

**FDA OVERSIGHT PART I:  
THE INFANT FORMULA SHORTAGE**

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**HEARING**

BEFORE THE  
SUBCOMMITTEE ON HEALTH CARE  
AND FINANCIAL SERVICES  
OF THE  
COMMITTEE ON OVERSIGHT  
AND ACCOUNTABILITY  
HOUSE OF REPRESENTATIVES  
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*Documents are available at: docs.house.gov.*



# **FDA OVERSIGHT PART I: THE INFANT FORMULA SHORTAGE**

**Tuesday, March 28, 2023**

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

The Subcommittee met, pursuant to notice, at 10:03 a.m., in room 2247, Rayburn House Office Building, Hon. Lisa McClain [Chairwoman of the Subcommittee] presiding.

Present: Representatives McClain, Gosar, Grothman, Luna, Langworthy, Porter, Ocasio-Cortez, Gomez, Balint, Lee, and Crockett.

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

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

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

Welcome to the Subcommittee on Health Care and Financial Services. To the witnesses, thank you very much for your attendance and participation today in today's oversight hearing of the FDA's response to the infant formula shortage. Today, we will hear from food safety experts to better understand how this crisis happened, how it could have been handled better, and determine whether the FDA is able to prevent a future crisis from occurring.

As many of you know, I have been outspoken in my frustration with the FDA's response to the infant formula shortage. The infant formula crisis underscores a major problem with the FDA. The FDA is responsible for 78 percent of the U.S. food supply, but the FDA is not prioritizing food safety. Instead of owning its failures, the FDA has used COVID-19 as an excuse to neglect inspections and justify poor performance. While states like Michigan were shut down, preventing Michiganders from making a living, the Federal Government was 100 percent open and was paying too many of its employees to stay home and not do their jobs adequately. How did this critical shortage happen? Well, let us go back to the beginning.

In the summer of 2021, the FDA was aware of significant supply chain disruptions resulting in potential shortages of several types of infant formula. By September 2021, the Abbott nutritional infant formula plant in Sturgis, Michigan, had not been inspected in two years. This plant produces 20 percent of the Nation's supply of

baby formula. Then in October, an Abbott whistleblower submitted a 34-page complaint to the FDA outlining the concerns at the Sturgis facility.

Despite this whistleblower and several reports of babies becoming sick, it took until January 31 of 2022 for the FDA to begin inspecting the Sturgis plant. A couple weeks later, Abbott voluntarily recalled its product and voluntarily shut down its Sturgis plant. Had the FDA or the Administration done anything to prepare for the closure or ensure the availability of infant formula across the country? No, they had not. The health of vulnerable infants that rely on formula is a single food source that was not a priority.

Today, we have more information that we didn't have before. We know that the FDA ignored the Abbott's employee's 34-page disclosure, detailing concerns about the Abbott facility in Sturgis. We know that the FDA's telework policy and lax approach to oversight left it unprepared to address the shortages when the Sturgis facility was shut down. Americans are tired of excuses, like blaming COVID-19 or claiming there isn't enough money in the budget while inspectors telework and fail to do their job. FDA regulators were paid to do a job, but chose not to use its remote inspection authority, which was specifically intended by Congress to ensure FDA could prevent this type of crisis. They did not do their job and collected a paycheck on the backs of hardworking Americans. Americans want accountability, especially as it pertains to their children.

Today, we are going to conduct a long-overdue oversight of the FDA's response to the infant shortage formula. We are going to determine the extent of the internal failures within the FDA that led to the crisis, and we are going to discuss ways that the FDA can actually improve its internal controls to prevent a supply chain crisis of this magnitude from happening again.

We are also going to examine whether the FDA's proposed restructuring will improve its ability to keep food safe. We owe it to parents, caregivers, and infants to get to the bottom of what happened and, most importantly, prevent it from happening again because nothing has changed. We owe it to the families of the babies that died as a result of this contaminated formula. So, thank you to our witnesses, and we look forward to hearing your testimony. And I now yield to Ranking Member, Ms. Porter, for her opening statement.

Ms. PORTER. Thank you very much, Madam Chairwoman. Today, I want to focus on answering this question. If a big infant formula company like Abbott had a bacterial contamination today, would the whole formula market be at risk again? And to answer that question, we need to know exactly how equipped the FDA is to be in the prevention business now that we have weathered the 2022 crisis. Today, if the FDA received a whistleblower complaint about contamination, would it take four months, as it did then, to get to the Deputy Commissioner's desk, and over the last year, have we done enough to give the FDA the authorities and resources it truly needs to be proactive about preventing supply shocks in critical food markets?

I know that some of my colleagues today, probably on both sides of the aisle, will be chomping at the bit to bash a Federal agency.

That is not where I am. Discrediting an agency without figuring out what went wrong and how to fix it is simply malpractice, but I am not afraid to say that the FDA has a lot of work to do, no matter who that offends. At the same time, I am also not afraid to say that Congress is part of the problem. We have to empower the FDA for it to succeed. That means that when there is a crisis, we need to give the FDA resources.

Last year, 12 Republicans joined Democrats to pass the Infant Formula Supplemental Appropriations Act to give the FDA funding to address and prevent formula shortages. For the other 192 lawmakers who voted no and are wondering why the FDA couldn't do more, you should put your money where your mouth is. But empowerment goes beyond money. A strong FDA must have the authority to know what is going on in production between inspections, and a strong FDA must be able to review present and past testing data to help it make decisions. Even with the best structure, leadership, and resources, the FDA is only as well equipped as its legal authorities allow it to be. An improved FDA is going to take some work, and it is not on any one person that we can fire or blame. This is a complex issue that is going to take real work to solve.

Now, as much as I am dedicated to solving the FDA part of the puzzle, we wouldn't be doing our job if we said that that is the only issue in the formula crisis. Ultimately, formula manufacturers are responsible for producing safe products. They have very few incentives to self-regulate when they are so powerful, but that doesn't mean we can let Abbott off the hook for its negligent behavior. Last year, Committee Democrats launched an investigation into Abbott's negligence that Republicans, sadly for me, declined to join. This needs to change. This is partially an FDA problem, but it is also partially a Big Business problem, and Republicans and Democrats can't pick and choose who to hold accountable.

What is more, we have to stop turning a blind eye to consolidation in our food markets. Abbott is 1 of 3 companies that control 90 percent of the formula market. If something goes wrong in one factory, there aren't many other options to turn to. That doesn't make for resilient markets. By diversifying supply, competitive markets could cure many of the formula shortage risks even with the other mistakes that were made.

Today, let us not give anyone or anything a pass, but at the same time, let us not make this hearing an attack. There are many commonsense moves we can regulate to diversify and strengthen the infant formula market. Let us learn those lessons today, and let us be successful by setting aside politics, to listen and learn, and take proactive approaches. That is what I intend to do, and I am grateful to the Chairwoman for convening this important hearing. I yield back.

Mrs. MCCLAIN. Thank you, Ms. Porter, and I am pleased to introduce our witnesses today who are here to discuss the FDA's response to the 2022 infant formula shortage. Mr. Frank Yiannas was the Deputy Commissioner of Food Policy Response at the Food and Drug Administration from December 2018 to February 2023. Previously, he was Vice President of Food Safety at Walmart and Director of Safety and Health for the Walt Disney Company. He received his B.S., Bachelor of Science, in microbiology from the Uni-

versity of Central Florida and his Masters of Public Health from the University of South Florida.

Mr. Peter Lurie is President and Executive Director for the Center of Science in the Public Interest. Previously, Dr. Lurie was an Associate Commissioner for Public Health Strategy and Analysis at the Food and Drug Administration. He received his Bachelor of Science in chemistry from Cornell University, M.D. from Albert Einstein College of Medicine, and M.P.H. from the University of California, Berkeley.

Pursuant to Committee Rule 9, the witnesses will please stand and raise their right hands.

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

[A chorus of ayes.]

Mrs. MCCLAIN. Let the record show that the witnesses all answered in the affirmative.

We appreciate all of you being here, and we sincerely look forward to your testimony, to get to the bottom of how this happened, and, more importantly, what do we do to make sure this doesn't happen again.

So, let me remind the witnesses that we have read your written statements, and they will appear in full in the hearing record. Please limit your oral statements to five minutes. As a reminder, please press the button on the microphone in front of you so that it is on, and the Members can hear you. When you begin to speak, the light in front of you will turn green. After four minutes, the light in front of you will turn yellow. When the red light comes up, your five minutes has expired, and we would ask you to please wrap up.

So, with that said, I recognize Mr. Yiannas to please begin with your opening statement.

**STATEMENT OF FRANK YIANNAS, FORMER DEPUTY COMMISSIONER, OFFICE OF FOOD POLICY & RESPONSE, U.S. FOOD & DRUG ADMINISTRATION**

Mr. YIANNAS. Chair McClain, Ranking Member Porter, and Members of the Subcommittee, thank you for inviting me here today to testify before you and, more importantly, for your interest in better understanding what happened, so we can prevent an infant formula of this nature from ever happening again. Our bosses, the American people, and especially the most vulnerable among them, infants, deserve that from us.

In February of last year, already amid unprecedented supply chain challenges brought upon by the pandemic, our Nation's parents learned of several confirmed illnesses among infants of a rare and potentially fatal bacterium called Cronobacter Sakazakii. Those illnesses, linked to a single manufacturing plant in Sturgis, Michigan, along with the findings of very egregious conditions at the facility, led Abbott to execute the largest recall of powdered infant formula in our Nation's history. It has been over a year since that recall took place and subsequent widespread infant formula shortage is that it caused. There has already been a congressional hearing on this matter. The FDA issued its own version of an in-



vestigation report titled, “Evaluation of The Infant Formula Response,” and there has been, as you know, extensive media coverage.

Yet despite these actions, a clear and transparent understanding of what took place and the contributing factors that allowed it to occur have remained elusive. While we stand here today, more than a year since the recall, it is my view that the state of the infant formula industry today is not much different than it was then. The public health surveillance system for this pathogen remains insufficient. The necessary safeguards have not been advanced at an inadequate pace to prevent future illnesses, and the infant formula supply chain continues to lack serious resiliency. In other words, the Nation remains one outbreak, one tornado, flood, or cyberattack away from finding itself in a similar place to that of February 17, 2022.

As we all now know, FDA’s response to a series of reports of multiple infants infected with Cronobacter, along with the letter received from a whistleblower, spanned a period of several months, beginning in September 2021. It wasn’t until January 31 of the following year, four months later, that the FDA began an official inspection of the Abbott Sturgis facility. Had the Agency responded quicker to some of the earlier signals, I believe this crisis could have been averted or at least the magnitude lessened.

As Deputy Commissioner for Food Policy and Response at that time, I was not made aware of the series of illnesses nor of a whistleblower complaint until February 10 of 2022. From the time I first learned of the incident, on that date of February 10, to the time it took Abbott to conduct a voluntary recall to protect infants, it was seven days, seven days contrasted to four months of time in which the series of events unfolded. Clearly, I really wish, and I should have been, notified sooner so I could have initiated containment steps earlier. Had that happened, I believe we might not be here today.

There is no question that FDA’s siloed and decentralized foods program structure and culture contributed to and exacerbated these delays. However, after the series of events that allowed these issues to escalate and build one upon another, by the time February 2022 rolled along, the containment of this incident became my charter. Clearly, I agree Abbott Nutrition bears the primary responsibility for this crisis. However, there are numerous other lessons learned, too, and there is more that the industry and regulators can and must do. In my written testimony, I have included a list of 11 specific recommendations that I hope you have had a chance to review.

In closing, the infant illnesses and deaths due to Cronobacter, the Abbott recall, and the cascading and devastating effects it had on infant formula availability and families in our country was all a preventable—let me emphasize—a preventable tragedy. It is my hope that we seek lessons learned and take the necessary actions to prevent such a crisis from ever happening again. I thank the Subcommittee for your interest, and I look forward to answering your questions.

Mrs. MCCLAIN. Thank you very much, Mr. Yiannas, and I recognize the next witness, Mr. Lurie, to please begin with your opening statement.

**STATEMENT OF PETER LURIE, PRESIDENT & EXECUTIVE DIRECTOR, CENTER FOR SCIENCE IN THE PUBLIC INTEREST**

Dr. LURIE. Good morning. I want to thank Chairman McClain, Ranking Member Porter, other Committee Members for inviting me as a witness on behalf of the Center for Science in the Public Interest. I am its President and Executive Director and a former Associate Commissioner at the FDA.

If we are to apportion blame for the now resolved powdered infant formula crisis, the best place to start is at the Abbott nutrition plant in Sturgis, Michigan, that produced the formula associated with the outbreak because it was there that infant formula, contaminated with Cronobacter, was destroyed years before the outbreak, without FDA being notified. It was there, according to a whistleblower, that there were lax cleaning practices, falsified records, and relevant information hidden from FDA inspectors. And it was there, that repeated FDA inspections revealed standing water, decaying dryers, failure to follow sanitary practices, and eventually multiple environmental samples testing positive for Cronobacter.

My testimony touches on the consolidation in the industry, but I am not going to address that further. You can read that in my written testimony, but we want to focus here on what the FDA did. Much of the FDA's response was entirely appropriate. The Agency convened an Agency-wide incident management group, sought to identify alternative suppliers, exercised enforcement discretion on a case-by-case basis to allow product to reach market, facilitated the importation of products from abroad, and used a risk benefit approach to release the most critical products.

In other respects, however, FDA's performance failed to live up to the high standards that American consumers expect and deserve. The whistleblower report went undelivered to senior Agency staff for months, and the Agency took too long to schedule a repeat inspection of the Sturgis facility, thus delaying the ultimate recall, the Agency audit, and internal review of its own response. But that report, while offering many strong recommendations, failed to provide a clear account of the events surrounding the recall or the mistakes made by Agency officials.

Better prevention and management of future crises requires at least three elements: authority, funding, and an effective organizational structure. On funding, the Food and Drug Omnibus Reform Act of 2022 required formula and medical food manufacturers to develop a supply redundancy risk management plan, mandated the creation of an office of critical foods at FDA, and it also required critical food manufacturers to notify FDA of interruptions in manufacturing likely to lead to meaningful disruptions in supply. But the Agency needs additional authorities and should have the authority to require manufacturers to notify the Agency of all positive test results and to require more frequent environmental testing in production facilities. It should also be able to compel manufacturers

to submit supply chain data, and although not an FDA issue, Cronobacter should be made a notifiable illness.

Second, the food program requires more funding. Rising costs have left the program with a number of FTEs, similar to what it had in 1978. But since then, FDA has been given increasing responsibilities, including broad new mandates over infant formula, dietary supplements, food labeling, and food safety. The President's FY 2024 budget calls for \$152 million in necessary new funding for the foods program, and this includes \$64 million for health and safe food for all, which includes support for improved oversight of infant formula. There is also \$12 million to establish a Center for Nutrition that will house its Office of Critical Foods.

We at CSPI believe that number should be closer to \$24 million because of the importance of nutrition programs. But together, these programs would support increased review capacity for infant formula premarket notifications, improved surveillance of formula related adverse events, and the development of better laboratory methods for Cronobacter, as well as a more rapid review of inspection findings.

Finally, Americans deserve a food program with a structure that is transparent, effective, and accountable. The formula crisis laid bare the high level of dysfunction, breakdowns in communication, and lack of clear lines of authority that characterized the FDA's response. The reorganization announced by FDA Commissioner Califf in January is an important step on a path toward addressing these issues. It captures the spirit of the Reagan-Udall Foundation report that the Agency had requested, and it does so in a manner that minimizes internal disruption.

First, it elevates the food program to the Deputy Commissioner level, which is higher than any other FDA food product center. Second, it dissolves a dysfunctional structure whereby three senior officials, with authority over the human foods program, all reported to the Commissioner, and none had clear authority over the program. Third, it clarifies the relationship between the Human Foods Program and the Office of Regulatory Affairs which inspects facilities, and, as noted, it establishes a new Center for Excellence in Nutrition and an Office of Critical Foods. While more detail is still necessary on this proposal, it is a significant step forward and lays the groundwork for a foods program led by a leader who is more empowered and accountable than any FDA food program leader in recent history.

No mother, no father should ever again face a desperate store-by-store search for a product simply to nourish their infants. Thank you.

Mrs. MCCLAIN. Thank you, Dr. Lurie. I recognize Ranking Member Porter for five minutes.

Ms. PORTER. Thank you, Madam Chairwoman, for your patience with my schedule today. The goal of this hearing is to stop the entire baby formula market from being at risk when there is bacterial contamination in a factory. So, I want to figure out how much progress we have made toward that goal by looking at what would happen if the Abbott contamination were to repeat itself.

So, Mr. Yiannas, let's say that a major formula manufacturer, and there are only a handful as you know, finds bacteria in their supply today. Does the law say the factory has to tell the FDA?

Mr. YIANNAS. The answer to that is no, other than the Abbott Sturgis facility, which, as you know, is under consent decree.

Ms. PORTER. So, I think this is really important that everyone hear this. So, I am going to ask you one more time. Let's say that a major formula manufacturer or factory found bacteria in their supply today. Does the law require them to tell the FDA?

Mr. YIANNAS. The answer is no. They should, but they are not required by law.

Ms. PORTER. But surely the FDA is now keeping a close eye on supply, so that they are ready for any disruption. What resources and authorities are now in place for the FDA, even though they have no requirement that anyone tell them, but should the FDA learn, what are the resources available for the FDA to do supply monitoring?

Mr. YIANNAS. That is an area of the program that needs further development. Historically, the FDA has been focused on food safety and nutrition, not supply chain availability. But after the pandemic, which I describe as the biggest test on the U.S. food system in a 100 years, we all realized that as an Agency, we needed more intelligence and data on how companies and supply chains actually worked. There were attempts to try to build those capabilities internally. They were met with a lot of resistance because it wasn't part of the core mission. But I am grateful that Congress, through the omnibus, has asked FDA to set up an Office of Critical Foods and to develop those type of capabilities.

Ms. PORTER. Do you think the Office of Critical Foods, as structured in the omnibus, will go far enough in supply chain monitoring, and are we making fast enough progress in getting it going?

Mr. YIANNAS. We started making progress before the infant formula crisis. Early during the pandemic, we knew that while the virus didn't cause transmission or illnesses through food, we knew it would wreak havoc to the food supply chain because ill workers, if not available, would affect supply chain continuity. And, so, we started to build those capabilities on what I describe as a shoestring budget without authorities, but it hasn't gone far enough. Although requests for additional fundings have been made to the commissioners and acting commissioners, like I said, it has been met with resistance. I think after the recall of 2022, now there is a greater appetite. Progress is being made, but it is not being made fast enough.

Ms. PORTER. Mr. Yiannas, since the law doesn't require, as we just learned, factories to report contamination, what incentives do monopolistic or a small number of suppliers, monopolistic companies have to self-regulate when the market isn't forcing the level of competition on quality and the FDA is still building out its monitoring apparatus?

Mr. YIANNAS. I think there is one critical component that was mentioned in the opening comments, is public health surveillance. Our ability to detect illnesses in society and learn about why they occur, what are the food vehicles that cause them, what are the contributing factors is critical to informing future prevention.

Today, Cronobacter Sakazakii is not a reportable disease other than in two states. And so, that is a real disincentive for the industry to know what is really happening and for them to take corrective action. So, I would say the time is now for us as a Nation to make Cronobacter Sakazakii a nationally notifiable disease and reportable in all 50 states.

Ms. PORTER. And I really appreciate it, in your testimony, that you came to us with concrete actions that we can take to actually address and better prevent this. So, I noticed that was your No. 1 recommendation in your list of 11. Dr. Lurie, with my remaining time, can I ask for your thoughts on how far you think reorganizing the Human Foods Program will go toward creating the proactive FDA that we all need to be safe?

Dr. LURIE. Yes. Well, I don't think one should overstate what can be accomplished through a reorganization. But I do think that what Commissioner Califf has come up with is a very reasonable attempt to, on the one hand, strengthen the food program, giving it the kind of prominence within the Agency that it has for a long time lacked, and yet at the same time to do so in a way that acknowledges the way that the Agency is currently structured such that any new situation is not unduly disruptive, and I think that they have done a pretty good balance of that. We have never had a Deputy Commissioner over the entire foods program before. Even when Mr. Yiannis was there, I am sure he will be the first to say that he never had that kind of authority. But the vision, currently, is to do exactly that and to elevate foods within the program in a way that has never been the case before.

Ms. PORTER. Thank you very much. I yield back.

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

Mr. GROTHMAN. Yes, I will ask Mr. Yiannas a few questions again. Currently, what is the structure of the FDA and its food programs?

Mr. YIANNAS. Currently, the foods program is what I call a very distributed in a decentralized organization. You have the Office of Food Policy and Response within the Commissioner's office, an office that I lead, of about 40 people. You have the largest office involving food, the Center for Food Safety and Nutrition, which to this day is led by Dr. Susan Mayne, who has recently announced her retirement. You have the field force—

Mr. GROTHMAN. OK. I hate to cut you out, but they only give us five minutes. Would you, therefore, describe the current structure as decentralized?

Mr. YIANNAS. Absolutely.

Mr. GROTHMAN. OK. Do you think that is a problem where it is also decentralized if you have a crisis like we had last year?

Mr. YIANNAS. I do. I think the decentralized and distributed nature of the organization caused information silos, not allowing critical data and information to flow to those that needed it quickly and that needed it most.

Mr. GROTHMAN. Did you elevate your concern before this crisis?

Mr. YIANNAS. Yes, sir.

Mr. GROTHMAN. OK. But nothing was done about your concern or—

Mr. YIANNAS. In the time that I was at FDA, which was a little bit over four years, I have had six different bosses, whether permanent or acting commissioners. It has been a rotating seat, and every single person that I have reported to has known my concerns.

Mr. GROTHMAN. OK. FDA Commissioner Califf released a restructuring plan for the program. In your opinion, does the Commissioner's restructuring plan do enough to resolve the Human Foods Program's organizational issues?

Mr. YIANNAS. Well, I believe Dr. Califf's plan is well intentioned. I do not think it will completely solve the issues at hand. No. 1, and I know we are limited in time, quickly is it has been referred to as a new foods program vision. A vision and strategy are very different than an organizational structure. It is a reorg. You need a strategy first, and you need a structure to support that strategy. That is No. 1.

No. 2, I will disagree with my colleague here. The proposal does not even go as far as previous deputy commissioners once had. At one time, previous deputy commissioners had oversight over CFSAN, over their offices in the Commissioner's office, over CVM, but not ORA. This new reorg does not even go as far as to what previous deputy commissioners had.

Mr. GROTHMAN. That is kind of shocking. In your opinion, because I think when I think of the FDA, I think of drugs and medical devices. Do you think the current culture at the FDA is such that by focusing on drugs and medical devices, they do that to the detriment of the food and food safety programs?

Mr. YIANNAS. I think the drug program being as big as it is, the fact that it is supported by user fees does hinder the foods program, and the overall Agency's focus on the foods program. As I mentioned, it is a very decentralized organization, something I had not experienced in the private sector. And as such, there are many multiple or microcultures within the broader organization, and it hinders our ability to create a one FDA culture.

Mr. GROTHMAN. OK. And do you feel, therefore, just as far as the head of the FDA, they kind of, again, because they are focusing on the drugs and all the money that flows there, do they kind of consider food—maybe it is an exaggeration to call it an afterthought—but a little bit of an afterthought.

Mr. YIANNAS. My experience and decisions that have been made, including financial ones on supply chain monitoring, food has taken a backseat to drugs.

Mr. GROTHMAN. OK. Is it appropriate for the FDA to inspect foods in the same way the FDA inspects drugs and medical devices, do you think?

Mr. YIANNAS. The approach would be slightly different. It is a different food with different risk factors, but we should be inspecting food facilities for sure.

Mr. GROTHMAN. OK. In December, the Reagan-Udall Foundation for the FDA conducted an operational evaluation of the FDA's Human Foods Program. Are you familiar with that report?

Mr. YIANNAS. I am.

Mr. GROTHMAN. OK. Could you go into it a little bit?

Mr. YIANNAS. Sure. The Commissioner and the Principal Deputy Commissioner selected Reagan-Udall because of the close associa-

tions with them. I do think they attempted to create a fairly independent report. They provided a series of options for restructuring with the Commissioner having the latitude to choose those different options. One of the things I really liked in their report is that they emphasized culture. You cannot fix FDA or strengthen FDA by just doing a reorg. You also have to address cultural issues.

Mr. GROTHMAN. OK. And do you think to a certain extent that it would be addressed if we separated the human foods and drugs division that forces maybe a stronger culture?

Mr. YIANNAS. I think that could be a factor that could contribute to a stronger one food program structure. There are other ways to do it as well.

Mr. GROTHMAN. OK. Thank you.

Mr. GOSAR. [Presiding]. I thank the gentleman. The gentlelady from New York, Ms. Ocasio-Cortez, is recognized.

Ms. OCASIO-CORTEZ. Thank you, Mr. Chair. Mr. Yiannas, Abbott Nutrition, Mead, and Perrigo control 90 percent of the infant formula market, correct?

Mr. YIANNAS. Yes.

Ms. OCASIO-CORTEZ. And at the time of the infant formula recall last year, Abbott manufactured 43 percent of the powdered infant formula produced in the U.S. Is that correct?

Mr. YIANNAS. That sounds approximately correct.

Ms. OCASIO-CORTEZ. And so, I think it is fair to say that any impact in supply from any one of these companies would profoundly impact the supply of formula for all Americans. And I wanted to dig into a little bit more of what happened at Abbott last year. Now, you, of course, were at the FDA during the Abbott recall last year, correct?

Mr. YIANNAS. I was.

Ms. OCASIO-CORTEZ. And at that time, in October 2021, the FDA received a whistleblower complaint regarding the sanitation conditions of Abbott facilities in Sturgis, Michigan. Could you recall some of the details of what that whistleblower complaint alleged?

Mr. YIANNAS. I can. It was a lengthy letter, 34 pages, I believe. There were allegations of falsification of records, of trying to keep information away from Federal inspectors. There were very serious allegations, I thought, in that whistleblower complaint.

Ms. OCASIO-CORTEZ. And after that complaint, the FDA did launch an investigation in January 2022, correct?

Mr. YIANNAS. Prior to that, they interviewed the informant, but they did go and inspect that facility in January 2022.

Ms. OCASIO-CORTEZ. And, in fact, it seems that the conditions were so horrible in this facility that the DOJ initiated a criminal investigation into the unsanitary workplace conditions in the Sturgis facility. Is that correct?

Mr. YIANNAS. That has been documented in the public literature, but I would say that is a conversation you should have with the DOJ.

Ms. OCASIO-CORTEZ. We also know that Abbott faced a number of lawsuits alleging tainted baby formula long before the recall happened. Following a seven-year legal battle for one family whose infant suffered debilitating brain damage, Abbott successfully

sought a court order sealing trial testimony and evidence regarding Abbott's testing and food safety protocols in that same plant. And that was seven years before the consumption of unsafe formulas resulted in the deaths of several more infants that led to the shortage.

We also see a pattern here that the Abbott company, which produces Similac and other major formulas, used ruthless tactics during their legal team to bury a lot of this information that its baby formula was causing brain damage or death in children for years before the recall happened. But I wanted to look a little bit and dig into the FDA's authorities that you were speaking into and what we need to do to prevent something like this from happening again?

Mr. Yiannas, to kind of repeat the point earlier, does the FDA currently have the authority to require firms to notify the FDA of positive results even when it does not leave the facility?

Mr. YIANNAS. It does not.

Ms. OCASIO-CORTEZ. It does not. And is the FDA, in your view, adequately funded and resourced to launch more aggressive inspections in these types of facilities?

Mr. YIANNAS. I believe we can do more with the existing resources. Clearly, with more resources, there is even more you can do, but I think with the current, existing resources, we can do a good job within baby formula.

Ms. OCASIO-CORTEZ. And does the FDA currently have a clear congressional authority to issue a mandatory recall, instead of just relying on these corporations to voluntarily issue a recall?

Mr. YIANNAS. We do through something called the Food Safety Modernization Act for foods under FSMA. Infant formula has its own rule. My experience has been if you present a firm with the evidence, you can execute a recall much faster than relying on a mandatory recall. If needed, the Agency won't hesitate to use it, but that takes longer, and usually the quickest path to action is to present the evidence so that the company will do so, and they usually do.

Ms. OCASIO-CORTEZ. And so, going back through this timeline here, Abbott did issue that voluntary recall after the FDA presented its evidence, correct?

Mr. YIANNAS. They did.

Ms. OCASIO-CORTEZ. And so, in your assessment, kind of looking through these things, it would be helpful, and one of the things that we should probably move on this Committee is to empower the FDA to require those firms to notify you. And, I know you had mentioned earlier about perhaps some additional measures, but for the purpose of the Committee and the proceedings, are there any other additional provisions that you would emphasize as well for us to consider?

Mr. YIANNAS. I would. Thank you for that very good question because I think we are all trying to prevent things like this from happening in the first place. And I agree 100 percent, the primary responsibility resides on Abbott. Abbott bears this because they ran an operation that was under a lack of control, insanitary, and producing products that were prone to contamination. We need to make Cronobacter a nationally notifiable disease, we need to



strengthen infant formula manufacturing standards, and we need to use state-of-the-art modern manufacturing approaches.

Some of these plants, as you know, are very old. I refer to them as legacy facilities, built in the 1940's. In the Abbott Sturgis facility alone, there was a spray dryer that had multiple cracks that was purchased and installed in 1960's. That piece of equipment is older than I am. There is a lot that has changed. We know a lot more now. We should require that they strengthen their preventative controls.

Another thing we should do, is we should ask them to do more robust verification that their procedures are working. One of the Achilles' heel that has allowed the Agency to become complacent is that our rule currently says infant formula must be tested at a N equals 30 sampling plan. That means that 30 samples are taken, 10 grams of sample per each, 300 grams are tested for Cronobacter Sakazakii. Some of these manufacturing runs can be huge, 50,000, 60,000 pounds. Three hundred grams is insignificant, and the probability of them finding contamination is virtually zero. It has been a free pass for them to say it is tested negative, we can sell this product.

Mrs. MCCLAIN. [Presiding.] Thank you, Mr. Yiannas. Thank you. The Chair now recognizes, Mrs. Luna.

Mrs. LUNA. Thank you guys for being here today. The bacteria outbreak in Abbott's nutrition manufacturing facility in Michigan is, in my opinion, just one of the many examples of the FDA's lack of oversight regarding not just food standards, but I would also argue, too, sometimes in the pharmaceutical industries. The FDA, as I am sure you all know, is intended to be the people's last line of defense, and although Abbott was responsible for not reporting this earlier, I do believe that there was a combination of issues that led to unfortunately this happening.

In fact, the FDA's failure to adequately inspect Abbott and listening to whistleblower's concern contributed greatly to the formula shortage as a whole, and it took months for the FDA to respond. Had they responded, infants could have been saved. And I would like to note that it stated in the briefing that we got that 40 percent of infants infected will die if they have this bacteria, which means that of the 15 Members who sit on this Committee, if 40 percent were infected as infants, six of these Members would not be here, so that is incredibly alarming.

But it is clear that FDA is not doing their job and does not prioritize food safety as well as many of the food additives, including hazardous food dyes like Red 40, Yellow Number 5 and Number 6, are banned in other countries around the world because of their harmful side effects, yet permissible in the United States.

The FDA continued to launch an ad campaign, lecturing parents about how alternative infant food formulas may lack nutrients vital to an infant's growth, yet has also, at the same time, approved drugs such as mifepristone for pregnant women that starves an unborn child of nutrients until they die, or what about the 1960's debacle with FDA approving thalidomide and actually covering up some of the investigations, according to an article by The New York Times, in an effort to keep this knowingly dangerous pharma-

ceutical on the market to the American people. So, needless to say, as a Member of Congress, I do not really trust the FDA.

It seems though that the FDA is for sale and will work with corporations to keep harmful products on the market, knowing the outcomes. We need to remove food additives that are detrimental to our health, and pharmaceuticals, and improve our inspections for foods across the board. Consumers buying food should be able to buy food and be able to trust it, not chemicals and additives that are toxic and known to carry risks. I guess my main concern, because I have heard your opening statement, and I appreciate your solutions to this, but why is it that Abbott is still an FDA-approved manufacturing facility for infant formula if they have knowingly covered this up because that is what it seems like.

Mr. YIANNAS. The facility did voluntarily shut down. Abbott has several manufacturing facilities. This occurred at the Sturgis facility. The facility did voluntarily shut down and, through the consent decree, there were a series of processes that they had to undergo to give us confidence that they could produce safe product. And they met those requirements per the consent decree, and so, now they are back in operation.

Mrs. LUNA. Has the FDA made any changes because I anticipate that due to COVID, you guys were not able to get into some of these facilities, but to only go to three of the, I believe, it was 23 facilities? It seems like, God forbid, something like this happens in the future, that needs to be changed. Frankly, if I was one of these parents, I would be completely ticked off at the FDA for not listening to those whistleblower complaints earlier.

Mr. YIANNAS. I think that is a fair criticism. Thank you. The FDA developed an internal policy that it would monitor COVID transmission around the country, and if it was above a certain level, they would not do inspections, even though they were deemed critical. If you look at other segments of the food safety profession, USDA inspectors continue to show up. They were considered critical infrastructure. If you look at many of the states, state inspectors considered to show up, so I think that is a fair conversation to have. Heaven forbid there is a future pandemic? If our FDA inspectors, critical infrastructure, critical personnel in critical structure, and is there a role for them to play?

Mrs. LUNA. But also, to something outside of COVID because it is very possible. I mean, I hate to say it, but I do not trust China, and biochemical is a very real threat in this country. So, obviously something outside of COVID would be important to keep you guys able to do your jobs.

Mr. YIANNAS. We also need to fully explore other means to gather intelligence, whether it is remote access of data and records.

Mrs. LUNA. OK. Thank you very much. Chairwoman, I yield my time.

Mrs. MCCLAIN. Thank you, Mrs. Luna. The Chair now recognizes Ms. Balint.

Ms. BALINT. Thank you, Madam Chair. Before I begin, I just want to say a colleague earlier mentioned mifepristone. I just want to say it is a safe and effective medication. We have to focus on infant formula today and not get distracted by essential medications

that we know are safe and women should have access to them. I want to get that on the record.

Next thing, you know, I can really empathize with parents who had to deal with the shortage. Breastfeeding was very challenging for me and my son, and I can certainly understand the intense fear and stress that comes when you are a parent and you do not know how you are going to take care of your kid. I mean, there is nothing more stressful as a parent than that. And one Vermont mom described bone-deep anxiety during the crisis—bone-deep anxiety, wondering whether she would be able to find formula for her child, and that really resonates with me.

We absolutely owe it to parents and, of course, children to make sure that we do not face another crisis, and I want to thank you for being here today so that we can ensure that this does not happen again. I represent Vermont, which is a rural state, and I am very concerned about how the crisis impacted low-income folks and rural Americans in particular. According to the Kaiser Family Foundation, infants born into lower-income and rural households are much more likely to rely on infant formula than other babies. Formula shortages hit these communities harder. More than 50 percent of infant formula across the country is purchased through the WIC Program, an excellent program which helps us to take care of children in this country. Far too many parents were forced to drive and drive and drive to try to find formula, to try to find food for their kids, and this is especially challenging in rural communities.

So, Dr. Lurie, how can we help ensure that going forward, low-income and rural families are a focus of our national strategy and response for preventing future shortages?

Mr. LURIE. Well, I think, as you probably know, the government has an enormous role to play when it comes to the provision of infant formula in this country since more than half of all infant formula is actually paid for by the WIC Program.

Ms. BALINT. Yes.

Mr. LURIE. So, that is absolutely critical. I think that, from what I can tell from the outside, the FDA did a pretty good job once the rubber really hit the road in this problem, to communicate with USDA, which runs the WIC Program, and to try to communicate with them in ways that kept the supply going best they could. But in the end, with the concentration in the market, there was just no way to keep up. And parents, understandably, began to hang on to product for fear that they would not be able to find it in the future, and that ended up with the kinds of empty shelves that we wound up seeing.

Ms. BALINT. And the other thing that I think we are all still reeling from, is there was the crisis of needing to drive from store to store trying to get ahead of the run on infant formula. But there is also a deep concern that I have about price gouging, and I have talked about that in this Committee before. And, so, you know, as you saw desperate parents realizing they could not find it in their local area and driving to the next town and the next town and the next town, they would then turn to the internet to find the formula that they could not find in the stores. And we began to hear stories of price gougers, getting up to 300 percent more for a can of infant

formula. And I know that the Biden-Harris Administration worked to crack down on the price gougers, but I do think Congress can do more to ensure that these scammers, individual scammers, and also greedy companies do not prey on the vulnerable families in these situations when all they are really thinking about is how do I feed my kid, right? How do I feed my kids?

So, Dr. Yiannas, why is a whole-of-government approach to this, a better response to this crisis? How do we need to look across government to have a response that really is meeting all of these individual issues?

Mr. YIANNAS. Thank you. That is an excellent question, especially as it relates to infant formula supply and resiliency because FDA is limited in what it can do. Clearly, FDA sets safety and nutrition standards, and we have spent an amount of time talking about that. FDA plays a role in market availability by accelerating approvals, and there is more that we can do, but there is only so much the FDA can do.

And a lot of the factors that drive the structure of the infant formula supply chain, its availability and resiliency, rely on other parts of government, for example, USDA and the WIC Program, as you mentioned. American taxpayers through the WIC Program buy over 50 percent of that infant formula, and there is something called sole-source state contracts, really creating an artificial market incentive for certain players to dominate in particular states.

If you have a crisis, with certain players dominating market share in a state, it is hard to be nimble and recover, and so, we have to look at the WIC contract process. The executive office of the Biden Administration was very helpful with the DPA and allowing us to make priority purchases to make sure critical ingredients that were in short supply went to these infant formula manufacturers. So, I found that this response requires an all-of-government effort, and we should continue to look at ways to strengthen how an all-of-government response occurs for shortages of critical foods.

Ms. BALINT. Thank you.

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

Mr. LANGWORTHY. Thank you so much, Madam Chairwoman, and thank you to the witnesses that have joined us here today. I mean, this is a topic, as my colleague from Vermont just outlined, I mean, that has really tackled families. I have staff members that have newborns that are still struggling with supply. I am a parent of a young son, five months old, myself. I mean, while this has not affected our family, it has affected so many of our constituents, and that helpless feeling of a parent that does not know how they are going to be able to feed their child is one that I think it is incumbent on this body to make sure it never happens again in this great country that we live in.

Mr. Yiannas, when was the FDA made aware of the Cronobacter outbreak at Abbott Sturgis plant?

Mr. YIANNAS. Well, the very first report of a Cronobacter illness linked to that plant was September 20.

Mr. LANGWORTHY. OK. Of 2021?

Mr. YIANNAS. 2021.

Mr. LANGWORTHY. And, Mr. Yiannas, is it true that soon after, in October 2021, the FDA received a whistleblower disclosure message regarding Abbott Nutrition's plant?

Mr. YIANNAS. That is true.

Mr. LANGWORTHY. OK. Now, to your knowledge, when was the earliest date that you received the notice of the whistleblower disclosure?

Mr. YIANNAS. I personally was not made aware of it until February 10 of the following year.

Mr. LANGWORTHY. OK. Now, Mr. Yiannas, that is four months after it was initially reported. What did the FDA blame this delay on?

Mr. YIANNAS. Several things. Initially, as you heard in the original congressional hearing, there was a lot of focus and discussion about mail rooms and that the mail rooms lost it. That whistleblower complaint was sent by FedEx, hard copies to multiple individuals and multiple offices, so that means it would have been lost at multiple office: at the White Oak Campus, at the CFSAN Campus in College Park, also a field office located in the north. So, allegedly, it was lost in the mailroom.

We do know that some individuals received copies by emails, and in hindsight, those should have been escalated to my office very rapidly, but those are some of the reasons that were reported. And then finally, in the report that the FDA put out, they said that we lacked the systems to actually detect these signals and escalate them.

Mr. LANGWORTHY. So again, it is the decentralization of the FDA that may be an issue here. I mean, it is 2023. The White House has declared the pandemic is over. It is almost two years since the first infant formula shortage, and our country is on the verge of perhaps another. In your opinion, how can this still be happening?

Mr. YIANNAS. I think that we have not taken enough urgent action. I think there are some things that we need to do. The long-term resiliency of the infant formula market is not something that can be solved overnight, so we are going to have to be intentional, and I hope Congress will request it. I am grateful that through the omnibus, you have asked that there be a resiliency report conducted, analysis of the infant formula supply chain resilience, and reported back to Congress. That is a good step, and we have to look at what are the market incentives and what are the contracts that WIC uses. For example, I think WIC contracts actually contributed to this crisis. But WIC might very well be part of the solution to the crisis, and so, but there is more we can do on the prevention that we can do faster. The resiliency and market consolidation is going to take a little bit longer to resolve.

Mr. LANGWORTHY. Now, I am aware that our infant formula supply is not even back at full capacity yet. Now, why is that taking so long? Is there not enough urgency delivered through the court of public opinion to these companies to wake up and ramp this up?

Mr. YIANNAS. One of the things we did—it is a great question—very rapidly building on this data analytic platform that I have described that we call 21 FORWARD to monitor food supply chains. We started adding additional functionality very quickly to deal with the current crisis. And one of the things the FDA has today

is really impressive, that they did not have before, we have manufacturers in this country of infant formula reporting production volumes to the FDA on a weekly basis, not required by law, but they are doing it.

FDA knows how much infant formula is being produced. We have good quantitative data and what is the national need to feed all infants in this country. So, we know production and consumption. We are tracking sales data. We are tracking how much infant formula is on shelves and where it is located through in stock improvement rates. And I can tell you that the call to action has been met. All the private sector companies that I have talked to have ramped up production. There has been what we call SKU consolidation. They limited the types of products they produce, so they can get more product out, so store shelves still will look scarce because there are less SKUs, stock keeping units, available, there is less variety. But I think in short order, we should find ourselves in a very much better situation.

Mr. LANGWORTHY. Thank you, Mr. Yiannas. I yield back.

Mrs. MCCLAIN. Thank you. The Chair now recognizes, Ms. Crockett.

Ms. CROCKETT. Thank you, Madam Chair, and thank you so much for being here today. Mr. Yiannas, I want to give you a little bit of an opportunity to flesh out some of the things that you have been talking about. But obviously, we have these constraints, because I think that you are offering us a really good glimpse into solutions, which sometimes in this building, as a freshman, I feel like we don't really get to solutions. And I think, I know at least in my district, they do not want us just kind of jumping on the bandwagon of rhetoric. They actually want us to solve problems.

And so, one of the things that you have mentioned that I think is interesting, as someone who also serves on the Ag Committee, and it is technically in Ag right now, is you talk about WIC, and you say that WIC was part of the problem as well as it could be part of the solution. Now, the way that my ears interpret that is that we have an opportunity in WIC because these are Federal contracts, right? And so, with that, we can then put certain constraints, regulations, things like that on our baby formula, and honestly, kind of like what we saw in the last session.

There was a vote that said that we would not be charging over \$35 for insulin. And next thing you know, guess what? The private sector, Eli Lilly followed suit because there are so many government contracts that, honestly, where are you going to compete, right? And so, if we have got 50 percent—I think that was the number that you gave us—of the folk that are actually getting this formula, they are getting it through WIC. So, can you just expand a little bit or expound a little bit upon how you think we can also be a solution?

Mr. YIANNAS. Sure. I think USDA is very open to this, and I would encourage you to have this conversation with them. They are reimagining the WIC Program, but if you think of the infant formula supply chain, the fact that it is very in-elastic, and very fragile and consolidated, generally supply chains form this way through market incentives, its resources, its dollars. The WIC contract of sole-source contracting, picking winners for certain states, there

have been studies that show, if you get a contract, if a manufacturer gets a contract in a state, they dominate in that state. Even for the infant formulas that are purchased outside of WIC, they just dominate.

So, we have created an artificial intelligence on picking winners and losers for who is going to have the majority of infant formula share in a particular state. But we can use this artificial market incentive, the fact that the government buys about half of all infant formula, to create a more diversified contract system, so you don't have sole ownership or sole dominance in particular states. When a crisis like this happens, if you are in, let us say, an Abbott-run state, all the grocery stores had SKUs and supply chains that were dependent on Abbott. And that is not very easy to change very quickly, and so, I think diversifying the contract process is a key to the solution.

The other thing I was very sensitive was to parents that could not get WIC products online. And many of you know this, WIC availability wasn't available online, and people had to travel many miles to find products. It would have been nice that even if you were a WIC customer, you could have gone online and searched for the infant formula that you needed.

And so, I would encourage this Subcommittee, Congress, and all relevant regulatory agencies to really work hard on how do we create the types of flexibilities and market incentives to create a more resilient infant formula supply chain in this country. It can be done. I don't think it is going to be that difficult, but we need to make sure that the groups are working together, that they are held accountable, and they are given timelines to make it happen because in my sense, the past year, things have moved along too slow.

Ms. CROCKETT. Thank you so much for that. And finally, I just want to talk for a second, you mentioned that the FDA can't, essentially,—I am paraphrasing—that the FDA can't just do whatever they want to do. I mean, they have to have the authority to do various things. And so, you know, the FDA gets its guidance from our Administration as well as from the Congress, and it seems like you are suggesting fixes that would implicate more regulations. What I hear you talking about is, maybe, listing this particular bacteria as one of those things that has to be reported because we can't rely on those that have a financial incentive to always do what is right. That is what regulations are for. So, it sounds like you are suggesting that we implement a few more regulations. Am I understanding you correctly?

Mr. YIANNAS. There are additional regulations needed to strengthen protections, no doubt. I would also say the entire infant formula industry needs to wake up and say what they are doing is not adequate enough. I am a strong believer for regulations, but I am also a strong believer for the free market to set the right type of conditions and standards because they are responsible and not being held accountable.

Ms. CROCKETT. Thank you so much.

Mrs. MCCLAIN. Thank you, and, Mr. Yiannas, I do agree with you, accountability is a wonderful tool, and I appreciate when the

accountability is there for all parties, so thank you for that. The Chair now recognizes Mr. Gosar for five minutes.

Mr. GOSAR. Thank you. Today's testimony only highlights the FDA's negligence in the response to the compromised baby formula. A lag time of four months from the time the FDA first received the news of food safety violations in the Michigan plant to inspection, is obviously unacceptable. Instead of ensuring safe food consumption, the FDA focused on approving COVID-19 vaccines that have led to devastating consequences for Americans.

As of January of this year, over 22,000 deaths and over 1 million adverse events caused by COVID-19 vaccines have been voluntarily reported to the CDC and the FDA. These numbers make COVID-19 vaccine 226 times as deadly as the flu vaccine, but these scary numbers may be on a low estimate. A 2010 study from the Agency of Health Research and Quality, found that the CDC Vaccine Adverse Event Reporting System undercounted vaccine deaths by a factor of 100. It is high time the FDA returned to its focus on protecting people's health rather than pushing experimental dangerous vaccines.

Mr. Yiannas, when did you first learn of the food safety violations occurring in the Michigan plant?

Mr. YIANNAS. February 10.

Mr. GOSAR. Now, the whistleblower relayed violations in FDA in October 2021. If you had known about these violations, what immediate actions would you have taken?

Mr. YIANNAS. Yes, I would have demanded that an inspection be done sooner. As you know, the inspection didn't occur until late January 2022. I would have demanded that the informant be interviewed sooner. As you know, there was a two-month gap between which the informant was interviewed. I would have questioned the termination or outcome of that interview, which concluded by the investigators that conducted it, that it was too vague for follow up or action. If you read that 34-page report and the allegations in there, I don't think you would say it is too vague. So, there would have been, I believe, with certainty quicker action, quicker inspection, follow up, additional testing. And, I believe that had we responded sooner, we could have curtailed or minimized this from reaching such a catastrophic level.

Mr. GOSAR. So, why do you believe the FDA officials ignored the emails containing these allegations of food safety violations from the whistleblower?

Mr. YIANNAS. I can't speak for the individuals that saw and why they didn't act on it more seriously, but I—

Mr. GOSAR. I mean, in other details where we have whistleblowers, I mean, we respond very quickly to them, so, I mean—

Mr. YIANNAS. We should have.

Mr. GOSAR [continuing]. it seems very odd.

Mr. YIANNAS. We should have.

Mr. GOSAR. Could you please explain the extent of the food safety violations occurring in the Michigan plant and what exactly were the violations?

Mr. YIANNAS. Well, I will tell you the conditions. I don't have a copy of the inspection report in front of me, but a lot of people have questioned how egregious were the conditions at Sturgis? And I



would say they were very egregious. First of all, we had four reported cases of *Cronobacter Sakazakii*, all linked to products produced in Sturgis. Sturgis is one of 21 plants servicing the U.S. market. While they had a large market share, the fact that all four illnesses consumed products produced in Sturgis was significant.

Upon our inspection, we found very egregious conditions. We found critical equipment, such as spray dryers, that had major cracks and disrepair. I mentioned this and I wrote them in my testimony. We found water leaks and water. Standing water in a dried infant formula plant is not a good mix. Our own inspectors found abundant samples positive for *Cronobacter Sakazakii* itself. We found up to five different genetic strains of *Cronobacter Sakazakii*, and we found evidence that Abbott itself had found *Cronobacter* in finished product, not just the environment, in finished product and never reported to it to us.

I have already explained that it is unlikely to test it in finished product. So, I think the abundance of evidence suggests that Abbott was operating under very unsanitary conditions and likely was sporadically contaminating infant formula. And it evaded final product testing because of probabilities and served to infants across the—

Mr. GOSAR. So, I'm going to fast track these. You made mention of monopolistic contracts, and I would like to explore that a little bit with you in regards to maybe how we could do this, maybe a fast track mechanism where you have more upfront dictations and then predicated follow-throughs. But, you know, I have a substantial ag community, and their response is very, very quick. With *E. coli* on lettuce, it is very, very timely. So, could you explain that? Because these contracts are very similar to what DOD has as their problem in sole sourcing.

Mr. YIANNAS. Yes, those contracts are run through USDA. So, I am not an expert on it and I won't be able to articulate it fully, so I highly recommend you talk to them, but I do think where there is a will there is a way, and we can accelerate action on WIC contracts.

Mr. GOSAR. Thank you, Mr. Yiannas.

Mrs. MCCLAIN. Thank you, Mr. Gosar. The Chair now recognizes Ms. Lee.

Ms. LEE. Thank you, Madam Chair. So, we spent the morning listening to people attack a formula supply chain they described as premature and inefficient recalls that worsen the issue, but when we are talking about sick babies, can we be too cautious? The reporting mechanisms did not work. We must do more to make sure this doesn't happen again. It is beyond regulation. This is a need to protect our most vulnerable population—infants—so we cannot allow weak regulations to allow children to die. Dr. Lurie, how should infant formula manufacturers have notified us of suspected contamination?

Mr. LURIE. Well, as you know, there is no requirement at present for them to do so. And so, you know, if I were an infant formula manufacturer, at the moment I have a sample that tests positive, my response is not to destroy product and tell nobody. My response is to test more widely. My response is to tell the regulatory agency involved, but that is not what they did.

Ms. LEE. Thank you. So, changing gears, as has been mentioned, infant formula manufacturers played a critical role in keeping babies fed and safe from foodborne illnesses. But when 90 percent of our supply is provided by three manufacturers like Abbott, American consumers lose. It took just one Abbott factory closure to throw this market into disarray. This industry is lacking the competition to maintain a robust market and protect our most vulnerable populations, infants who are being put at risk.

Dr. Lurie, how can Congress foster competition within the infant formula market to promote safety and accessibility?

Mr. LURIE. Well, I will just say first that, you know, I worked on drug shortages when I was at FDA, and it was quite the same problem when it came to generic injectables. It was a concentrated market, and you had a supply chain that was very friable that could break at any moment and there would be very few people who could step in, and that is very much what we saw on infant formula.

I do want to say one thing, though, about the WIC Program, which I think, you know, it is not a sole-source program. It is a single contractor in each state program. That is different. But, as important as it is to look at the WIC Program and whatever role it might have played in the concentration of the market, it is also important to remember that the way the contracts are currently constructed is saving this government about \$1.6 billion a year. And if we have to pay, somehow, you know, either this Congress is going to have to come up with \$1.6 billion or there is going to be a \$1.6 billion smaller amount of infant formula produced.

So, we need a solution. I think the Federal Trade Commission should be taking a close look at this, but we should be careful, you know, when we talk about reform at WIC, that we make sure that access to the infant formula is part of the formulation as well.

Ms. LEE. Thank you. You know, if our Congress is serious about this, we also want to investigate Abbott to get at the heart of what prompted the recalls and shortages, so we must continue to work to diversify our domestic suppliers and increase the resiliency of the infant formula market. Americans can't afford to keep relying on three manufacturers to prop up such a vital industry. I yield back.

Mrs. McCLAIN. Thank you. The Chair now recognizes Mr. Gomez for five minutes.

Mr. GOMEZ. Thank you, Chair. First, let me just thank the Chair for having this important hearing and focusing on the issue, although she can't control all her Members. You know, bringing in COVID and vaccines, I think is not an appropriate place here, especially when it comes to this issue, because the American people have a profound interest in this.

And I have a profound interest in this. I became a new dad for the first time last August, and as we were approaching the due date, I was watching the issue with a very, very interested eye, because it was like, OK, of course, we can try to breastfeed, but sometimes you got to make up the difference. And that was something that scared me, and something that concerned me, so I was watching it very, very, very carefully.

One thing I want to kind of really focus on is even if we had the ideal—your FDA with appropriate staffing, reporting—can that make up for the fact that there is market concentration? And I am also on the Ways and Means Committee that deals with trade issues. Can we really make up for the market concentration of 90 percent of the formula with these three companies even if we had an ideal, perfect, pristine FDA working in an exquisite form, Mr. Yiannas? And then I will ask Mr. Lurie.

Mr. YIANNAS. And the answer to that question is no. As I stated earlier, there are limited authorities and limited levers that FDA can pull to affect the market concentration and diversity. Again, the FDA approves these products. They set the safety standards and the nutrition standards, and the only way they can accelerate this is by making approvals go a little bit faster. The true levers on how you affect market resilience and market diversification reside outside of FDA.

Mr. GOMEZ. Mr. Lurie, you mentioned you had some comments in your written testimony.

Mr. LURIE. No, I think I have had the opportunity to make them, but I agree with what Mr. Yiannas is saying. This is not, in that sense, primarily an FDA problem. It is a trade problem. It is a market problem. And, FDA has very few levers when it comes to that. But, you know, the President's budget does have some funding that would allow faster approval of new infant formula entrants, and the Agency has done a lot in the current crisis to permit the entry of foreign products into the market. And so, that has diversified, at least for a short while, the available products, but it won't sustain us in the long term.

Mr. GOMEZ. And is that temporary, or is that a permanent—

Mr. LURIE. That is temporary.

Mr. GOMEZ. What needs to occur in order to make it permanent? Would you tell—

Mr. LURIE. Yes. My understanding is that it is an authority that has elapsed. Isn't that correct?

Mr. YIANNAS. Yes, they are looking at trying to create permanent pathways. Anybody right now could apply for a new infant formula product to hit the U.S. market. Having stated that, despite the heroic efforts, and they were heroic by the Administration, Operation Fly Formula and the enforcement discretion. And, if you looked at the total quantity of infant formula that was brought into the country in that manner, it was just like icing on the cake. It didn't make a significant material difference, and so, domestic manufacturing is something that we really need to focus on.

Mr. GOMEZ. So, after my son was born, I actually did face a situation where I had to go store to store, and the shelves were empty. You know, I can't remember—those first few months are kind of blurry—I can't remember if it was September, October. And even today, they still seem bare, the shelves. Are we still facing a supply problem, or are we facing a psychological shortage problem, like people are stocking up because they think that there could be another disruption?

Mr. YIANNAS. I will take a shot at that because I was so involved in actually creating the systems to track this. And this is an excel-

lent question, and it provides us an opportunity to explain to the American public what was happening.

There is something called an in-stock rate. The different infant formulas that you might have, what percentage of them are in-stock at your favorite grocery store or drug chain. Before the pandemic, in-stock rates were in the mid-90's. That is good. That is considered good. 95 percent of the types of infant formulas you desired would be present when you went to the grocery store. The pandemic caused supply chain disruptions, and those in-stock rates started to drop to the low 90's, maybe even 89, even before the recall. That massive recall, with Abbott's Sturgis facility being so big, caused that to drop even further, and it dropped well into the 60's at one point.

The worst it probably got was in the month of May, when a lot of news reports started being published, and we had a run with people buying more than their normal amount. Instead of buying 1 unit for the week, you were worried there wouldn't be enough, and you do what we call pantry loading. We do not criticize parents for doing that. It is a totally rational behavior, but thereafter, we started to improve, and before I left the Agency about a month ago, we were at those 90 percent in-stock rates.

Now having stated that, I told you that the shelves will not look the same because the assortment has been reduced. Manufacturers are producing less high volume in certain types. As a Nation, we are producing more infant formula than ever before, but variety has been reduced. I hope that explains it.

Mr. GOMEZ. Thank you so much.

Mrs. MCCLAIN. Thank you, and I now recognize myself for five minutes.

I think you made a very excellent point on the domestic manufacturing of this, not only for mothers, and fathers, and babies themselves. To be able to control the domestic manufacturing, I think, is critical for obvious reasons as well as, you know, national security as well. It is good to invest in business, and it is good to invest in business domestically. If the pandemic taught us anything, it was that.

But, I am going to shift gears a little bit. On May 25, 2020, Commissioner Califf testified before Congress that there were nine staff working on infant formula at the FDA. Is that an accurate statement? Yes, sir, Mr. Yiannas?

Mr. YIANNAS. I think that statement deserves clarification. There was nine individuals at that time working in the Office of Nutrition and Labeling. These individuals are specifically involved with approving new infant formula submissions. But the reality—I led the IMG. There were dozens and dozens of people working on infant formula at FDA: the field staff that does the inspections, the laboratory staff that does the testing, the administrative staff that responds in a crisis. And so, I feel that that statement could have been misleading, and it deserves clarification. There are more than nine people working on infant formula at FDA.

Mrs. MCCLAIN. Were they working on the right things?

Mr. YIANNAS. You know, in hindsight, I wish they would have been working on some additional things. I mean, if you are responsible for approving new infant formulas, one of the things we saw

in the crisis is that that team knew very little about the market. They didn't have data, which is readily available, on who owns what share, very quickly, where is it produced, how is the market performing. This data is readily available—what is the in-stock rate? And we found ourselves, in the midst of a crisis, having to scramble to collect data and build systems that I think should have been there before the crisis.

Mrs. MCCLAIN. Did they approve any new?

Mr. YIANNAS. That is a great question to ask, is how many new products have been approved and how long does it take them to do. It is a good question. I don't know the answer to that question.

Mrs. MCCLAIN. OK. In your opinion, does the Solomon report objectively evaluate the FDA's response to the infant formula shortage?

Mr. YIANNAS. The way I will answer that, is that I felt it was a very controlled report. A couple of things that I will say. One, it was not independent, correct? It was created internally by FDA. Whenever a crisis of this magnitude happens, it is good to have some independence. No. 2, I think you have already heard comments, it was presented at a very high level and doesn't get to really the root issues for you understand what really happened. I would just ask you to compare my written testimony, compare it to the Solomon report, and say did you learn new things that were a little bit more detailed. So, I don't think it went far enough, deep enough, and that it offered the appropriate solutions.

Mrs. MCCLAIN. Why do you think that was? I mean, we had a major crisis in our country that affected the most vulnerable, infants, and it seems like we just kind of glossed over some things. Why?

Mr. YIANNAS. I think because it lacked independence. It was conducted internally, and, you know, clearly, there was a very, what I would call, rose-covered lens approach to writing that report.

Mrs. MCCLAIN. So, were you permitted to contribute to the report?

Mr. YIANNAS. You know, when the crisis first happened, since the fact that I wasn't notified on February 10 and my office was the Office of Food Policy Response, I immediately wanted to know how could something like this happen and what could we do to prevent it from ever happening again. And so, I asked all program components to start developing a timeline, but shortly thereafter, the Principal Deputy Commissioner and the Chief of Staff told me that they would develop the timeline. And shortly thereafter, we learned that the Principal Deputy Commissioner would write the report or create the report.

I specifically recall mentioning to the Commissioner that I get it, since I am in the food program, if you want independence. But the Principal Deputy Commissioner that was leading the report was the Acting Commissioner on whose watch all of this happened, and I didn't think that was a good idea. So, in the May hearing, I learned for the first time that it would be Steve Solomon writing it. So, I wish I would have had the opportunity to conduct that investigation, but I was not offered. I was not interviewed by Steve Solomon. I was interviewed by direct reports to the Principal Deputy Commissioner. I did have a meeting with Steve Solomon after

the report was written, but had I written it, I would have written it quite differently.

Mrs. MCCLAIN. Thank you, Mr. Yiannas. We are going to switch gears. In closing, I want to thank our panelists once again for their important and insightful testimony today, and I really commend you both on doing something that does not really happen a lot here, and that is you came with some solutions on how to correct the problem. I mean, we all know that there is a problem. I mean, anybody who has had a child or known somebody who has a child—I mean, there is a problem.

So, I often say we cannot fix a problem that we first do not admit exists. We all admit that it exists, and I applaud and commend your efforts on some ideas on how do we work to make sure that this problem does not help again. So, with that, I commend you both for that.

I yield to the Ranking Member now for her closing remarks. Thank you.

Ms. PORTER. Thank you, Madam Chairwoman. I agree, and want to echo what she said about the professionalism that you both brought to this hearing and really helping Members focus not on the partisan nature of this, but on the solutions. And, anyone who has seen how I do hearings know that I will call out wrong where I see wrong, and no matter who is in charge or who it may offend, and the truth is, nobody gets a pass today.

Yes, the FDA must do better. It could have been faster. It could have been more adept in anticipating the formula crisis. It could have been more thorough in its after-action review and learning from the mistakes. So, there is no pass for the FDA here. Lawmakers, though, also have to do better by providing the FDA with the resources and authorities that they are telling us they need in order to get the results the American people deserve, so no pass for government.

What is more, big businesses can do better regardless of who is looking over their shoulder. It is their job to produce safe, quality products. That is the cost of doing business in food. Abbott engaged in negligent behavior, full stop. It prompted a formula recall. It put Americans at risk, and it undermined the stability of the formula market, so no pass for big businesses.

And, finally, even with shortcomings from the government and from industry, we wouldn't be here today talking about supply shortages if baby formula were sold in the strong, competitive marketplace. For too long, Washington has allowed markets to consolidate, domestic manufacturers to offshore, and critical infrastructure, including regulators, to crumble. Luckily, the Biden Administration has done a great deal in the last year to respond to disruptions and invest in our supply chains and to enforce competition policy. They are thinking toward the future.

That is what our Committee is doing here today. And I think that is the mindset that Washington-at-large needs to have, so that we never have to wonder if infant formula will be available for anyone or what other critical food may face a shortage from contamination or other health risks, so no pass today for Washington. No pass today for manufacturers. No pass here for anyone except, I

think, the professional and helpful suggestions from both of our witnesses.

So, I am eager to take what we have learned at the hearing today, strengthen the FDA, hold big business accountable, and focus on policy solutions. I yield back and, again, thank the Chairwoman for this hearing.

Mrs. MCCLAIN. Thank you, Ms. Porter, and I thank you for your help as well.

I ask unanimous consent to enter three statements into the record. The first one is a Statement by the former FDA officials; Statement by Consumer Reports; and No. 3, a Statement by Consumer Brands Associated.

So, ordered.

Mrs. MCCLAIN. I now recognize myself for closing statement.

Republicans and Democrats agree that Abbott is responsible for the Cronobacter outbreak at the Sturgis facility. I don't think there is any getting around it. They own it. But what I want to make sure that we are doing, is we hold government to the same standards, at least the same standards, as we hold private businesses too. That is our job. There is no question about that.

Abbott is facing SEC, FTC, and DOJ investigations. Abbott is also facing lawsuits, as they should, from grieving families who have lost a child. They are, and will be, held accountable for any negligence, but the FDA is just as guilty. The FDA is guilty of neglecting its inspection duties. The FDA is guilty of neglecting its duty to fully understand the fragile infants formula supply chain. The FDA is guilty for failing to prepare for the potential shutdown of the Sturgis facility, but, unlike Abbott, the FDA has not been held accountable. Clearly, there is a double standard.

And now, the FDA wants Congress to reward its negligence with more money to the tune of \$372 million for not doing their job. When Congress appropriates funding to the FDA for food safety and inspection efforts, it has a duty to conduct those efforts. We would not be here today talking about this if the FDA had done what it is supposed to do. Today's hearing has illustrated just how ineffective the FDA's food safety efforts are, and I want to put the emphasis on food safety, right? I said earlier 70 some percent of their job is food safety. Yet, they are not really doing a real good job of that, and I think you both agreed with me in your testimony on that.

The FDA Commissioner is turning a blind eye to the reality that its Agency is in turmoil. American families deserve to trust that their baby formula is safe. Instead, Americans are facing the uncertainty of continued recalls of baby formula. Just last week, several lots of Gerber formula were recalled for potential Cronobacter contamination, just last week. What has been shared by the witnesses today has been extremely remarkable. The FDA needs to be held accountable for its lack of transparency to the Congress and the American people, just as we are holding Abbott accountable as well.

FDA officials discounted and ignored the whistleblower report. That is concerning to me. They failed to react quickly to reports of the Cronobacter infections. They failed to conduct an objective internal review, and they failed to take ownership of their actions.

Now, they are trying to hide behind a weak proposed restructuring plan to distract from their failing and deflect blame, of which I commend you two for actually coming up with some solutions that I think we actually can work with. We will not allow them to avoid accountability for their failure to do their job. We have invited FDA officials to appear in a follow up on April 19, and we will hold them accountable.

So again, I thank you both for your time. I thank you both for your insight. I thank my Ranking Member, Ms. Porter, for her help on this Committee hearing. And I hope we can make the necessary changes to instill faith in the American people, and especially with parents out there with newborn babies.

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

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

[Whereupon, at 11:33 a.m., the Subcommittee was adjourned.]

