UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA, *et al.*, *ex rel.* SCOTT MILLARD, KRISTINE COOPER, and LOREN COOPER, Plaintiffs, v. ABBOTT LABORATORIES, Defendant.	No. 1:22-cv-994 Hon. Hala Y Jarbou Chief United States District Judge

UNITED STATES' COMPLAINT IN INTERVENTION AGAINST ABBOTT LABORATORIES

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PRELIMINARY STATEMENT

Infants in the U.S. Department of Agriculture's ("USDA") Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC") consume over half of all infant formula in the United States. Abbott Laboratories ("Abbott") is one of just a few WIC infant formula manufacturers and manufactures the familiar products Similac®, Similac Alimentum®, and EleCare®. Millions of American families rely solely on the WIC program and Abbott to feed their infants every year. The USDA, State agencies, and WIC participants trusted that Abbott complied with applicable statutory, regulatory, and contractual requirements while supplying infant formulas to one of the nation's most vulnerable populations.

Abbott knowingly failed to manufacture its powder infant formulas at the Sturgis, Michigan facility in a manner that ensured its products were in compliance with its statutory, regulatory, and contractual obligations. Despite this, Abbott has yet to pay back a single dollar to the USDA for its infant formulas, specifically powder infant formula manufactured at the Sturgis facility between October 1, 2020 and June 4, 2022, which was subject to a Class I recall and otherwise failed to comply with USDA requirements. The United States brings this complaint to make the USDA whole so that it can continue to fund State agencies that serve the country's infants through the WIC program.

By notice to the Court on August 4, 2025, the United States of America ("United States") partially intervened in the above-captioned case. The United States alleges the following regarding Defendant Abbott:

INTRODUCTION

1. The United States, on behalf of the USDA, brings this action against Abbott, which manufactures powder infant formula. The United States brings this action under the False Claims Act ("FCA"), 31 U.S.C. § 3729, seeking treble damages and penalties, and to recover all available damages under the common law for unjust enrichment.

2. The USDA manages and funds the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC"), which is a federally funded program that provides participants with monthly supplemental food packages tailored to their dietary needs, breastfeeding support to nursing mothers, nutrition education, and referrals to a range of health and social services.

3. Over half of the infant formula purchased in the United States is paid for with USDA funds allocated to State agencies and Indian tribal organizations ("State agencies") to administer the WIC program ("WIC benefits"). Abbott was the sole supplier of infant formula to State agencies that provide WIC benefits to approximately half of all infants who were formula-fed (either partially or fully) between 2013 and 2023.

4. The USDA requires that all infant formula purchased with WIC benefits ("WIC infant formula") meets certain statutory, regulatory, and contractual requirements.

5. Specifically, the USDA requires that WIC infant formula manufacturers certify compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations, known as current good manufacturing practices ("cGMP"), in responses to bid

solicitations and contracts executed with State agencies to supply infant formula paid for with WIC benefits. 7 C.F.R. §§ 246.16a(j)(2), 246.10(g).

6. In bidding for State contracts to supply infant formula to the WIC program, Abbott certified to the State agencies that its infant formulas complied with the FDCA and cGMP. 7 C.F.R. § 246.10(g).

7. Abbott was aware of its statutory, regulatory, and contractual obligations as a supplier of powder infant formula to the WIC program.

8. State agencies relied on certifications in Abbott's bid responses and executed contracts with Abbott.

9. Abbott misrepresented to the USDA, State agencies, and WIC participants that its powder infant formula manufactured at the Sturgis, Michigan facility complied with the USDA requirements for WIC infant formula, including compliance with the FDCA and cGMP.

10. On May 16, 2022, the United States filed a Complaint for Permanent Injunction on behalf of the U.S. Food and Drug Administration ("FDA") against Abbott seeking permanent injunction due to FDCA violations at the Sturgis facility after a recall of powder infant formula and facility shutdown. *United States v. Abbott Laboratories et al.*, No. 1:22-cv-00441, ECF No. 1, PageID.1-21 (W.D. Mich. May 16, 2022).

11. The FDA complaint alleged that Abbott failed to process its infant formula in a manner that complied with cGMP and "under conditions that fail[ed] to protect the food against the risk of contamination from bacteria." *Id.* at No. 1:22-cv-00441 PageID.2.

12. Abbott was out of compliance with its statutory, regulatory, and contractual obligations because it failed to process its powder infant formula under conditions that protected against the risk of contamination from microorganisms. 21 C.F.R. § 106.3 defines

microorganisms as "yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance."

13. Abbott also failed to properly test for the presence of microorganisms, failed to accurately document and investigate the potential and confirmed presence of microorganisms, and withheld information from FDA related to the presence of microorganisms in the Sturgis facility.

14. As a result, Abbott knowingly presented, or caused others to present, false or fraudulent claims for payment for powder infant formula manufactured at the Sturgis facility that failed to comply with requirements imposed by statute, regulation, and contracts with State agencies, in violation of 31 U.S.C. § 3729(a)(1)(A).

15. Abbott also knowingly made false statements material to false claims in connection with WIC infant formula, in violation of 31 U.S.C. § 3729(a)(1)(B).

16. In addition, Abbott was unjustly enriched when WIC participants used WIC benefits to purchase Abbott infant formula that did not meet the statutory, regulatory, and contractual requirements for WIC infant formula.

JURISDICTION AND VENUE

17. This Court has original subject matter jurisdiction under 31 U.S.C. § 3730 and 28 U.S.C. §§ 1331, 1345 and supplemental jurisdiction over the common law cause of action pursuant to 28 U.S.C. § 1367(a).

18. The Court may exercise personal jurisdiction over Abbott, and venue is appropriate in this Court under 31 U.S.C. § 3732(a), because Abbott can be found, resides, transacts business, and/or committed proscribed acts in this District.

PARTIES

19. The United States brings this action on behalf of the USDA, which funds and regulates the WIC program, established under the Child Nutrition Act of 1966. 42 U.S.C. § 1771 *et seq*.

20. Relators are current and former Abbott employees. Relator Scott Millard is a former employee of Abbott's Quality Systems Department at the Sturgis facility. Relator Kristine Cooper is a current Quality Assurance Supervisor at Abbott's Casa Grande, Arizona facility. She previously worked in the Quality Systems Department at the Sturgis facility from August 2017 to January 2022. Relator Loren Cooper is a current Maintenance Technician at the Casa Grande facility. He previously worked in maintenance at the Sturgis facility from April 2019 to January 2022.

21. Abbott Nutrition is a division of Abbott Laboratories with a principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott conducts business nationwide, including in this District. Abbott manufactures and sells infant formulas and nutritional therapy products, including the following powder infant formulas purchased using WIC benefits: Similac® PM 60/40, Similac® Sensitive for Spit-Up, Similac® Advance, Similac® Sensitive, Similac Total Comfort®, Similac Pro-Advance®, Similac Pro-Sensitive®, Similac NeoSure®, Similac Alimentum®, Elecare® Infant, and Elecare® Jr.

22. Prior to 2022, Abbott was the largest powder infant formula manufacturer in the United States and held a 47 percent market share of powder infant formula.

BACKGROUND

I. Federal Regulation of Infant Formula

23. Congress established the WIC program through a 1972 amendment to the Child Nutrition Act, 42 U.S.C. § 1771 *et seq*., which created a two-year pilot program. H.R. 14896,

92nd Cong. § 17 (1972). WIC became a permanent program in 1975 and remains authorized through Section 17 of the Child Nutrition Act, now codified at 42 U.S.C. § 1786.

24. The Child Nutrition Act, as amended, provides the following requirements for manufacturers of WIC infant formula:

> To be eligible to participate in the program authorized by this section, a manufacturer of infant formula that supplies formula for the program shall—register with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act…and before bidding for a State contract to supply infant formula for the program, certify with the State health department that the formula complies with such Act and regulations issued pursuant to such Act. 42 U.S.C. § 1786(f)(15).

25. USDA implementing regulations mirror the statute:

> Infant formula manufacturers supplying formula to the WIC Program must be registered with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act…Such manufacturers wishing to bid for a State contract to supply infant formula to the Program must certify with the State health department that their formulas comply with the Federal Food, Drug, and Cosmetic Act and regulations…7 C.F.R. § 246.10(g).

26. The USDA's Food and Nutrition Service ("USDA-FNS") establishes the rules and regulations for WIC at the federal level. USDA regulations define "WIC formula" to include three types of products: "infant formula, exempt infant formula, or WIC-eligible nutritionals." 7 C.F.R § 246.10(e)(12).

27. USDA regulations define "infant formula" as "…a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 350a) and the regulations at 21 CFR parts 106 and 107." 7 C.F.R. § 246.2. The FDCA, in turn, defines "infant formula" to mean "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk."

21 U.S.C. § 321(z). 21 CFR parts 106 and 107 are specific sets of FDA regulations that address requirements for infant formula, including the cGMP for manufacturing infant formula.

28. "Standard" infant formula is for healthy, full-term babies without specific dietary needs. Abbott's powder infant formula Similac Advance is an example of a standard infant formula that WIC participants purchased using WIC benefits.

29. WIC benefits also cover "exempt infant formula." USDA regulations define "exempt infant formula" as "an infant formula that meets the requirements for an exempt infant formula under section 412(h) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 350a(h)) and the regulations at 21 CFR parts 106 and 107." 7 C.F.R. § 246.2. Under the FDCA, "exempt infant formula" is infant formula specifically formulated and labeled for infants with unusual medical or dietary needs, such as inborn errors of metabolism or low birth weight. 21 U.S.C. § 350a(h)(1). "Exempt infant formulas" are exempt from select regulations governing the manufacture of infant formulas. *Id.*

30. Abbott's powder infant formulas Similac Alimentum and EleCare are examples of exempt infant formulas that WIC participants purchased using WIC benefits.

31. Thus, any infant formula that is obtained through the redemption of WIC benefits must meet the USDA requirements for WIC formula, including compliance with the FDCA and cGMP.

32. FDA does not approve infant formulas, but it regulates the production of infant formula and food. The FDCA also requires that infant formula manufacturers notify FDA before marketing a new formula to ensure compliance with federal nutrition requirements.

33. The FDCA and cGMP require that manufacturers establish a system of controls designed to ensure that infant formulas do not become adulterated due to the presence of

microorganisms in the formula or processing environment and set forth certain testing requirements for specific microorganisms, such as *Cronobacter* spp. and *Salmonella*. 21 C.F.R. § 106.55.

34. *Cronobacter* spp. is a genus (or group) of bacteria that can cause serious and potentially life-threatening infections, particularly in infants. *Cronobacter sakazakii* ("*C. sak.*") is a species of *Cronobacter* spp. that can particularly thrive in dry foods, including powder infant formulas. In infants, *C. sak.* can cause serious health issues, such as sepsis, meningitis, or even death.

35. FDA promulgated cGMP regulations for infant formula. *See* 21 C.F.R. Part 106, Subpart B. These regulations specify the "minimum current good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula." 21 C.F.R. § 106.5(a).

36. Similarly, FDA promulgated cGMP regulations for food. *See* 21 C.F.R. Part 117, Subpart B. These regulations require, among other things, that manufacturing conditions and practices protect against contamination of food and food-contact surfaces from any source. 21 C.F.R. § 117.1.

37. The FDCA requires that "infant formula" comply with the cGMP regulations for infant formula (21 C.F.R. Part 106, Subpart B) and food (21 C.F.R. Part 110 and Part 117, Subpart B), and "exempt infant formula" comply with the cGMP regulations for food. 21 C.F.R. Part 110, Subparts A and B; 21 C.F.R. Part 117, Subpart B.

38. "Infant formula, including an infant formula powder, shall be deemed to be adulterated if…the processing of such infant formula is not in compliance with the good manufacturing practices and the quality control procedures prescribed by the Secretary under

subsection (b)(2)." 21 U.S.C. § 350a(a)(3). "A food shall be deemed to be adulterated— if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health…" 21 U.S.C. § 342(a)(4).

39. The failure to comply with cGMP renders infant formula and exempt infant formula adulterated.

40. FDA conducts inspections of all domestic and foreign facilities that manufacture infant formulas for the U.S. market. These inspections include a review of manufacturing processes, quality control procedures, and sample testing for nutrient content and certain pathogens, such as *Cronobacter* spp. and *Salmonella*.

41. FDA Form 483 ("FDA 483") may be issued to facility management at the conclusion of an inspection noting objectionable conditions observed during the inspection that may constitute violations of the FDCA and related regulations. The FDA 483 lists observations in the order of significance that indicate potential violations of FDA laws or regulations, but it is not a final determination of non-compliance. There may be other objectionable conditions that exist at a facility that are not cited in the FDA 483. FDA investigators are instructed to note only personal observations during an inspection. Facilities are responsible for taking corrective action to address the cited objectionable conditions and any related but uncited objectionable conditions that exist.

42. FDA conducted the following inspections of the Sturgis facility and issued three FDA 483s to Abbott from 2018 through 2022:

Abbott Manufacturing Facility	Inspection Dates	FDA 483
Sturgis	9/10/2018-9/18/2018	No
Sturgis	9/16/2019-9/24/2019	Yes
Sturgis	9/20/2021-9/24/2021	Yes

Abbott Manufacturing Facility	Inspection Dates	FDA 483
Sturgis	1/31/2022-3/18/2022	Yes
Sturgis	5/28/2022-6/2/2022	No

II. The WIC Program and Infant Formula

43. The USDA-FNS administers the WIC program at the federal level in partnership with federal, state, and local agencies.

44. State agencies procure most infant formula that WIC participants purchase through competitively bid, single-supplier contracts with manufacturers ("contract manufacturers"). Contract manufacturers agree to provide large rebates to State agencies in exchange for being the exclusive supplier of certain infant formula available to WIC participants in that state ("contract formula").

45. Based on medical need, State agencies may also allow WIC participants to use WIC benefits to purchase "exempt infant formulas" (sometimes called "specialty formulas") that are designed for infants with specific medical conditions or other dietary needs that standard formula cannot address. Infant formula manufacturers do not provide rebates for "exempt infant formulas," so exempt infant formulas are considered "non-contract formula."

46. State agencies are responsible for authorizing WIC vendors and entering into agreements with vendors. 7 C.F.R. §§ 246.12(g)-(h). The USDA establishes minimum requirements that State agencies must evaluate when authorizing WIC vendors, including competitive pricing, business integrity, whether the owner has been disqualified from or assessed a financial penalty by the Supplemental Nutrition Assistance Program, and the variety and quantity of foods available in the store. 7 C.F.R. §§ 246.12(g)(3)(i)-(iii). Over 40,000 vendors throughout the United States are currently authorized to accept WIC.

47. Infant formula manufacturers sell their products to authorized WIC vendors.

48. State agencies use Universal Product Codes ("UPCs") or Price Look-Up codes ("PLUs") through the Authorized Product List ("APL") to identify WIC-eligible infant formula to authorized WIC vendors. With the APL, the vendor is aware of WIC-eligible infant formula details, including the manufacturer, formula type, physical form, and container size. The infant formula detailed on the APL may vary across State agencies. Vendors are also aware of which WIC-eligible infant formulas are contract or non-contract based on State agency communication.

III. State Agency Bid Solicitations and Contracts

49. State agencies solicit competitive bids from infant formula manufacturers to serve as the state's exclusive contract manufacturer for the WIC program. Pursuant to USDA requirements, when submitting a bid to the State agency, manufacturers must certify that their infant formulas: (1) meet the definition of infant formula in section 201(z) of the FDCA (21 U.S.C. § 321(z)); and (2) meet the requirements for infant formula under section 412 of the FDCA (21 U.S.C. § 350a) and the regulations at 21 CFR parts 106 and 107 per 7 C.F.R. § 246.2, which include manufacturing according to cGMP.

50. The USDA also requires that State agency bid solicitations and contracts include the registration and certification requirements outlined in the FDCA and implementing regulations, as specified by USDA regulations at 7 C.F.R. §§ 246.10(g), 246.16a(j)(2).

51. Manufacturers accordingly respond to State agency bid solicitations by submitting bids that include certifications that: (1) their infant formula complies with the definition of "infant formula" in the FDCA (21 U.S.C. § 321(z)) and meets the requirements for an infant formula under section 412, and regulations at 21 CFR parts 106 and 107; and (2) their proposed rebate amount.

52. The State agency selects the manufacturer offering the lowest total monthly net price or the highest monthly rebate per 7 C.F.R. § 246.16a(c)(5). The "net price" is the difference between the retail price and the rebate amount offered by the manufacturer pursuant to the State agency contract. Thus, the competitive bidding process encourages manufacturers to offer large rebates (*i.e.,* lower net prices). In some states, the manufacturer's rebate may be as high as 95 percent of the manufacturer's wholesale price.

53. The State agency subsequently executes a contract with the selected manufacturer. Pursuant to USDA requirements, minimum State agency contract requirements include the following: (1) compliance with all federal, state and local laws, rules and regulations; (2) certification that infant formulas meet the definition of infant formula in FDA statutes and regulations; and (3) registration with FDA and certification that infant formulas comply with the FDCA and related regulations. 7 C.F.R. § 246.16a(n).

54. As allowed by USDA regulation, some State agency contracts exceed the minimum USDA requirements. 7 C.F.R. § 246.10(b)(1)(i). For example, some State agency contracts require manufacturers to certify the performance of reasonable quality assurance activities and testing and the correction of all material deficiencies discovered during quality assurance activities and testing or to follow a specific process in the event of a product recall, including contractual remedies in the event of a recall of infant formula.

55. Some State agency contracts also attach the USDA WIC regulations located at 7 CFR part 246 that include the following FDCA provisions: (1) infant formula "means a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 350a) and the regulations

at 21 CFR parts 106 and 107;" and (2) "manufacturers wishing to bid for a State contract to supply infant formula to the program must certify with the State health department that their formulas comply with the Federal Food, Drug, and Cosmetic Act and regulations issued pursuant to the Act."

56. The table below lists the State agencies with which Abbott held WIC infant formula contracts beginning in 2014.

State Agency(ies)	Effective Dates
National Association of State Procurement Officials ("NASPO"): Alaska; American Samoa; Arizona; Mariana Islands; Delaware; DC; Guam; Hawaii; Idaho; Inter Tribal Council of Arizona; Inter-Tribal Council of Nevada; Kansas; Maryland; Montana; Navajo Nation; Nevada; Oregon; Osage Nation; Pueblo of Isleta; Utah; US Virgin Islands; Washington; West Virginia; Wyoming	1/29/2019-1/28/2022
Florida	2/1/2020-1/31/2023
Kentucky	10/29/2021-10/28/2024
Louisiana	1/1/2018-12/31/2022
New England and Tribal Organizations ("NEATO"): Cherokee Nation, Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont	10/1/2016-9/30/2026
Michigan	11/1/2021-10/31/2026
Missouri Alliance: Missouri, Nebraska, South Dakota, North Dakota	1/1/2021-9/30/2023
New York	10/1/2021-9/30/2026
North Carolina, New Mexico, Arkansas Alliance	10/1/2015-9/30/2018
Pennsylvania	10/1/2013-9/30/2018 10/1/2018-9/30/2023

State Agency(ies)	Effective Dates
Tennessee	7/1/2014-6/30/2019 7/1/2019-6/30/2022
Texas, Minnesota, Iowa, Choctaw Nation Alliance	10/1/2017-9/30/2022
Virginia	11/1/2016-10/31/2021 11/1/2021-10/31/2024
Wisconsin	11/1/2021-12/31/2026

57. Being the contract manufacturer for a State agency also yields tangential and meaningful benefits to the manufacturer, including: (1) increased market share for non-contract/ specialty infant formulas that WIC participants purchase using WIC benefits; (2) increased market share for contract formulas that WIC participants purchase beyond the WIC food package allotment; and (3) increased shelf space or display prominence for all infant formula at authorized WIC vendors.

IV. WIC Requirements for Non-Contract Infant Formula

58. The statutory and regulatory requirements that WIC formula comply with the FDCA, including cGMP, apply to both contract and exempt infant formulas that WIC participants purchase using WIC benefits.

59. USDA regulations define "WIC formula" to include "…infant formula, exempt infant formula, or WIC-eligible nutritionals." Any infant formula, including non-contract formula, that is paid for using WIC benefits must meet the USDA requirements for infant formula, which include compliance with cGMP.

60. WIC participants with a medically diagnosed condition that prevents or restricts the use of standard infant formulas may purchase non-contract infant formula from authorized

WIC vendors using WIC benefits. State agencies have specific procedures for determining eligibility for exempt infant formulas.

V. WIC Infant Formula Benefit

61. State agencies provide WIC participants with WIC benefits via food instruments, including Electronic Benefits Transfer ("EBT") cards (functioning similarly to a debit card) loaded with USDA funds. 7 C.F.R. § 246.12(x)(2)(i).

62. WIC participants receive a monthly benefit from one of seven science-based food packages, according to life stage nutritional needs. 7 C.F.R. § 246.10(e).

63. WIC participants use their WIC benefits to purchase items in their food package, which may include infant formulas, from authorized WIC vendors.

64. WIC participants with certain medical or dietary conditions who have obtained medical documentation may also use WIC benefits to purchase non-contract formula at retail price.

65. Authorized WIC vendors submit WIC benefit transactions to State agencies, in accordance with the redemption procedures described in their vendor agreement. The State agency reimburses authorized WIC vendors for the retail price of the WIC formulas purchased using WIC benefits.

66. State agencies then invoice the contract manufacturer based on the total number of contract formulas redeemed with WIC benefits during the prior month and the rebate amount that the contract manufacturer owes for each infant formula purchase.

67. The cost of contract formula to the WIC program is the difference between the retail price paid to the authorized WIC vendor and the rebate amount the manufacturer pays to the State agency.

68. The cost of non-contract formula to the WIC program is the retail price paid to the authorized WIC vendor.

VI. Abbott Recall, FDA Complaint for Permanent Injunction, and Consent Decree

69. In early 2022, Abbott's powder infant formulas manufactured at the Sturgis facility between 2020 and 2022 were identified as potentially associated with four infant illnesses, including illness from *C. sak.* or *Salmonella* infections.

70. On February 15, 2022, Abbott ceased production at the Sturgis facility, following consumer complaints and reports of potentially related infant illness, and FDA's findings of insanitary conditions at the facility during the 2022 inspection, including the presence of *C. sak.*

71. On February 17, 2022, Abbott voluntarily initiated a recall of certain powder infant formulas manufactured at the Sturgis facility, including Similac, Similac Alimentum, and EleCare. FDA classified this recall as a Class I recall, which is a recall that presents a situation in which there is a reasonable probability that the use or exposure to the recalled product will cause serious adverse health consequences or death.

72. On February 28, 2022, Abbott expanded the Class I recall to include additional powder infant formulas manufactured at the Sturgis facility.

73. At the time of the recall, Abbott reported to FDA that it had manufactured approximately 14,876,663 cases of products and distributed approximately 12,936,525 of those cases of products subject to the recall into commerce. The recall included powder infant formulas manufactured in the Sturgis facility with an expiration date of April 1, 2022 or later, which based on Abbott production records, corresponded to all powder formulas manufactured at the Sturgis facility between November 14, 2020 and February 1, 2022.

74. On May 16, 2022, on behalf of FDA, the United States filed a complaint (the "FDA Complaint") against Abbott seeking to permanently enjoin Abbott from violating the FDCA relating to its manufacturing of infant formula at the Sturgis facility. *United States v. Abbott Laboratories et al.*, No. 1:22-cv-00441, ECF No. 1, PageID.1-21 (W.D. Mich. May 16, 2022). The FDA Complaint detailed Abbott's numerous alleged violations of the FDCA, including that its infant formulas were adulterated because they were processed in a manner that did not comply with cGMP. *See* 21 U.S.C. § 350a.

75. The FDA Complaint alleged that "defendants manufacture infant formulas, including infant formulas in powdered form…under conditions and practices that fail to protect the food against the risk of contamination from bacteria including, but not limited to, Cronobacter sakazakii ("C. sak.") or Salmonella." *Id.* at No. 1:22-cv-00441 PageID.2.

76. The FDA Complaint also alleged that "[o]ngoing inadequacies in manufacturing conditions and practices at [Abbott] facilities demonstrate that [Abbott] has been unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants, a consumer group particularly vulnerable to foodborne pathogens." *Id.* at No. 1:22-cv-00441 PageID.4.

77. The FDA Complaint further alleged that "Abbott introduced infant formula and human food into interstate commerce that were adulterated…in that they have been processed in a manner that does not comply with current good manufacturing practice requirements…" *Id.* at No. 1:22-cv-00441 PageID.16.

78. On May 16, 2022, Abbott entered into a Consent Decree with the United States, on behalf of FDA, setting forth the corrective actions necessary to resume production and to

maintain compliance with the manufacturing requirements for the Sturgis facility going forward. *Id.* at No. 1:22-cv-00441 PageID.62-94.

VII. The False Claims Act

79. The FCA provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person. 31 U.S.C. § 3729(a)(1).

80. For purposes of the FCA, the terms "knowing" and "knowingly" mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. *Id.* at § 3729(b)(1).

81. The FCA defines the term "claim," in pertinent part, as

> …any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that…is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government—(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.] *Id.* at § 3729(b)(2).

82. The statute defines the term "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* at § 3729(b)(4).

FACTUAL ALLEGATIONS

I. Abbott Misrepresented to the USDA, State Agencies, and WIC Participants That Its Powder Infant Formula Manufactured at the Sturgis, Michigan Facility Complied with the USDA Requirements for WIC Infant Formula, Including Compliance with the FDCA

A. Abbott Failed to Maintain the Sturgis Facility in a Clean and Sanitary Condition

83. Abbott failed to maintain buildings used in the manufacture of infant formulas in a clean and sanitary condition, as required by 21 C.F.R. §106.20(a), including due to the presence of uncontrolled water and the use of deteriorating equipment.

1. Abbott Lost its "War on Water" Campaigns

84. Abbott was aware that the presence of uncontrolled water in the manufacturing environment put powder infant formulas at increased risk of microorganism ("micro") contamination yet failed to resolve the underlying causes of the uncontrolled water.

85. For example, rather than taking the necessary steps to permanently address uncontrolled water in the environment, Abbott's remediation efforts were limited to inadequate, temporary solutions. These efforts included periodic "War on Water" campaigns detailed in this May 2019 Sturgis Sanitation Department poster draft:

86. Water leaks persisted throughout the Sturgis facility. A former employee of the Sturgis facility stated that "roof leaks were a common occurrence." Sturgis maintenance personnel shift notes from September 2018 documented "[w]ater leaking from ceiling in HPLC [high performance liquid chromatography room] above Vitamin C prep." One month later, a Sturgis microbiology lab employee attached water leak photos to an email and noted the same area with a leak that was unresolved: "[t]his water leak is slowly taking over the HPLC room. It is running and dripping all over our equipment & solutions. It is now running through the wall to the outside of the lab and making multiple streams and puddles that are causing many hazards from a micro and safety standpoint." At the same time, an internal "Quarterly Management Review" PowerPoint called out "[r]oof areas with debris and standing water" as "internal audit selected findings."

87. The Sturgis facility frequently diverted leaks rather than permanently addressing their root causes. For example, rather than addressing the underlying structural issues, "specialty" roof leak umbrellas were used to divert leaks in product processing areas. A Sturgis facilities engineer confirmed that diverting a leak is a "temporary solution." Yet, in October 2019, the Sturgis Plant Sanitation Manager wrote in a text message to maintenance personnel, "Line 3 DePal has a leak and the line is down for cleaning now but I'm not allowing the line to start back up without getting this leak resolved…" Maintenance personnel responded that "[m]aintenance guys are there around the clock an[d] can handle put[t]ing up a leak umbrella with no problem." Similarly, in a November 2020 text message exchange between Sturgis personnel, the Plant Sanitation Manager asked: "What's the status of the leak in line 5?" Sturgis maintenance personnel responded that it was "[b]eing diverted to a drain with a leak umbrella." The issues persisted in March 2021 when the Sturgis Plant Sanitation Manager wrote in a text

message, "[t]here is a leak umbrella and hose outside the line 3 depal room on the 1st floor…" Acknowledging that leak diversion was not an appropriate solution to preventing micro contamination, a January 2022 "FDA Inspection Preparation" slide deck instructed the Sturgis facility that there should be "no water" and to "address any umbrellas in the production areas."

88. Abbott corporate leadership identified the wet environment as a potential risk to product safety at the Sturgis facility. For example, the Director of Food Safety at Abbott communicated with other corporate leaders regarding a meeting with FDA stating, "…we should be prepared to address how we control moisture in our product and production process…Are there any improvements [we] could site here on moisture control…Also who [*sic*] we have procedures around dry out of the dryer and powder handling equipment to control moisture in the environment?" Similarly, as noted above, Abbott identified "uncontrolled water" as a "significant contributor to the growth and persistence of micro, including pathogens in food processing environments." These documents also stated that the purpose and advantage of controlling water was to "[r]educe water available for microbial growth."

89. Despite recurring and unsuccessful "War on Water" campaigns, water issues persisted at the Sturgis facility until 2022. For example, in May 2021, a "major finding" in an internal audit report for the Sturgis facility was the presence of five water leaks. Similarly, just a few months later in July 2021, a third party issued a report related to an investigation of a beetle ingress at the Sturgis facility, including a finding that the "…control of standing water and excess water is needed on the roof. Roof repairs are needed where leaks are being detected on the interior."

90. In the 2021 FDA Establishment Inspection Report ("EIR"), FDA documented standing water. FDA issued a FDA 483 following the 2021 inspection, including as Observation

1 "specifically, 09/20/2021 and 09/21/2021, in Building 1-D, Dryer 3, standing water was observed in the following locations: under and adjacent to the...air handling unit, outside the…door associated with the Dry Blending Room and in the clean-out-of-place (COP) area. On 09/23/2021, in the same room, standing water was observed on the floor…"

91. In October 2021, the CAPA [Corrective and Preventive Action] Coordinator at the Sturgis facility stated: "It appears we have a standing water problem in plant and a[n] employee awareness issue also…After getting the FDA Observation 1 for 3 areas with standing water in manufacturing areas you would think our Area Owners & FLLs would be more vigilant on standing water."

92. FDA repeated the same observation from 2021 in the FDA 483 issued to Sturgis in 2022: "Standing water observed in powdered infant formula production areas is a repeat observation from the FDA inspection dated 9/20/21-9/24/21," listing four separate areas where FDA observed standing water in the facility.

93. The presence of dripping water, water leaks, and condensation also existed in Abbott's spray dryer tower while production was ongoing. In addition, between January 1, 2020 and February 1, 2022, a total of 310 water events were documented in Abbott records in dry production areas for powder infant formulas, including several water leaks necessitating repairs of the Sturgis roof.

94. Despite persistent and documented water issues at the Sturgis facility, in February 2022, a Technical Consultant working for Abbott's Corporate Headquarters noted that the micro contamination at Sturgis, confirmed by FDA testing, "could have all been avoided" if Abbott had adopted certain practices to address leaks and other issues that exposed powder formulas to moisture that it considered as early as 2018 but failed to implement.

B. Abbott Knowingly Operated Deteriorated Major Manufacturing Equipment

1. The Spray Dryers at the Sturgis Facility Were Degraded

95. Spray drying, where a liquid mixture is transformed into a dry powder, is a crucial process in manufacturing powder infant formulas.

96. The FDA Complaint alleged that Abbott failed to ensure that all surfaces of equipment and utensils that contact raw ingredients, in-process materials, or infant formulas were cleaned, sanitized, and maintained in a manner that protected infant formulas from being contaminated by any source, as required by 21 C.F.R. § 106.30(b).

97. Abbott personnel documented numerous and substantial cracks and pits in Spray Dryers 3 and 4 at the Sturgis facility. For example, in August 2018, Abbott conducted inspections of Spray Dryers 3 and 4 and documented that both had cracks.

98. The structural problems with the Sturgis spray dryers only increased over time. In January 2019, the "Dryer team identified a hair line crack on the main inspection door of Dryer #3."

99. The deterioration was attributable in part to the age of Abbott's spray dryers. Spray Dryer 3 was installed at Sturgis in 1963, and Spray Dryer 4 was installed at Sturgis in 1983. Abbott acknowledged that Spray Dryer 3 is "the oldest AN production asset within the manufacturing network."

100. The 2019 FDA EIR noted spray dryer cracks and pits. Specifically, it mentioned a "small stress crack" on the main inspection door of Spray Dryer 4 and a "small surface pit under the bustle at west side of floor-line." It also noted "one 3"" long crack on upper left hand side of the inspection door," "one crack repaired under the bustle on the north-west bustle

retractable spray," and "one crack on the #1 cyclone transition duct to the bustle about 2" long" of Spray Dryer 3.

101. In a February 2021 company PowerPoint titled "D3 [Dryer 3] Backfill Evaluation," the company identified multiple components of Spray Dryer 3 that were in "Poor" condition at that time, including the bustle, which was described as a "key structural component of [the] dryer[.]"

102. The 2021 FDA EIR noted the same spray dryer deterioration observations as the 2019 FDA EIR. Specifically, it noted the following defects in Spray Dryer 3: "small ¼" long crack repaired, upper left door frame corner, small ¼" long crack repaired, upper right door frame corner, small ½" long crack repaired, south east under bustle near spray, pit welded on sight glass frame, east side, crack 6" long on South side under bustle at duct outlet, east cyclone duct crack 2" long under the bustle." In this same report, FDA noted the following defects in Spray Dryer 4: "southeast side top of head on side wall, small pitting repaired, west side under bustle 24" diameter section replacement, mid-lower cone west side, repaired small pit, middle lower cone east side, repaired 1/8" crack, cracked braces under screen, crack on transition to scrubber and crack on spray nozzle repaired." Finally, in the 2021 EIR, FDA documented a discussion that FDA investigators had with Abbott where FDA instructed Abbott to speak with its third party dryer inspector "…about conducting a more thorough inspection of dryer #3 in the future," suggesting that the inspector provide photos of the defects before and after repair.

103. Abbott records documented the history of internal deterioration of the spray dryers at the Sturgis facility. For example, an August 2021 spray dryer inspection showed damage including, but not limited to, cracks and pits inside the dryers' main chambers. This

type of damage created the potential for niches and harborage sites for micro contamination to persist, particularly in the presence of moisture.

104. Documenting the spray dryers' continuing deterioration, Observation 2 of the FDA 483 issued to Abbott in 2022 noted: "[p]er your firm's spray dryer inspection reports, spray dryers #3 and #4 have a history of internal deterioration dating back to September 2018."

105. Abbott chose to continue operating the spray dryers at the Sturgis facility with known issues. For example, in a Sturgis maintenance personnel exchange during the 2022 FDA inspection, one employee inquired: "They found a crack in dryer 4…So d4 shut down?" The other employee responded, "Nope they're running it." Similarly, Abbott personnel explicitly acknowledged the facility's "…plans to continue to use the equipment [dryer 4] knowingly w[ith] leaks."

2. Spray Dryer Deterioration and Other Dryer Issues Were Repeatedly Identified as a Potential Cause of Microorganism Contamination

106. Abbott repeatedly investigated spray dryer cracks and pits as potential root causes for *Cronobacter* spp. and other micro contamination in the Sturgis facility through 2022.

107. For example, in June 2018, there was a positive *Cronobacter* spp. finding in the manufacturing environment. The root cause investigation identified "a pocket holding residual dried product was found under a trough drain on the Dryer 4 Main inspection dryer…that could get wet causing this Micro event."

108. Similarly in July 2019, a Sturgis employee texted the Site Director: "…we are seeing some micro noise and have at least one batch impacted. May be D[ryer] 4."

109. In a March 2020 "Monthly Connection Call – Sturgis Micro," the company assessed two positive micro contamination results where Spray Dryer 4 was identified as the "common link."

110. In June 2021, a potential root cause related to the investigation of an elevated or "out of specification" test result indicated that the potential micro contamination was due to "Dryer 4 Elevated Humidity…this created an environment enabling micro activity."

111. In March 2022, while FDA was onsite, Abbott's investigation of a positive micro contamination result on an EleCare batch found that the "Dryer 3 crack inspection resulted in observations that were required to be corrected," including "the potential to impact the manufacturing process."

112. Abbott also knowingly made its spray dryer conditions worse by lengthening dryer campaigns, *i.e.*, increasing the number of product batches that passed through the dryers between clean-in-place ("CIP") cycles, to increase production capacity. CIP requires a period of equipment shutdown, so more frequent CIP cycles result in less production.

113. For example, a July 2019 investigation for an out of specification positive result indicating micro contamination in a finished product batch identified: "the potential root cause of this event was the extension of the Dryer 4 Evaporator campaign from 10 batches to 11 which potentially may have led to the elevated micro counts."

114. Nonetheless, in the Sturgis Site Director's 2019 Performance Assessment, an identified "2020 Opportunities/Key to Success" was: "Dryer #4 – Increase weekly campaign size back to 15 in parallel to mitigation of micro."

115. Even though Abbott knew that increased dryer campaign lengths increased the risk of micro growth, the Sturgis facility exceeded those known thresholds to maximize production and meet production quotas.

3. Abbott Prioritized Profits Over Investments and Repairs

116. Despite well-documented deterioration, Abbott failed to invest in capital improvements or replacement of major manufacturing equipment at the Sturgis facility, including electing not to purchase a new spray dryer.

117. For example, since at least October 2019, Abbott was evaluating the purchase of an additional spray dryer ("Dryer 5") at the Sturgis facility. Abbott management ultimately chose not to make capital expenditures. Instead, Abbott chose to increase production on failing equipment at the Sturgis facility, specifically for the highly profitable Similac Alimentum and EleCare products.

118. In March 2019, Abbott developed "The Business Case for Specialty Powder Capacity Expansion," identifying "a new specialty dryer" at the Sturgis Facility as the "Preferred Option" for the specialty powder expansion.

119. Two years later, in February 2021, in spite of continued, known issues with the spray dyers, Abbott again assessed Spray Dryer 3 increased capacity to "[o]btain additional powder capacity in US by establishing limited use scenario(s) for Dryer 3 process train while avoiding major site infrastructure investment at Sturgis," noting that one of the "US Powder Capacity Considerations" was "WIC strategy – increased volume to continue?"

120. The culture at Abbott's Sturgis facility was to maximize production while using the least amount of resources, personnel, and structural investment. Abbott's refusals to make capital expenditures were not isolated to the spray dryers. For example, in a February 2022 exchange between Abbott's Quality department leaders after the plant shut down and recall, a senior leader inquired: "how many dedicated HC [headcount] do we have in Sturgis to focus on food safety/sanitation?" The colleague responded: "I would say dedicated is 2…" The leader

responded, "[p]robably not enough for such a big and complex site." The colleague agreed and added, "[p]robably not when you add in the aging infrastructure."

C. Abbott Failed to Validate Key Manufacturing Processes

121. The Sturgis facility used an unvalidated dryout procedure until late 2022. The purpose of dryout is to ensure that the spray dryers are thoroughly dried after water is introduced during clean-in-place ("CIP") and prior to restarting spray dryers post-CIP, all to minimize the risk of micro contamination. Because this process was unvalidated, Abbott had not ensured its dryout process achieved complete dryness prior to restarting powder infant formula processing.

122. Abbott's related Standard Operating Procedure ("SOP") did not contain a validated dryout process. Indeed, Observation 2 of the FDA 483 issued to the Sturgis facility in 2022 noted "…that the dry out steps for both spray dryers were not validated to ensure complete drying is achieved."

123. Moreover, Abbott personnel acknowledged that its dryout process was not validated. For example, in August 2018, Abbott's Director of Food Safety inquired whether Sturgis had "procedures around dry out of the dryer and powder handling equipment to control moisture in the environment."

124. After FDA required Abbott to validate its dryout process in 2022 as part of its obligations under the Consent Decree, Abbott attempted to validate its existing dryout process without making any changes but failed to achieve validation. The Sturgis Quality Assurance Project Lead confirmed that Abbott was previously unable to determine whether the dryers were sufficiently dry after cleaning to prevent micro contamination. He reported to the Quality Engineer: "They are trying to use an engineering study to look at our current dry out, so we can

validate without changing the parameters. It has now failed twice, there is some concern due to potential to implicate the past dry outs."

125. Ultimately, Abbott did not implement a validated dryout procedure until late 2022.

II. Abbott's Culture of Concealment Resulted in a Failure to Identify, Document, Investigate, and Prevent the Presence of Microorganisms

126. The Sturgis facility manufactured powder infant formulas under conditions and practices that failed to protect the products against the risk of micro contamination.

127. Abbott's environmental and finished product testing indicated the presence *Cronobacter* spp. inside the Sturgis facility.

128. cGMP required that Abbott "…test representative samples of each production aggregate of powdered infant formula at the final product stage, before distribution, to ensure that each production aggregate meets the microbiological quality standards…" (21 C.F.R. § 106.55(c)) and "…make and retain records, in accordance with § 106.100(e)(5)(ii) and (f)(7), on the testing of infant formulas for microorganisms." *Id.* § 106.55(d). cGMP also required Abbott to "…establish a system of process controls covering all stages of processing that is designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment." 21 C.F.R. § 106.55(a).

129. Abbott was aware of the relevant cGMP requirements as evidenced by its own SOPs that outlined processes for assessing micro "risks during manufacturing introduced by ingredients, process (storage times and temperatures) and equipment...to provide evidence of overall product bioburden load."

130. Abbott's Global Microbiological Standards SOP also set forth the minimum testing frequency for specific manufacturing areas, including for in-process powder phase/milk

base powder, and detailed requirements for when products test positive for a microorganism, including documenting the elevated or "out of specification" test result in quality records.

131. Abbott's Environmental Monitoring for Qualified Buildings, Facilities, and Utilities SOP addressed the minimum requirements for environmental monitoring and testing to "minimize or prevent environmental pathogens and environmental bioburden from contaminating the product." This SOP established target bio burden "action levels" based on potential impact to product quality by establishing "a limit to what is acceptable for normal operations" and stated that "when results are above the action level, corrections to process, procedures, or equipment may be required."

132. Abbott trained all Sturgis employees on the potential risks that micro contamination poses in the manufacturing environment and the product and the company's responsibility to prevent such contamination.

133. Despite Abbott's knowledge of the regulatory requirements, as reflected in its own SOPs, Abbott failed to document, adequately test for, and, when specifically asked by FDA, failed to inform FDA of all potential micro contamination.

134. Abbott's overall attitude toward transparency and diligence in protecting its product from micro contamination is summarized in a March 2022 message from senior Abbott leadership, notably sent after the Sturgis facility shut down and recall: "[j]ust don't want to give more [to FDA] than what we committed."

135. The culture of concealment permeated the Sturgis facility through 2022. For example, in May 2019, the Director of Quality Assurance requested that the Sturgis Site Director alter pest data records (an indicator of facility cleanliness) to "…eliminate certain buildings…to…make the data reflect positively." A few days later, the Sturgis Director of

Quality Assurance advised: "[i]f it smells clean, looks clean and shiny and organized then [internal and FDA auditors] are less likely to want to dig in see what else they can find."

A. Abbott Failed to Maintain Adequate Testing Records and Investigate Positive Results

136. Abbott failed to identify, document, and investigate any issues that could impact product quality, including potential micro contamination, confirmed micro contamination, and positive indicators of micro contamination in both the manufacturing environment and powder infant formula products.

137. Company policies also required that a quality record be used to document test results indicating potential or actual micro contamination in the environment or product. Abbott classified quality records into three categories based on the severity of the risk of contamination: (1) Nonconformance – "the non-fulfillment of a Food Safety, Medical Safety, and/or Regulatory requirements;" (2) Potential Nonconformance – "the potential non-fulfillment of a Food Safety, Medical Safety, and/or Regulatory requirements;" and (3) Quality Assessment – "an evaluation of an event to comprehend the potential non-fulfillment of a Food Safety, Medical Safety, and/or Regulatory requirement." The classification of the quality record dictated the extent of investigation required to identify the root cause of the potential or actual contamination.

138. Abbott failed to document and investigate potential and actual micro contamination. For example, the Plant Quality Assurance Manager at Sturgis suggested classifying certain results from environmental testing that indicated the presence of micro contamination (referred to as "Over Action Levels" or "OALs") as "informational" rather than as "EMP [environmental monitoring program] failures." An Abbott corporate leader testified that "informational" is not an appropriate or accurate classification for a finding indicating potential

micro contamination and that any such results should have been part of the environmental monitoring program, which would require follow up testing for *Cronobacter* spp.

139. The Sturgis Plant Quality Director routinely instructed Sturgis Micro Lab personnel to refrain from documenting positive environmental contamination results. Consequently, no follow-up testing was done to confirm the presence of *Cronobacter* spp. or *Salmonella,* and these results were not included in trend analyses that should have been used to evaluate the safety of the environment and powder infant formula product.

140. For example, quality and lab personnel at the Sturgis facility were explicitly instructed to downgrade classifications of quality records so that "root cause analysis" was not triggered and so that quality issues would not impact monthly quality "metrics."

141. Communications among Sturgis personnel show why its failure to classify test results indicating micro contamination (referred to as "OALs") as part of EMP failures is significant. For example, in January 2020, the Director of Quality Assurance requested the reclassification of OALs so they would not hit the nonconformance metric for Sturgis: "…I do not see anywhere in it that defines all confirmed OALs, trends, or other are required to be a nonconformance. Only that they will be documented in our CAPA system…I believe we should be changing our open NC's [nonconformance reports] to PNC's [potential nonconformance reports]," "…so I would like all of these open ones [NCs] converted to PNC's please…It's hitting our NC Rate metric…" Eventually, the Sturgis Micro Lab manager complied: "I have converted all Micro NCRs currently open to pNCRs."

142. Abbott required the Sturgis facility to provide certain performance metrics, which were often presented during leadership meetings. One assessment metric was the nonconformance rate reduction, which was calculated as follows:

Metric Calculation Definition

Non-conformances [Target: Division specific]

$$\frac{\textit{Total number approved}}{\textit{Number of lots, batches or units dispositioned}} \times 1{,}000$$

143. The Sturgis facility prioritized performance metrics above accurately categorizing quality records within the facility and investigating and addressing issues based on their accurate categorizations. An Abbott employee confirmed that if a CAPA was part of a metric, the CAPA would often be closed irrespective of whether the problem was addressed. The Sturgis Site Director was also known to "push shortcuts" to hit metrics.

144. The classification of micro contamination test results also directly impacted what Abbott represented to FDA. During FDA inspections, investigators typically request to review documentation of positive results for product and environmental testing and related trend analyses, root cause analyses, and quality investigations. For example, when FDA asked for NCs during the 2021 inspection, Abbott only provided NCs and not PNCs. Therefore, Abbott never provided FDA with the January 2020 data on positive indicators of micro contamination identified by the Director of Quality Assurance because the quality records were downgraded to avoid "hitting metrics."

145. Abbott's mischaracterization of test results in quality records and the company's failure to conduct follow up testing and document results may have inhibited FDA's ability to properly evaluate cGMP compliance and product safety risk at the Sturgis facility.

B. Abbott Avoided Testing for the Presence of Microorganisms

146. Before 2022, most of Abbott's environmental testing (*i.e.*, testing of the production environment, not the infant formula products) was conducted after thorough cleaning

of the related surfaces. Witnesses stated that the areas to be tested were made known to responsible personnel and cleaned thoroughly prior to swabbing, while shortcuts were taken on cleaning the rest of the equipment and manufacturing environment. This obviated the purpose of testing, which is to evaluate the actual, real-time production environment to ensure that sanitation practices are sufficient to control product contamination.

147. When FDA began its own environmental testing in February 2022, Sturgis employees remarked that it was more robust than their own testing and on the significant increase in the presence of potential micro contamination. In a February 2022 exchange between two Sturgis Micro Lab personnel, one employee advised the other: "[Y]ou should not give departments a swab list [a list of locations where testing would take place]." The other employee responded: "I have no intentions of giving them lists anymore. After all the plates that are completely loaded after EB [*Enterobacteria*] enrichment [indicating the potential for contamination], the proof they spot clean is glaringly obvious."

148. Sturgis personnel were also justifiably concerned that more frequent and expansive testing would lead to more positive test results. In October 2022, the Sturgis Quality Operations Director for Quality Assurance wrote: "I want to make sure that we are weighing the pros/cons of instituting this activity. The act of [testing] adds some risk in itself…"

149. In 2021, the Director of Quality Assurance inquired "[w]hy did we do dynamic swabs [testing] in this area as part of our routine LMP program when we knew we had outstanding CAPA items to complete? I would think we would not put the areas into the rotation until the CAPA items identified from the last set of failures were implemented…otherwise we're setting ourselves up to continue to have failures." The Micro Lab manager expressed concern that electing to stop testing while rates of indicators of potential contamination increased could

result in product risk: "[t]wo months of bad monitoring results, a pathogen confirmation, vector swabs and no interim changes to help lower the dynamic load as we wait for corrective actions? Not sure where the break down is in the maintenance of their area. Loss of accountability?"

150. Yet another example of how Abbott failed to adequately test for micro contamination and was not forthcoming with FDA relates to the Sturgis facility's routine use of the BAX® PCR System ("BAX") until 2022 to test for the presence of *Cronobacter* spp. in finished product and confirmatory environmental testing.

151. In November 2018, a Research Scientist in the Global Analytical and Food Safety Department at Abbott issued an internal memo to Sturgis and other sites related to the BAX's testing limitations. The memo explicitly concluded that the BAX Q7 assay was unable to detect all species – specifically *Cronobacter dublinesis* – of the *Cronobacter* spp. genus below certain concentration levels.

152. Senior Abbott leaders were aware that this posed regulatory and product quality issues. For example, senior Abbott personnel explicitly acknowledged: "[y]ou will hear everyone speak to C. sak around here, but we actually are required [by FDA] to assure no Cronobacter species are present."

153. Nonetheless, Abbott failed to correct this known testing deficiency for four years after it was identified, because, as Abbott personnel confirmed, it chose not to prioritize the capital expenditure necessary to replace the BAX machine with a system that tested for all *Cronobacter* spp. species.

154. As a result, during this four-year period, Abbott could not and did not confirm whether any of its finished product distributed and sold in the United States was contaminated with *Cronobacter dublinesis* at certain detectable concentrations.

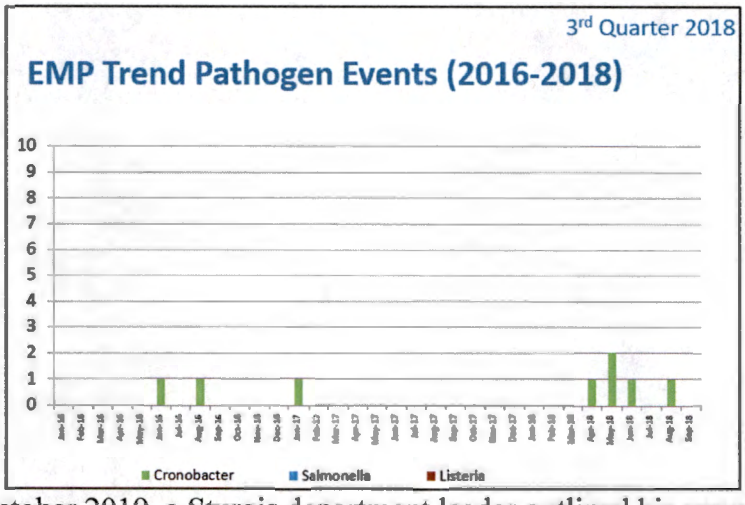
155. Despite these documented internal concerns regarding BAX's detection failure and Abbott's awareness that it was required to test for all species of *Cronobacter* spp., Abbott also misrepresented to FDA that it conducted testing at Sturgis for *all* species of *Cronobacter* spp. until 2022.

156. It was not until February 2022, during FDA's inspection, that Abbott corporate leaders replaced the BAX machine with an alternative testing device that had the required testing capabilities.

C. Abbott Was Aware That the Sturgis Facility Had a Recurring Presence of Microorganisms and Failed to Disclose Positive Test Results to FDA

157. Despite Abbott's minimal testing and inadequate documentation practices, quality records showed positive in-process, finished product, and environmental test results for *Cronobacter* spp. and other micro contamination.

158. For example, over time, Abbott knew that the Sturgis facility had sharply increased positive *Cronobacter* environmental pathogen events:

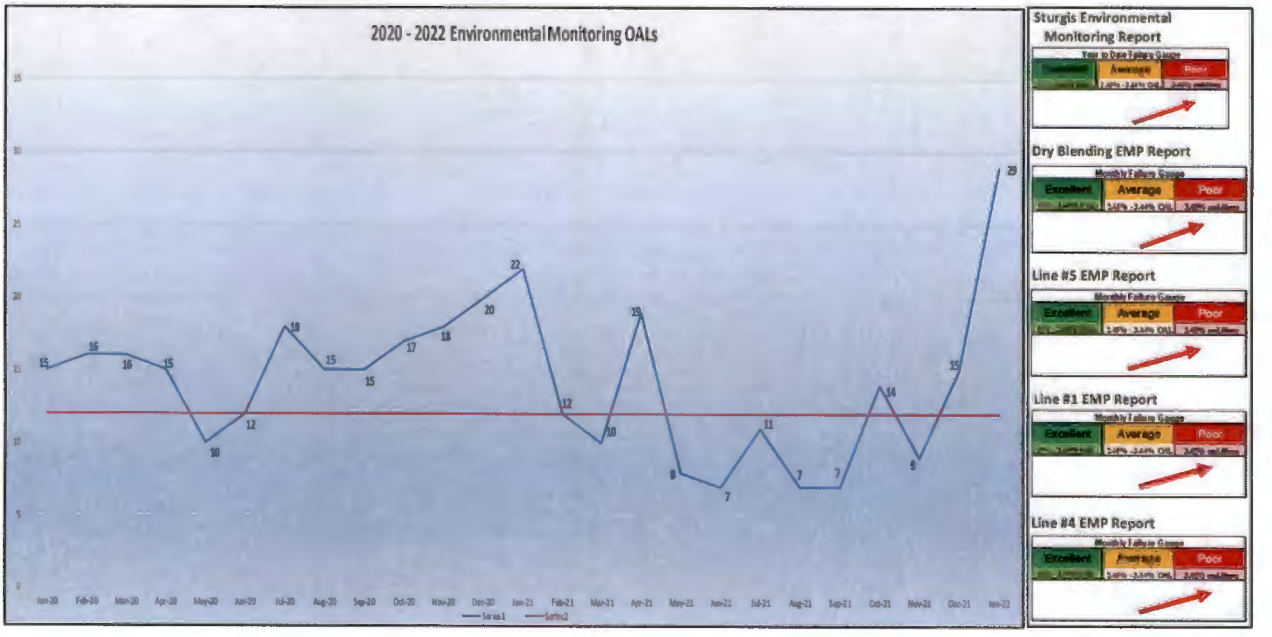


159. In October 2019, a Sturgis department leader outlined his concerns that "micro signals show no improvement against August and continues to trend unfavorably. These signals are good indicators that we are either not cleaning our high care areas well enough or keeping

them clean during production. As August showed with the Cronobacter batches, increased swab failures reveal we're at greater risk for product impact. Overall, we need to do better."

160. Only days before FDA arrived on site in late January 2022, Sturgis managers discussed that the facility was still struggling to maintain a safe environment for the production of powder infant formulas. For example, the Micro Lab manager shared results from environmental swabs taken on Line 5 (powder infant formula line) while in production: "[t]he results are very concerning about the environment of Line 5 while in production…with the environment out of control [with potential micro contamination], there is high risk to protecting our product."

161. Specifically, environmental monitoring reports from the months immediately preceding the 2022 FDA inspection indicated a significant rise in positive test results for environmental contamination OALs at the Sturgis facility, as shown below.



162. Aware of the consequences of FDA discovering the unsuccessful efforts to control the micro risk posed to its powder infant formula product, Abbott personnel withheld

positive test results when responding to requests from FDA investigators for any positive test results during the 2019 and 2022 inspections at the Sturgis facility.

163. In 2019, Abbott was aware of, and failed to disclose, a positive *C. sak.* finished product result to FDA during an FDA inspection in response to FDA investigators' request for all of Abbott's finished product testing.

164. Similarly, while onsite in February 2022, an FDA investigator requested information on micro trends. Even though the Site Quality Assurance Director was aware of the significant rise in reports of potential micro contamination in January 2022, rather than providing the most timely and complete information to FDA, the Site Quality Assurance Director decided not "to show them [FDA] January swabs" and instead provided less accurate and more favorable data. This misrepresentation took place while FDA was at Sturgis investigating reports of illness and findings of insanitary conditions at the facility, including the presence of *Cronobacter* spp.

III. Abbott Falsely Certified Compliance with Material Statutory, Regulatory, and Contractual Requirements for WIC Powder Infant Formula Manufactured at the Sturgis Facility

165. As described above, Abbott failed to perform "reasonable quality assurance activities and testing and correct all material deficiencies discovered during the quality assurance activities and testing," as required by the USDA requirements for WIC infant formula and State contracts, including compliance with the FDCA and cGMP regulations.

166. These failures put Abbott's powder infant formula manufactured at the Sturgis facility at unacceptable risk of contamination and significantly impacted the products' reliability, quality, and safety.

167. As a manufacturer in the WIC program, Abbott represented that its powder infant formulas, including contract and non-contract formulas, complied with the USDA statutory and regulatory requirements for WIC infant formula.

168. Abbott also certified compliance with WIC infant formula obligations in its bid submissions and contracts executed with State agencies, including compliance with the FDCA.

169. The USDA required Abbott's certifications to State agencies that its WIC infant formula manufactured at the Sturgis facility complied with applicable requirements to be eligible to supply infant formula to the WIC program.

170. Abbott did not disclose to the USDA or State agencies that it misrepresented its compliance with WIC infant formula obligations and was in breach of material provisions of its State agency contracts and requirements imposed by USDA statutes and regulations.

171. For example, on March 10, 2022, Abbott's authorized signatory signed the WIC contract with the State of California during ongoing FDA regulatory activity at the Sturgis facility and certified that its infant formula complied with the FDCA and that the product was "free from defects in labor, material, and manufacture, and…in compliance with Bid specifications." Abbott leadership also planned to meet with California State agency WIC officials during a "2022 Sr. Leadership Roadshow," presumably to quell concerns about the ongoing issues at the Sturgis facility so that Abbott could secure a significant contract with the State of California.

172. Abbott sold its powder infant formula to authorized WIC vendors knowing that at least some of the formula would be purchased by WIC participants using WIC benefits, which are USDA funds allocated to State agencies to administer the WIC program.

173. Authorized WIC vendors sought payment from WIC participants for Abbott's powder infant formula that failed to comply with contractual, statutory, and regulatory requirements that were material to the USDA.

174. As described above, WIC participants used WIC benefits to purchase non-compliant infant formula from authorized WIC vendors.

175. Thus, Abbott caused authorized WIC vendors to present false claims for payment of USDA funds when WIC participants used WIC benefits to purchase these infant formulas.

176. The table below includes examples of individual WIC participant's purchases of Abbott powder infant formula using WIC benefits. These examples are false claims for payment of USDA funds for powder infant formulas that Abbott manufactured at the Sturgis facility because Abbott failed to comply with requirements imposed by statute, regulation, and contracts.

Product Name	State Agency	Contract or Non-Contract Formula	Date	Retail Price	Rebate Amount	Net Price
Similac Total Comfort	Texas	Contract	12/1/2020	$17.98	$17.33	$0.66
Similac Advance	Pennsylvania	Contract	6/4/2021	$4.37	$4.19	$0.73
Similac Alimentum	Pennsylvania	Non-contract	8/9/2021	$9.99	N/A	$9.99
Similac Advance	Michigan	Contract	11/19/2021	$18.39	$14.93	$2.50
Similac Alimentum	Michigan	Non-contract	12/5/2021	$31.79	N/A	$31.79
EleCare	Michigan	Non-contract	1/26/2022	$47.29	N/A	$47.29
EleCare	Texas	Non-contract	2/1/2022	$47.80	N/A	$47.80

IV. Abbott's Contract Certifications for Powder Infant Formula Manufactured at the Sturgis Facility Were Material to State Agency Bid Solicitation Awards and Contract Execution Decisions

177. The totality of the allegations outlined above—the 2022 Class I recall, the Consent Decree, Abbott's failure to maintain accurate quality records, Abbott's failure to

conduct appropriate testing for micro contamination, and Abbott's lack of transparency about data indicating potential or actual micro contamination—demonstrates Abbott's material noncompliance with its statutory, regulatory, and contractual obligations as a WIC infant formula manufacturer.

178. As detailed above, State agency contracts contained material provisions that required Abbott's infant formula to meet standards set forth in the FDCA and cGMP regulations.

179. The USDA required, and State agencies relied on, Abbott's certification that its infant formulas complied with these material contract provisions, including that the infant formula met standards set forth in the FDCA, cGMP, and the quality-related terms of the State agency contracts.

180. The USDA would not have allowed any funds to be used by State agencies for the purchase of powder infant formula manufactured at the Sturgis facility by WIC participants had it known that the infant formulas failed to comply with USDA statutes and regulations and State agency contracts.

181. Abbott knew that its infant formula products were purchased using WIC benefits. Abbott knew that its false certifications to compliance with contractual, statutory, and regulatory requirements for infant formula and human food directly affected State agency decisions to accept Abbott's bids and execute contracts with Abbott, and the USDA's decision to allow State agencies to enter contracts that enabled WIC participants to purchase Abbott's powder infant formula using WIC benefits.

COUNT I
(False Claims Act: Causing False or Fraudulent Claims)
(31 U.S.C. § 3729(a)(1)(A))

182. The United States realleges and incorporates by reference all paragraphs of this complaint set out above.

183. By virtue of the acts described above, Abbott knowingly presented, or caused others to present, false or fraudulent claims for payment, in violation of 31 U.S.C. § 3729(a)(1)(A). Specifically, Abbott knowingly presented, or caused to be presented, false claims for payment under the USDA WIC program for contract and non-contract powder infant formula manufactured at the Sturgis facility, which Abbott expressly or impliedly certified complied with applicable statutory, regulatory, and contractual requirements.

184. Payment of the false and fraudulent claims was a reasonable and foreseeable result of Abbott's conduct.

185. By reason of the foregoing, the United States suffered actual damages because of Abbott's wrongful conduct in an amount to be determined at trial and therefore is entitled under the False Claims Act to treble damages plus a civil penalty for each false or fraudulent claim.

COUNT II
(False Claims Act: False Statements Material to False Claims)
(31 U.S.C. § 3729(a)(1)(B))

186. The United States realleges and incorporates by reference all paragraphs of this complaint set out above.

187. By virtue of the acts described above, Abbott knowingly made, used, or caused to be made or used false statements material to a false claim for payment, in violation of 31 U.S.C. § 3729(a)(1)(B). Specifically, Abbott made or caused to be made false statements material to false claims for payment under the USDA WIC program for contract and non-contract powder infant formula manufactured at the Sturgis facility which Abbott knew failed to comply with applicable statutory, regulatory, and contractual requirements. All claims were knowingly false claims under the False Claims Act.

188. Payment of the false claims was a reasonable and foreseeable consequence of Abbott's statements and actions.

189. By reason of the foregoing, the United States suffered actual damages because of Abbott's wrongful conduct in an amount to be determined at trial and therefore is entitled under the False Claims Act to treble damages plus a civil penalty for each false record or statement material to a false claim.

COUNT III
(Unjust Enrichment)

190. The United States realleges and incorporates by reference all paragraphs of this complaint set out above.

191. The United States paid for non-compliant powder infant formulas manufactured at the Sturgis facility due to false statements and omissions by Abbott.

192. The United States is entitled to the return of all payments by the United States directly or indirectly to Abbott for powder infant formula manufactured at the Sturgis facility that failed to comply with applicable statutory, regulatory, and contractual requirements.

193. By virtue of the conduct and acts described above, Abbott was unjustly enriched at the expense of the United States in an amount to be determined, which, under the circumstances, in equity and good conscience, and as dictated by the needs of justice and fairness, should be returned to the United States or would be unconscionable for Abbott to retain.

PRAYER FOR RELIEF

WHEREFORE, the United States respectfully prays for judgment in its favor as follows:

194. As to the First and Second Causes of Action (False Claims Act): for (i) statutory damages in an amount to be established at trial, trebled as required by law, and such penalties as are required by law; (ii) the costs of this action, plus interest, as provided by law, and (iii) any other relief that this Court deems appropriate, to be determined at a trial by jury.

195. As to the Third Cause of Action (Unjust Enrichment): for (i) a full accounting of all revenues (and interest thereon) and costs incurred by Abbott on powder infant formula sales manufactured at the Sturgis facility and paid for using USDA funds for non-compliant formula due to Abbott's conduct, and (ii) disgorgement of all profits earned and/or imposition of a constructive trust in favor of the United States on those profits.

196. All other and further relief as the Court may deem just and proper.

DEMAND FOR A JURY TRIAL

The United States hereby demands a jury trial on all claims alleged herein.

Dated: November 13, 2025

Respectfully submitted,

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