Congress of the United States
Washington, DC 20515

September 19, 2022

Dr. Robert Califf
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Califf,

We are writing to you today with continued concerns involving the systemic problems within the U.S. Food and Drug Administration's (FDA) Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Food Policy and Response. Recent controversies resulting from failed regulatory frameworks, as you yourself described it,[1] have caused significant marketplace disruptions and threatened the health and well-being of millions of Americans, most notably infants, as a result. As leader of the FDA, you are responsible for addressing these policy failures and we request details on how you are working to resolve long-standing regulatory issues.

We welcome the recent announcement that FDA would commission an external review of how the regulatory functions within CFSAN and the Office of Food Policy and Response are working.[2] On August 17, the Foundation announced that it has enlisted a former FDA Commissioner, Jane Henney, to lead the CFSAN and Office of Food Policy review.[3]

While the announcement notes that they "will work with additional external evaluators who bring relevant expertise from both inside and outside federal government" and that "they will have access to multiple subject matter experts," the announcement does not explain who these experts are, nor does it clarify how industries regulated by these Centers can offer input.[4] It provides some information about the process including stakeholder engagement, and it is our hope that the review will provide a meaningful opportunity for such engagement and that the resulting reports will be unbiased and objective. While we are interested in the Reagan-Udall Foundation's findings, this report should not be used as a substitute for you, as the leader of the agency, to fix FDA's issues internally. Regardless of the findings, you will still be responsible for

[1] https://www.fda.gov/news-events/press-announcements/fda-conducting-evaluation-key-agency-activities-strengthen-operations
[2] https://reaganudall.org/news-and-events/coverage/fda-announces-external-review-food-safety-and-tobacco-regulatory-offices
[3] https://reaganudall.org/news-and-events/announcements/henney-silvis-tapped-lead-evaluators
[4] *Id.*

addressing these issues within FDA and answering to Congress for the decisions being made at FDA under your leadership.

The Office of Food Policy and Response and CFSAN are responsible for the safety and regulation of critical issues related to food. Within the past year, the Office of Food Policy and Response and CFSAN has been engulfed in controversy because of its botched response to reported safety issues at a major baby formula manufacturing facility, causing a dangerously low supply of infant formula across the United States that is still ongoing.[5]

The conditions that led to the infant formula shortage began at the onset of COVID-19,[6] while a more detrimental supply stress on the market began in February of this year after Abbott Nutrition voluntarily recalled certain infant formula products and paused production at its Sturgis, Michigan, manufacturing facility.[7] This came after the agency received three case complaints regarding Cronobacter infections that were potentially linked to Abbott Nutrition's formulas; the first case complaint was received by the FDA in September 2021.[8]

As a result of an announced inspection by FDA in which the agency "[found] significant, fundamental sanitation, building, and equipment issues," in addition to "potential positive samples" reported in February that were also taken during a site inspection earlier that month, the agency recommended the company voluntarily recall certain questionable products from the market.[9] The inspection lasted a month, but the facility was effectively shut down until June of this year,[10] despite the CDC finding no link between Abbott formulas and infant illnesses,[11] with Datasembly reporting a 40 percent shortage in April alone.[12]

However, the agency's failure to act sooner to immediately address the imminent crisis, despite having multiple warning signs, represents a fundamental breakdown in regulatory decision-making creating undue uncertainly in a supply chain that has been strained throughout the COVID-19 pandemic and leaving parents wondering how they will feed their children.

First, the FDA received a total of three case complaints detailing Salmonella and Cronobacter infections potentially associated with Abbott Nutrition formula products between September 2021 and January 2022; the FDA later determined the Salmonella complaint was not linked to Abbott products.[13] Yet, the FDA notified the facility of a planned for-cause inspection on December 30, 2021, and finally inspected the facility in January 2022 after a total of four

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[5] https://www.washingtonpost.com/business/2022/05/25/baby-formula-shortage-abbott-hearing/
[6] https://www.fda.gov/media/158737/download
[7] https://www.fda.gov/news-events/press-announcements/fda-provides-new-updates-activities-mitigate-infant-formula-supply-challenges-abbott-nutrition
[8] https://www.fda.gov/media/158737/download
[9] *Id.*
[10] https://www.cnbc.com/2022/07/09/production-resumes-at-troubled-abbott-baby-formula-factory.html
[11] https://abbott.mediaroom.com/2022-05-16-Abbott-Enters-into-Consent-Decree-with-U-S-Food-and-Drug-Administration-for-its-Sturgis,-Mich-,-Plant-Agreement-Creates-Pathway-to-Reopen-Facility
[12] https://www.cnbc.com/2022/05/09/40-percent-of-americas-baby-formula-supplies-are-out-of-stock.html
[13] https://www.fda.gov/media/158737/download

complaints were filed, according to testimony you gave to the House Energy and Commerce Committee Subcommittee on Oversight and Investigations on May 25 of this year.[14]

Additionally, a whistleblower filed a complaint with FDA in October 2021 which was not elevated to the director of CFSAN and then acting-FDA Commissioner until February 10 of this year,[15] after the agency announced inspections of the Abbott facility, and just days prior to recommending the voluntary product recall.[16]

The FDA then admitted in Congressional testimony that due to COVID-19 staffing issues, there was an "isolated failure in FDA's mailroom" leading to this four-month delay in the top officials receiving this timely information.[17]

The entire mishandling of this infant formula crisis is unacceptable and jeopardizes the health and well-being of millions of infants and those who rely on medically necessary metabolic formulas produced by Abbott Nutrition. Given this, we request responses to the following inquiries:

1. The inspection of the Abbott facility took over a month to complete,[18] yielding no direct connection between the detected Cronobacter cases to the facility.[19] How long do these inspections typically take?
    a. Is there a process in place to ensure inspections are streamlined in the event any reductions in production could result in significant supply shortages?
        i. If so, please outline this process and any steps you are personally taking to make changes or improvements to this process.

2. By the FDA's own records, the whistleblower complaint received in October 2021 was only finally elevated to the Director of CFSAN in February 2022.[20] What is the agency's current process to address whistleblower complaints?
    a. Does the agency prioritize complaints dealing with products that are susceptible to significant supply disruptions if the products in question were to be recalled?
    b. Please outline this process.

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[14] https://energycommerce.house.gov/committee-activity/hearings/hearing-on-formula-safety-and-supply-protecting-the-health-of-america-s
https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FDA%20Testimony%20ECOI%20Infant%20Formula%205.25.2022%20final.pdf
https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/FDA%20Testimony%20ECOI%20Infant%20Formula%205.25.2022%20final.pdf

[15] https://energycommerce.house.gov/committee-activity/hearings/hearing-on-formula-safety-and-supply-protecting-the-health-of-america-s

[16] https://www.fda.gov/media/158737/download

[17] *Id.*

[18] *Id.*

[19] https://www.abbott.com/corpnewsroom/nutrition-health-and-wellness/abbott-update-on-powder-formula-recall.html

[20] https://energycommerce.house.gov/committee-activity/hearings/hearing-on-formula-safety-and-supply-protecting-the-health-of-america-s

c. Have you instructed others within your agency to make changes in the whistleblower process? If so, please identify those changes and who you instructed to make those changes.

In addition, even after the inspection in January, and after FDA kept the facility shut down, it wasn't until May 10 that the agency acted to relieve shortages that existed before the inspection of the plant.[21] On that date, the agency implemented several administrative steps to get more formula products on the shelves.[22]

We request answers on the delay in effectuating these policies, overall impact of these policies, including on patient safety, and an assessment of whether these policies can be permanently implemented.

1. On May 10, the agency announced several regulatory flexibilities, including:
    a. Expediting review of manufacturing process changes to increase supply, expediting certificates to allow for flexibility in the movement of certain products coming into the U.S. from abroad, streamlining import entry review process for certain products, and exercising enforcement discretion on minor labeling issues for both domestic and important products.[23]
        i. For each flexibility, please outline:
            1. Any internal communications in 2021 or 2022 relating to the rationale for implementation of these flexibilities;
            2. The date of which the option was first presented to the CFSAN Director, FDA Commissioner, or head of the Office of Food Policy and Response;
            3. The rationale for delay between January 2022 and May 2022 for implementing these policies;
            4. How the agency has operationalized these policies;
            5. The number of applications received, denied, or approved resulting from these flexibilities;
            6. How many more formula products have entered the market as a result;
            7. If there have been reported safety issues;
            8. Whether these policies could be permanently implemented;
            9. Whether the FDA would need additional resources to permanently enact these polices, and;
            10. Specific resources needed.

[21] https://www.fda.gov/news-events/press-announcements/fda-takes-important-steps-improve-supply-infant-and-specialty-formula-products
[22] *Id.*
[23] *Id.*

There have also been several legislative efforts to address this ongoing formula crisis and ensure this can never happen again, including the introduction of H.R. 7830, the Babies Need More Formula Now Act of 2022,[24] and H.R. 8010, the More Options for Infants and Parents Act.[25]

1. Can the policies mentioned in each bill be implemented administratively?
2. If no, will you work with us on these policies or similar legislation?
3. Please outline specific concerns, if any, with each bill.

Please respond to the following inquiries by October 17, 2022. Thank you for your attention to this important issue.

Sincerely,

Brett Guthrie
Member of Congress

H. Morgan Griffith
Member of Congress

[24] https://www.congress.gov/bill/117th-congress/house-bill/7830
[25] https://www.congress.gov/bill/117th-congress/house-bill/8010?q=%7B%22search%22%3A%5B%22%22%5D%7D&s=1&r=2