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ONE HUNDRED SEVENTEENTH CONGRESS

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Congress of the United States
House of Representatives
COMMITTEE ON OVERSIGHT AND REFORM
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https://oversight.house.gov

March 24, 2022

Dr. Robert Califf
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Califf:

I wrote to you earlier this week regarding the Food and Drug Administration's (FDA) failure to protect Americans from a heart pump device associated with over 3,000 deaths. I am now writing to request information about FDA's delayed response in addressing contaminated infant formula now linked to five hospitalizations and two deaths. According to public reporting, FDA learned in September 2021 about contaminated formula produced at an Abbott Nutrition facility in Sturgis, Michigan, but failed to issue a public warning until February.[1] Newly released FDA inspection reports show that Abbott Nutrition failed to maintain sanitary conditions and procedures at the plant for years.[2] FDA must do more to protect vulnerable infants from foodborne illnesses and warn their caregivers of potential dangers.

FDA was first on notice of the contaminated formula in September 2021, when Minnesota health authorities alerted FDA that they had traced one infant's *Cronobacter sakazakii* infection back to formula produced at the facility.[3] *Cronobacter sakazakii* infections

[1] *FDA Learned of Suspected Infant Formula Illness Four Months Before Recall*, Politico (Feb. 18, 2022) (online at www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226); Food and Drug Administration, *FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan* (online at www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility) (accessed March 16, 2022) (as of FDA's February 17 announcement, formula was linked to four hospitalizations and was a potential cause of one death; on February 28, formula was linked to a fifth hospitalization and second death).

[2] *Plant Behind Abbott Baby Formula Recall Was Unsanitary, FDA Finds*, CBS News (Mar. 23, 2022) (online at www.cbsnews.com/news/abbott-baby-formula-recall-fda-details/).

[3] *FDA Learned of Suspected Infant Formula Illness Four Months Before Recall*, Politico (Feb. 18, 2022) (online at www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226).

are rare, but can lead to severe and life-threatening illnesses, including sepsis and meningitis.[4] When *Cronobacter sakazakii* causes meningitis, the mortality rate can be as high as 44%.[5]

FDA inspected the Abbott facility in late September and noted unsanitary conditions at the plant, but did not issue a warning.[6] FDA received two more reports of *Cronobacter sakazakii* infections tied to the facility between September and December, and also received a complaint about a *Salmonella* Newport illness linked to the facility.[7] FDA finally issued a warning to consumers on February 17, when Abbott voluntarily recalled the formula.[8] As of February 17, FDA knew the *Cronobacter sakazakii* and *Salmonella* Newport infections had led to four hospitalizations and may have contributed to one death. On February 28, the Centers for Disease Control and Prevention announced a fourth *Cronobacter sakazakii* infection linked to the facility, which may have contributed to a second death.[9]

Between January 31 and March 18, 2022, FDA again inspected the facility. Shockingly, FDA found that the Abbott facility failed to maintain clean surfaces for handling formula. FDA also found a history of *Cronobacter sakazakii* contamination at the plant, including eight such instances between 2019 and 2022.[10]

FDA is tasked with protecting all Americans from life-threatening foodborne illness outbreaks, but fell short in protecting vulnerable infants from contaminated formula. FDA must do more to ensure no lives are lost, or babies sickened, due to delayed inspections and late consumer warnings.

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[4] Food and Drug Administration, *FDA Investigation of Cronobacter Infections: Powdered Infant Formula* (online at www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022) (accessed Mar. 23, 2022).

[5] Margaret Taylor et al., *Two Cases of* Cronobacter Sakazakii *Meningitis in Infants* (Sept. 2021) (online at https://journals.lww.com/pidj/Fulltext/2021/09000/Two_Cases_of_Cronobacter_Sakazakii_Meningitis_in.20.aspx).

[6] *Plant Behind Abbott Baby Formula Recall Was Unsanitary, FDA Finds*, CBS News (Mar. 23, 2022) (online at www.cbsnews.com/news/abbott-baby-formula-recall-fda-details/).

[7] *FDA Learned of Suspected Infant Formula Illness Four Months Before Recall*, Politico (Feb. 18, 2022) (online at www.politico.com/news/2022/02/18/fda-infant-formula-illness-four-months-before-recall-00010226).

[8] *Id.*; Food and Drug Administration, *FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan* (online at www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility) (accessed March 16, 2022); Food and Drug Administration, *Company Announcement: Abbott Voluntarily Recalls Powder Formulas Manufactured at One Plant* (Feb. 17, 2022) (online at www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/abbott-voluntarily-recalls-powder-formulas-manufactured-one-plant).

[9] Food and Drug Administration, *FDA Warns Consumers Not to Use Certain Powdered Infant Formula Produced in Abbott Nutrition's Facility in Sturgis, Michigan* (online at www.fda.gov/news-events/press-announcements/fda-warns-consumers-not-use-certain-powdered-infant-formula-produced-abbott-nutritions-facility) (accessed March 16, 2022).

[10] *Plant Behind Abbott Baby Formula Recall Was Unsanitary, FDA Finds*, CBS News (Mar. 23, 2022) (online at www.cbsnews.com/news/abbott-baby-formula-recall-fda-details/); Food and Drug Administration, *FDA Investigation of Cronobacter Infections: Powdered Infant Formula* (online at www.fda.gov/food/outbreaks-foodborne-illness/fda-investigation-cronobacter-and-salmonella-complaints-powdered-infant-formula-february-2022) (accessed Mar. 23, 2022).

To assist the Subcommittee in its review of this matter, we request that you provide the following information by April 7, 2022:

1. Why did FDA wait until February 17, 2022, to issue a warning to consumers not to use certain powdered infant formula produced at the Abbott Nutrition facility in Sturgis, Michigan?

2. What steps, if any, is FDA taking to ensure that it more quickly inspects facilities, and issues consumer warnings, after reports of foodborne illnesses linked to particular facilities?

We also request that you provide all documents and communications, from September 1, 2021, to the present, by April 7, 2022, related to the following topics:

1. Reports from Minnesota health authorities regarding *Cronobacter sakazakii* or *Salmonella* Newport infections traced back to the facility; and

2. FDA's steps to address the reported infections at the facility.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Subcommittee's request. Please contact Subcommittee staff at (202) 225-5051 if you have any questions about this request.

Sincerely,

Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Michael Cloud, Ranking Member
Subcommittee on Economic and Consumer Policy

Responding to Oversight Committee Document Requests

1. In complying with this request, produce all responsive documents that are in your possession, custody, or control, whether held by you or your past or present agents, employees, and representatives acting on your behalf. Produce all documents that you have a legal right to obtain, that you have a right to copy, or to which you have access, as well as documents that you have placed in the temporary possession, custody, or control of any third party.

2. Requested documents, and all documents reasonably related to the requested documents, should not be destroyed, altered, removed, transferred, or otherwise made inaccessible to the Committee.

3. In the event that any entity, organization, or individual denoted in this request is or has been known by any name other than that herein denoted, the request shall be read also to include that alternative identification.

4. The Committee's preference is to receive documents in electronic form (i.e., CD, memory stick, thumb drive, or secure file transfer) in lieu of paper productions.

5. Documents produced in electronic format should be organized, identified, and indexed electronically.

6. Electronic document productions should be prepared according to the following standards:

    a. The production should consist of single page Tagged Image File ("TIF"), files accompanied by a Concordance-format load file, an Opticon reference file, and a file defining the fields and character lengths of the load file.

    b. Document numbers in the load file should match document Bates numbers and TIF file names.

    c. If the production is completed through a series of multiple partial productions, field names and file order in all load files should match.

    d. All electronic documents produced to the Committee should include the following fields of metadata specific to each document, and no modifications should be made to the original metadata:

        BEGDOC, ENDDOC, TEXT, BEGATTACH, ENDATTACH, PAGECOUNT, CUSTODIAN, RECORDTYPE, DATE, TIME, SENTDATE, SENTTIME, BEGINDATE, BEGINTIME, ENDDATE, ENDTIME, AUTHOR, FROM, CC, TO, BCC, SUBJECT, TITLE, FILENAME, FILEEXT, FILESIZE, DATECREATED, TIMECREATED, DATELASTMOD, TIMELASTMOD,

INTMSGID, INTMSGHEADER, NATIVELINK, INTFILPATH, EXCEPTION, BEGATTACH.

7. Documents produced to the Committee should include an index describing the contents of the production. To the extent more than one CD, hard drive, memory stick, thumb drive, zip file, box, or folder is produced, each should contain an index describing its contents.

8. Documents produced in response to this request shall be produced together with copies of file labels, dividers, or identifying markers with which they were associated when the request was served.

9. When you produce documents, you should identify the paragraph(s) or request(s) in the Committee's letter to which the documents respond.

10. The fact that any other person or entity also possesses non-identical or identical copies of the same documents shall not be a basis to withhold any information.

11. The pendency of or potential for litigation shall not be a basis to withhold any information.

12. In accordance with 5 U.S.C.§ 552(d), the Freedom of Information Act (FOIA) and any statutory exemptions to FOIA shall not be a basis for withholding any information.

13. Pursuant to 5 U.S.C. § 552a(b)(9), the Privacy Act shall not be a basis for withholding information.

14. If compliance with the request cannot be made in full by the specified return date, compliance shall be made to the extent possible by that date. An explanation of why full compliance is not possible shall be provided along with any partial production.

15. In the event that a document is withheld on the basis of privilege, provide a privilege log containing the following information concerning any such document: (a) every privilege asserted; (b) the type of document; (c) the general subject matter; (d) the date, author, addressee, and any other recipient(s); (e) the relationship of the author and addressee to each other; and (f) the basis for the privilege(s) asserted.

16. If any document responsive to this request was, but no longer is, in your possession, custody, or control, identify the document (by date, author, subject, and recipients), and explain the circumstances under which the document ceased to be in your possession, custody, or control.

17. If a date or other descriptive detail set forth in this request referring to a document is inaccurate, but the actual date or other descriptive detail is known to you or is otherwise apparent from the context of the request, produce all documents that would be responsive as if the date or other descriptive detail were correct.

18. This request is continuing in nature and applies to any newly-discovered information. Any record, document, compilation of data, or information not produced because it has not been located or discovered by the return date shall be produced immediately upon subsequent location or discovery.

19. All documents shall be Bates-stamped sequentially and produced sequentially.

20. Two sets of each production shall be delivered, one set to the Majority Staff and one set to the Minority Staff. When documents are produced to the Committee, production sets shall be delivered to the Majority Staff in Room 2157 of the Rayburn House Office Building and the Minority Staff in Room 2105 of the Rayburn House Office Building.

21. Upon completion of the production, submit a written certification, signed by you or your counsel, stating that: (1) a diligent search has been completed of all documents in your possession, custody, or control that reasonably could contain responsive documents; and (2) all documents located during the search that are responsive have been produced to the Committee.

Definitions

1. The term "document" means any written, recorded, or graphic matter of any nature whatsoever, regardless of how recorded, and whether original or copy, including, but not limited to, the following: memoranda, reports, expense reports, books, manuals, instructions, financial reports, data, working papers, records, notes, letters, notices, confirmations, telegrams, receipts, appraisals, pamphlets, magazines, newspapers, prospectuses, communications, electronic mail (email), contracts, cables, notations of any type of conversation, telephone call, meeting or other inter-office or intra-office communication, bulletins, printed matter, computer printouts, teletypes, invoices, transcripts, diaries, analyses, returns, summaries, minutes, bills, accounts, estimates, projections, comparisons, messages, correspondence, press releases, circulars, financial statements, reviews, opinions, offers, studies and investigations, questionnaires and surveys, and work sheets (and all drafts, preliminary versions, alterations, modifications, revisions, changes, and amendments of any of the foregoing, as well as any attachments or appendices thereto), and graphic or oral records or representations of any kind (including without limitation, photographs, charts, graphs, microfiche, microfilm, videotape, recordings and motion pictures), and electronic, mechanical, and electric records or representations of any kind (including, without limitation, tapes, cassettes, disks, and recordings) and other written, printed, typed, or other graphic or recorded matter of any kind or nature, however produced or reproduced, and whether preserved in writing, film, tape, disk, videotape, or otherwise. A document bearing any notation not a part of the original text is to be considered a separate document. A draft or non-identical copy is a separate document within the meaning of this term.

2. The term "communication" means each manner or means of disclosure or exchange of information, regardless of means utilized, whether oral, electronic, by document or otherwise, and whether in a meeting, by telephone, facsimile, mail, releases, electronic

message including email (desktop or mobile device), text message, instant message, MMS or SMS message, message application, or otherwise.

3. The terms “and” and “or” shall be construed broadly and either conjunctively or disjunctively to bring within the scope of this request any information that might otherwise be construed to be outside its scope. The singular includes plural number, and vice versa. The masculine includes the feminine and neutral genders.

4. The term “including” shall be construed broadly to mean “including, but not limited to.”

5. The term “Company” means the named legal entity as well as any units, firms, partnerships, associations, corporations, limited liability companies, trusts, subsidiaries, affiliates, divisions, departments, branches, joint ventures, proprietorships, syndicates, or other legal, business or government entities over which the named legal entity exercises control or in which the named entity has any ownership whatsoever.

6. The term “identify,” when used in a question about individuals, means to provide the following information: (a) the individual’s complete name and title; (b) the individual’s business or personal address and phone number; and (c) any and all known aliases.

7. The term “related to” or “referring or relating to,” with respect to any given subject, means anything that constitutes, contains, embodies, reflects, identifies, states, refers to, deals with, or is pertinent to that subject in any manner whatsoever.

8. The term “employee” means any past or present agent, borrowed employee, casual employee, consultant, contractor, de facto employee, detailee, fellow, independent contractor, intern, joint adventurer, loaned employee, officer, part-time employee, permanent employee, provisional employee, special government employee, subcontractor, or any other type of service provider.

9. The term “individual” means all natural persons and all persons or entities acting on their behalf.