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House Energy & Commerce Oversight and Investigations Subcommittee Hearing on Formula Safety and Supply

On Wednesday (May 25), the House Energy & Commerce Oversight and Investigations Subcommittee held an investigative hearing on "Formula Safety and Supply: Protecting the Health of America's Babies." During the hearing, committee members raised concerns about the events that led to the current infant formula shortage, including the Biden administration's and the Food and Drug Administration's (FDA) response, limited competition in the market, and actions taken by infant formula manufacturers. Specifically, lawmakers raised concerns about delays in the response and problematic culture at Abbott's Sturgis, MI, facility which prevented employees from raising potential safety concerns.

Lawmakers heard testimony from two panels of witnesses: the first comprised of FDA leaders and the second comprised of leaders from the nation's three leading infant formula manufacturers. During the first panel, FDA Commissioner Robert Califf and other senior FDA leaders fielded questions on the agency's response timeline and Dr. Califf committed to conducting an investigation into the current problem, as well as a broader review of the FDA's food safety processes to improve oversight. During the second panel, representatives from Abbott, Gerber, and Reckitt discussed efforts to increase supply of infant formula in the United States, with all three expressing optimism that supply will be re-established in the coming weeks and months.

- *For more information*: https://energycommerce.house.gov/committee-activity/hearings/hearing-on-formula-safety-and-supply-protecting-the-health-of-america-s

Opening statements

Subcommittee Chair Diana DeGette (D-CO). "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 FDA, Abbott, and the other two leading formula manufacturers on why caregivers are scrambling to find the necessary nutrition for their babies and children. … 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. … Today we seek clarity on what the [FDA] was doing behind the scenes during this critical time period and what lessons have been learned from this situation. … The bottom line is that FDA needs the resources to make sure that the 'Food' part of the 'Food and Drug Administration' is not an after-thought." Full Statement.

Subcommittee Ranking Member Morgan Griffith (R-VA). "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. … The big question I have today is why did the Biden administration let the shortage become so dire before acting within the urgency? … I don't understand how the FDA can justify three months to respond to this crisis. … 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." Full Statement.

Committee Chair Frank Pallone (D-NJ). "Today, because of the baby formula shortage, 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. … Our solutions will undoubtedly include legislation. The Energy and Commerce Committee has jurisdiction over the FDA and will initiate any authorizing legislation. … There needs to more competition, so that these few manufacturers don't have a monopoly. … Additional legislation will be necessary to improve transparency and reporting requirements, and to empower FDA to set limits more quickly on contamination. … Put simply, 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." Full statement.

Committee Ranking Member Cathy McMorris (R-WA). "There are several reasons for the 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. … This hearing is an opportunity to ensure parents are certain that the FDA does not repeat mistakes that lead to these shortages. I'm 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." Full Statement.

Witness testimony Panel I

Robert M. Califf, M.D., Commissioner, Food and Drug Administration. Dr. Califf said, "We have provided you with an extensive written testimony that describes the recent history of this problem and gives detail on the timeline." Dr. Califf said FDA learned of the first case of *Cronobacter sakazakii* in an infant who consumed formula from Abbott's manufacturing facility in Sturgis, MI, on Sept. 20, 2021, and conducted a "for cause, onsite inspection" of the facility on Jan. 31, 2022. Dr. Califf acknowledged that the timeline was too slow but said there's no evidence of "intention delay or maleficence." He said the FDA is conducting an internal review to identify needed procedural or structural changes at the agency to improve food safety oversight and response. Dr. Califf called the Sturgis facility inspection results "shocking" and stated that Abbott had no backup plan in place if production were halted. Dr. Califf outlined several actions the FDA took to avoid supply chain issues and cited data showing volume remained stable, but distribution was uneven. He said reports of shortages proliferated in the last month, resulting in an increase in sales that eventually outpaced production. He outlined additional actions the FDA and the Biden administration have taken in the past month to increase supply. However, Dr. Califf told subcommittee members the FDA needs additional funding and authority to prevent future shortages. Full statement.

Frank Yiannas, M.P.H., Deputy Commissioner, Food Policy and Response, FDA, and Susan Mayne, Ph.D., Director, Center for Food Safety and Applied Nutrition, FDA, also provided responses to congressional inquiries.

Witness testimony Panel II

Christopher J. Calamari, President, U.S. and Canada Nutrition, Senior Vice President, Abbott. "The current infant formula shortage is heart-breaking. On behalf of everyone at Abbott, I want to express our extraordinary disappointment about this shortage. We are deeply, deeply sorry, and we are committed to ensuring that this never happens again. Safety comes first. … 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 increase capacity in the U.S. market. We've airlifted millions of cans of infant formula powder into the U.S. from our FDA-facility in Ireland. … Second, we have converted other Abbott manufacturing lines to create Similac liquid … Third, we are running our other manufacturing facilities … 24/7 to help replenish supply in the market. Fourth, we are working with the FDA and U.S. agencies to ensure that WIC [The Special Supplemental Nutrition Program for Women, Infants, and Children] participants will continue to be able to obtain formula free of charge. And fifth, for babies with specialized needs

we are releasing metabolic formula previously on hold and working with other manufacturers to address demand. … We also are establishing a $5 million fund to support families … and by the end of June we expect to be providing more formula to Americans than we were in January before the recall." Full Statement.

Scott Fitz, Vice President, Technical and Production, Gerber Products Company. "At Gerber, our mission is 'anything for baby' and that promise has driven our business for generations. … While Gerber is a small manufacturer in the U.S. infant formula market with 8.1% market share, we are working tirelessly to help parents and caregivers get the formula they need so their babies can thrive. … In March and April, we increased availability of our infant formula in the market by roughly 50%. … [I]nfant formula [is] a critically important product for parents, caregivers, and babies. For this reason, we must all come together to address this shortage and ensure families have the formula they need." Full Statement.

Robert Cleveland, Senior Vice President, Nutrition, North America and Europe, Reckitt. "At Mead Johnson Nutrition, which is fully owned by Rickett, we recognize that the formula shortage is a very serious issue, because we understand the responsibility we have in making the single source of nutrition for so many infants and other vulnerable people. … The Abbott recall event was the precipitating event of the current supply situation. That sudden supply loss, compounded with continuing challenges with supply chain inputs and residual pantry loading connected with the COVID-19 pandemic, has led to the crisis we are dealing with today. In response to the shortage, … we are doing everything possible to put more products on shelves while always maintaining the highest standards of safety and quality. … Overall, this has allowed us to supply 30% more formula so far this year as compared to this time last year." Full Statement.

Q&A

Subcommittee Chair DeGette (D-CO) asked Dr. Califf why the FDA's response was so slow. "By my count, it took about four months from when the agency first became aware of these reported cases of *Cronobacter* infection to inspect the Sturgis plant, then it took two more weeks for Abbott to stop production, and then it took three months more for the FDA and Abbott to enter into a consent decree" outlining steps for the facility to reopen. In total, DeGette said, it "could be up to a year from the first inspection of the plant last year and full production." In response, Dr. Califf said Rep. DeGette is right to be concerned, acknowledging that the response was too slow and there were "suboptimal" decisions along the way. He said FDA plans to get through the crisis and then use the results of the internal review to reform overall processes. Dr. Califf also praised Rep. DeGette's efforts on the 21st Century Cures Act and regulatory improvements made for medical products and said the FDA needs a similar effort on the food side.

During the second panel, Rep. DeGette asked what additional protocols Abbott is adopting to avoid future issues. Mr. Calamari said the Sturgis facility is undergoing improvements that "range from the physical to the process and all throughout the facility, including installing non-porous flooring, improving processes and traffic patterns within the plant, and additional training for employees. In response to a question about preparing for future shortages, Mr. Fitz said Gerber is a small player in the U.S. market and that steps, such as those allowing importation from foreign manufacturing sites have been helpful. Mr. Cleveland said Mead Johnson Nutrition is working with the FDA to enable it to import infant formula from a Mexico facility for sale in the United States. To address the current shortage, Mr. Cleveland encouraged families to call manufacturer hotlines for help obtaining formula, consult with pediatricians, and to shop widely.

Subcommittee Ranking Member Morgan Griffith (R-VA) also pressed Dr. Califf on the FDA's response timeline, asking why it took the agency nearly three months to relax regulations to increase infant formula supply in the United States. Dr. Califf said the FDA has been monitoring supply volume and sales and, except for a few areas, until recently the supply appeared to be keeping up with demand.

During the second panel, Rep. Griffith asked each panelist when they first started seeing supply chain issues related to infant formula. Mr. Calamari said there was increased demand during the COVID-19 pandemic, Mr. Fitz said late February after the Abbott product recall, and Mr. Cleveland said early signals during COVID, but immediately after the recall. In response to a question on culture problems at the Sturgis facility, Mr. Calamari said he does not believe culture is the problem and that the company is working with the FDA to get the facility up and running.

Committee Chair Pallone asked how consumers will be able to access formula coming in as part of the latest administrative efforts. Dr. Califf declined to give a set amount of time but said it could take several weeks until there is a surplus of formula. He recommended consumers go to HHS.gov/formula for information on distribution and hotlines to manufacturers. Pallone also asked what Congress can do to help the FDA, such as imposing new reporting requirements on manufacturers and granting FDA authority to act more quickly when contaminations are identified. Dr. Califf said the FDA has consistently asked for additional authorities to respond to infant formula shortages and welcomed Rep. Pallone's suggestions. He also said there is no national system in place to track supply.

Rep. Pallone pressed the second panel on actions that can be taken to help consumers find formula now, as opposed to a month from now. However, panelists offered limited immediate actions, noting full supply could take several weeks.

Committee Ranking Member McMorris asked about the pandemic relief funding that Congress authorized for the FDA to create a data analytics tool to monitor the supply chains of various products, including infant formula. Dr. Califf said the FDA built a tool but was unable to create a robust platform. In addition, Dr. Mayne said the FDA does not have the authority to demand data from companies to adequately monitor the supply chain. In response to a question on the FDA's impact analysis from closing the Sturgis facility, Dr. Mayne said the agency had anticipated the shortages and that information informed the voluntary recall recommendation and drove FDA efforts to work with other manufacturers to increase production, as well as other actions such as regulatory flexibilities and asking retailers to limit purchasing.

During the second panel, Rep. McMorris noted that FDA reviews identified safety concerns at the Sturgis facility in both 2019 and 2021 and asked what Abbott is doing to address those issues. Mr. Calamari said Abbott fixed problems identified in 2019 and 2021. Since February, he said Abbott has been working to increase supply outside of the Sturgis facility, but with the new consent decree reached with the FDA it expects to begin production at the plant in a few weeks.

Rep. Kathleen Rice (D-NY) asked what steps the FDA is taking to address the delayed response. Dr. Califf said one key problem was it took several months before Mr. Yiannas and other senior FDA officials were made aware of the situation at the Sturgis facility so the FDA has implemented a new escalation requirement similar to those seen in hospital quality programs that empower nurses to report issues seen in surgeries. However, he said there are other vulnerabilities, including an exhausted workforce and underfunded agency. Rice also asked about FDA's complaint notification process, which Dr. Mayne explained can take several weeks or months.

During the second panel, Mr. Calarmari said he did not become aware of an FDA whistle-blower report alleging safety concerns at the Sturgis facility until April. When asked why the employee did not use Abbott's confidential reporting program to flag concerns, Mr. Calamari said he was unsure, but that Abbott intends to reinforce its zero-tolerance retaliation policy and promote a culture of safety and employee feedback.

Rep. David McKinley (R-WV) asked what the FDA is doing to combat the spread of misinformation on social media and how the House-passed $28 million emergency funding bill will increase access to baby formula. Dr. Califf said stopping misinformation is "critical" and that the FDA needs to be "more proactive and preventive." He noted that

FDA could use additional funding to ensure the Abbott facility resumes operations, inspect product being imported into the United States, and upgrade information systems.

Rep. Jan Schakowsky (D-IL) said she is "furious" about the FDA's handling of food safety. She noted that FDA staff received a whistle-blower report in October 2021, which senior food staff officials did not respond to until four months later in February. Dr. Califf reiterated that he feels the process was too slow and noted some of the steps, such as the new escalation requirement, that the FDA has put in place. She noted that she has legislation called the Food Chemical Reassessment Act to improve the safety of the U.S. food supply and urged Dr. Califf to "put food back into the Food and Drug Administration."

During the second panel, Rep. Schakowsky said the whistle blower reports and past FDA reviews suggest safety and quality have not been at the top of Abbott's agenda.

Rep. Billy Long (R-MO) asked Dr. Califf to rate his and his agency's performance to which Dr. Califf assigned himself a 4 or 5 and FDA staff a 9 to 10. He said the result is not what the FDA wanted but that the people on the ground are working as hard as they can with inadequate systems and funding. Long also asked about communications between the FDA and the Health and Human Services (HHS) Secretary and the White House. Dr. Califf said they've had regular communications with both HHS and the White House, and that HHS Secretary Xavier Becerra has been "tremendously helpful" in aiding efforts to increase production of infant formula.

During the second hearing, Rep. Long asked each panelist how their market share has changed before and after the Abbott recall. Mr. Calamari said about 40% of Abbott formula was made in the Sturgis facility and that Abbott makes up about 40% of the U.S. infant formula market. Mr. Fitz said Geber represented 8% market share, and now represents about 9%. Mr. Cleveland said Mead Johnson Nutrition was about 34% of U.S. market before the recall and post recall is about 56% of U.S. market.

Rep. Paul Tonko (D-NY) asked Mr. Yannis why there was so little communication between the FDA and the public in the months leading up to the February Abbott recalls. Mr. Yiannis said as soon as he become aware of the safety issue they worked quickly to recall the product and alert the public, but prior to that there was no actionable data to communicate. Dr. Califf said there "was a lack of coordination" and going forward the FDA will make changes across the board to improve FDA oversight of food safety and some of those larger changes may require congressional approval.

During the second hearing, Rep. Tonko focused his questions on the supply chain challenges prior to and since the Abbott recall. Mr. Cleveland said Mead Johnson Nutrition experienced numerous input challenges like other manufacturers during the COVID-19 pandemic. Mr. Fitz said Gerber struggled with material supply components, transportation, and COVID-related labor challenges but they were able to resolve those as they arose.

Rep. Gary Palmer (R-AL) asked about management structure and why it took several months for Mr. Yiannis to see the whistle-blower report to which Mr. Yiannis said he is unsure of the cause of the delay, but that the FDA is conducting a review to examine the issue. Rep. Palmer expressed a desire to fix issues related to management structure at the FDA to ensure leaders have the right information.

During the second panel, Rep. Palmer asked Mr. Calamari about discussions between the FDA and Abbott about problems at the Sturgis plant.

Rep. Kim Schrier (D-WA) said that when she practiced as a pediatrician they would receive regular notifications about medication shortages and asked whether there should be a similar warning system for infant formula. Dr. Califf said an early warning system for infant formula does not currently exist and the FDA has repeatedly asked for that authority from Congress, but industry has opposed it. In response to a question about the changes that will be put in place at the Sturgis plant so the public can feel confident in the product it produces, Dr. Califf said he

cannot comment on whether there may or may not be criminal proceedings, but that the FDA will be directly overseeing the reopening to ensure the physical plant, as well as the right personnel are in place. All other plants will continue to be inspected once a year.

During the second panel, Rep. Schrier said the baby formula industry is unique in that 90% of U.S. market formula is made in the U.S and said there appears to be a cultural problem at the Sturgis facility. In response, Mr. Calamari said their priority is regaining public trust and getting Sturgis back to safe production. He also noted that the whistle blower allegations have not yet been confirmed and are being investigated.

Rep. John Joyce (R-PA) asked how imported formula will reach rural parts of the country. Dr. Califf said the batches coming in are being directed to areas with the biggest need for specialty formula, such as infants with metabolic issues. He said pediatricians are very involved and aware that HHS has a website and hotlines to manufacturers if you have an infant in need of this specialty formula. He asked Dr. Mayne about the initial *Cronobacter* investigation. Dr. Mayne said the data show that the FDA cannot rule in or rule out that the *Cronobacter* was caused by this plant.

During the second panel, Rep. Joyce asked what the government can do right now to ease supply constraints and what regulations can help. Mr. Fitz said the steps the FDA is taking to import products from overseas allow them to safely increase production. Mr. Calamari said securing ingredients, such as agricultural oils, and continuity of supply and distribution and speed to market will be essential going forward. Mr. Cleveland agreed that agricultural oils are important.

Rep. Raul Ruiz (D-CA) said online retailers are engaging in price gouging amid the infant formula crisis, creating disparities in who has access to formula. Rep. Ruiz asked what low-income and other families can do today to access formula, noting that some Americans are turning to potentially harmful options and home remedies. Dr. Mayne said they've advised consumers to avoid single purchases from abroad that have not come through an FDA-approved facility, avoid making formula at home or diluting formula. Dr. Mayne said they are monitoring the borders to ensure counterfeit products do not enter the country.

During the second panel, Rep. Ruiz asked what Abbott is doing as the primary supplier of WIC formula. Mr. Calamari said Abbott takes its WIC commitment very seriously and is working with the USDA and state agencies to provide information to WIC families.

Rep. Scott Peters (D-CA) asked how the FDA has coordinated its actions with other agencies to alleviate the shortage. Dr. Califf said the FDA coordinates with all relevant agencies including the Centers for Disease Control and Prevention (CDC), the Agriculture Department, economic advisers, and the supply chain committees that have been in place throughout the pandemic. In addition, he said the domestic and global industries have responded to increase production. Dr. Califf also said the FDA is having daily conversations with the manufacturers.

During the second hearing, Rep. Peters asked Mr. Calamari how Abbott is investing in safety and quality to which he said the company spends tens of millions of dollars on quality and maintenance and is committed to investing in doing what it takes to ensure this does not happen again.

Rep. Annie Kuster (D-NH) asked if Dr. Califf to share any updates on Abbott's efforts to implement the consent decree. Dr. Califf said FDA met with Abbott's leadership on Tuesday (May 24) to review hundreds of action steps, many of which Abbott has already made progress on. He said he feels confident in their ability to resume operations and the plan is for specialty formula to be the first product back in production. As an example, he said, before they open the production area they must completely clean and conduct three rounds of testing to ensure compliance. Asked if breastmilk from milk banks is safe and regulated, Dr. Mayne said human milk is regulated as a food.

During the second hearing, Kuster asked when Gerber knew about the infant formula shortage. In response, Mr. Fitz said, "We became aware when FDA notified us of the Abbott recall but we did not know the scale or extent of the outage." In the following months, he said "we released an additional 50% of product which is substantial for us".

Rep. Lori Trahan (D-MA) asked Dr. Mayne about the nature of infant formula regulations. Dr. Mayne said FDA is legally required to ensure products have adequate nutrition and growth levels, as well as safe production practices. She also said FDA is taking steps to ensure new product coming from foreign countries adheres to FDA standards. Rep. Trahan asked Dr. Califf to describe the scope of the FDA's internal investigation. Dr. Califf said the initial review in response to the current crisis will go through "great detail" and those findings will be made public, but there will also be a review of the entire food system, which is vast and may take longer to implement because the FDA requires congressional approval for certain changes.

During the second hearing, Rep. Trahan also asked about quality controls Abbott is taking to address quality and safety issues at the Sturgis facility.

Rep. Michael Burgess (R-TX) said he believes Dr. Califf is the right person to be leading through this crisis and can use his past FDA experience and private sector experience to implement needed information system improvements at the agency. He also asked about the missing pieces, such as the unconfirmed source of the initial infant formula contamination. Dr. Califf noted that *Cronobacter* is not currently a reportable bacterium and making it reportable would improve response.

During the second panel, Rep. Burgess asked about the timeline of events. Mr. Calamari said Abbott conducted their own investigations in response to the initial *Cronobacter* infection complaint and found no issues. He said Abbott was not aware of the whistle blower complaint until April when it was made public by Congress. When asked, Mr. Calamari also said Abbott would support making *Cronobacter* reportable.

Rep. Tom O'Halleran (D-AZ) expressed frustration that this is not the first time the Sturgis facility has had problems, citing a recent *New York Times* article. He said the FDA needs to re-examine processes to ensure the Sturgis and other facilities are safe and have redundancy plans in place. Dr. Califf agreed that the manufacturer should have redundancy plans in place and asked Congress to give the FDA the authority to require it.

Rep. Debbie Dingell (D-MI) discussed the importance of coordination between agencies, particularly the FDA and the CDC, and asked Dr. Mayne how her center coordinated with the CDC and state departments of health. Dr. Mayne said the FDA worked closely with states to get needed data but said there needs to be better processes in place to give the FDA access to data when it receives consumer complaints. Dr. Mayne said there are several new authorities that could be helpful to prevent future incidents, including new authorities regarding industry testing at facilities.

During the second hearing, Rep. Dingell discussed her concerns about repeated issues at the Sturgis facility and asked what manufacturers are doing in response to price gouging practices. All three witnesses said they take those claims very seriously and have processes in place to address price gouging.

Rep. Fred Upton (R-MI) called in to the hearing from Sturgis, MI, and said he'd recently visited the facility and they've made "massive changes" to the facility with the goal of resuming production by June 4. He asked Dr. Califf how the FDA would spend the $28 million included in a House-passed emergency funding bill. Dr. Califf said the FDA needs more people, inspectors, and investigators.

Rep. Nanette Barragán (D-CA) talked about the impact on WIC families and asked Dr. Califf if the agency needs a deputy commissioner for food to be reinstated. Dr. Califf said there's larger reforms that need to take place

beyond a single role and his goal is to put a plan in place to identify and implement those changes with support from Congress.

Rep. Larry Bucshon (R-IN) said the FDA may need operational restructuring but asked about vacant positions at the agency. Dr. Califf did not have the current number of vacant positions. Rep. Bucshon also asked about the four-month delay in Dr. Mayne and Mr. Yiannis receiving copies of the whistle-blower complaints. Dr. Califf said the FDA has fixed that escalation issue.

Rep. Lisa Rochester (D-DE) asked about the rise in counterfeit and other potentially harmful products. Dr. Califf said the FDA is working with the Department of Justice on the issue but that they have limited resources to address the problem. Rep. Rochester also discussed the America COMPETES Act's requirements to diversify supply chains.

Rep. Buddy Carter (R-GA) spoke about his 6-month-old grandchild and the family text chain to find formula and expressed disappointment in the time it took for the FDA and the administration to take action. Dr. Mayne attributed the current shortage to several incidents, including the pandemic, the Abbott recall, and the war in Ukraine, which is a major exporter of sunflower oil, which many manufacturers need to make infant formula.

During the second panel, Rep. Carter asked about the root cause of the current shortage. Mr. Calamari said the COVID-19 pandemic has challenged supply of key ingredients and materials and increased demand. Mr. Fitz also mentioned supply chain issues, but said the current shortage was exacerbated by the recall and shutdown of a major manufacturer. Mr. Cleveland said the lesson to be learned from this incident is how to be more flexible in response to something like this.

Rep. Darren Soto (D-FL) praised Congress for passing a bill to ease WIC regulations for infant formula and President Biden for invoking the Defense Production Act but called out his Republican colleagues for voting against the House-passed $28 million emergency funding bill for FDA. Dr. Califf said the funding would help the FDA's efforts to reopen the Sturgis facility. Dr. Califf also said he would support provisions to diversify infant formula manufacturing as part of the America COMPETES Act.

If you have questions, please contact Heather Meade or Heather Bell.