And we are making those steps to address in the plant, physically, processes.

[Inaudible] the observations. We are working rigorously to address them. I think the team's commitment and passion to quickly address them is there.

And Representative, we are going to learn from this. We are going to get better as a result of this. The pride we have feeding families for decades, this has been an

opportunity to improve, and we are going to do so.

*Mr. Griffith. Well, and I understand you are trying to put the best --

[Audio malfunction.]

*Mr. Griffith. -- in my district last week, and I was very pleased when they said to me, "You got to put on these shoe covers.'' I had not been with muddy feet climbing on the roof.

But the FDA commissioner said that is what they found, that your folks didn't seem to think that was a problem at the Sturgis plant, when they had roofers on the roof working around, and then they walked through the food production section with mud on their feet. And so, even if a whistleblower is wrong, and they weren't hiding stuff from you, when you see things like not inspecting the cans at the proper time, and when there is food in the seams -- could be getting in the seams later, causing a bacterial problem, and you see muddy feet walking through, it doesn't take a food scientist to figure out you don't want going through a facility like that somebody who has got muddy feet and just came off the roof.

So I beg to differ. I think you do have a problem, but I hope you will address it. Can you at least give me a commitment that, if you see any signs of that happening in the future, that you yourself will put eyes on that problem,

and try to rectify it more quickly? Because this was going on for years at Sturgis, apparently.

*Mr. Calamari. Representative, yes. Yes, we will.

*Mr. Griffith. All right. I appreciate that.

To all the witnesses, when did you first start to see signs of infant formula supply chain issues?

[Pause.]

*Mr. Griffith. Somebody has got to go first.

Mr. Calamari, you go first, and then we will go to Mr. Fitz.

*Mr. Calamari. So we first started seeing increased demand for products really coming out of the COVID time period. And there weren't more births, there weren't increases in formula feeding rates. We saw households buying more, and that would have been coming out against -- coming out of COVID timeframe.

*Mr. Griffith. All right. Is that the same for you, Mr. Fitz?

*Mr. Fitz. Certainly related to this current issue we became aware of the recall at the same time the general population and the media did. FDA contacted us. I don't know if it was the next day or within the next week about the situation, and so we increased our production and increased our --

*Mr. Griffith. Next day or next week, what is the

timeframe on that?

*Mr. Fitz. Sorry?

*Mr. Griffith. You said about the same time. One was coming out of COVID, the other was, you said, at about the same time, and then you got contacted by the FDA. When was that?

*Mr. Fitz. After the public announcement of the Abbott recall.

*Mr. Griffith. So, okay, some time in late February or early March.

Mr. Cleveland?

*Mr. Cleveland. Yes, sir. We had seen an increase in demand roughly from the middle of last year that was probably attributed to many shortages in consumer packaged goods at that time, and consumers rightly concerned, and making sure they had enough infant formula. But certainly the moment in time we are talking about right now began immediately after the recall and -- on February 18th.

*Mr. Griffith. And Mr. Cleveland, was that the first time you had heard from the FDA about supply chain issues?

*Mr. Cleveland. The FDA reached out to us immediately after the recall, and began speaking to us about issues that could be related to it. Yes, sir.

*Mr. Griffith. And if you might give me discretion, Madam Chair -- but had you heard from the FDA before that on

a regular basis?

*Mr. Cleveland. Sir, we are always in contact with the FDA. We are --

*Mr. Griffith. On supplies.

*Mr. Cleveland. -- [inaudible] industry with many discussions.

*Mr. Griffith. I understand, but were they talking to you about supply chain prior to that?

*Mr. Cleveland. We hadn't been in extensive conversations about supply chain before that, no.

*Mr. Griffith. Thank you very much.

I yield back, Madam Chair. Thank you for your discretion.

*Ms. DeGette. Thank you. The chair now recognizes Chairman Pallone for five minutes.

*The Chairman. Thank you, Chairwoman DeGette.

Gentleman, I have to be honest. If I were listening to this, to your comments, I wouldn't be very happy right now if I was looking for baby formula, because all I heard Mr. Calamari say is we are going to get the plant up by June 1st, and within six and eight weeks, you know, we will be able to supply more.

Well, you know, I -- we need to do something to get this stuff out now. In other words, you know, my constituents don't want to wait six to eight weeks, if that is what I

heard.

And then, of course, I heard Mr. Gerber say, well, you know, don't worry too much, because we are flying in stuff from abroad. And I know that the Biden Administration is doing a lot with the Defense Production Act and this operation that they have going.

But what I don't understand is -- to Mr. Calamari, is there anything you can do to speed this up, or do you have stuff that can come from abroad?

And then I will ask Mr. Fitz, you know, what does this mean with this stuff coming in -- working with the Administration? Can we expect to get to normal in less than six to eight weeks? And how are you getting the word out to people, so that they know that it is available?

So let's start with Mr. Calamari. Is there anything you can do to speed up the six to eight weeks, or can you do anything that you have supply from abroad? You know, quickly, because I want to get to Mr. Fitz.

*Mr. Calamari. Chair Pallone, absolutely. We are taking many actions beyond Sturgis reopening. We are daily getting six to eight flights from Cootehill, Ireland, our FDA facility, and we will be delivering millions of cans in the weeks to come.

We are also --

*The Chairman. All right. So, how is that -- how

quickly can we expect to be getting back to normal then between that and Sturgis?

*Mr. Calamari. So by the end of June we will deliver more product in June than we did in January, before the recall. And from there we are going to continue to sustain those efforts to make sure we consistently --

*The Chairman. It sounds like it is still another month, and I am not happy with that. I wish there was some way you could do better.

Mr. Fitz, same thing. You are taking stuff from abroad, you are trying to increase production. We are still talking the end of June?

*Mr. Fitz. Respectfully, Congressman, we are a small player in the U.S. market, and our capacity is aligned to that. So the exceptional measures that FDA is taking to allow us to tap into the global Nestle network is a big step for us. With these additional filings that we've made we now have access to more of the global Nestle network, and are working to quickly replenish supply.

But we can't fill the gap left by a much bigger competitor here in the U.S., because our capacity is just not aligned --

*The Chairman. Well, is there anything more that the Administration can do or you can do collectively to move up this deadline so people get this stuff quicker?

I will go to the last speaker, if you will. Mr. Cleveland. Is there anything that can be done collectively, or with our help that would speed this up so we -- it doesn't take another month or over to get to a norm, to the -- to normalcy?

*Mr. Cleveland. Well, frankly, sir we are moving as -- and your concerns are absolutely merited with the shelves looking the way they are. We are moving as fast as we can, as well. And we expect to be able to take advantage of the FDA's import exception very, very soon to bring product in from our facility in Singapore, especially. And we think that will make a dent within the market within the month of June.

And the Defense Procurement Act is helping us -- or Production Act, excuse me -- is helping us to secure valuable inputs that should increase our supply in June, as well. But realistically, it will take some weeks for that to be felt at the shelf in a significant way.

*The Chairman. And what about -- how are you going to get the word out that this is available? I asked this same question to the FDA administrator. I am always worried that people aren't going to know where to go, how to get this stuff. Anybody want to take a crack at that?

[No response.]

*The Chairman. Mr. Calamari?

*Mr. Calamari. Chair Pallone, we have a variety of resources. We have formula finding on our websites. We have 1-800 numbers. We are also arming our sales representatives with information to help guide parents and families to where there might be product. And we are continuing to update that information --

*The Chairman. All right. Well, I know my time is running out. But through you, Madam Chair, I would like each of these gentlemen to get back to us about how they are getting the word out as this stuff comes back online, because I am very much afraid that people are not going to know how to get it. So if, through you, Madam Chair, I could ask each of them to get back to us with that information of what they are doing. Thank you.

*Ms. DeGette. We will ask the witnesses to supplement their statements with that. Thank you.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. DeGette. The chair will now recognize the ranking member of the full committee, Mrs. McMorris Rodgers, for five minutes.

*Mrs. Rodgers. Thank you, Madam Chair. According to the Washington Post editorial by Robert Ford, CEO of Abbott, "The FDA's investigation did discover a bacteria in our plant that we will not tolerate.’‘

Mr. Calamari, what is Abbott's understanding as to why a bacteria was discovered in the Sturgis plant?

*Mr. Calamari. Representative, thank you for the question. So the bacteria in question was found in a part of the facility that is not in contact with product, which is absolutely not acceptable, to be clear. And we have taken action to make sure we put processes and training in place so that that does not happen.

I will say that the bacteria infection in question is commonly occurring, and part of our process is to test that to make sure we catch it before it gets distributed to product.

*Mrs. Rodgers. Thank you. Does Abbott agree with the government's view that there were persistent problems at the Sturgis plant, and that Abbott failed to take sustainable corrective action?

*Mr. Calamari. Representative, what I can tell you is we have a decade of reviews and inspections at that -- at the

Sturgis facility. And in 2019, when there was an observation, we quickly addressed it. In 2021, we've taken action to address them, those observations.

So we value our relationship with our regulators. We have a safety-first, and we prioritize compliance, and we want to make sure we continue to invest in those processes going forward to come out of this even stronger.

*Mrs. Rodgers. Well, how can you give us confidence that Abbott is going to address the underlying causes of continued compliance problems?

*Mr. Calamari. Representative, I was there last week. And we, as a leadership team, are fully committed, all resources against it. We are aligned as leaders to make sure we put the necessary steps and sustained actions in place so that this doesn't happen again.

*Mrs. Rodgers. When was your company first contacted by the White House about the emergency response to the shortage problem?

*Mr. Calamari. Representative, so we've been working on -- more recently with the White House, coming out of the recent announcements President Biden has made. But we've been working on trying to get back to supply, and we've been working on our action plan from the moment in February and before, when we became aware that we were going to need to get more capacity online.

*Mrs. Rodgers. So you have been working on addressing these issues since February to get back online?

*Mr. Calamari. So we've been working on a variety of actions. We've been airlifting our product from Cootehill, Ireland. That's something we've always done, and we've increased the amounts of doing so.

In February and March, when we became aware of the recall, that's when we started making the necessary steps to convert our adult manufacturing lines to liquid. So we've been acting on this in a variety of workstreams to make sure we can get as much product available as possible as soon as possible.

*Mrs. Rodgers. So what is the difference between what you started doing in February versus where we are today, and the consent decree and what you are going to be able to accomplish in the next two weeks?

*Mr. Calamari. I think the big piece with the consent decree does -- it allows us to go forward with Sturgis with an aligned set of principles that we can work with FDA, and make sure we are producing in an aligned fashion. That is the big step forward, because that will increase our capacity versus the previous actions by an additional 40 percent.

*Mrs. Rodgers. So how does that differ from the actions that you were taking in February versus what is in the consent decree?

*Mr. Calamari. The actions in February, we were working -- we have a variety of manufacturing facilities, so we were working on increasing supply in non-Sturgis-related facilities. The consent decree is very specific to the Sturgis facility, and allows us to act in an aligned fashion in production going forward.

*Mrs. Rodgers. Were -- have you been -- since February have you been taking action in Sturgis to address the concerns that have been raised around bacteria in the plant?

*Mr. Calamari. Yes, we have. We've been taking a variety of actions to improve the plant's capabilities and its infrastructure. And we've taken action from the get-go.

*Mrs. Rodgers. But you haven't been able to satisfy the FDA yet?

*Mr. Calamari. I think the -- with the consent decree, we are now in an aligned position to move forward.

*Mrs. Rodgers. I am just trying to understand how we are going to be able to accomplish this in a two-week period, when over months, it sounds like, the company has been attempting to address the bacteria that was that was found.

*Mr. Calamari. So Representative, what we've done is we've made a variety of updates to the plant. And now we are in the stages -- it is a 700,000-square-foot facility. So now we are cleaning, testing, validating to make sure every process step is in place, every quality check is in place to

make sure, when we get up and running, we could do so in a sustained fashion.

*Mrs. Rodgers. Okay. Well, thank you.

Thank you, Madam Chair, for holding this hearing today. It is very important that we get -- address this crisis. I appreciate the chance to ask the question. Thank you.

*Ms. DeGette. Thank you so much.

Ms. Kuster, you are recognized for five minutes.

*Ms. Kuster. Thank you so much, Madam Chair. I am grateful for this hearing, and for these -- this second panel of witnesses.

Here in the Granite State, in New Hampshire, families are -- and families all across the country -- are scrambling for baby formula, driving miles across state lines, forming local donation pools, even falling victim to scams and counterfeit products out of desperation.

And while Abbott bears responsibility for why its product recalls were necessary at all -- and, by the way, we are all shocked to hear about the conditions in the Sturgis plant -- it was ultimately the safe thing to do, to recall the product to ensure the health and well-being of infants across this country.

Now, however, it is going to take an industry-wide dedication to increase production so retailers can keep shelves stocked for desperate families.

Mr. Fitz, your testimony states that Gerber recognizes "the gravity of the current shortage, and the impact it is having on families and babies across the country.'' When specifically did Gerber understand that American consumers would experience an infant formula shortage, and how soon thereafter were you able to escalate production efforts at Gerber?

*Mr. Fitz. Thank you for the question, Congresswoman. Certainly, the -- we at Gerber, many of us are parents, and that has been our inspiration. And I am proud of the way we have risen to the challenge being, again, in the U.S., a small supplier, to attempt to fill the void.

So we became aware, as I mentioned in my earlier testimony, when FDA notified us that there was a recall at Abbott, but we had no visibility to the scale or the extent of the outage.

What we did do is, during the immediate months following in March and April, supply an additional 50 percent of product, or release an additional 50 percent of product to the market, which is substantial for us. And we are continuing to increase our production as much as possible to support the current need.

*Ms. Kuster. Thank you. Would it change your business plans generally, overall -- and this is hypothetical, but I think it is something we need to consider -- if the WIC --

Women, Infants, and Children -- formula was not sole source, but if you could participate in that program, would that make a difference in your business model?

*Mr. Fitz. Well, I can tell you, as, again, a small player in the U.S. market, it is difficult for us to compete against two larger competitors.

*Ms. Kuster. And if you had a larger potential market, would you see growth in Gerber production of baby formula?

*Mr. Fitz. Well, as you are probably aware, Nestle is a large manufacturer of infant formula, globally. And if we saw the market opportunity here, I am sure we would invest to satisfy that need, opportunity.

*Ms. Kuster. Thank you. The Biden Administration has announced multiple measures to help expedite supply chain solutions to get manufacturers the raw materials needed to get products to market.

According to your testimony, Mr. Cleveland, Reckitt has been working with the Administration at all levels. How specifically has Reckitt been working with the FDA and the White House to get products to families faster?

And have these joint efforts been effective to date?

*Mr. Cleveland. Well, thank you for the question, and the answer is yes, they have. The White House has been a strong partner since the time we spoke to them. We have been -- they have been helping us work on input issues we've been

having. We've started to have some real victories there. We are starting to see some inputs where we had struggled, and some of those are freed up and now headed to our plants. And that is really what is going to be needed to ensure we can run those at full capacity. And if we can do that, we know we can supply more to the market than we are even today.

*Ms. Kuster. And I would ask you a similar question. If you knew that you had an opportunity to participate in the Women, Infant, and Children program, would that make a difference in your business model going forward?

*Mr. Cleveland. We are an active participant in the WIC program today. We've been supporting it for many years. It is a good program. It was challenged during this period of time, due to the shortage. And the USDA, we've worked with them to make changes to make it more flexible, and so that formula is more available to those participants because they are the most vulnerable, and they are our top concern. And we've made a lot of progress in that area, as well.

*Ms. Kuster. Great, thank you. And finally, American families need to rest assured that companies are not cutting corners on safety as they ramp up production. So back to you, Mr. Cleveland. What is Reckitt doing to make sure that your own facilities and products maintain high quality and safety for American infants as your company expedites its production schedule?

*Mr. Cleveland. Well, this is -- it is near pharmaceutical grade manufacturing. Infant formula is a -- it is a sole source of nutrition for a very vulnerable population. Safety must be first. While we have definitely ramped up our production as much as we can, we are taking no shortcuts for safety. We can't.

*Ms. Kuster. Thank you.

*Mr. Cleveland. And now, especially. So no, we are -- this is our number-one concern.

*Ms. Kuster. Thank you, Madam Chair. I yield back.

*Ms. DeGette. Thank you so much.

Mr. Burgess, you are now recognized for five minutes.

*Mr. Burgess. I thank the chair.

Mr. Calamari, let me ask you. According to Dr. Califf's testimony, an infant got sick with cronobacter. The powdered formula was identified as a nutritional source. And so the FDA notified Abbott the third week in September. Is that correct?

*Mr. Calamari. So, yes, there was a report of an infant illness in September. Yes.

*Mr. Burgess. And then the -- well, let me just ask you. Did that set off a series of investigations in your plant?

You have referenced things like the non-porous floors. We've heard about a leaky roof. Were there things that you

thought maybe we ought to start seeing some of these things, or did we have to wait for a whistleblower?

*Mr. Calamari. We absolutely -- we have processes and protocols in place. When there is a signal for an illness, a reported illness, we have -- we look to our batch records that link to that product in question. We look at the complaint rates. And we did that in this example. And there were no signals from those reviews and processes that there was anything more -- any more to the instance.

*Mr. Burgess. Well, okay, fair enough. So then four weeks goes by, and a whistleblower complaint is delivered to the FDA. And I presume they contacted you straight away after they got the whistleblower complaint, is that correct?

*Mr. Calamari. Representative, no. We became aware of the whistleblower complaint in the end of April, when it was made public by Congress.

*Mr. Burgess. So the time lag between October and February was internal to the FDA, and not part of your normal quality assurance process.

*Mr. Calamari. Correct. I became aware of it in the April timeframe, when it was made public by Congress.

*Mr. Burgess. That is actually disturbing, that there was not better communication. I recognize Dr. Califf said something got lost in the mail. Absolutely unacceptable. And surely we at the Federal level need to correct that.

Let me just ask you this, Mr. Calamari. Dr. Califf said that a cronobacter infection or cronobacter isolation should be a reportable incident. Is -- would that be your understanding, and would you be accepting of that?

*Mr. Calamari. Representative, yes. We have processes in place where we signal the identification of cronobacter.

*Mr. Burgess. So -- but CDC says cronobacter can occur in the environment, that -- so it would have to be a cronobacter infection in a child, or would it be the isolation of cronobacter in a non-porous floor?

*Mr. Calamari. We would support that. We would support that.

*Mr. Burgess. Well, so if the whistleblower complaint was not made immediately available to you, but then, when it was, was it your decision then to cease operations at the plant in Sturgis until you got the difficulties corrected, or was that an FDA decision?

*Mr. Calamari. Representative, regarding the whistleblower complaint, it is an ongoing review, and it is an ongoing investigation. And given the independent nature of that inquiry, I wouldn't want to speak to that.

But what I can tell you is I have been at Abbott 17 years, and the Abbott I know prioritizes compliance. It encourages employees to speak up.

*Mr. Burgess. And correct, that is what you would want.

I mean, just like Dr. Califf, I -- in my professional career I dealt with Abbott, I dealt with Mead Johnson, I dealt with Gerber. I know all of you to be -- I mean, you do have the best interests of your clients, your patients, at heart. But somehow things didn't quite measure up this time.

And so I guess Mr. Califf -- when, then, in the decision-making chain -- when did it become obvious to you that we were going to have to close the Sturgis plant, or halt the Sturgis plant?

*Mr. Calamari. So we agreed to a voluntary recall in the February timeframe. It was -- with the information we had at the time, with the unknowns, and given the nature of this patient population, safety and the -- for the most vulnerable is important, and the most critical thing.

So looking back now, we would have done it again with the information we had at the time, and that was in the February timeframe.

*Mr. Burgess. But the voluntary recall is not the same as just complete cessation of activity at the plant, correct?

*Mr. Calamari. We -- it would have been in the mid-February timeframe.

*Mr. Burgess. I have got some other questions I will submit in writing, but I would like to -- I would be interested in how you notified the downstream consumer and the other participants in the supply chain that this,

unfortunately, was occurring, and that we would need to be prepared for it. But I will submit those in writing.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Burgess. Thank you, Madam Chair.

*Mr. Calamari. We can follow up with --

*Ms. DeGette. Thank you so much. Thank you.

Miss Rice, you are now recognized for five minutes.

*Miss Rice. Thank you, Madam Chair.

Mr. Calamari, if I could just continue along the lines of -- I just want to clarify. You were informed of the whistleblower and their report. They went directly to another source. They did not go to you. Is that right? With the problems in --

*Mr. Calamari. Yes. I would have become aware in the end of April timeframe.

*Miss Rice. So tell me what -- I mean, what system do you have in place to ensure that things like this don't happen, and that you are leaving it to a whistleblower to bring it to the public -- to Federal agencies' attention in order -- before you can -- before you even know about it? I mean, what are your procedures that you have to ensure that you find out about these problems first, through an oversight program that you implement?

*Mr. Calamari. Representative, I think it is a very key area you have -- you are commenting on.

We do have a process in place where employees can raise their voice, and speak up, and --

*Miss Rice. Talk about that. What is that process?

*Mr. Calamari. So it is independently administered. So there -- it respects the confidentiality of the employee, and it is administered through part of the organization outside, you know, that is set apart and independent, so that any questions and inquiries can be independently administered and reviewed.

*Miss Rice. And are people made aware that they have this avenue to report things that they see within a facility that they think are -- is not right?

*Mr. Calamari. Yes, they do. We encourage employees to speak up, and we -- and safety and compliance is a top priority.

*Miss Rice. So why was this not brought directly to your attention?

*Mr. Calamari. Representative, this -- the nature of this process is this -- when it was made public, it was shared with FDA. And I was not directly aware of the investigation until that time.

*Miss Rice. Well, I guess I am -- my question is, if you have what you are describing as a specific program to allow employees to go directly to someone within the company to register an issue with something that is going on in any one of your facilities, why didn't that happen here?

*Mr. Calamari. Representative, what -- I just want to make sure I -- when I say Abbott did not find out about it

until the -- it was made public in the end of April. And it was the -- the particular individual who raised the complaint, it was their choice to use that mechanism to raise the complaint.

*Miss Rice. Okay. So what are you going to do to ensure that people go to you first, and not do what they did -- have to go to take the steps that they did here? Because these -- it sounds to me like this is not an isolated incident. These things have happened at your facilities. Maybe not this specific thing leading to this incredible shortage of essential nourishment for babies. But why did your system fail here?

And what are you going to do to make sure that it doesn't happen again, that this -- that there is a quality control within your company that employees respect and believe is going to be effective and not come back on them?

*Mr. Calamari. Representative, we encourage employees to speak up. We are going to reinforce that we are a culture where we support employees to raise concerns if they see them. And I think that is one of our ongoing commitments as an organization.

*Miss Rice. Do you offer any kind of reward for people who bring this information forward, to actually encourage people to be on the lookout, and to not fear coming forward to higher-ups in the company?

*Mr. Calamari. We encourage it by reinforcing that their voice counts, that we have a zero tolerance policy for retaliation against these types of complaints. And that is our commitment to support those employees to speak up.

*Miss Rice. And so it failed. Clearly, you are not getting that message out to your employees, or you would have been aware of this before anyone else was. Would that be correct?

*Mr. Calamari. I think it is always important that we could always use this as an opportunity to reinforce our principles.

I will say that the individual chose to raise their concerns in this matter, and I think we have to -- you know, we have to revisit how we make sure we get -- reinforce that we are a culture of speaking up and supporting training and compliance.

*Miss Rice. Are you just making that decision now, or is this something that you were aware of before me asking you these questions?

You -- do you understand that that is something that you have to work on in your company?

*Mr. Calamari. Representative, absolutely. We are committed to those principles.

*Miss Rice. Madam Chair, I yield back the balance of my time.

*Ms. DeGette. Thank you. The chair now recognizes Mr. Long for five minutes.

*Mr. Long. Thank you, Madam Chairman.

For Mr. Calamari, prior to Abbott's recall in February, what percentage of Abbott's total U.S. infant formula was made in your Michigan facility?

*Mr. Calamari. Approximately 40 percent.

*Mr. Long. And prior to the recall in February, what percent of the U.S. market did your company's infant formula produce or account for?

*Mr. Calamari. Abbott is approximately 40 percent of the market.

*Mr. Long. Okay. And then for Mr. Fitz the same question.

Prior to the Abbott recall in February, what percentage of the U.S. market did your company's infant formula product account for?

*Mr. Fitz. Our -- we represent about eight percent market share.

*Mr. Long. I am sorry?

*Mr. Fitz. We represent about eight percent market share.

*Mr. Long. Eight? Okay. So for Mr. Cleveland, same question.

Prior to the recall in February, what percent of the

U.S. market does your infant formula product account for?

*Mr. Cleveland. We were approximately 34 percent of the U.S. market before the recall.

*Mr. Long. Okay, and has that changed, post-recall?

*Mr. Cleveland. Yes, sir. With the recall, many consumers that were no longer able to use the Abbott brand switched to ours, and our share is now approximately 56 percent of the U.S. market.

*Mr. Long. And same question for Mr. Fitz on [inaudible].

*Mr. Fitz. I think you are asking the same question of us. Our market share has inched up about one percentage point, so we are about nine percent now.

*Mr. Long. Okay, yes, I was trying to ask the same question of both of you.

So with that, I think [inaudible] Madam Chairwoman, and yield back.

*Ms. DeGette. Does the gentleman yield back?

*Mr. Long. Yes, I yield back.

*Ms. DeGette. All right. Thank you so much.

Ms. Schakowsky, you are recognized for five minutes.

*Ms. Schakowsky. Thank you, Madam Chair.

I have to tell you, Mr. Calamari, that I am actually livid at what happened at Abbott's Sturgis plant, and I have -- really having a hard time figuring out how that was

allowed to happen.

We've all heard about the inspections that were done and, quite frankly, it is pretty disgusting, what we heard about the water on the floors, and the water leaking from the ceiling, and conditions that could lead to contamination. And I don't know how a company that has a reputation like yours and a responsibility like yours could actually get into a situation like that. So I am not surprised it is going to take you a while to get your act together and clean the place up to get it out.

And I also heard your apologies. And I just want to say something. You don't owe an apology to this Congress. You owe an apology to the parents of children who got sick, and possibly a couple that have died, and to all the families out there who are really struggling and suffering because they can't get the product that you produce so much of -- and in fact, I think probably too much of it. And we talked a little bit earlier about the concentration of power.

So, you know, Mr. Calamari, I also note that we've been talking about the whistleblower, that Abbott actually -- I will talk about that in a second, but Abbott only took action to recall formula after the FDA learned that more babies had become sick, and after four babies were actually already sick, and it looks like two died.

So I want to ask. Mr. Calamari, the witness -- the

whistleblower suggests that safety and quality have not been always at the top of your agenda. So I want to ask you, will you take responsibility for your current employers to make sure that they comply with the FDA, all of the safety requirements for infant formula?

*Mr. Calamari. Yes.

*Ms. Schakowsky. I also want to ask -- let's see -- in Mr. -- I am sorry -- oh, for Reckitt, Mr. Cleveland.

So in your testimony, Reckitt has been working with the FDA on ways to do -- to expedite the appropriate behaviors. And I am just wondering if you could just tell us a little bit about what you are doing in the -- especially in the Mexico facility.

*Mr. Cleveland. Thank you, Madam. The Mexico facility has been making infant formula for Latin American infants for many, many years, and grown thousands of babies very successfully and healthily, and with quality infant formula. And we had begun just before the recall the process of getting that plant certified by the FDA so it could be a permanent source of supply for the U.S. market.

Obviously, since the recall we've been working with FDA on can we compress the timeline to that approval so that product from that plant can be available to address the shortage right now to fill the shelves. And that is an ongoing process. And the FDA is moving quickly with us on

it.

We are also taking advantage of the FDA's import exception to submit for approval to bring product from our plant in Singapore, which has also been making infant formula for children throughout Asia for many, many years, and very successfully, and we think could go a long way to helping with the current shortage at the shelf here in the U.S. And those are active conversations, practically every day with the FDA, on how to get both of those options in line and moving very quickly.

*Ms. Schakowsky. Thank you. We are looking forward to that.

Mr. Fitz, how is Gerber coordinating with the FDA to make sure that these products are quickly delivered to American families without compromising quality and safety standards?

*Mr. Fitz. Yes, so thank you for the question. Certainly, the current urgency is there, and we have already applied for two -- made two requests to FDA for exceptional approval to temporarily import product from a German facility that makes product for all European and global markets. And we are -- we've submitted those two applications within the past week.

*Ms. Schakowsky. Thank you.

Thank you, Madam Chair, for your indulgence. I yield

back.

*Ms. DeGette. I thank the gentlelady.

Mr. Palmer, you are now recognized for five minutes.

*Mr. Palmer. Thank you, Madam Chairman.

And following on my colleague, Ms. Schakowsky, I am going to just lay out some things here, Mr. Calamari, that I am going to ask you to respond to in a moment.

But in 2019 Abbott found a cronobacter, a potentially deadly pathogen in your product. It was also determined that an inadequate pathogen testing was being done at your Sturgis plant to ensure that the required quality standards were being met. Your company had received complaints from nurses and parents who believed your product was making infants sick. I think you received 16 of those between 2019 and 2021. Yet there were no inspections from October 2019 until 2021 by either the FDA or Michigan, despite the fact that you knew there were problems.

The 2021 inspections, when they did start back, found numerous violations, mishandling raw materials, mishandling packaging and equipment, pitting in the dryers that could result in growth of bacteria, failure to maintain the building and clean and sanitary conditions, as has been mentioned several times in this hearing and the previous panel.

And what is interesting to me is that, when the

inspections finally started -- the pattern of the FDA routinely was surprise visits, but Abbott was notified several days in advance of that inspection. Were you informed? Were you notified that the FDA would be inspecting the plant?

*Mr. Calamari. So the -- there is an annual inspection process, and we would have known that, and each year we anticipate a scheduled --

*Mr. Palmer. That is not what I am asking you. Were you notified that the FDA was coming to that facility?

*Mr. Calamari. No, I was not.

*Mr. Palmer. Okay, so I will follow up on that later. Of course, it is not the usual manner that the FDA does these inspections.

The other interesting thing about the inspection is that, even though these issues were identified, they were not included in the FDA's report. And I am wondering if there was a discussion between Abbott management and the FDA in regard to what the inspection found. Was there a discussion that -- between Abbott and the FDA about the problems at the plant?

*Mr. Calamari. Representative, I am not aware of any such discussion.

*Mr. Palmer. Were you aware of these issues before the FDA inspection?

*Mr. Calamari. I personally was not.

*Mr. Palmer. Okay. Who would have been?

*Mr. Calamari. Our team in Sturgis would regularly be working on the processes and steps necessary to make sure we are producing to satisfaction.

*Mr. Palmer. Could you give us -- submit to the committee the names of the people who would have had access to this information, who would have known that you had these issues with the mishandling of your materials and your packaging and your equipment, who would have known about the complaints, would have known that the cronobacter pathogen was found in some of your products, that would have known that you were not doing adequate product safety testing? Could you give us the names of those people who would have known that ahead of the FDA inspection and post-FDA inspection?

*Mr. Calamari. Representative, we can follow up with that information.

*Mr. Palmer. Madam Chairman, would it be appropriate for the committee to officially request that those people be identified?

*Ms. DeGette. The witnesses are always requested to answer questions submitted by the committee members, so they will be asked to do that in due course.

*Mr. Palmer. Well, my concern about this is that we now

have a major problem with this, not just the supply chain. This is a failure across the board with your company. I mean, you testified that Abbott represents about 40 percent of the product that is out there. It is closer to 50 percent, I believe, and 40 percent of it is produced at the Sturgis factory.

And what I don't understand, and what I would like for you to answer in these remaining seconds, is why Abbott didn't immediately address these issues without having to be told to by the FDA or anybody else.

*Mr. Calamari. Representative, we prioritize safety and compliance in our plants, and we are committed to doing so and getting better coming out of this event.

*Mr. Palmer. Madam Chairman, for the record, I am not satisfied with the witness's answers, and I appreciate your indulgence, and I yield back.

*Ms. DeGette. Thank you. I thank the gentleman.

Mr. Tonko, you are recognized for five minutes.

*Mr. Tonko. Thank you, Madam Chair.

While the recall of Abbott products is responsible for the severity of the formula shortage facing Americans today, reporting shows that supply challenges existed prior to the February 2022 recall and Sturgis facility shutdown. In fact, pandemic-related supply chain disruptions contributed to higher out-of-stock rates than usual in the second half of

2021. We can't overlook the role of these raw materials and transportation strains may have on the longer-term resiliency of the infant formula supply in our United States.

So, Mr. Cleveland, you referenced these continuing supply chain challenges connected with the COVID-19 pandemic in your testimony. What type of supply chain challenges did Reckitt experience in 2021, and what measures did the company employ to try to mitigate the impacts?

*Mr. Cleveland. Yes, sir. And I don't think in this regard we are very different than most manufacturers in America. Supply chains are complex, and they are often global.

So input challenges could be anything such as packaging problems. It could be we couldn't get paperboard. Maybe we lacked certain oils that go into our products. Really, the list is -- it is long, and it is complex, and, frankly, it changes on a regular basis.

We've been able to overcome it and keep production flowing, and been able to increase since the recall because of, frankly, heroic efforts from our procurement team. And whenever one of these shortages appears, they reach out to a network of backup suppliers and alternates seeking, you know, inputs that could substitute the ones that we were no longer able to get. They have been very successful at doing so, although, you know, certainly we could have produced more if

we had had a constant and steady stream of inputs, and hadn't struggled with the issues we've had.

And again, the White House and -- has been very helpful with us, the Administration, in helping to secure inputs during the midst of this crisis. And we are starting to see an improvement on many fronts.

*Mr. Tonko. Mr. Fitz, your testimony also mentions global supply chain challenges as a factor the company has had to contend with. What, if any, steps has Gerber taken to maintain its production and distribution supply?

*Mr. Fitz. Yes, thank you for the question. Certainly, our industry is not immune to the global supply chain challenges brought on by the pandemic. We struggled with material supply issues, intermittent material supply issues, whether it be ingredients or packaging components. We struggled with material quality issues related to the pandemic. We've had transportation and logistics issues, just getting trucks and truck drivers available to move the products and supplies that we need. And we've had COVID-related labor challenges and higher turnover than normal, with all things that have impacted us.

Through the course of the pandemic, though, we've resolved these on an ongoing basis, one at a time, as they have come up. We are putting -- trying to put in more robust business continuity plans in place for critical components

and ones that we know we will have challenges with in the future.

*Mr. Tonko. Okay, and I would like to know whether there were conversations, obviously, about the supply concerns as the challenges grew over the past year. All three manufacturers testifying today have been coordinating with the Biden Administration in recent weeks. But what about efforts over the past year?

Mr. Fitz, did Gerber engage in any discussions with the FDA or with other Federal agencies regarding the growing supply chain concerns prior to February's Abbott product recall and Sturgis plant closure?

*Mr. Fitz. So we have regular involvement with FDA. I don't think we've highlighted these issues in particular. Again, for us, they have been intermittent and periodic and different in every time. And we've made significant efforts through the -- through our teams, through our procurement organizations to solve them, and resolve them, and continue to produce.

And over the past --

*Mr. Tonko. But did you not think that FDA should be notified, or at least aware of your struggle?

*Mr. Fitz. Should FDA be aware of our struggle on --

*Mr. Tonko. Yes, should you have -- yes. Should you have shared those concerns for supply chain?

*Mr. Fitz. If it could help, we would certainly be willing to do that, yes.

*Mr. Tonko. Well, should you have during the last year?

*Mr. Fitz. Well, as I testified, the issues that have come up for us, we've been able to resolve. Through the last six months our in-stock rates have averaged 86 percent.

*Mr. Tonko. Well, Mr. Cleveland, at what point after noticing supply chain disruptions did Reckitt begin coordinating with the FDA, or with WIC agencies and retailers to address potential disruptions?

*Mr. Cleveland. Well, as soon as the recall occurred, we reached out to our retailers to discuss with them the significance of what that event would be. We made sure that we had all the existing inventory available to us to push out to those retailers and then encourage them to push their inventory to shelf, as well.

Since then we've been working with the USDA to increase flexibility of the program to meet the WIC consumer's needs, because that is our top priority consumer. And finally, with the Administration, the effort has been on inputs to manufacturing, so that we can increase the total amount we make, and get that to shelf much quicker.

*Mr. Tonko. Well, my time is done, but if you could respond in writing about actions that you had taken before February, that would be helpful, too.

[The information follows:]

**********COMMITTEE INSERT**********

*Mr. Tonko. Thank you, Madam Chair --

*Ms. DeGette. I thank the gentleman.

*Mr. Tonko. -- I yield back.

*Ms. DeGette. The chair now recognizes Mr. Joyce for five minutes.

*Mr. Joyce. Thank you, Madam Chair and Ranking Member Griffith, for holding this.

And thank you to the second panel of witnesses for appearing today, because we all recognize it is very important that we hear from industry and manufacturers as well as government regulators in this whole process. And to that end, I would ask that all three of you -- Mr. Calamari, Mr. Fitz, and Mr. Cleveland -- that you weigh in on the following question.

We've heard at length in this hearing, which is now in its fourth hour, about regulations, about supply chain. But my question is going to take a different approach to this, and I need to know what effectively government can do right now to ease supply constraints. And I would ask each of you what regulations could be modified to ease or increase infant formula supply -- Mr. Cleveland, you stated that -- to fill the shelves. I think all the parents, all the caregivers for infants right now want to know how we can get to that. But how do we get to that point without compromising the safety of the products that you produce?

So, Mr. Fitz, I am going to start with you. What -- if you could change -- if you could, make recommendations to this oversight committee to increase infant formula supply, but not compromise the safety of the products for the families, the children who rely on them.

*Mr. Fitz. Yes, thank you for the question, Congressman. I think it is a very good one in the current situation.

But I do believe that the steps the FDA is taking to allow temporary flexibility for importing products from safe manufacturers overseas that are approved in foreign countries, as we are doing now, at least for Nestle, that allows us to tap into our global network and quickly respond to the situation at hand.

*Mr. Joyce. And we talked earlier in the hearing today. I agree that that is certainly a viable solution. I represent a rural area in Pennsylvania, and I look to see how the rural areas can be supplied with that, as well.

Mr. Calamari, as a representative here for Abbott -- and I definitely respect you being here and taking these difficult questions, I respect you as a leader answering that -- but if you could, address what regulations you felt could be changed to increase, without compromising safety, increasing, as Mr. Cleveland said earlier, to fill the shelves.

*Mr. Calamari. Representative, thank you for the comments and for the question. I think I would characterize two key areas where we could continue to improve.

One is on securing ingredients. The road ahead, as we think about continuity of supply, is something we have to make sure we are very much prepared for. So continuing to work on secure supply of ingredients.

And distribution. Distribution is a speed to market, never cutting the quality steps, never cutting the testing steps, but making sure we have accelerated distribution and ability to get it to the customers and the consumers would be the areas I would say we need now, and we are going to continue to need in the weeks and months ahead.

*Mr. Joyce. Mr. Calamari, address that just a little bit further for me, if you would, please. Specifically in the supply chain, are there specific ingredients that you look right now are challenged?

*Mr. Calamari. On the horizon we see, in the manufacture of infant formula, agricultural oils are absolutely essential. Paper is absolutely essential. The cost of fuel to supply and distribute the product is essential. So I would call out those key elements, ranging from agricultural oils to the cost to deliver the product, would be the biggest areas of focus.

*Mr. Joyce. Thank you. I appreciate it. And now our

final panelist.

You are going to be the cleanup batter. What, as far as government regulation, Mr. Cleveland -- because I used your quote about filling the shelves -- and I stopped this morning at a local supermarket, and you are right, those shelves are not filled, and parents and caregivers are quite concerned about that. So how -- and from a government point of view -- can we, without compromising safety of your product, how can we work -- what regulations could be modified to ease what you are facing right now?

*Mr. Cleveland. Well, thank you for the question, sir. And as cleanup batter, I -- you know, I can add incrementally to the -- what has gone before me, because many of the suggestions that ourselves and I am sure the other manufacturers have made to the Administration and other parts of the government have been implemented.

So focusing on those most at medical need through the import exceptions, I think, is an excellent idea. And then making sure that we increase the flexibility of the WIC program to make sure that the vulnerable women and infants in that program are taken care of, and they have safe access to product, I think, was essential. And I think the USDA has implemented at this point all of our suggestions to do that, which has been very helpful.

But the one final thing I will end on the inputs is

really the logistics, because the agricultural oils is a very good point. That is an essential input to our process, as well. But one of the things we find is the logistics of getting those from our supplier to our plants with sufficient trucks to do so has also been challenging. So it is not only just the inputs, but, as we've heard before, it is also getting the trucks and the logistics in place, as well.

*Mr. Joyce. Thank you for the comments.

Madam Chair, I see my time has expired. But again, I thank you for this important hearing today.

*Ms. DeGette. Thank you. Thank you so much.

Mr. Ruiz, you are now recognized for five minutes.

*Mr. Ruiz. Thank you.

Every aspect of the current infant formula shortage is alarming, and I am most disturbed that the parents, caregivers, babies, and children most impacted by the supply strains are those who are already living meal to meal with food insecurity. That is particularly true for families that rely on the Special Supplemental Nutrition Program for Women, Infants and Children, the WIC program. And this committee does not have jurisdiction of WIC, but the manufacturers' relationships with the program is central to the disproportionate impact of the shortage on low-income families.

As I understand it, Abbott contracts with approximately

34 state WIC agencies, and serves more than 47 percent of the 1.2 million children receiving WIC formula benefits. This means that, when Abbott's products were recalled, caregivers who are already in vulnerable and precarious financial positions felt the product's absence from the shelves the most.

So Mr. Calamari, as the primary supplier of infant formula for WIC beneficiaries, does your company have obligations to these families?

And if so, what specific actions has Abbott taken to ensure that its non-recalled products or even competitor options are available to these vulnerable families?

*Mr. Calamari. Representative, we take our WIC commitment and our WIC obligations very seriously.

One of the key actions I identified in my opening comments was when we airlift product, we are airlifting Similac from Ireland. That product we are shipping over is the number-one product we provide on the WIC program. We prioritized that early in our action plan, and are going to continue to sustain that in our action plan going forward.

In addition, what we've also done is we've paid competitive rebates. In other words, when our product is not available, we will pay the rebate on other manufacturer's products so families can continue to get access to the nutrition they need.

Going forward, we are going to pay those rebates through August, and it is an area that we will continue to look at as we think about the improvement going forward.

*Mr. Ruiz. How do you do the outreach, the education to the families that you would pay the rebate?

And are you doing them in Spanish, as well as in English?

*Mr. Calamari. So we work very closely with two key stakeholders -- USDA, but also the state WIC agencies, where we provide materials bilingual, and we work with the agencies to make sure we are providing the necessary information customized by state to make sure we are communicating the current status to their constituents.

*Mr. Ruiz. Mr. Cleveland, your company, Reckitt, also supplies with WIC beneficiaries with infant formula in the United States. According to company statements, as of 2020 Reckitt held the WIC contract in 15 states, and was providing formula for approximately 44 percent of all WIC-eligible infants in this country.

How has Reckitt been coordinating with states and WIC beneficiaries to expand its product availability to low-income Americans in this current crisis?

And what additional steps must we take to avoid similar disruption in the lives of these marginalized families in the future?

*Mr. Cleveland. Well, thank you for that question. And since the recall began, we are the next largest manufacturer of scale to meet the needs of those WIC consumers now in all states, not just ours, but the others as well. And that is a tremendous responsibility.

To be able to do that effectively, we reached out and spoke to the USTA almost immediately seeking flexibility, for example, in the size format. And while that sounds small, it is very significant, because what that means is the WIC consumer doesn't have to look for one particular size of product at the shelf. They can find any size of the shelf to fulfill their benefits with [sic]. And that has allowed us to continue production and step up to meet the requirements of those consumers.

We've since worked with the USDA to find a number of other ways to flexibly administer the program, because, really, the focus for the WIC consumer is the same as the others, making sure she has safe access to formula, and doesn't have to compete with non-WIC consumers to get it. So the more sizes, the more formats, the more manufacturers that the program can support, the more likely she is to have her needs met. And that is really where we've been focused, is make as much as we can, and then make sure that the WIC consumer can access that through her benefits.

And again, the USDA has implemented just about every

suggestion we've asked them for over the last few weeks. And we think we are doing as good of a job as we can.

*Mr. Ruiz. Well, I -- you know, I commend the Administration for being responsive, and action -- and the swift action to meet the needs of these families, and hope that the manufacturers continue to do the same in the years to come. Because I am deeply concerned that low-income families are bearing the brunt of this crisis of supply.

And I yield back.

*Ms. DeGette. I thank the gentleman. Mr. Peters, you are now recognized for five minutes.

*Mr. Peters. Thank you, Madam Chair. I have got some questions for Mr. Calamari.

In your testimony you indicated that Abbott has invested "billions of dollars'' in things like growing production capacity, creating new specialized formulas, enhancing safety and quality. I am particularly interested in that latter point.

So how much of your resources, either as a percentage or -- of annual expenditures or a ballpark figure does Abbott devote to ensuring the safety of the infant formula products it produces?

*Mr. Calamari. Congressman, what I could tell you is we spend tens of millions of dollars on quality and on maintenance. And specific to Sturgis, we -- that was a

foremost investment, as well.

*Mr. Peters. Do you think, given what you know now, that you should be spending more, you should be devoting more to ensuring the safety of your product on the market?

*Mr. Calamari. Representative, I think we are absolutely committed to investing in doing what it is going to take to make sure we consistently make product to the standards we all want, and that we are -- that this never happens again. So we are going to invest and make sure those resources are available.

*Mr. Peters. Since 2009 the FDA has conducted approximately 20 inspections of Abbott's Sturgis facility. As I understand -- this has been discussed a little bit before -- even prior to FDA's recent investigation in January, the two inspections before that also found objectionable conditions or practices.

The 2021 inspection in September found that Abbott did not maintain its building in a clean and sanitary condition. FDA inspectors observed standing water near dryers used in the production of infant formula, saw personnel working directly with infant formula not washing their hands.

You know, I have got to say, it has been a while since I had infants in my household, but we never gave a second thought to the cleanliness of baby formula. I don't imagine most people even have a second thought about the reliability

of that product.

But the FDA left the corrective actions up to Abbott following the 2019 and 2021 inspections. Can you -- Mr. Calamari, can you specify all the corrective actions that Abbott took to address the citations following each of those inspections?

*Mr. Calamari. So we took in each of those instances immediate action to address the observations. Some of the key areas of improvement where we've taken action including the installation of new flooring, the identification of new processes for how to manage traffic in the plant, and also very specific training on individuals to what -- the safety protocols they need to do, so that this does not happen again.

*Mr. Peters. It is really unfortunate that the inaction over the years has contributed to -- indirectly to this burden, through the recall and so forth, families just trying to feed their children. That is falling heavily, as I think Dr. Ruiz pointed out, on the under-served -- 4,000 families get WIC in -- women and children's assistance -- in my in my district.

I am happy that we had this hearing, and I hope that the things will change. But it is really unfortunate that inaction has contributed to this burden.

And I will yield back.

*Ms. DeGette. I thank the gentleman. The chair now recognizes Ms. Schrier for five minutes.

*Ms. Schrier. Thank you, Madam Chair. And I am going to tee off a little bit what my colleague, Mr. Peters, was just talking about.

I just first want to thank our panel of witnesses for being with us today, for feeding America's infants. I want to make sure we get some questions answered, and hopefully reassure parents who have rightfully been very concerned by the shortage and by the safety issues.

As some of my colleagues have already mentioned, the baby formula industry in our country is really unique in that about 90 percent of the product is made right here in the United States, and the vast majority is made by your 3 companies. And so it should be no surprise that, when something goes wrong, like what happened in Sturgis, it really rocks the whole industry.

And the facility in Sturgis is responsible for 40 percent of Abbott's formula on the market, and makes up about 20 percent of the total formula on the market in the U.S. And that is really significant, especially when this year Similac has the contract with WIC.

So I think there is these two main questions on parent's minds right now. And the first is, knowing those statistics, how could you not have anticipated that shutting down the

Sturgis facility would affect the market and the ability to find formula, especially while people were stocking up because of the pandemic?

And why didn't you do anything at that point to mitigate the shortages?

So I guess, as I said in the first panel, you know, for babies under four to six months, this is their nutrition, this and breastfeeding, and that is it. And most babies rely on formula. There is no other option. So, you know, it is especially the case if you have babies relying on these specialty formulas.

So, Mr. Calamari, can you tell me when you started importing formula from Ireland? Because to most of us, it seems like that just happened in the last week.

*Mr. Calamari. Representative, thank you for the questions.

So we started increasing our imports from Ireland. We did it in January. We did it in February, and we really started increasing it in the months to follow. But that was one of a series of actions we took. We also took immediate action after the recall to convert our adult liquid manufacturing lines to make Similac. We also started taking action on addressing in the 483 observations what needed to be done at Sturgis. And we also increased production at our Ohio, Virginia, and Arizona plant.

So while we were working on Sturgis, we took a series of actions to make sure we were getting more product into the marketplace.

*Ms. Schrier. Thank you. And, you know, while you are mentioning Sturgis and getting that up and running, that is the second question on parents' minds and pediatricians, and it is about trust, and why should we trust that, once the factory is reopened, that those contamination problems will have been corrected?

Because there was a problem in 2019 that evidently didn't get fixed. There was no inspection in 2020. In 2021, that inspection kind of coincidentally happened when one baby got sick. And we just heard from the FDA commissioner some pretty damning reports. And we read the whistleblower reports about, you know, the roof and the floor, for sure. And I understand you have replaced those, but also the lack of handwashing, unsanitary conditions, the shoes, the falsifying records, the testing empty cans instead of full cans so that you could be assured that it would have a negative or a normal test result.

Like, it seems like there is this a cultural problem at the Sturgis facility -- I hope it is not at other ones -- that really raises questions in my mind about -- you can put all these requirements on, but if we have a culture and management at that facility that is falsifying results, why

should we trust that?

So I want to know what is happening there. Is management being fired, and what kind of oversight are you going to have?

*Mr. Calamari. Representative, I think there is two key elements to what you are referring to.

One is specific to we -- trust, and getting Sturgis back to producing at the level we all want. And we are very much aligned with FDA on the standards and the process steps, and what needs to be done in the facility. And we are taking action on that right now.

*Ms. Schrier. So you are. What I want to know is the people who for the past several years have been covering up, skirting around the rules, misreporting how much formula is in cans because there were inconsistencies with weights -- like, this lackadaisical disregard for standards. I understand that you get it, and I understand your standards. What about them?

*Mr. Calamari. Representative, respectfully, the whistleblower allegations, we don't know them to be true. That is an open investigation, and it is ongoing.

What I can tell you is I was at Sturgis last week. The employees I saw are committed to the highest quality. They are committed to learn going forward, to get even better. So I would really just want to reemphasize that, because that is

so critical.

And the whistleblower allegations, again, have not been proven to be true, and that is an ongoing investigation that is very much being done independently.

*Ms. Schrier. Fair point. Thank you.

I yield back.

*Ms. DeGette. Thank you. Mrs. Trahan, you are now recognized for five minutes.

*Mrs. Trahan. Thank you, Madam Chair.

Mr. Calamari, I represent a diverse district which is home to one of the most under-served cities across the entire state of Massachusetts. The City of Lawrence is a minority majority city with a poverty rate of 21 percent. On a per capita basis the city suffered greater numbers of COVID-19 infections than any other city or town in Massachusetts. Now, this has already stretched the city's limited resources, and adversely impacted the hardworking families there.

So it is almost unthinkable that now the very same families who suffered the most throughout the pandemic are those who are once again disproportionately impacted, this time by the baby formula shortage. You know, for Bay Staters, Abbott's Similac baby formula is the exclusive brand for WIC. Although Abbott's recall has impacted states across the country, it has fallen hardest on states like Massachusetts that have contracted with Abbott.

So on May 17th, I, along with my colleagues from the Massachusetts delegation, we sent you a letter. We haven't received the response yet, so I would like to follow up on some of the questions now.

I was pleased to hear, obviously, that Abbott entered into a consent decree agreement with the FDA, committing to fully correct all five of the deficient observations from the January through March 2022 FDA inspection, and to develop plans to reduce and control the risk of bacterial contamination in its products. But it also never should have got to this point if you, in fact, had proper safety protocols in place that were reinforced with a culture of surfacing problems, as my colleagues, Congresswoman Rice and Schrier have pointed out.

Mr. Calamari, Abbott has publicly stated that the company could restart the Sturgis plant within the two weeks of FDA approval. Your testimony walks through several specific improvements in states that Abbott is "installing non-porous, easily cleanable sanitary floors,'' and "confirming process consistency by validating the dry-out test method and verifying the dry-out procedures.''

It seems like these are things that should have already been in place well before the recall was necessary. So why is Abbott only taking these steps now?

And how can we feel certain that there aren't other

systemic problems at the Sturgis plant being left unaddressed?

*Mr. Calamari. Representative, thank you for the question.

Sturgis is a facility that has been inspected annually for a decade, and it had many, many years of no observations. It is a plant that has been feeding families for decades.

In 2019 and 2021 we did find and identify areas where we needed to improve. Those observations were identified, and we took immediate action.

Specific to 2022, we are prepared and we are working around the clock, every -- all hands on deck to address the issues raised so we can get the facility up. The first week of June is our goal, and that is what everyone's working towards.

*Mrs. Trahan. So some prior observations from FDA's Sturgis facility reflect a potentially lax culture when it comes to maintaining a sanitary product environment.

You mentioned protocols where employees are encouraged to flag safety lapses. Prior to the whistleblower how many times have employees registered complaints with safety internally to managers in the company?

*Mr. Calamari. Representative, I appreciate the question. I am going to have to get back to you with the specific numbers.

*Mrs. Trahan. How about additional training or controls? What are you putting in place to ensure that this is not an issue when you reopen the Sturgis plant and, according to your testimony, "more than double your production'‘?

*Mr. Calamari. So we will continue to investigate all reports, and make sure we have a zero conduct -- zero tolerance policy for retaliation or misconduct.

We have our ethics and compliance office and our hotlines there as additional resources to make sure our employees are heard, and that there is an avenue to speak up, and hear your voice, and have your voice raised if you see something.

*Mrs. Trahan. Well, hopefully those employees that speak up will be rewarded. The fastest way for you to turn around your culture, I think, is to show folks that you are so committed to surfacing problems that you will reward employees who actually bring those problems to your attention, so that you can get working on fixing them.

Finally, Mr. Calamari, what is Abbott planning to do with the infant formula held but not recalled at the Sturgis plant since February 17th?

Are you planning to release any of these products? And if so, how is the company ensuring the safety and quality of these products?

*Mr. Calamari. So Representative, I think you are assuming -- you are referring to the product that is on hold. That product will remain on hold, consistent with the consent decree.

We have made an amendment to the consent decree to release EleCare product, in alignment with FDA.

*Mrs. Trahan. Okay, thank you.

Madam Chair, I yield back.

*Ms. DeGette. Thank you. The chair will now go to members who are not members of the subcommittee. And with that I will first recognize Mrs. Dingell for five minutes.

*Mrs. Dingell. Thank you, Madam Chair and Ranking Member Griffin [sic], for convening this second panel, as well.

You know, I have to be really clear about why we are here today, because Abbott Nutrition has consistently failed for years to implement basic safety procedures at Sturgis, Michigan. And it hurts me to say that, because I am a Michigan girl.

But we know that back in 2010 Abbott was forced to recall baby formula produced at the facility due to contamination with beetles and larvae. And the FDA inspection reports in 2019, 2021, and 2022 show Abbott failed to implement safeguards to keep its infant formula free from contamination at the facility. And indeed, the FDA did

recover cronobacter bacteria from at least one swab of what appears to be a contact surface earlier this year at the Sturgis facility.

And this is all in addition to the whistleblower complaint, which alleges a culture of putting -- and I don't like saying this, but I am worried about all these babies and families across the country -- putting profits ahead of safety. And the inspector general report says, "Abbott has failed to implement and actively enforce adequate internal controls with respect to the Sturgis site.''

So Mr. Calamari, has there been any accountability in Abbott for these egregious safety failures?

Why has the company continuously neglected basic safety procedures at this facility, as documented by FDA and the Abbott whistleblower?

*Mr. Calamari. Representative, thank you for the questions.

And first, I want to reiterate our commitment to families and commitment -- we take our responsibility very seriously.

Specific to the Sturgis plant, it has a regular inspection calendar. Over the last 10 years there we were inspected, and we had no observations but for the 2019 and the 2021 observations. And we quickly addressed those issues, and we are committed to addressing all the elements

as outlined in the consent decree where we are aligned on the step forward.

Specific to the whistleblower, though, we do not know those allegations to be true. It is an -- we take it very seriously. It is an open investigation. And given its independence, I wouldn't want to comment. But I would tell you I have been at Abbott 17 years. The Abbott I know encourages compliance, and encourages employees to speak up.

*Mrs. Dingell. Well, it is going to take more than words. And I want to believe you. And this isn't something that, you know, can be spun. So I know that you have to, as a company, rebuild people's trust in Abbott's products, and the safety failures that have occurred.

And because of what has happened at the Sturgis plant, American families and Americans across the country are continuing to search for infant formula in stores and online, where scammers and scalpers have been taking advantage of the shortage. Mr. Calamari, is Abbott engaging with state or Federal agencies to identify or report online scams involving its infant formula brands?

*Mr. Calamari. Representative, I -- to your comments, first, we are not just going to offer words. We are going to offer concrete actions, and we are committed to working around the clock to making sure we address the issues that have been raised in the hearing.

Specific to pricing, we have no tolerance for price gouging, and we are working closely to make sure our products get to consumers affordably and safely.

*Mrs. Dingell. So are you working to help report scams? Is anybody working to identify people trying to scam people online with fake product?

*Mr. Calamari. So we work with our retail partners in coordination to make sure that we are getting our products listed -- the appropriate pricing, and the appropriate product is listed.

*Mrs. Dingell. I am going to ask Mr. Cleveland very quickly.

Does Reckitt monitor for counterfeit or other scams involving its products? And if so, what is the process in place for reporting such scams?

*Mr. Cleveland. Thank you, Representative. This was -- this -- these behaviors of price gouging online were one of the first -- one of the things I mentioned with President Biden, and he was taking it very, very seriously.

And for our own purposes, if we are aware of stolen product, or it becomes -- we become aware of it, we have corporate security. And if necessary, they can work with the appropriate law enforcement authorities or with the retailer, where that might be occurring, to try to put a stop to it. So we do have processes for that, yes.

*Mrs. Dingell. And --

*Mr. Cleveland. And we take it very seriously.

*Mrs. Dingell. Mr. Fitz, I have 10 seconds, so I want to commend you for Gerber's partnership with the Biden Administration to bring your products produced in Europe here, and ask you too, is the -- are you working with the FDA to ensure foreign-produced formulas don't give scammers an opportunity to [inaudible] families looking for alternatives?

*Mr. Fitz. Thank you for the question, Congresswoman. Yes, we certainly monitor that. Similar to the previous answers, we have our call centers that look into that. And when we identify fake product, take action.

*Mrs. Dingell. Thank you, Madam Chair. I yield back.

*Ms. DeGette. Thank you. The chair now recognizes Mr. Bucshon for five minutes.

*Mr. Bucshon. Thank you, Madam Chairwoman. Mead Johnson Nutrition, with a major liquid formula manufacturing facility in Evansville, Indiana, in my district, was acquired by Reckitt in 2017, and I want to take this opportunity to thank the employees at this facility for their hard work during this crisis to help get formula back on the shelves.

Mr. Calamari, a couple of things -- and a lot of this -- some of this has been covered. But is the plant -- does the plant in Sturgis use paper records for work orders and other things, or are they -- come into the electronic age?

*Mr. Calamari. So we work with the FDA on the process for how to appropriately document information, and do so in that collaboration.

*Mr. Bucshon. Okay. So that is not the answer to the question, which means you use paper records. I will take that as a -- that you use paper records, if you won't say yes or no on that.

*Mr. Calamari. Representative, we have a combination of both electronic capabilities and paper capabilities.

*Mr. Bucshon. Okay. Does the Sturgis -- does or did the Sturgis plant follow Abbott's company-wide systems of internal controls or accountability, or are they kind of on their own?

*Mr. Calamari. Sturgis is very much connected with our quality system and our accountability measures. So they would be part of that.

*Mr. Bucshon. Okay. And yes, and so you obviously have evidence of that, since you are under oath.

Does Abbott, as a company -- again, I am a big private-sector guy, but this is a really serious issue here. Does Abbott have an employee-driven health, safety, and compliance program or programs at its facilities? Because that has clearly been one of the potential issues here at Sturgis, is that the people there don't feel like they have the ability to be part of a team that works toward a common goal of

having a safe, healthy, in-compliance facility. Does Abbott have an employee-driven health, safety, or compliance program in its company or at its facilities?

*Mr. Calamari. Representative, I was at Sturgis last week, and that -- I saw the employees there. I saw the team members there. They are empowered to speak up, and they are passionate about the products that they make, and they make those products as if they were for their own family. I saw generations of employees working there --

*Mr. Bucshon. Sure, and I believe that. But is there a coordinated program that meets -- a lot of places meet on a daily basis, and -- or do they have a -- you know, an electronic way to communicate their concerns that is considered by the management there, literally, in many of these facilities on a daily basis?

I have some of these type of manufacturing facilities in my district.

Or is this just -- you know, it is one thing to talk to the employees and say, hey, and everybody talk about it, but is there really a structure in place?

*Mr. Calamari. So we have electronic means to submit and speak up if you see something. We also have anonymous 1-800 numbers. So we have mechanisms for our employees to speak up if they see something, and do so anonymously.

*Mr. Bucshon. Yes, so -- because it just seems -- you

know, look, again, I am a big private-sector guy, and I just hate this situation we are in here. But it just seems like that facility's culture is a problem. And this has been mentioned by members on both sides of the aisle. It is a longstanding, large cultural problem that you see in some facilities that have been open for decades with multigenerational people, both in and out of management. And it seems to me that the company needs to do better in -- with oversight.

Mr. Cleveland, we have spoken recently, and you -- a lot of the questions that may -- I might have asked you have been answered. But I just want to give you the last minute here to say -- is there anything that you haven't been able to mention that would help get baby formula back on the shelves today?

*Mr. Cleveland. Sir, the number-one thing we need -- and thank you for the opportunity to reinforce it -- is access to -- consistent access to sufficient input materials to our manufacturing facilities, so that we can make as much as possible [inaudible] shelves as quickly as possible [inaudible] put this behind us.

And we are --

*Mr. Bucshon. Thank you for that --

*Mr. Cleveland. -- [inaudible] the government to do that.

*Mr. Bucshon. -- that answer. Yes, and I know you are doing a lot of other things, including working on getting formula from some of your overseas manufacturing facilities, and I appreciate that.

So I appreciate all the witnesses, and I yield back.

*Ms. DeGette. I thank the gentleman.

Mr. Carter, you are recognized for five minutes.

*Mr. Carter. Thank you, Madam Chair, and thank each of you for being here.

Look, this is a serious problem, as I know all of you are aware of. I told the first panel, you know, I am blessed with six grandchildren. I have a six-month-old grandchild in Atlanta. I have got them all over the country. We sent out a family text with a picture of the milk that Mary Emma needs, just hoping that somebody somewhere could find it. I mean, it is just serious.

In fact, I had a mother in one of my cities that I have the honor and privilege of representing in Brunswick. And she wrote to me, "I have had issues finding my son's formula since March. Now my son's formula is no longer in stock. I pray that I have enough to get him through his first birthday.''

Look, we need an Operation Warp Speed for infant formula right now. There is no question about that. We need to get it on the shelves as quickly as we can.

But this was something that was happening before the plant was shut down in Michigan. This was something that was evolving over time. What do you think is the root cause?

Mr. Calamari, I will ask you. What do you think was leading to this? I mean, was it COVID-19? Was it Ukraine? We need to know, because we don't want this to ever happen again. This is -- I think this is one of the worst things we have had happen in a long time.

*Mr. Calamari. Representative, I think it is a really fair point, and a really key question you are raising.

We think about the backdrop of COVID, supply and demand, some of those fundamental relationships really got challenged in what has become a very sustained fashion. On the supply side we saw a lot of the things we've talked about: ingredients becoming increasingly challenging to get, cost to get those ingredients to the critical places became harder.

But we also saw demand increase, and demand increase not because there were more births, not because of more formula feeding, but some kind of changes that were subtle but just increased very significantly.

So when I think back on the reflection that we're all going to need to look back on this is how could we be in a situation, as I said in my opening comments, for capacity and redundancy, so that we're never in this situation again?

*Mr. Carter. Okay, and the supply chain issues, is that

because some of the ingredients were coming from other countries?

*Mr. Calamari. Representative, yes. So the -- we -- global supply chains are such that we have ingredients coming from global sources, and that is the nature of our supply chain.

*Mr. Carter. And so one of the solutions would be manufacturing in America, so that we are not held hostage by other countries. Is that what -- I am not trying to put words in your mouth, but I am trying to understand.

*Mr. Calamari. So we have five manufacturing facilities in the United States, and we do our production overwhelmingly in the United States.

I think a key element would be how do we make sure -- and I think this is some of the stuff with the DPA -- where we can ensure those ingredients, supplies are secured, and those inputs are secured, which could be a great step about improving the situation, both in the near term and the longer term.

*Mr. Carter. Mr. Fitz, I will ask you. What do you think led to this, outside of what happened with the plant in Michigan?

Obviously, that amplified it, made it worse. But it was already a problem. What -- Mr. Fitz, what can we make sure -- what can we do to make sure that this doesn't happen

again?

*Mr. Fitz. Yes, thank you for the question. Certainly, there have been challenges throughout the pandemic and the global supply chain issues related to that for material supply, again, transportation issues and labor issues. But we've been consistently been able to attack those and manage through those with minor disruptions. It really has been exacerbated by the absence of a major manufacturer from the marketplace right now for us.

*Mr. Carter. Okay. Mr. Cleveland, I will ask you the same question.

*Mr. Cleveland. I agree with some of the previous comments that were made.

The one thing I would say is, in many ways -- and an example I will use is the Women, Infant, and Children program, the WIC program -- when something like this happens, because I don't think we can ever be 100 percent guaranteed, the key is to be flexible in how we respond to it, either through administration or things like the WIC program, the way that we can bring imports into the country from other facilities. I think that is the major lesson to learn from this in the future, is how to be more flexible in response to something like this.

*Mr. Carter. Yes. Well, thank you all for your responses. It is important we never let this happen again.

It is important -- as I said earlier, we need an Operation Warp Speed for infant formula right now, and we need to get it on the shelves as soon as possible, or get it from overseas if it is acceptable and meets all of our quality standards. But we need it now. People in the districts -- in my district, they need it.

So thank you, Madam Chair, for allowing me to waive on, and I yield back.

*Ms. DeGette. Thank you, Mr. Carter.

Well, we have come towards the end of our hearing now. I would like to recognize the ranking member, Mr. Griffith, for any final comments or questions he might have.

*Mr. Griffith. Yes, I am going to make some comments. Thank you, Madam Chair. I appreciate that. This has been a good hearing, and I want to thank you, Madam Chair, for having this hearing.

And I want to thank the witnesses for participating. It has not been an easy hearing for a lot of the witnesses, nor should it have been.

We have learned some things. One, notwithstanding comments to the contrary, I am convinced that Abbott needs a change of culture at the Sturgis plant. Something is not right there, and there has been problems there for a number of years. That is something they will have to decide, but something that we need to keep an eye on to make sure they

don't continue to have recurring problems.

The FDA needs to help us help them. And it is not all about money. It is about using the authority that -- for food inspection that they already have, and to use the processes that they already have, and to try to figure out how to be a little more nimble, and figure out how they can acquire information on supply chains without necessarily having to use subpoenas, or have some new division of their agency created.

And for us, whether it is inspections of food products or medicines, as the appropriate committee we need to examine how we can improve the inspection process that the FDA does.

For example, surprise inspections are a good thing. This is not the first hearing that I have been involved in where folks were more concerned about getting subpoenas, or making sure that they notified the plant they were coming in. And I know it is more polite to notify them than to just show up and say, hey, we are from the FDA, we are here to look around. But this is not about being polite. This is about making sure that what we are inspecting is actually being inspected, and not dressed up for a special holiday or special inspection. It is about making sure that things are safe, and things are being done right.

And then we have to make sure that they understand that you don't always have to send in a big squad to do a surprise

inspection. You know, a single employee with a cell phone and a camera would have picked up at the Sturgis plant a recurring problem with standing water in the facility. It might not have caught muddy boots going through the food preparation area, or the infant formula preparation area, but it would have caught standing water on a more regular basis, and you would have said, whoa, whoa, whoa, this is a serious problem. It breeds the likelihood of bacteria growing.

Now, that is just one, but -- of the areas that we can look at. There is dozens. And I hope, as we move forward over the next few years, Madam Chair, that you and I, working together, can figure out what other hearings we need to have to make sure these things happen. And the rest of the committee will work to make sure that we can make the FDA a more responsive agency when it comes to making sure that our food supply is safe.

And with that, I yield back.

*Ms. DeGette. I thank the gentleman. And I will say in closing my constituents are frequently surprised when I tell them that Congress is a lot more bipartisan than people realize. But what you saw in the hearing today is concern from all of us about our constituents whose babies and children don't have the nutrition that they need because of this unfortunate situation, and a desperation on everybody's part to figure out how we can get this formula to our

constituents as quickly as possible.

I do agree with my colleague that money doesn't always help in these situations. But in my years of experience overseeing the FDA, it surely would help us if we had more inspectors and more people who could take some of these whistleblower complaints, especially in sensitive areas like this, and process them more quickly so we don't end up with a catastrophe like this. But we also need to look at the FDA's authorities to see if they need them.

With respect to the companies who are here today, I just have two comments.

Mr. Calamari, you know, I believe that this has, obviously, been a shock to Abbott, what has happened. And I do believe that there is a commitment to fixing it. But as Mr. Griffith just said, and others, this plant has had issues for quite some years, not just the last year. They had issues going back to 2010. And when I and other people asked you about what new protocols you were putting in place to be able to identify problems like this if they occur again, and then address them immediately without waiting for FDA interference, I frankly found your answers to be vague. You talked about how you were putting in new flooring, how you were doing this or that.

So what we would ask -- I think we would all ask -- is as Abbott develops new procedures, to actually not just hope

that the employees want to change the corporate culture, but how you are going to embed that in the culture. If you can, please let us know so that we can assure our constituents that we won't have a crisis like this again.

And then I just want -- I have one last question, which I am going to ask to Mr. Cleveland. And we asked some of the witnesses these questions before, but I never really got much of an answer. Like, if my constituent or -- like, let's say my daughter, who has a six-week-old baby, called me up and said, "I need to get some formula for my baby, and my store shelves are bare,'' what can we tell them between now and all of the emergency measures we put into place -- start putting formula on the shelves? Who should they call? Where can they go to try to get some of this limited product right now? What is the practical suggestion?

*Mr. Cleveland. It is very unfortunate you have to answer that question or ask that question. And -- but let me do my best to answer it.

*Ms. DeGette. Thank you.

*Mr. Cleveland. I think the shelves -- the reality is they don't have anywhere near the product that they do [sic].

So one of the things I have often said during this crisis is, you know, it takes a village to raise a child. In this case, sometimes it is taking a village to find infant formula.

So the first thing to do is work with your network of family and friends. And as they go to the stores, look for the product that is there. And I have seen many mothers and grandmothers and fathers and cousins doing this on the shelf.

You can call our consumer response center. Now, to be fair, those folks are doing a phenomenal job of fielding waves and waves of calls. But we will help you, if you call. That is one other resource.

The physician's office is another. Sometimes they do have the samples that are required, and they can help transition between finding product on the shelf.

And then I would be sure to look online, as well as in person at the store, and be open to other formats. Many mothers have a particular -- or fathers have a particular type of format they like. You may need to be more flexible in the format that you use, but all infant formula regulated by the FDA is safe for your infant, whether it is a liquid or a powder or what size it is in.

And so I would say shop widely, see your doctor, enroll your family friends, give us a call if you need to, and be flexible. And I think those are the best approaches you can take right now, while we work to fill the shelves as quickly as we can.

*Ms. DeGette. And we are going to get it done as quickly as we can. I know all three companies here are

committed to doing that. So thank you, and thank you to our other witnesses, all three of you, for participating.

Pursuant to Committee rules -- and we have discussed this during the hearing -- members have 10 business days to submit additional questions for the record to be answered by the witnesses who have appeared before the subcommittee. And I would ask all of you gentlemen to please do that.

In addition, we would like to insert into the record by unanimous consent an article from Politico regarding FDA's food safety authorities and oversight, published April 8, 2022 that Ms. Schakowsky offered.

And without objection, so ordered.

[The information follows:]

**********COMMITTEE INSERT**********

*Ms. DeGette. And with that, the subcommittee is adjourned.

[Whereupon, at 4:17 p.m., the subcommittee was adjourned.]