UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA, and the STATES of ARKANSAS, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, COMMONWEALTH OF MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, UTAH, VERMONT, COMMMONWEALTH OF VIRGINIA, WASHINGTON, WISCONSIN, AND THE DISTRICT OF COLUMBIA, *ex rel.*	)
Scott Millard, Kristine Cooper, and Loren Cooper, *Plaintiffs*,	)
v.	) Case No. 1:22-cv-994
ABBOTT LABORATORIES, *Defendant*.	) Hon. Hala Y. Jarbou Chief United States District Judge

CONSOLIDATED COMPLAINT OF THE INTERVENING STATES AGAINST ABBOTT LABORATORIES

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PRELIMINARY STATEMENT

Millions of Americans rely on states' Medicaid programs, which provide health coverage to individuals and families with lower incomes, including children, parents, people who are pregnant, elderly people, and people with disabilities. Infants in the United States 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. Tragically, millions of American families with infants and children across the country suffer from allergies, intolerances, or metabolic issues that force them to rely on certain specialty, amino acid-based and metabolic infant formula life-sustaining products. Medicaid covers the cost of these formulas to eligible recipients. Abbott Laboratories ("Abbott"), one of a few large Medicaid and WIC Prrogram infant formula manufacturers, manufactures the familiar products Similac®, Similac Alimentum®, and EleCare®. The USDA, State agencies, WIC participants, and State Medicaid 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, however, knowingly failed to manufacture its powder infant formulas at its Sturgis, Michigan facility in a manner that ensured its products were in compliance with its federal and state statutory, regulatory, and contractual obligations. Despite this, Abbott has yet to pay back a single dollar to any state Medicaid program for its infant formulas, specifically powder infant formula manufactured at the Sturgis facility between 2020 and 2022, which was subject to a Class I recall and otherwise failed to comply with state Medicaid requirements. The Intervening Plaintiff States bring this complaint to make each state Medicaid or WIC program whole so that it can continue to fund State agencies that serve the country's infants through the Medicaid and WIC programs.

On August 4, 2025, the States of California, Maryland, and Tennessee filed a Notice of Intervention in the above-captioned case. (ECF No. 65.) On November 21, 2025, the States of Connecticut and New York and the Commonwealth of Massachusetts filed a Joint Motion to Intervene for Good Cause (ECF No. 93)[1] in the above-captioned case. California, Connecticut, Maryland, Massachusetts, New York, and Tennessee (collectively, the "Intervening States") allege as follows with respect to Defendant Abbott Laboratories:

INTRODUCTION

1. This is a civil action brought by the Intervening States against Abbott, which manufactures exempt or specialty infant formula that is used as a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food (22 Cal. Code Regs. § 51313.3(e)(2)). The Intervening States bring this action to recover treble damages and civil penalties for Abbott's fraudulent conduct under their respective state False Claims Acts, state statutes, and the common law.

2. Abbott also manufactures standard infant formula which can be consumed by infants who do not need exempt or specialty formula, and which is suitable as a complete or partial substitute for human milk. 21 U.S.C. § 321(z).

3. The United States Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS"), is responsible for the administration of all federal healthcare programs. Title XIX of the Social Security Act ("Medicaid" or the "Medicaid Program") authorizes grants to states for medical assistance to individuals whose income and resources are not sufficient to meet the costs of necessary medical care. 42 U.S.C. § 1396; 42 C.F.R. § 430.0; *see* 42 U.S.C.

[1] This Motion is pending decision of the Court.

§§ 1396-1396v. The Medicaid Program is jointly funded by the federal government and participating states.

4. As a condition of receiving federal funding, each state is required to establish a single state agency that is responsible for administering its Medicaid program, including determining eligibility for benefits and ensuring compliance with federal regulations. 42 C.F.R. § 431.10.

5. Medicaid single state agencies require infant formula product manufacturers to comply with certain statutory, regulatory, and in some instances contractual obligations before Medicaid dollars can be used to purchase or reimburse their products.

6. As discussed below, at a minimum, single state agencies require all infant formula manufacturers to comply with the Federal Food, Drug, and Cosmetic Act ("FDCA") and current good manufacturing practices ("cGMP").

7. Many states have analogous health and food safety laws and regulations that similarly require the manufacturing of food to be unadulterated and infant formula that is free of health hazards.

8. Abbott was aware of its statutory, regulatory, and contractual obligations as a supplier of powder infant formula to state Medicaid programs.

9. The Intervening States' Medicaid programs relied on Abbott's certification and representation that its product manufacturing was compliant with applicable cGMP, as well as federal and state laws, regulations, and (where applicable) contracts that govern the manufacturing of specialty infant formula and nutritional therapy products before permitting the sale or reimbursement of Abbott infant formula and nutritional therapy products within their respective states.

10. Abbott misrepresented to state agencies that the powder infant formula and nutritional therapy products manufactured at its Sturgis, Michigan facility complied with the Medicaid requirements for such products , the FDCA, and cGMP.

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

12. The Complaint filed by the United States on behalf of the FDA ("FDA Complaint") alleged that Abbott failed to process its infant formula in a manner that complied with cGMP and manufactured its infant formula "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.

13. On November 13, 2025, the United States filed a Complaint in Partial Intervention on behalf of the USDA against Abbott in this matter ("U.S. Complaint"). The United States brings 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. *United States, et al., ex rel. Scott Millard, Kristine Cooper, and Loren Cooper v. Abbott Laboratories et al.* (ECF No. 88) (W.D. Mich. November 13, 2025).

14. The U.S. Complaint alleges: (1) Abbott misrepresented to the USDA, state agencies, and WIC participants that its powder infant formula manufactured at the Sturgis, Michigan facility complied with USDA requirements for WIC infant formula, including compliance with the FDCA; (2) Abbott falsely certified compliance with material statutory,

regulatory, and contractual requirements for WIC powder infant formula manufactured at the Sturgis facility; and (3) Abbott's contract certifications for powder infant formula manufactured at the Sturgis facility were material to state agency bid awards and contract execution decisions using USDA funds, all in violation of 31 U.S.C. § 3729 (FCA). ECF No. 88, PageID.43-44.

15. 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, which are "yeasts, molds, bacteria, and viruses and includes, but is not limited to, species having public health significance." 21 C.F.R. § 106.3.

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

17. As a result, Abbott knowingly presented, or caused others to present, false or fraudulent claims for payment for powder specialty infant formula manufactured at the Sturgis facility that failed to comply with requirements imposed by statutes, regulations, and contracts with State agencies, in violation of the Intervening States False Claims Acts and or Medicaid False Claims Acts.

18. Abbott also knowingly made false statements material to false claims in connection with Medicaid reimbursed specialty infant formula, in violation of the Intervening States' False Claims Acts.

19. In addition, Abbott was unjustly enriched when Medicaid and WIC participants used Medicaid and WIC benefits to purchase Abbott infant formula that did not meet federal and

state statutory, regulatory, and contractual requirements for Medicaid and WIC funded infant formula.

JURISDICTION AND VENUE

20. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1345, 1367(a). Additionally, the Court has supplemental jurisdiction over the state causes of action pursuant to 28 U.S.C. § 1367(a). The Court may exercise personal jurisdiction over Abbott, and venue is appropriate in this Court under 31 U.S.C. § 3732(a) and 28 USC § 1391(b), because many of the false or fraudulent acts committed by Abbott occurred in this District.

PARTIES

A. Intervening States

21. Plaintiff the State of California, acting through the California Attorney General's Division of Medi-Cal Fraud and Elder Abuse ("California") brings this action pursuant to the California Attorney General's authority under the California False Claims Act. The California Department of Health Care Services ("DHCS"), an agency of the State of California, administers the California Medicaid program.

22. Plaintiff the State of Connecticut, acting through the Connecticut Office of Attorney General ("Connecticut"), brings this action pursuant to the Connecticut Attorney General's authority under the Connecticut False Claims Act. Connecticut law authorizes the State to bring a civil action against any person that violates the Connecticut False Claims Act. Conn. Gen. Stat. § 4-276.

23. Plaintiff the Commonwealth of Massachusetts is a sovereign state and body politic duly organized by law and is represented by the Massachusetts Attorney General, who brings this action in the public interest and on behalf of the Massachusetts, its citizens, taxpayers, the

Massachusetts Executive Office of Health and Human Services ("EOHHS"), MassHealth, which jointly administers the Massachusetts Medicaid program with the United States, and the Nutrition Division of the Bureau of Family Health and Nutrition in the Department of Public Health, which administers the Special Supplemental Nutrition Program for WIC.

24. The State of Maryland is a free, sovereign, and independent State. Maryland law authorizes the State to bring a civil action against any person or provider that violates the False Health Claims Act. MD. Code. Ann., Health-Gen. § 2-603(a).

25. Plaintiff, the State of New York, acting through the New York Attorney General's Office ("New York") brings this action pursuant to the New York Attorney General's authority under the New York False Claims Act ("NYFCA"), N.Y. State Fin. Law § 187 et seq.

26. Plaintiff, the State of Tennessee, acting through the Tennessee Office of Attorney General and Reporter ("Tennessee"), brings this action pursuant to the Tennessee Attorney General's authority under the Tennessee Medicaid False Claims Act ("TMFCA"). Tennessee law authorizes the State to bring a civil action against any person that violates the TMFCA. Tenn. Code Ann. § 71-5-183.

B. Relators

27. 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.

C. Defendant Abbott

28. Abbott Laboratories is an Illinois corporation listed on the New York Stock Exchange (ABT) and a component of the S&P 100 with a market cap of over $200 billion. Abbott conducts business nationwide, including in this District, with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064. Abbott manufactures and markets numerous varieties of powdered and liquid infant formula. These products contain key nutrients for infant development, including but not limited to fats and fatty acids, carbohydrates, oligosaccharides (prebiotics), lutein and beta carotene for eye development, vitamins E, D, and A, and minerals such as iron, calcium, phosphorus, and zinc. Abbott manufactures and sells infant formulas and nutritional therapy products, including, but not limited to, the following powder infant and nutritional therapy formulas purchased using Medicaid benefits: Similac® PM 60/40, Similac NeoSure®, Similac Alimentum®, Similac Alimentum® Ready to Feed, Similac® Special Care, Elecare® and Elecare® Jr.

29. 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

30. Title XIX of the Social Security Act ("Medicaid" or the "Medicaid Program") authorizes grants to states for medical assistance to individuals whose income and resources are not sufficient to meet the costs of necessary medical care. 42 U.S.C. § 1396; 42 C.F.R. § 430.0; *see* 42 U.S.C. §§1396-1396v. The Medicaid Program is jointly funded by the federal government and participating states. The amount of federal funding in a state's program ("Federal Financial Participation") is determined by a statutory formula set forth in 42 U.S.C. §§ 1396b(a) and 1396d(b). A state that elects to participate in the Medicaid Program must establish a plan for

providing medical assistance to qualified beneficiaries. 42 U.S.C. §§ 1396a(a)-(b); *see* 42 C.F.R. § 430(A) &: (B); CMS State Medicaid Manual § 13025. In exchange, the federal government, through CMS, pays to the state the federal portion of the expenditures made by the state to providers, and ensures that the state complies with minimum standards in the administration of the Medicaid Program. 42 U.S.C. §§ 1396, 1396a, and 1396b.

31. Every state that elects to participate in the Medicaid Program must establish and maintain a State Plan consistent with federal law regarding the coverage of conditions necessitating the use of Abbott's infant formula and nutritional therapy products. State Plans must be reviewed and approved by CMS.

I. General Federal Regulations of Infant Formula

32. 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). "Exempt infant formula" must also 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.

33. "Infant formula" means "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).

34. "Food" means "(1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article." 21 U.S.C.A. § 321(f).

35. The manufacturing process for powdered infant formula involves wet blending the nutrients in stainless steel tanks and mixing in milk, pasteurizing the liquid through a rapid heating and cooling process, homogenizing the liquid to break fat and oil particles into small droplets, checking the contents of the liquid, administering a heat treatment, spray drying the liquid to

reduce it to a powder, and blending in dry ingredients for certain products such as Similac® PM 60/40, Similac NeoSure®, Similac Alimentum®, Similac Alimentum® Ready to Feed, Similac® Special Care, Elecare® and Elecare® Jr.

A. FDA and FDCA Requirements Prohibit Adulteration

36. The FDA does not approve infant formulas, but it regulates the production of infant formula and food. The FDCA prohibits the introduction or delivery for introduction into interstate commerce of any food that is adulterated. 21 U.S.C. § 331(a). The Act also prohibits "the alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act" concerning a food "while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated." 21 U.S.C. § 331(k).

37. Under the FDCA, food is deemed adulterated:

> (1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health...; or
>
> (2)(A) if it bears or contains any added poisonous or added deleterious substance…that is unsafe within the meaning of section 346 of this title; or (B) if it bears or contains a pesticide chemical residue that is unsafe within the meaning of section 346a(a) of this title; or (C) if it is or if it bears or contains (i) any food additive that is unsafe within the meaning of section 348 of this title; ... or
>
> (3) if it consists in, whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or
>
> (4) 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).

38. Infant formula, including an infant formula powder, is deemed to be adulterated if:

> (1) such infant formula does not provide nutrients as required by subsection (i),
>
> (2) such infant formula does not meet the quality factor requirements prescribed by the [Health and Human Services] Secretary under subsection (b)(1), or
>
> (3) 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).

39. The FDCA prohibits a manufacturer from approving or releasing infant formula that does not meet nutrient and quality requirements or that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration. 21 C.F.R. § 106.70(d). Likewise, the approval and release of any ingredient, container, or closure not manufactured, packaged, labeled, or held under conditions to prevent adulteration is prohibited. 21 C.F.R. § 106.40(f)(3). Other FDA provisions set forth in 21 C.F.R. Parts 106 and 107 address cGMP requirements, nutrient quality control procedures, maintenance of batch records, submission requirements, and infant formula recalls.

B. cGMP and Quality Factor Requirements for Infant Formula and Nutritional Therapy Products

40. The cGMP applicable to human food generally require that "the manufacturer, processor, packer, and holder of food must at all times utilize quality control operations that reduce natural or unavoidable defects to the lowest level currently feasible." 21 C.F.R. § 117.110(a). *See also* 21 C.F.R. §§ 117.80(a)(1), 117.35(d), 117.10(b).

41. The FDA promulgated cGMP regulations for infant formulas at 21 C.F.R. Part 106 and 107, Subpart B ("Infant Formula cGMP Regulations"). These regulations are designed to ensure the safety of infant formula and prevent the manufacture of adulterated infant formula. They also require manufacturers to implement a system of controls to cover all stages of manufacturing to prevent adulteration of infant formula from microorganisms, such as *Cronobacter* spp. and *Salmonella*. *See* Interim Final Rule, Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula. 79 Fed. Reg. 7934, 7935 (Feb. 10, 2014); *see also* Final Rule, Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula. 79 Fed. Reg. 33,057 (June 10, 2014).

42. *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.

43. The FDA's detailed cGMP and quality factor requirements pertaining to infant formula specifically are below:

44. **Ingredients, Containers, and Closures.** 21 C.F.R. § 106.40(d) provides: "A manufacturer shall develop written specifications for ingredients, containers, and closures used in manufacturing infant formula and shall develop and follow written procedures to determine whether all ingredients, containers, and closures meet these specifications. When any specification is not met, an individual qualified by education, training, or experience shall conduct a documented review, shall determine whether a failure to meet such a specification could result in an adulterated

infant formula, and shall make and document a material disposition decision to reject the ingredient, container, or closure or the affected infant formula; to reprocess or otherwise recondition the ingredient, container, or closure or the affected infant formula; or to approve and release the ingredient, container, or closure or the affected infant formula for use."

45. 21 C.F.R. § 106.50(d)(4) requires, in pertinent part, that a manufacturer "[e]nsur[e] that each container of finished product is properly sealed."

46. **Packaging and Labeling.** 21 C.F.R. § 106.60(a) provides that "[a] manufacturer shall examine packaged and labeled infant formula during finishing operations to ensure that all containers and packages in the production aggregate have the correct label, the correct use-by date, and the correct code established under § 106.80."

47. 21 C.F.R. § 106.60(b) requires: "Labels shall be designed, printed, and applied so that the labels remain legible and attached during the conditions of processing, storage, handling, distribution, and use."

48. 21 C.F.R. § 106.80 requires that "each production aggregate of infant formula[] be coded with a sequential number that identifies the product and the establishment where the product was packed and that permits tracing of all stages of manufacture of that production aggregate, including the year, the days of the year, and the period during those days that the product was packed, and the receipt and handling of raw materials used."

49. **Personnel.** 21 C.F.R. § 106.l0(a) provides: "A manufacturer shall employ sufficient personnel, qualified by education, training, or experience, to perform all operations, including all required recordkeeping, in the manufacture, processing, packing, and holding of each infant formula and to supervise such operations to ensure that the operations are correctly and fully performed."

50. **Equipment and Utensils.** 21 C.F.R. § 106.30(a) provides that "[a] manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are of appropriate design and are installed to facilitate their intended function and their cleaning and maintenance."

51. 21 C.F.R. § 106.30(b) provides, in pertinent part: "A manufacturer shall ensure that equipment and utensils used in the manufacture, processing, packing, or holding of an infant formula are constructed so that surfaces that contact ingredients, in-process materials, or infant formula are made of nontoxic materials and are not reactive or absorptive. A manufacturer shall ensure that such equipment and utensils are designed to be easily cleanable and to withstand the environment of their intended use and that all surfaces that contact ingredients, in-process materials, or infant formula are cleaned and sanitized, as necessary, and are maintained to protect infant formula from being contaminated by any source ...."

52. 21 C.F.R. § 106.30(f) provides, in pertinent part: "[a] manufacturer shall ensure that equipment and utensils used in the manufacture of infant formula are cleaned, sanitized, and maintained at regular intervals to prevent adulteration of the infant formula. [ ] An individual qualified by education, training, or experience to conduct such a review shall review all cleaning, sanitizing, and maintenance to ensure that it has been satisfactorily completed ...."

53. A manufacturer must make and retain all records on: "[e]quipment cleaning, sanitizing, and maintenance that show the date and time of such cleaning, sanitizing, and maintenance and the production aggregate number of each infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance." 21 C.F.R. § 106.100(f)(4). Furthermore, "the person performing and checking the cleaning, sanitizing, and

maintenance shall date and sign or initial the record indicating that the work was performed." 21 C.F.R. § 106.100(f)(4).

54. Relatedly, a manufacturer must prepare and maintain records relating to "accuracy checks of instruments and controls," including records specifying "the instrument or control being checked, the date of the accuracy check, the standard used, the calibration method used, the results found, any actions taken if the instrument is found to be out of calibration, and the initials or name of the individual performing the test." 21 C.F.R. § 106.100(f)(2).

55. **Systems.** 21 C.F.R. § 106.35(b) provides:

> All systems shall be designed, installed, tested, and maintained in a manner that will ensure that they are capable of performing their intended function and of producing or analyzing infant formula in accordance with this subpart and subpart C of this part.
>
> > (1) A manufacturer shall ensure, at any point, step, or stage where control is necessary to prevent adulteration of the infant formula, that all hardware is routinely inspected and checked according to written procedures and that hardware that is capable of being calibrated is routinely calibrated according to written procedures.
> >
> > (2) A manufacturer shall check and document the accuracy of input into, and output generated by, any system used in the production or quality control of an infant formula to ensure that the infant formula is not adulterated ....
> >
> > (3) A manufacturer shall ensure that each system is validated prior to the release for distribution of any infant formula manufactured using the system.
> >
> > (4) A manufacturer shall ensure that any system that is modified is revalidated following the modification and prior to the release for distribution of any infant formula manufactured using the modified system.

56. The manufacturer must make and retain all records on: "[a]ll mechanical and electronic equipment used in the production or quality control of infant formula,"

including "(iii [r]ecords that document installation, calibration, testing or validation, and maintenance of the systems used." 21 C.F.R. § 106.100(f)(5).

57. Further, 21 C.F.R. § 106.20(a) provides: "Buildings used in the manufacture, processing, packing, or holding of infant formula shall be maintained in a clean and sanitary condition and shall have space for the separation of incompatible operations, such as the handling of raw materials, the manufacture of the product, and packaging and labeling operations."

58. The failure to comply with cGMP regulations for infant formula and human food renders food adulterated within the meaning of 21 U.S.C. § 342(a)(4). *See* 21 C.F.R. §§ 117.1(a)(1)(ii), 110.5(a).

C. FDA Recordkeeping Requirements

59. FDA's recordkeeping requirements, applicable to human food generally and infant formula and nutritional therapy products, establish Abbott's obligations with respect to preparing, maintaining, and making available records.

60. **Recordkeeping Pertaining to Human Food.** 21 C.F.R. § 117.305 requires, in relevant part, that any records pertaining to human food:

> (a) Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original records), or electronic record;
>
> (b) Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;
>
> (c) Be accurate, indelible, and legible;
>
> (d) Be created concurrently with performance of the activity documented;
>
> (e) Be as detailed as necessary to provide history of work performed; and
>
> (f) Include: (1) Information adequate to identify the plant or facility*(e.g.,* the name, and when necessary, the location of the plant or facility); (2) The date and, when appropriate, the time of the activity documented; (3) The signature or initials of the

person performing the activity; and (4) Where appropriate, the identity of the product and the lot code, if any.

61. **Recordkeeping Pertaining to Infant Formula.** For each production aggregate of infant formula, a manufacturer must prepare and maintain records that include complete information relating to the production and control of the production aggregate, including: (i) the master manufacturing order (21 C.F.R. § 106.l00(e)(l)); and (ii) records on ingredients, containers, and closures used in the manufacture of infant formula, including the results of any test or examination performed thereon and the disposition thereof. 21 C.F.R. § 106.100(f)(6).

62. For any deviations from the master manufacturing order, any corrective actions, and the monitoring of such events, every manufacturer must maintain records concerning:

> (a) Any such deviations and any corrective actions taken because of the deviation. 21 C.F.R. § 106.100(e)(2).
>
> (b) The monitoring at any point, step, or stage in the manufacturer's production process where control is deemed necessary to prevent adulteration, including: (i) A list of the specifications established at each point, step, or stage in the production process where control is deemed necessary to prevent adulteration; (ii) the actual values obtained during the monitoring operation, any deviations from established specifications, and any corrective actions taken; and (iii) identification of the person monitoring. 21 C.F.R. § 106.100(e)(3).
>
> (c) The conclusions and follow up, along with the identity of the individual qualified by education, training, or experience who investigated: (i) any deviations from the master manufacturing order and any corrective actions taken; (ii) any finding that a production aggregate or any of its ingredients failed to meet the infant formula manufacturer's specifications; and (iii) a failure to meet any specification at any point, step, or stage in the production process where control is deemed necessary to prevent adulteration. 21 C.F.R. § 106.100(e)(4).

63. In addition, every manufacturer is required to maintain the following testing records:

> (a) All results of testing on the in-process production aggregate, at the final product stage, and on finished product throughout the shelf life of the

> product, including: (i) results of all quality control testing to verify that each required nutrient is present at the required levels and that all other nutrients added by the manufacturer are present at the appropriate level; and (ii) for powdered infant formula, results of any testing conducted to verify compliance with the microbiological quality standards. 21 C.F.R. § 106.l00(e)(S).
>
> (b) Frequency and results of testing of the water used in the production of infant formula. 21 C.F.R. § 106.l00(f)(l).
>
> (c) A full description of the methodology used to test powdered infant formula to verify compliance with the microbiological quality standards and the methodology used to do quality control testing. 21 C.F.R. § 106.100(f)(7).

64. Every manufacturer must also maintain detailed procedures concerning how all complaints concerning infant formula are to be handled, with "complaint" to be construed as "any allegation ... expressing dissatisfaction with a product for any reason, including concerns about the possible existence of a hazard to health and about... quality." 21 C.F.R. § 106.l00(k).

65. **Requirement to Make All Records Readily Available.** Under 21 C.F.R. § 106.100(1), every infant formula manufacturer must make "readily available for authorized inspection ***all records*** required under [Part 106] or copies of such records" (emphasis added). Specifically, every manufacturer must maintain ***"all records*** required under [Part 106] in a manner that ensures that ... the Food and Drug Administration can be provided with access to such records within 24 hours." 21 C.F.R. § 106.l00(m) (emphasis added). Notably, these obligations require the manufacturer to make available for authorized inspection all records pertaining to any deviations from the master manufacturing order and any corrective actions as well as the written conclusions and follow-up of any investigations of such deviations. 21 C.F.R. §§ 106.100(e)(2),(e)(4).

66. The FDCA and its implementing regulations do not permit an infant formula manufacturer to remove or omit certain records prior to making ***"all records"*** available for authorized inspection based on discretion or internal process.

67. Further, a failure to comply with these record requirements renders the related infant formula adulterated under section 412(a)(2) of the FDCA with respect to quality factor requirements and adulterated under section 412(a)(3) of the FDCA with respect to cGMP and quality control requirements. 21 C.F.R. § 106.l00(r).

68. As required under 21 C.F.R. § 117.305, which applies to records pertaining to the manufacturing or production of human food generally, all such records must be create concurrently with the activity being documented, "be accurate", and "[c]ontain the ***actual values and observations*** obtained during monitoring and, as appropriate, during verification activities" (emphasis added). In other words, non-contemporaneous, reconstructed, or incomplete data is not permitted.

D. Exempt Infant Formula Under FDA and FDCA

69. This Complaint refers to the exempt infant formulas that Abbott manufactured at the Sturgis facility as "the Specialty Infant Formulas." Specialty Infant Formulas are intended to address inborn errors of metabolism and other conditions, such as severe food allergies. Microbiological contamination of any infant formula, including the Specialty Infant Formulas and the Standard Infant Formulas, can have devastating and potentially deadly effects on vulnerable infants.

70. The FDCA exempts certain infant formulas from several aspects of 21 U.S.C.§ 350a—the specific provision of FDCA governing the manufacture and adulteration of infant formula—including provisions relating to compliance with Infant Formula cGMP Regulations and Infant Formula Record Requirements. *See* 21 U.S.C. § 350a(h) (providing exemption from, among others, the requirements in 21 U.S.C. §§ 350a(a)(3), 350a(b)(2), and 350a(b)(4)). The exemption applies to infant formula "which is represented and labeled for use by

an infant—(A) who has an inborn error of metabolism or a low birth weight, or (B) who otherwise has an unusual medical or dietary problem." 21 U.S.C. § 350a(h)(1). This type of product is known as an "exempt infant formula." FDA promulgated regulations that establish conditions with which a manufacturer must comply to obtain and retain this exemption. *See* 21 U.S.C. §§ 350a(h)(1) and 350a(h)(2); 21 C.F.R. § 107.50.

71. Inborn errors of metabolism are rare, inherited (genetic) disorders in which the body cannot properly turn food into energy. They are caused by defects in specific proteins (enzymes) that help break down (metabolize) certain nutrients in food. These disorders result in the buildup of toxic compounds in the brain and other important organ systems, and they can cause a wide range of medical problems. Several inborn errors of metabolism are life threatening and known to cause severe and permanent brain damage and associated problems such as developmental delay, movement disorder, and/or coma. Infants with inborn errors of metabolism cannot tolerate certain nutrients (*e.g.*, certain amino acids) found in infant formulas; therefore, these infants need specialty infant formulas to meet their nutritional needs to support and promote growth while avoiding the offending nutrient(s). Other types of disorders requiring specialty infant formulas are severe allergies where infants cannot tolerate proteins that are not broken down and require alternate types of infant formulas, such as amino acid-based formulas.

72. Not all exempt infant formula is available at the retail level. These "formulas typically are prescribed by a physician, and must be requested from a pharmacist or are distributed directly to institutions such as hospitals, clinics, and State or Federal agencies. Such formulas are also generally represented and labeled solely to provide dietary management for specific diseases or conditions that are clinically serious or life-threatening and generally are required for prolonged periods of time." 21 C.F.R. § 107.50(c)(1).

73. The FDA specifies that "[e]ach manufacturer of an infant formula…shall establish quality control procedures designed to ensure that the infant formula meets applicable nutrient requirements…including any special nutritional characteristics for the specific disorders or conditions for which the formula is represented for use. Each manufacturer shall maintain records of such quality control procedures sufficient to permit a public health evaluation of each manufactured batch of infant formula and shall permit any authorized FDA employee at all reasonable times to have access to and to copy and verify the records referred to in this paragraph." 21 C.F.R. § 107.50(c)(3).

74. 21 U.S.C. § 350a(h)(1) places a specific notice requirement on infant formula manufacturers: "(1) If the manufacturer of an infant formula has knowledge which reasonably supports the conclusion that an infant formula which has been processed by the manufacturer and which has left an establishment subject to the control of the manufacturer-- (A) may not provide the nutrients required by subsection (i), or (B) may be otherwise adulterated or misbranded, the manufacturer shall promptly notify the [Health and Human Services] Secretary of such knowledge. If the Secretary determines that the infant formula presents a risk to human health, the manufacturer shall immediately take all actions necessary to recall shipments of such infant formula from all wholesale and retail establishments, consistent with recall regulations and guidelines issued by the Secretary." 21 U.S.C. § 350a(e)(1).

75. Under 21 U.S.C. § 350a(h)(1), the manufacturing of exempt specialty infant formula triggers compliance with cGMP food requirements consistent with Title 21 of the Code of Federal Regulations Chapter 1, Subchapter B, Part 110. Specifically, 21 C.F.R. § 110.5 outlines:

> (1) The criteria and definitions in this part shall apply in determining whether a food is adulterated (1) within the meaning of section 402(a)(3) of the act in that the food has been manufactured under such conditions that it is unfit for food; or

> (2) within the meaning of section 402(a)(4) of the act in that the food 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. The criteria and definitions in this part also apply in determining whether a food is in violation of section 361 of the Public Health Service Act (42 U.S.C. § 264).

76. Additional 21 C.F.R. Part 110 provisions require that, "[a]ll operations in the receiving, inspecting, transporting, segregating, preparing, manufacturing, packaging, and storing of food shall be conducted in accordance with adequate sanitation principles." 21 C.F.R. § 110.80. Ensuring proper sanitation requires, inter alia, "[a]ll food manufacturing, including packaging and storage, shall be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, or for the contamination of food. 21 C.F.R. § 110.80(b)(2).

E. FDA Inspection of Abbott's Infant Formula

77. 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 *C. sak.* and *Salmonella*.

78. 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.

79. 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	FDA483
Sturgis	9/10/2018-9/18/2018	No
Sturgis	9/16/2019-9/24/2019	Yes
Sturgis	9/20/2021-9/24/202 1	Yes
Sturgis	l/3 l/2022-3/18/2022	Yes
Sturgis	5/28/2022-6/2/2022	No

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

80. Infant fatalities and hundreds of injuries have been reported to FDA for investigation, including several babies' deaths tied to *C. sak.* confirmed by the United States Centers for Disease Control and Prevention ("CDC").[2] [3] 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.

81. 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, including the presence of *C. sak.,* during the 2022 inspection.

[2] *See Food Safety News*, "Nine Baby Deaths Reported to FDA During Abbott Nutrition Investigation," June 8 2022, available at https://www.foodsafetynews.com/2022/06/nine-baby-deaths-reported-to-fda-during-abbott-nutrition-investigation/ (last visited Nov. 20, 2025).

[3] *See The Washington Post*, "New documents show more claims of baby formula illness and death," June 10, 2022, *available at* https://www.washingtonpost.com/business/2022/06/10/baby-formula-deaths-abbott/ (last visited Nov. 20, 2025).

82. 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.

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

84. 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.

85. On May 16, 2022, on behalf of FDA, the United States filed 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.*, (ECF No. 1), No. 1:22-cv-00441 PageID.1-21 (W.D. Mich. May 16, 2022). The FDA Complaint detailed Abbott's numerous alleged violations of the FDCA, including that Abbott's infant formulas were adulterated because they were processed in a manner that did not comply with cGMP. *See* 21 U.S.C. § 350a.

86. 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, *C. sak.* and

Salmonella." *United States v. Abbott Laboratories et al.*, (ECF No. 1), No. 1:22-cv-00441 PageID.2 (W.D. Mich. May 16, 2022).

87. 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.

88. 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.

89. 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.

III. The Intervening States' Medicaid Programs and Infant Formula/Nutritional Therapy Requirements

90. Medicaid is a joint federal-state program that provides health care benefits, including, but not limited to, prescription drug and nutritional therapy coverage, to qualified groups such as the elderly, impoverished or disabled. The federal government offers funding to state Medicaid programs provided they meet certain minimum requirements set forth under the federal Medicaid statute. *See* 42 U.S.C. § 1396a. The amount of federal funding afforded to each state's Medicaid program, otherwise known as the Federal Medical Assistance Percentage ("FMAP"), is based on each state's per capita income compared to the national average. *Id*. at

§ 1396d(b). Each state pays the remaining balance that the FMAP funds do not cover out of the state's budget ("State Share").

91. A state that elects to participate in the Medicaid Program must establish a plan for providing medical assistance to qualified beneficiaries. 42 U.S.C. §§ 1396a(a)-(b); *see* 42 C.F.R. §§ 430(A) &: (B); CMS State Medicaid Manual § 13025.

92. In exchange, the federal government, through CMS, pays to the state the federal portion of the expenditures made by the state to providers, and ensures that the state complies with minimum standards in the administration of the Medicaid Program. 42 U.S.C. §§ 1396, 1396a, and 1396b.

A. The California Medicaid Program

93. DHCS is responsible for the administration and supervision of the Medicaid program in California, which is commonly referred to as "Medi-Cal." DHCS is empowered to adopt and enforce rules and regulations necessary to administer the Medicaid program under the authority of California Welfare and Institutions Code § 10725 and §§ 14000 et seq.

94. In California, the Medicaid program provides comprehensive health care services to low-income adults and children offered through fee-for-service ("FFS") and through Medicaid Managed Care Organizations ("MCOs") health plans such as the Molina Healthcare of California Partner Plan, Inc. and the Inland Empire Health Plan.

95. Medical care and services, including enteral nutrition products like specialty infant formula products (e.g. Elecare, Similac, and Alimentum) and nutritional therapy products, are reimbursed by the State of California after claims are submitted to Medi-Cal. Under California law, only actively-enrolled Medi-Cal providers may receive reimbursements from Medi-Cal for

providing products or services to Medi-Cal members. Cal. Welf. & Inst. Code, §§ 14043.1, subds. (h) & (o); 14043.2.

96. Enteral nutrition products are those that are commonly under the purview of a physician or licensed prescriber, require a prescription and can be used as a therapeutic regimen to prevent serious disability or death in patients with medically diagnosed conditions that preclude the full use of regular food. Cal. Code Regs. tit. 22, § 51313.3(e)(2).

97. In 2013, the Legislature added California Welfare and Institutions Code § 14132.86(a), effective May 1, 2014, to eliminate a prior restriction in § 14132(ab)(2) that generally limited Medi-Cal coverage for enteral nutrition products to those that were administered only by tube feeding. Prior to May 1, 2014, California Welfare and Institutions Code § 14132(ab)(3) allowed for coverage for non-tube-fed enteral products only where "the product has been shown to be neither investigational nor experimental when used as part of a therapeutic regimen to prevent serious disability or death." Section 14132.86(a) eliminated that restriction and specified that the purchase of all prescribed enteral nutrition products is covered by Medi-Cal provided the products are approved by DHCS for inclusion on its enteral nutrition products list pursuant to California Welfare and Institutions Code § 14105.8. Therefore, manufacturers' prescription-level powdered enteral nutrition products became eligible for reimbursement through Medi-Cal as of May 1, 2014, but only if they qualify for inclusion on the enteral nutrition product list. As explained below, the only way for a product to be included on that list is through review and approval by DHCS and the incorporation of that product into an executed contract between the manufacturer and DHCS. Cal. Welf. & Inst. Code § 14105.8.

98. In California Welfare and Institutions Code section 14132.86(b), the Legislature directed DHCS to implement section 14132.86 through a provider bulletin or similar document.

DHCS did so on April 11, 2014 by way of Policy Letter 14-003. This policy directive was issued to "All Medi-Cal Managed Care Health Plans" (which is another way of referring to MCOs). The stated purpose of the policy directive was to inform MCOs of the implementation of section 14132.86 and to give them guidance on additional policies for covering medically necessary enteral nutrition products. DHCS therefore made it clear for MCOs that they are subject to the coverage expansion of section 14132.86(a).

99. This means that MCOs can cover and reimburse providers for prescribed enteral nutrition products, but only those products that have been reviewed and approved by DHCS under California Welfare and Institutions Code section 14105.8 (through the standards and process described below) and entered onto the list through the contracts with DHCS. Enteral nutrition products that are on DHCS's enteral nutrition list and subject to the DHCS contracts are therefore dispensed to both fee-for-service and MCO Medi-Cal recipients and billed by pharmacy providers for reimbursement through both payment programs. This list is commonly referred to as the *Medical Rx List of Enteral Nutrition Products* ("*Medi-Cal Rx List*").

100. All enteral nutrition products require prior authorization (PA) with required documentation to demonstrate there is medical necessity and the established criteria is met. Standard, Specialized, Elemental and Semi-Elemental, Metabolic, or Specialty Infant Products requested on a PA must be on the *Medi-Cal Rx List*.

101. DHCS is responsible for reviewing and evaluating enteral nutrition therapy products (e.g. specialty infant formulas) for retention on, addition to, or deletion from the *Medi-Cal Rx List* in accordance with California Welfare and Institutions Code section 14105.8.

102. DHCS' review and evaluation for the *Medi-Cal Rx List* is part of a Product Category Review (PCR) considering the following five criteria: the **safety of the product**, the

effectiveness of the product, the essential need for the product, the potential for misuse of the product, and the immediate or long-term cost effectiveness of the product. Welf. & Inst. Code, § 14105.8(b)(1) (emphasis added).

103. Enteral nutrition formula product safety evaluation criteria looks at the relative freedom from side effects that is determined by reviewing contraindications, precautions, warnings and adverse effects of the enteral nutrition product. Evaluation of safety may involve a single enteral nutrition product or comparisons between two or more enteral nutrition products, and may take into account such factors as the safety of alternative methods of treatment or the relationship of the safety of an enteral nutrition product to the severity of prognosis of the medical conditions for which the enteral nutrition product is indicated. Product manufacturing, handling packaging requirements are also considered when evaluating safety.

104. All Abbott contracts with DHCS to provide infant formula and nutritional therapy products for Medi-Cal members through Medi-Cal's Enteral Nutrition Product Program contain express language requiring Abbott to:

a. Submit for review a current "Good Manufacturing Practices" (cGMP) certificate documenting the manufacturing facility for each product proposed, evidence of compliance with cGMP consistent with Title 21 of the Code of Federal Regulations Chapter 1, Subchapter B, Part 110, evidence of compliance with the FDA Bioterrorism Act regulations, and written verification on company letterhead signed by a person with legal authority that, upon request from DHCS, Contractor would make available copies of most recent inspection reports (FDA Form 483 or the Department "Report of Observations") and related documents resulting from FDA or the California Department of Public Health's Food, Drug and Radiation Safety Office inspections. All reports, findings, and related

documents resulting from the facility inspection(s) including, but not limited to, good manufacturing practices (GMP) as applied to food, manufacturing and quality assurance procedures, food manufacturer sanitation requirements, sample collection and analysis results, warning letters, and corrective actions taken by Contractor and the time-frame for completion of corrections shall be provided to the Department upon request, within 15 calendar days of the request.

b. Abide by all State and federal laws and regulations applicable to enteral nutrition products, foods, and infant formula. These laws include, but are not limited to, the Sherman Food, Drug, and Cosmetic Law [hereafter "SFDCL] (Part 5 (commencing with Section 109875) of Division 104 of the California Health and Safety Code), the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.), and the regulations promulgated there under.

c. Notify DHCS in writing within 60 calendar days of all facility inspections conducted during the term of this Agreement by the FDA, the Department of Public Health's Food, Drug and Radiation Safety Office, or the state agency responsible for such inspections in the state where the manufacturer's facility is located. Contractor shall provide inspection documents to the Department upon request, within 15 calendar days of the request.

105. Additionally, DHCS initiates the PCR process approximately every three years to determine whether products will be retained on, added to, or deleted from the *Medi-Cal Rx List*. As part of the PCR process, a manufacturer affirmatively re-certifies compliance with applicable cGMP, as well as federal and state laws and regulations that govern the manufacturing of all enteral formula including specialty infant formula and nutrition therapy products.

106. The express command in the applicable contracts that Abbott shall comply with the SFDCL imposed, at all times alleged in this Complaint, mandatory obligations on Abbott to distribute and sell into the Medi-Cal Enteral Nutrition Products Program only products which were manufactured, produced, prepared, packed, and held under safe and sanitary conditions.

107. Specifically, the SFDCL provides: "It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any food that is adulterated." Cal. Health & Safety Code § 110620.

108. Abbott is a "person" within the meaning of the SFDCL, because "person" under that law includes not just individuals, but also firms, corporations, limited liability companies, and companies. Cal. Health & Safety Code § 109995.

109. Abbott's infant formula and nutritional therapy products manufactured and sold under California's Enteral Nutrition Product program are "food" within the meaning of the SFDCL. "Food" means either of the following:

(a) Any article used or intended for use for food, drink, confection, condiment, or chewing gum by man or other animal.

(b) Any article used or intended for use as a component of any article designated in subdivision (a).

110. Also, "infant formula" under the SFDCL "shall have the same definition as that term is used in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 321(z))." Cal. Health & Safety Code § 109951. Thus, "infant formula" under the SFDCL is a special category of "food" that, under the SFDCL, cannot lawfully be manufactured, sold, delivered, held, or offered for sale if it is adulterated. Cal. Health & Safety Code, § 110620.

111. The summary process by which Medi-Cal reimburses Abbott specialty infant and nutritional therapy formulas is as follows:

a. Abbott petitions DHCS to consider its proposed enteral nutrition product for retention on, addition to, or deletion from the *Medi-Cal Rx List.* In doing so, Abbott provides documentation and certification of compliance with cGMP, as required by paragraph 104.

b. DHCS reviews the proposed enteral nutrition product for the five criteria including product safety using the criteria outlined in paragraph 102.

c. If DHCS determines the enteral nutrition product is safe and beneficial for Medi-Cal members, Abbott enters into a discount pricing agreement with DHCS to be added to the *Medi-Cal Rx List* that can be accessible to Medi-Cal members.

d. A Medi-Cal beneficiary experiencing symptoms that suggest a need for specialized nutrition visits a provider who determines there is a medical necessity to prescribe a listed enteral nutrition product for outpatient use. The prescriber subsequently writes a prescription for a particular enteral nutrition product which triggers a request for prior authorization from Medi-Cal.

e. The Medi-Cal member goes to a Medi-Cal a pharmacy provider who may purchase the enteral nutrition product from a wholesaler, distributor, or Abbott at not more than the price set by Abbott's agreement with DHCS and published on the Contracted *Medi-Cal Rx List*.

f. The Medi-Cal pharmacy provider fills the prescription and submits claims to Medi-Cal Rx for reimbursement when it dispenses the formula.

g. Medi-Cal reimburses the pharmacy provider that billed and dispensed the prescription with Medicaid funds.

112. Put simply, Abbott causes Medi-Cal to expend funds on enteral nutrition products by affirmatively certifying via contractual agreement every three years to comply with applicable cGMP, and federal and state laws and regulations that govern the manufacturing of enteral nutrition products .

113. Under the facts alleged below regarding Abbott's unsafe and unsanitary manufacturing, preparation, packing, and holding practices with respect to specialty infant formula and nutritional products covered by its contracts with Medi-Cal, Abbott's products were, at all times alleged herein, "adulterated within the meaning of the SFDCL in at least the following ways:

a. "Any food is adulterated if bears or contains any…deleterious substance that may render it injurious to health of man…that may consume it." Cal. Health & Safety Code § 110545.

b. "Any food is adulterated if it consists in whole or in part of any diseased, contaminated, filthy, putrid, or decomposed substance, or if it is otherwise unfit for food." Cal. Health & Safety Code § 110560.

c. "Any food is adulterated if it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered unwholesome, diseased, or injurious to health." Cal. Health & Safety Code § 110565.

d. "Any food is adulterated…if damage or inferiority has been concealed in any manner." Cal. Health & Safety Code § 110585.

114. Independently of Abbott's material breaches of its contracts with Medi-Cal through the multiple violations of federal statutory and regulatory requirements in the ways recited in detail in Sections I through VI of the Factual Allegations Section below, Abbott's violations of the SFDCL through these same extensive, continuous, pervasive, and repeated unsafe manufacturing, preparation, packing, holding, distribution, and sales practices constituted material breaches of Abbott's contracts with Medi-Cal. Had Abbott's employees not knowingly and intentionally engaged in fraudulent acts and omissions to conceal these violations of the SFDCL from Medi-

Cal and other state and federal agencies, these breaches would have been material to DHCS' and the Medi-Cal Program's decision as to whether Abbott's products should be kept on the *Medi-Cal Rx List* (in the same manner as the violations of the federal statutory and regulatory requirements were material to this decision). Material factors in DHCS' and the Medi-Cal Program's continued inclusion of Abbott's products on that list and the decisions to pay Medi-Cal claims resulting from the purchase of Abbott's products through that program were DHCS' reliance on Abbott's fulfillment of its obligations under the contracts to comply with the SFDCL and its obligations under the contracts to comply with the federal statutory and regulatory requirements recited below. Both are independently sufficient grounds on which Abbott is liable to California for the causes of action raised herein.

115. As a result, claims tainted by material deviations from these standards are ineligible for payment and punishable by criminal and/or civil action in California.

B. The Connecticut Medicaid Program

116. The Connecticut Department of Social Services ("Department") is the single state agency that administers the Connecticut Medicaid program using federal and state funds. Conn. Gen. Stat. § 17b-2. The Connecticut Medicaid program is included within the Connecticut Medical Assistance Program ("CMAP").

117. Enteral nutrition products such as infant formulas are reimbursed by the State of Connecticut pursuant to claims submitted by the providers of such products. Effective no later than December 1, 2021, the Connecticut Medicaid program is the primary payer for exempt infant formulas for dually enrolled WIC and Medicaid program beneficiaries. Connecticut Department of Social Services, Medical Assistance Program Provider Bulletin 2021-99 (December 2021).

118. When Connecticut Medicaid providers submit claims for payment to the

Connecticut Medicaid Program, they expressly and/or impliedly certify that the goods and services for which reimbursement is sought comply with federal and state law, and that reimbursement will be made from federal and state funds. Section 2 of the CMAP provider agreement states that a provider agrees "[t]o abide by and comply with all federal and state statutes, regulations, and policies pertaining to Provider's participation in the Connecticut Medical Assistance Program, as they may be amended from time to time."

119. Therefore, federal laws and regulations govern the manufacturing, storage, and distribution practices of companies that provide infant formulas and enteral nutritional products to Connecticut Medicaid beneficiaries. Under Regulations of Connecticut State Agencies ("R.C.S.A.") section 17b-252-531(b), "[T]he department shall not make payment for any Medical Assistance Program goods or services which are not covered under, and furnished in accordance with federal and state statutes and regulations including 42 USC 1396b(f)…."

120. The Connecticut Medicaid Program will only pay for goods and services that are medically appropriate and medically necessary. "Payment, by the department, to all providers shall be limited to medically appropriate and medically necessary goods or services furnished to Medical Assistance Program clients." R.C.S.A. § 17b-252-531. "Medically appropriate" means "health care that is provided in a timely manner and meets professionally recognized standards of acceptable medical care; is delivered in the appropriate setting; and is the least costly of multiple, equally-effective alternative treatments or diagnostic modalities." R.C.S.A. § 17b-262-523 (12). "Medically necessary" means "health care provided to correct or diminish the adverse effects of a medical condition or mental illness; assist an individual in attaining or maintaining an optimal level of health; diagnose a condition; or prevent a medical condition from occurring." R.C.S.A. § 17b-262-523 (15).

121. When Connecticut Medicaid program providers, including providers of enteral nutrition products, submit claims to the Connecticut Medicaid program, they expressly and/or impliedly certify that the products for which they seek reimbursement are medically appropriate and medically necessary for a Connecticut Medicaid program beneficiary. Connecticut regulations require that any overpayment for CMAP goods or services, defined as the excess over the authorized payment and including, but not limited to, any payment obtained through fraud or abuse, shall be payable to the Department. R.C.S.A. §§ 17b-262-523(18), 17b-262-533.

C. The Massachusetts Medicaid Program

122. The Massachusetts Medicaid program ("MassHealth") is administered by the EOHHS. MassHealth members may receive coverage through MassHealth fee-for-service ("FFS") or managed care entities ("MCEs"), third-party insurers that administer services to MassHealth members.

123. MassHealth regulations define a "member" as "a person determined by the MassHealth agency to be eligible for MassHealth." 130 C.M.R. § 450.101. The regulations do not distinguish between those members receiving benefits through MassHealth FFS or through MCEs. Thus, claims submitted by providers with respect to services to members through any of these mechanisms must comply with MassHealth regulations.

124. MassHealth pays for infant formula – which is considered an enteral nutrition product – only if medically necessary and, historically, only with prior authorization ("PA").[4] *See* MassHealth All Provider Bulletin 343 (May 2022). MassHealth reimburses infant formula under its durable medical equipment ("DME") and pharmacy programs. *See id.*; *see also* MassHealth

[4] MassHealth relaxed the PA requirements for both pharmacies and DME suppliers in 2022 in light of the infant formula shortage. See MassHealth All Provider Bulletin No. 343 (May 2022).

All Provider Bulletin 340 (March 2022). Pursuant to these programs, MassHealth classifies infant formula as DME and as a non-drug product. *See* MassHealth All Provider Bulletin 343 (May 2022). As such, MassHealth participants with a medical need for infant formula can obtain it through pharmacies or directly from DME suppliers. *Id.*

125. MassHealth bases its determination of medical necessity for infant formula on an individual, case-by-case basis, and current clinical evidence. https://www.mass.gov/guides/masshealth-guidelines-for-medical-necessity-determination-for-enteral-nutrition-and-special-medical-formulas. Medical need must be manifested by the presence of both a medical condition known to cause nutritional risk and evidence of nutritional and/or growth implications that are not amenable to the use of regular food or standard formula. *Id.* Examples of qualifying medical conditions include cow's milk or soy protein allergies, anatomical abnormalities adversely affecting digestion and absorption, and neurological conditions impeding swallowing or chewing. *Id.* All of MassHealth's guidelines, including those concerning infant formula, are based on "generally accepted standards of practice, review of the medical literature, and federal and state policies and laws applicable to Medicaid programs." *Id.*

126. MassHealth payment for medically necessary infant formula can occur in three ways: (1) a DME provider that is already working with an eligible member may arrange for the delivery of the infant formula and then submit a claim to MassHealth for the formula to be paid as part of the member's DME benefit; (2) a member may go into a pharmacy that has a special DME designation[5] and purchase it, and the pharmacy can subsequently submit a claim to MassHealth

[5] A DME designation is a special enrollment type that enables a pharmacy to bill MassHealth for DME in addition to prescription drugs. *See, e.g.*, 130 C.M.R. § 409.404. To receive this designation, a pharmacy must apply to MassHealth and meet specific eligibility requirements delineated at 130 C.M.R. § 409.000 (DME Services) and 130 C.M.R. § 450.000 (Administrative and Billing Regulations). *Id.*

for the formula to be paid as part of the member's DME benefit; or (3) as of 2022, a member may go into any pharmacy and purchase infant formula; the pharmacy then can submit a claim to MassHealth through MassHealth's Pharmacy Online Processing System ("POPS") using a non-drug product code.

127. All infant formula products marketed and sold in the United States, whether domestic or imported, must meet the FDA's rigorous safety and quality requirements. MassHealth would not reimburse its DME and pharmacy providers for infant formula products if it was aware that they did not comport with those requirements.

128. Furthermore, MassHealth's reimbursement of infant formula claims hinges on the determination of medical necessity, which presupposes that the underlying product itself is compliant, safe, and effective for the treatment of the MassHealth's member's particular medical need. MassHealth will not reimburse claims for inherently defective or unsafe products, as such products cannot conceivably serve any medical necessity. On the contrary, such products may inflict great harm, as in the case of adulterated, substandard, and noncompliant infant formula.

129. The administrative and billing regulations governing MassHealth providers are laid out, in part, at 130 C.M.R. §§ 450.000 et seq. MassHealth has also promulgated various guidelines regarding DME providers, 130 C.M.R. §§ 409.000 et seq., as well as infant formula specifically, *see, e.g.*, https://www.mass.gov/guides/masshealth-guidelines-for-medical-necessity-determination-for-enteral-nutrition-and-special-medical-formulas. The regulations governing pharmacy services are laid out at 130 C.M.R. §§ 406.000 et seq.

i. Specific Pharmacy and DME Services Regulations

130. MassHealth pays for "pharmacy services only when provided to eligible MassHealth members, subject to the restrictions and limitations described in MassHealth regulations." 130 C.M.R. § 406.403(A)(1).

131. The MassHealth agency pays through POPS for products not classified as drugs only if such products are listed in the Non-drug Product List section of the MassHealth Drug List. 130 C.M.R. § 406.412. MassHealth will pay for items on the Non-drug Product List, such as infant formula, "only if the pharmacy has in its possession a prescription that meets all requirements for a legal prescription under all applicable federal and state laws and regulations." 130 C.M.R. § 406.411.

132. All DME, including infant formula, must be non-experimental, non-investigational, of proven quality and dependability, and must conform to all applicable federal and state product standards. 130 C.M.R. § 409.401. All DME must also be approved for community use by the FDA. 130 C.M.R. § 409.413. DME should only be dispensed if it is consistent with MassHealth and industry quality standards, given the medical need for which the DME is prescribed and the member's medical condition. 130 C.M.R. § 409.405.

133. DME that "cannot reasonably be expected to make a meaningful contribution to the treatment of a member's illness, disability, or injury" is not considered medically necessary by MassHealth. 130 C.M.R. § 409.414.

ii. All Provider Regulations

134. In addition to the regulations governing specific provider types, all MassHealth providers, including DME and pharmacy providers, are subject to the "all provider" regulations at 130 C.M.R. §§ 450.000 et seq.

135. Pursuant to these requirements, MassHealth will not in any circumstances pay for "services that are not medically necessary." 130 C.M.R. § 450.204. A service is medically necessary if it is "reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, cause suffering or pain, cause physical deformity or malfunction, threaten to cause or to aggravate a handicap, or result in illness or infirmity" and "if there is no other medical service or site of service, comparable in effect, available, and suitable for the member requesting the service, that is more conservative or less costly to the MassHealth agency." *Id.*

136. Medically necessary services must be of a quality that meets professionally recognized standards of health care. *Id.*

137. These "all provider" regulations also state, in relevant part, that every provider under contract with MassHealth agrees to comply with all laws, rules, and regulations governing MassHealth. 130 C.M.R. § 450.223(C)(1).

138. The regulations also state that every provider under contract with MassHealth certifies when submitting a claim for payment that "the information submitted in, with, or in support of the claim is true, accurate, and complete." 130 C.M.R. § 450.223(C)(2)(e). Therefore, providers impliedly certify that they are complying with applicable regulations when submitting claims for payment.

D. The Maryland Medicaid Program

139. The Maryland Legislature has designated the Maryland Department of Health ("MDH") as the state agency that administers Medicaid. *See* Md. Code Ann., Health Gen. §15-103; COMAR 10.09.62 – 10.09.75; and 42 C.F.R. § 431.10.

140. Enteral nutrition products, including specialty infant formulas, are reimbursed by

the State of Maryland pursuant to claims submitted by the providers of such products. COMAR 10.09.12.06.F.

141. As a condition of participation in Medicaid, providers must "[e]nsure compliance with all the [Medicaid] provisions listed in the Code of Maryland Regulations (COMAR) designated for their provider type." COMAR 10.09.36.03(A)(1). All Medicaid payments are "contingent upon a provider's full compliance" with relevant state and federal requirements. COMAR 10.09.36.04.D. Therefore, *federal* laws and regulations govern the manufacturing, storage and distribution practices of companies that provide infant formula and enteral nutritional products to Maryland Medicaid recipients.

E. The New York Medicaid Program

142. The Medicaid program is the primary payer for WIC exempt infant formulas and medical foods issued to WIC participants who are also Medicaid beneficiaries. Annually, WIC state agencies are required to coordinate with their state Medicaid counterpart to ensure that the nutritional needs of mutual participants are met. 7 C.F.R. 246.10(e)(3)(vi); also see WIC Policy Memorandum #2015-07.

143. The New York State Department of Health (NYDOH), an agency of the State of New York, has been designated by the New York Legislature as the single state agency to administer New York's Medicaid program. N.Y. Social Services Law § 363-a (1). NYDOH is empowered to promulgate rules that are necessary for administering its programs, including Medicaid. N.Y. Social Services Law § 363-a (2); N.Y. Social Services Law § 363-c.

144. Medical care and services, including physician-administered prescription drugs provided to eligible beneficiaries, are reimbursed by the State of New York after claims are submitted by healthcare providers to the New York Medicaid program.

145. Claims are defined as a request or demand for money or property, whether under a contract or otherwise. *See* N.Y. Social Services Law § 153-b; N.Y. S. Fin. Law § 188(1).

146. Under N.Y. Social Services Law § 153-b, NYDOH's Medical Assistance Board is authorized to adopt rules regarding the implementation of Medicaid programs and the requirements, obligations, and rights of providers of medical services.

147. Enteral infant formulas, which are designed to be administered directly into the gastrointestinal tract like those manufactured by Abbott, are reimbursable by New York State's Medicaid program with a prescription and prior approval. 18 NYCRR § 505.5(g)(3).

148. New York providers, including those who are Abbott customers, submit claims for enteral infant formulas to NYDOH, by first submitting the NYS Medicaid Program – Enteral Formula Prior Authorization Prescriber Worksheet through the NY Medicaid Enteral Portal and thereafter submitting the claim for reimbursement to NYDOH utilizing the National Drug Code (NDC) that corresponds to the particular infant formula prescribed to the recipient.

149. Once NYDOH receives a provider claim for enteral formulas like those produced by Abbott and confirms that any applicable prior authorization criteria have been satisfied, NYDOH reimburses the provider based upon the reimbursement methodology set forth in New York's State Plan and further described in the New York State eMedNY Billing Guidelines and NYRx (the New York State Medicaid Pharmacy Program), which require that all providers that service New York Medicaid recipients follow all federal and New York State laws, regulations and Medicaid policies.

150. New York Medicaid requires that Medicaid providers comply with the terms of the claim form as well as the pre-authorization form as a precondition of government payment. New York Medicaid also requires compliance with program policies, along with applicable statutes,

regulations, and guidelines (including manuals and bulletins), as a precondition of government payment or reimbursement.

151. The New York State Medicaid Program Enteral Formula Prior Authorization Prescriber Worksheet provides that the Medicaid benefit for enteral formula reimbursement is governed by 18 NYCRR § 505.5, which applies to durable medical equipment ("DME") and medical/surgical supplies.

152. New York State sets forth conditions for Medicaid payment for DME and medical supplies in 18 NYCRR § 505.5(d)(1)(vii), under the subsection entitled "General Payment Policy," which specifies that the provider is responsible for defects in quality and workmanship as a condition of payment.

153. Both federal and New York state statutes prohibit the introduction of any adulterated foods or drugs into commerce. 21 U.S.C.A. § 331; *see also* N.Y. Education Law § 6815(1)(a); N.Y. Agric. & Mkts. Law § 199-A. More specifically, New York Education Law provides that it is a misdemeanor offense for any person to manufacture, sell, deliver for sale, hold for sale or offer for sale any drug, device or cosmetic that is adulterated. N.Y. Education Law § 6811(9). Furthermore, New York law defines adulterated food or drugs to include food or drugs that has been produced, prepared, packaged, or held in unsanitary conditions whereby it may have been rendered contaminated or injurious to health. N.Y. Agric. & Mkts. Law § 200(4); N.Y. Education Law § 6815(1)(a)(2).

154. Further, the New York Medicaid program will only pay for "medical care, services and supplies which are medically necessary and appropriate, consistent with quality care and generally accepted professional standards." Medicaid will not pay for treatments that are not medically necessary or appropriate. *See, e.g.*, 18 N.Y.C.R.R. §§ 500.1(b); 515.2(b)(1)(i)(c).

Moreover, The New York State Medicaid Program Durable Medical Equipment Procedure Code Manual specifically states "[a]ny item dispensed in violation of Federal, State or Local Law is not reimbursable by New York State Medicaid." (pg. 3 paragraph 9).

155. Additionally, New York prohibits the submission of Medicaid claims for unfurnished medical care services or supplies or furnishing medical care, services or supplies that fail to meet professionally recognized standards for health care and considers these "unacceptable practices" that constitute fraud or abuse of the Medicaid program. N.Y. Comp. Codes R. & Regs. Tit. 18 § 515.2(a); N.Y. Comp. Codes R. & Regs. Tit. 18 § 515.2(a).

The New York Medicaid program expects that its Medicaid providers only prescribe drugs or medical items that meet these requirements.

156. Abbot knowingly caused New York Medicaid providers to submit false claims that violated these requirements.

157. Following the Relators' disclosures, FDA inspections in 2021 and 2022 at the Sturgis facility confirmed Abbott's violations. The FDA issued numerous Form 483 Inspectional Observations concluding, *inter alia*, that Abbott failed to "establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the infant formula or in the processing environment" and "ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source." *See gen.* Department of Health and Human Services, Food and Drug Administration, Form FDA 483 Inspectional Observations (Mar. 18, 2022). These failures were observed and published, but Abbott concealed the true nature of the conditions at the Sturgis facility.

158. In so doing, Abbott knowingly violated state and federal regulations ensuring only safe and effective infant formula be placed in the market for prescription and consumption. Making false claims, false representations or failures to disclose and unacceptable recordkeeping are also unacceptable practices under New York law. N.Y. Comp. Codes R. & Regs. Tit. 18 § 515.2(b). New York regulations provide that "[n]o payments will be made to or on behalf of any person for the medical care, services or supplies furnished . . . in violation of any condition of participation in the program." (18 NYCRR § 515.5[a]; cf. 18 NYCRR §§ 515.5[b], [e].) In New York State, all conditions of participation in the Medicaid Program are also conditions of payment.

Specifically, to receive reimbursement from Medicaid in New York State, all providers must sign a Certification Statement for Provider Billing Medicaid (the "Medicaid Certification"). The Medicaid Certification reads, in pertinent part:

> I (or the entity) have furnished or caused to be furnished the care, services, and supplies itemized and done so in accordance with applicable federal and state laws and regulations . . . * * * In submitting claims under this agreement I understand and agree that I (or the entity) shall be subject to and bound by all rules, regulations, policies, standards, fee codes and procedures of the New York State Department of Health and the Office of the Medicaid Inspector General as set forth in statute or title 18 of the Official Compilation of Codes, Rules and Regulation of New York State and other publications of the Department, including eMedNY Provider Manuals and other official bulletins of the Department . . .

eMedNY is the electronic system for New York State's Medicaid Program. The eMedNY system allows New York State Medicaid providers to submit claims and receive payments for Medicaid covered services provided to eligible members.

As a result of its actions, Abbott knowingly caused New York Medicaid providers to submit false claims and New York reasonably relied on those false claims in making Medicaid payments for Abbott formula that was adulterated and subject to an FDA recall or would have been subject to an FDA recall but-for Abbott's fraudulent conduct.

F. The Tennessee Medicaid Program

159. Tennessee participates in the Medicaid program pursuant to Tenn. Code Ann. §§ 71-5-101 to –199. The federal government, through CMS, provides approximately 65 percent of the funds used by the Tennessee Medicaid program to provide medical assistance to individuals enrolled in the Medicaid program.

160. In return for receipt of federal subsidies, Tennessee is required to administer its Medicaid program in conformity with a state plan that satisfies the requirements of the Social Security Act and accompanying regulations. 42 U.S.C. §§ 1396–1396w; Tenn. Code Ann. § 71-5-102. In Tennessee, the Department of Finance & Administration administers the state Medicaid program through the Bureau of TennCare ("TennCare"). Tenn. Code Ann. § 71-5-104. TennCare operates as a special demonstration project authorized by the Secretary of Health and Human Services under the waiver authority conferred by 42 U.S.C. § 1315. The Department of Finance & Administration supervises TennCare's administration of medical assistance for eligible recipients. Tenn. Code Ann. § 71-5-105-107. The Department of Finance & Administration is authorized to promulgate rules and regulations to carry out the purposes of TennCare. Tenn. Code Ann. §§ 71-5-124 to –134.

161. TennCare contracts with private managed care organizations ("MCOs") through contracts, known as Contractor Risk Agreements ("CRAs"), which must follow the requirements of 42 U.S.C. § 1395mm, along with any related federal rules and regulations. Tenn. Code Ann. § 71-5-128. The MCOs contract directly with providers to provide healthcare services to eligible TennCare beneficiaries. Providers who have entered into such a contract with an MCC are known as Participating Providers. Tenn. Comp. R. & Regs. § 1200-13-13-.01(91). Pursuant to the CRAs, TennCare distributes the combined state and federal Medicaid funding to the MCOs,

which then pay Participating Providers for treatment of TennCare beneficiaries. TennCare-eligible persons seeking medical assistance enroll in an MCO to receive healthcare services from a Participating Provider.

162. TennCare administers pharmacy benefits for TennCare beneficiaries through a private entity known as a pharmacy benefits manager ("PBM"). When presented with a prescription from a TennCare beneficiary, the pharmacy dispenses drugs to the beneficiary and then submits a claim for payment to the PBM, which reviews the claim and pays the pharmacy. The PBM, in turn, seeks reimbursement from TennCare for the claims it pays out to the pharmacies.

163. From January 2018 to present, TennCare's PBM was OptumRx, Inc.

i. TennCare Reimbursement Requirements

164. TennCare will only pay for medical items and services that are within the scope of the TennCare program and that are medically necessary. Tenn. Code Ann. § 71-5-144(a).

165. Medical items must be "safe and effective." Tenn. Code Ann. § 71-5-144(b)(2).

166. For medical items, such as specialty formula products, to qualify as safe and effective, the type and level of medical item or service must be consistent with the symptoms or diagnosis and treatment of the particular medical condition, and the reasonably anticipated medical benefits of the item or service must outweigh the reasonably anticipated medical risks based on the enrollee's condition and scientifically supported evidence. Tenn. Code Ann. § 71-5-144(b)(2).

167. Pursuant to the Tennessee Food, Drug, and Cosmetic Act ("Tennessee FDCA"), the following acts are prohibited within the State of Tennessee:

> (1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device or cosmetic that is adulterated or misbranded;

> (2) The adulteration or misbranding of any food, drug, device or cosmetic;
>
> (9) The alteration, mutilation, destruction, obliteration or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device or cosmetic, if the act is done while the article is held for sale and results in the articles being misbranded.

Tenn. Code Ann. § 53-1-103(a).

168. TennCare's Pharmacy Provider Manual further requires pharmacies to recognize and abide by all state and federal laws, rules, regulations, and guidelines in any services provided to TennCare members and which results in the submission of claims. Adherence to federal regulations includes complying with the Tennessee FDCA and ensuring that any infant formula offered for distribution meets the requirements under 7 C.F.R. §§ 246. l 0(e)(1)(iii) and (e)(2)(iii) and is "suitable for routine issuance to the majority of generally healthy, full-term infants." 7 C.F.R. § 246.16a(c)(4).

169. TennCare expects that its pharmacists only prescribe drugs or medical items that meet these requirements.

170. Abbott caused TennCare pharmacists to submit claims that violated these requirements. Following the Relators' disclosures, FDA inspections in 2021 and 2022 at the Sturgis facility confirmed Abbott's violations. The FDA issued numerous Form 483 Inspectional Observations concluding, *inter alia*, that Abbott failed to "establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the infant formula or in the processing environment" and "ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source." *See gen.* Department of Health and Human Services, Food and Drug Administration, Form FDA 483 Inspectional Observations (Mar.

18, 2022). These failures were observed and published, but Abbott concealed the true nature of the conditions at the Sturgis facility.

171. In so doing, Abbott knowingly violated state and federal regulations ensuring only safe and effective infant formula be placed in the market for prescription and consumption. As a result of its actions, Abbott caused TennCare pharmacists to submit false claims when they wrote prescriptions for infant formula that was subject to an FDA recall or would have been subject to an FDA recall but-for Abbott's fraudulent conduct.

IV. The Massachusetts's WIC Program

A. WIC Coverage of Infant Formula in Massachusetts

172. The Commonwealth realleges and incorporates by reference paragraphs 4 through 13 and 43 through 68, and 83 through 165 ("Incorporated Paragraphs") of the United States' Complaint in Partial Intervention (ECF No. 88) ("U.S. Complaint"), inclusive, as though fully stated here.

173. Through the WIC program, the federal government provides grants to the states to support the nutritional needs of qualifying low-income women who are pregnant, breastfeeding, and post-partum, and of children up to age five who are at nutritional risk. 42 U.S.C. § 1786; 7 C.F.R. § 246.

174. In Massachusetts, the WIC program is administered by the Nutrition Division of the Bureau of Family Health and Nutrition in the Department of Public Health ("DPH").

175. Massachusetts passed the Childhood Hunger Relief Act ("CHRA") in 1993 and became the first state in the nation to supplement federal WIC funding with additional state appropriations. Mass Gen. Laws ch. 111(i), § 1, et. seq. During the relevant period, Massachusetts

allocated over $11.8 million each fiscal year to WIC through the CHRA, representing an additional 11 to 13 percent increase in total funds available to Massachusetts's WIC program.

176. The monies in Massachusetts's WIC program fund a variety of nutrition-based services such as nutrition education and counseling and breastfeeding support, as well as providing individual WIC program participants with benefits they can use to purchase healthy foods.

177. Infant formula makes up a significant portion of the healthy foods Massachusetts WIC participants purchase with their benefits, and both federal WIC grant funds and CHRA-appropriated funds are used to pay for this formula.

178. Under WIC, states purchase infant formula through a competitive, single-supplier contract system. State WIC agencies solicit sealed bids from infant formula manufacturers to supply infant formula at a discount through a rebate system. 7 C.F.R. § 246.16a(c). The winner is the manufacturer whose net price, determined by the retail price of formula less the manufacturer rebate (hereinafter, the "WIC Net Price"), is the lowest. 7 C.F.R. § 246.16a(c)(5). This manufacturer is granted a multi-year contract under which its infant formula will be the exclusive brand available for purchase through the state's WIC program.

179. Massachusetts does not directly pay manufacturers for formula purchased through the WIC program. Instead, each WIC participant is issued an Electronic Benefits Transaction ("EBT") card they can use to purchase covered infant formula from a retailer.

180. Participants buy this formula from a retailer at full retail price. Massachusetts then indirectly reimburses the retailer through a third party EBT processor. The retailer is paid the full retail price through a combination of federal and state WIC monies and Massachusetts invoices the manufacturer for the contracted rebate amount, reducing the net cost to for the WIC program to the WIC Net Price.

B. Massachusetts's Infant Formula Contracts with Abbott

181. Massachusetts contracts for WIC formula through its membership in a consortium of states called NEATO – the New England and Tribal Organization. Through NEATO, member states jointly solicit bids from suppliers of infant formula, leveraging their aggregated purchasing power to obtain higher rebates from formula manufacturers. NEATO administers the bidding process and drafts a contract between the selected formula manufacturer and the participating states. The states sign a single master contract, and each state may add an appendix containing additional contract terms specific to that state. Massachusetts added an appendix including a term that required Abbott to "ensure that the Manufacturer's products continually comply with all applicable federal and state laws and regulations."

182. Throughout the relevant period, Abbott was the contracted formula manufacturer and supplier for NEATO member states, including Massachusetts.

183. As described in Incorporated Paragraph 24, before bidding on a WIC formula contract, manufacturers must register with the United States Secretary of Health and Human Services under the FDCA and must certify that their formula complies with the relevant FDCA and regulations issued pursuant to the FDCA. 42 U.S.C. § 1786(f)(15); 7 C.F.R. § 246.l0(g), 246.16a(j)(2). Abbott made such certifications in connection with all contracts it held to provide infant formula through Massachusetts's WIC program throughout the relevant period (the "Massachusetts WIC contracts").

184. Pursuant to USDA requirements, when submitting a WIC formula contract bid, 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. § 32l(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 C.F.R. parts 106 and

107 per 7 C.F.R. § 246.2, which include manufacturing according to current cGMP as defined in 21 C.F.R. Part 106. Abbott made such certifications in connection with the Massachusetts WIC contracts.

185. Manufacturers thus 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 and meets the requirements for infant formula under the FDCA and regulations issued pursuant to the FDCA. Abbott made such certifications in connection with the Massachusetts WIC contracts.

186. The Massachusetts WIC contracts explicitly defined "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."

187. Under the Massachusetts WIC contracts, Abbott agreed to supply enough "infant formula" to serve the needs of 100 percent of Massachusetts's WIC participants eligible to purchase formula with their benefits and Massachusetts agreed that its WIC participants could purchase only Abbott's infant formula ("contract formula") with their WIC benefits. The only exceptions to this exclusivity agreement were cases where infants had certain medical needs or where Abbott was not able to make enough formula available to the WIC program.

C. Abbott's Sales of Infant Formula through the Massachusetts WIC Program

188. Throughout the relevant period, Abbott was the exclusive contracted manufacturer and supplier of infant formula purchased in Massachusetts with WIC benefits.

189. Throughout the relevant period, tens of thousands of Massachusetts WIC participants were eligible to purchase Abbott's infant formula, and each month these participants used their WIC benefits to purchase tens of thousands of units of Abbott's infant formula.

D. Abbott's False Certifications

190. As set forth at Incorporated Paragraphs 83 through 165, Abbott failed to comply with requirements for infant formula mandated under federal statutes and regulations and the Massachusetts WIC contracts.

191. Yet, in its bids to NEATO for infant formula contracts throughout the relevant period, Abbott certified its compliance with all applicable statutes and regulations. Specifically, Abbott made the following false certifications:

a. that its infant formula was in compliance with federal regulations issued pursuant to the FDCA;

b. that all forms of its formula met the requirements of 7 C.F.R. § 246.10(e)(1)(iii) and (2)(iii) and were suitable for routine issuance to the majority of generally healthy, full-term infants; and

c. that it would supply infant formula meeting the requirements of 7 C.F.R. § 246.10(e)(1)(iii) and (2)(iii) sufficient to meet the needs of 100% of Massachusetts's WIC participants eligible to purchase formula.

192. The bids Abbott submitted to NEATO, including the false certifications made therein, were explicitly incorporated into the Massachusetts WIC contracts during the relevant period.

193. Further, in the Massachusetts WIC contracts, Abbott falsely certified that it would provide infant formula to Massachusetts WIC beneficiaries that continually complied with section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 321(z)) and that met 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.

194. As outlined in Incorporated Paragraphs 83 to 165, Abbott was aware that its formula did not, in fact, comply with the relevant standards set forth in the FDCA and cGMP.

E. Abbott's False Certifications Were Material to Massachusetts's Decisions to Contract with Abbott and to Pay Claims for Abbott Formula

195. When awarding formula contracts to Abbott, NEATO relied on Abbott's certifications that its infant formula complied with the relevant standards set forth in the FDCA and cGMP.

196. When entering into the Massachusetts WIC contracts, Massachusetts relied on Abbott's certifications that its infant formula complied with the relevant standards set forth in the FDCA and cGMP.

197. Throughout the relevant period, Massachusetts relied on Abbott's certifications that its infant formula complied with the relevant standards set forth in the FDCA and cGMP in deciding to pay claims submitted by retailers for Abbott infant formula purchased by WIC participants using their WIC benefits.

198. Abbott was aware that NEATO relied on its certifications that its infant formula complied with the relevant standards set forth in the FDCA and cGMP in selecting Abbott to be the sole manufacturer and supplier to its members, including Massachusetts, and that Massachusetts relied on those certifications when deciding to enter into the Massachusetts WIC contracts.

199. Abbott was aware that its noncompliant formula sold in Massachusetts was purchased by WIC beneficiaries with WIC benefits.

200. Had Massachusetts known that Abbott's infant formula did not comply with the relevant standards set forth in the FDCA and cGMP, it would have enabled WIC participants to

use their benefits to purchase alternative brands of formula and would not have authorized purchases of Abbott formula with WIC benefits.

V. The Intervening States' False Claims Acts and State Statutes

201. Each of the Intervening States has its own state false claims act or state statute that imposes liability for, among other things, knowingly submitting, or causing to be submitted, false or fraudulent claims to the States' Medicaid programs, and for knowingly making, using, or causing to be made or used, false records or statements material to false or fraudulent claims made to the States' Medicaid programs.

A. The California False Claims Act

202. The California False Claims Act ("CFCA") closely follows the federal False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733. The CFCA provides, in pertinent part, that a person is liable to the State of California for a civil penalty plus three times the amount of damages that the State sustains because of the act of the person, if the person: (a)(1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval; (a)(2) Knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim.

203. As used in the CFCA section 12650(b),

> (1) "Claim" means any request or demand, whether under a contract or otherwise, for money, property, or services…
>
> (1)(A) Is presented to an officer, employee, or agent of the state…
>
> (1)(B) Is made to a contractor, grantee, or other recipient, if the money, property, or service is to be spent or used on a state or any political subdivision's behalf or to advance a state or political subdivision's program or interest, and if the state or political subdivision meets either of the following conditions:
>
> > (1)(B)(i) Provides or has provided any portion of the money, property, or service requested or demanded.
> >
> > (1)(B)(ii) Reimburses the contractor, grantee, or other recipient for any

> portion of the money, property, or service that is requested or demanded.
>
> (1)(B)(3) "Knowing" and "knowingly" mean that a person, with respect to information, does any of the following:
>
> > (1)(B)(3)(A) Has actual knowledge of the information.
> >
> > (1)(B)(3)(B) Acts in deliberate ignorance of the truth or falsity of the information.
> >
> > (1)(B)(3)(C) Acts in reckless disregard of the truth of falsity of the information

204. Proof of specific intent to defraud is not required.

205. "Material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money, property, or services.

B. The Connecticut False Claims Act

206. Under the Connecticut False Claims Act (CTFCA), a person may not "[k]nowingly present or cause to be presented a false or fraudulent claim for payment or approval" or "[k]nowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim." Conn. Gen. Stat. § 4-275 (a)(1), (2). "Knowingly" means that a person "[h]as actual knowledge of the information;" "acts in deliberate ignorance of the truth or falsity of the information;" or "acts in reckless disregard of the truth or falsity of the information." *Id.* at § 4-274 (1). "Material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id.* § 4-274 (6).

207. A person who violates the CTFCA is liable for:

> (1) A civil penalty of not less than five thousand five hundred dollars or more than eleven thousand dollars, or as adjusted from time to time by the federal Civil Penalties Inflation Adjustment Act of 1990, 28 USC 2461, (2) three times the amount of damages that the state sustains because of the act of that person, and (3) the costs of prosecution of such violation.

Conn. Gen. Stat. § 4-275 (b).

C. The Massachusetts False Claims Act and Medicaid False Claims Statute

208. The Massachusetts False Claims Act ("MFCA") establishes liability for any person who "(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof; . . . [or] (8) enters into an agreement, contract or understanding with an official of the commonwealth or a political subdivision thereof knowing the information contained therein is false." Mass. Gen. Laws ch. 12, § 5B(a).

209. Any person who violates these or the other provisions of the MFCA is liable for "a civil penalty of not less than $5,500 and not more than $11,000 per violation, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, plus 3 times the amount of damages, including consequential damages, that the commonwealth or a political subdivision thereof sustains because of such violation." Mass. Gen. Laws ch. 12, § 5B(a) (internal citations omitted).

210. The MFCA defines "knowingly" as "possessing actual knowledge of relevant information, acting with deliberate ignorance of the truth or falsity of the information or acting in reckless disregard of the truth or falsity of the information; provided, however, that no proof of specific intent to defraud shall be required." Mass. Gen. Laws ch. 12, § 5A.

211. The MFCA defines "material" as "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." Mass. Gen. Laws ch. 12, § 5A.

212. The Massachusetts Medicaid False Claims statute, Mass. Gen. Laws. ch. 118E, § 40, is violated by any person who furnishes items or services to MassHealth for which payment may be made by MassHealth, who: "(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under this chapter." Mass. Gen. Laws. ch. 118E, § 40.

213. If any person violates the provisions of the Massachusetts Medicaid False Claims statute, the Commonwealth is entitled to recover three times the amount of damages sustained, including the costs of investigation and litigation. *See* Mass. Gen. Laws. ch. 118E, § 44.

D. The Maryland False Health Claims Act

214. Under the Maryland False Health Claims Act, a person may not "[k]nowingly present or cause to be presented a false or fraudulent claim for payment or approval"; "[k]nowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim"; "[c]onspire to commit a violation" of the False Health Claim Act; or "[k]nowingly make any other false or fraudulent claim against a State health plan or State health program." *Id.* at § 2-602(a)(1)-(3), (9). Under the Maryland False Health Claims Act, "knowingly" means that a person "[h]as actual knowledge of the information;" "[a]cts in deliberate ignorance of the truth or falsity of the information;" or "[a]cts in reckless disregard of the truth or falsity of the information." *Id.* at § 2-601(f).

215. A person found liable for violations of the Maryland False Health Claims Act is liable for up to a $10,000 penalty per violation and/or up to three times the damage sustained by the State. *Id.* at § 2-602(b)(1).

E. The New York False Claims Act

216. The New York False Claims Act 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;
>
> (b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> . . .
>
> (g) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the state or a local government; or
>
> (h) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the state or a local government, or conspires to do the same;
>
> shall be liable to the state or a local government, as applicable, for a civil penalty of not less than six thousand dollars and not more than twelve thousand dollars, as adjusted to be equal to the civil penalty allowed under the federal False Claims Act, 31 U.S.C. sec. 3729, et seq., as amended, as adjusted for inflation by the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended (28 U.S.C. 2461 note; Pub. L. No. 101-410), plus three times the amount of all damages, including consequential damages, which the state or local government sustains because of the act of that person.

N.Y. State Fin. Law § 189.

217. Under the New York False Claims Act, "knowing and knowingly"

> (a) means 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; and
>
> (b) require no proof of specific intent to defraud, provided, however that acts occurring by mistake or as a result of mere negligence are not covered by this article.

N.Y. State Fin. Law § 188(3).

218. In addition, the New York False Claims Act defines a "claim" to mean

> (a) . . . any request or demand, whether under a contract or otherwise, for money or property that
>
> (i) is presented to an officer, employee or agent of the state or a local government; or
>
> (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the state or a local government's behalf or to advance a state or local government program or interest, and if the state or local government (A) provides or has provided any portion of the money or property requested or demanded; or (B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded;
>
> (b) does not include requests or demands for money or property that the state or a local government has already paid to an individual as compensation for government employment or as an income subsidy with no restrictions on that individual's use of the money or property.

N.Y. State Fin. Law § 188(1).

219. New York Social Services Law § 145-b(1)(a) provides in pertinent part as follows:

> It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter.

220. Under New York Social Services Law § 145-b,

> "statement or representation" includes, but is not limited to: a claim for payment made to the state, a political subdivision of the state, or an entity performing services under contract to the state or a political subdivision of the state; an acknowledgment, certification, claim, ratification or report of data which serves as the basis for a claim or a rate of payment, financial information whether in a cost report or otherwise, health care services available or rendered, and the qualifications of a person that is or has rendered health care services.

N.Y. Soc. Serv. Law § 145-b(1)(b).

221. New York Executive Law § 63(12) provides, in relevant part, as follows:

> Whenever any person shall engage in repeated fraudulent or illegal acts or otherwise demonstrate persistent fraud or illegality in the carrying on, conducting or transaction of business, the attorney general may apply . . . for an order enjoining the continuance of such business activity or of any fraudulent or illegal acts, [and] directing restitution and damages . . . .

222. New York Executive Law § 63-c(1) provides, in relevant part, as follows:

> Where any money, funds, credits, or other property, held or owned by the state, or held or owned officially or otherwise for or in behalf of a governmental or other public interest, . . . has heretofore been . . . without right obtained, received, converted, or disposed of, an action to recover the same, or to recover damages or other compensation for so obtaining, receiving, paying, converting, or disposing of the same, or both, may be maintained by the state in any court of the state, or before any court or tribunal of the United States, or of any other state, or of any territory of the United States, or of any foreign country, having jurisdiction thereof.

F. The Tennessee Medicaid False Claims Act

223. The Tennessee Medicaid False Claims Act (TMFCA), Tenn. Code Ann. §§ 71-5-182 to -185, provides in pertinent part that a person who:

> (a)(1)(A) Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval under the medicaid program;
>
> (a)(1)(B) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim under the medicaid program . . . is liable to the state for a civil penalty of not less than five thousand dollars ($5,000) and not more than twenty-five thousand dollars ($25,000), adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, compiled in 28 U.S.C. § 2461 note; Public Law 101-410, plus three (3) times the amount of damages which the state sustains because of the act of that person.
>
> . . .
>
> (b) For purposes of this section, "knowing" and "knowingly" mean that a person, with respect to information:
>
> (1) Has actual knowledge of the information;

(2) Acts in deliberate ignorance of the truth or falsity of the information; or

(3) Acts in reckless disregard of the truth or falsity of the information, and no proof of specific intent to defraud is required.

Tenn. Code Ann. § 71-5-182.

224. A statement or omission is "material" if it has a natural tendency to influence, or is capable of influencing, the payment or receipt of money or property by TennCare. Tenn. Code Ann. § 71-5-182(e).

225. Defendant is a "person" within the meaning of Tenn. Code Ann. § 71-5-182 and was at all relevant times a provider, contractor, supplier, or entity participating in or receiving payment from Tennessee's Medicaid program (referred to as "TennCare").

FACTUAL ALLEGATIONS

I. Abbott Misrepresented to State Agencies That Its Powder Infant and Nutritional Therapy Formulas Manufactured at the Sturgis, Michigan Facility Complied with the Medicaid Requirements for Infant and Nutritional Therapy Formulas, Including Compliance with the FDCA and cGMP

226. As one of the largest United States manufacturers of infant formula and nutritional therapy products, Abbott knew the relevant laws and regulations governing formula that is reimbursed by the Intervening States' Medicaid programs, and that conditions at its Sturgis facility flagrantly violated these rules. Yet Abbott did not correct these horribly dangerous conditions, putting millions of vulnerable infants and children at risk, and covered up its unlawfulness by misrepresenting its statutory compliance to the United States.

227. Manufacturing infant formula or nutritional therapy products involves a multi-step process, including required testing at different stages. Compliant products are created by following specific procedures with specific ingredients, processes, and testing methods. The precise

procedures depend on the type of product and can be impacted by process deviations, out of specification results, and contamination. The general sequence of steps from manufacturing to shipping (with sampling and analytical testing points bolded and italicized and the relevant departments and employees in parentheses) entails:

- Raw Ingredients and Commodities Received (Incoming Lab/Warehouse)
- Batch Calculation Process (Quality Systems or Analytical Lab)
- Work Order Creation (Quality Systems or Analytical Lab)
- Mineral and Vitamin Weigh Rooms (Processing)
- Mixing (Processing)
- ***Analytical Testing: Ratio, AST & RAV (Analytical Lab)***
- ***Microbiological Testing In-Process ("IP") (Microbiological Lab)***
- Drying (Dryer Department)
- ***Analytical Testing: Drying In-Process ("DIP") (Sturgis Analytical Lab)***
- Powder Filling (Powder Packaging)
- Powder Packaging (Powder Packaging)
- ***Final Product Sampling***
- ***Final Product Testing (Analytical and Microbiological Labs) – General Tests and Microbiological Tests***
- Post-Production (Quality Systems)
- Quality Review (Quality Systems)
- Batch Review (Quality Systems)
- Batch Release (Quality Assurance and Quality Systems)
- Inventory Control Software (CAMBAR) Release (Quality Assurance and Quality Systems)
- Shipping (Abbott Division)

228. As described herein, Abbott knows of systemic violations along multiple points in the manufacturing process and employs a "time code removal" scheme to avoid destroying product, including product containing microbiological contamination. Despite this knowledge Abbott withheld critical information, including documentation, from FDA investigators to avoid detection, thereby putting at risk the health and safety of millions of infants and children.

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

229. Abbott failed to maintain buildings and procedures used in the manufacture of infant formulas and nutritional therapy products in a clean and sanitary condition, as required by 21 C.F.R. section106.20(a), including, the use of deteriorating equipment due to the presence of uncontrolled water, and employees failing to don protective apparel. These ongoing failures were revealed in the FDA's inspectional findings from the 2022 Inspection between January 31, and March 18, 2022 (hereinafter referred to as "the FDA's 2022 Inspection at Sturgis") which establish that Abbott lacked adequate measures to ensure the safety and quality of the Specialty Infant Formulas, the Standard Infant Formulas, and the powdered food for older children that Abbott manufactured at the Sturgis facility.

i. Abbott's Inadequate Clean-in-Place Procedures Compromised Product Safety by Failing to Validate Key Manufacturing Processes

230. Clean-In-Place ("CIP") procedures refer to a validated process to clean equipment used in the production and packaging of infant formula and nutritional therapy products. CIP is an essential component of quality systems to ensure product safety and avoid contamination. In practice, CIP involves the automated cleaning of the interior surfaces of piping, tanks, and fillers. Due to the size of this equipment, cleaning is performed in place using turbulent flow through piping or spray balls for large surfaces.

231. Adequate, controlled CIP procedures are required by the FDCA and its implementing regulations. Specifically, Abbott is required to ensure (i) all surfaces that contact ingredients, in-process materials, or infant formula and nutritional therapy products are cleaned and sanitized as necessary and at regular intervals to prevent adulteration of infant formula and

nutritional therapy products, and (ii) those locations are maintained to protect from contamination from any source. 21 C.F.R. § 106.30(b); 21 C.F.R. § 106.30(f).

232. A critical aspect of well-controlled CIP procedures includes drying the equipment. The purpose of dry out is to ensure that the spray dryers are thoroughly dried after water is introduced during CIP and prior to restarting spray dryers post-CIP, all to minimize the risk of micro contamination. Failure to properly maintain and dry the equipment following a CIP wash leaves contaminants such as bacteria to affect the product flowing through or into the equipment.

233. The equipment at Sturgis associated with the drying process is old and consistently in need of repair. Product flow pipes were pitted and resulted in small holes that led to bacteria entering the piping system or not adequately washed through during CIP washes.

234. The Sturgis facility used an unvalidated dry out procedure until late 2022. Abbott personnel acknowledged that its dry out 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."

235. Because this process was unvalidated, Abbott had not ensured its dry out process achieved complete dryness prior to restarting powder infant formula processing.

236. Abbott's related Standard Operating Procedure ("SOP") did not contain a validated dry out process. The Director of Program Management at Sturgis conceded the fact that Abbott's dry out "validation on the dryers haven't been validated for 70 years." This is consistent with Observation 2 of the FDA 483 issued to the Sturgis facility in 2022 that noted "…that the dry out steps for both spray dryers were not validated to ensure complete drying is achieved."

237. An invalidated process is in direct conflict with federal laws, as well as Abbott's own Global Microbiological Standards, which recognized that "[r]esidual moisture in dry-

blending equipment will support the outgrowth of microorganisms and influence the quality of the finished product. Cleaning procedures must include procedures to rapidly and adequately dry all equipment."[6]

238. The CIP practices at Sturgis are additionally deficient due to the lack of process control and record compliance and retention. FDCA and its implementing regulations require that "[a]n individual qualified by education, training, or experience to conduct such a review shall review all cleaning, sanitizing, and maintenance to ensure that it has been satisfactorily completed...." as well as the retention of signed records of cleaning checks. 21 C.F.R. § 106.30(f); *see also* 21 C.F.R. § 106.100(f)(4).

239. Sturgis failed to have staff in place with sufficient training and experience to review CIP records. Moreover, CIP records were not regularly reviewed prior to the release of a batch, and Abbott did not require CIP checklists to have signature authentications or Quality Systems Department ("QS") staff audits. A "Sanitation Preventive Controls Improvement Project Charter" committee was formed at Sturgis to review known deviations in the CIP process. The deviations memorialized in documents included incompleteness/inaccuracy of records, untimely CIP record submissions to QS, failure of QS staff to review CIP records prior to batch release, and absence of a reliable filing system for CIP records to minimize the frequency of misfiled or unretrievable CIP records. Although it was repeatedly recommended that a CIP engineer or equivalently trained

[6] Abbott – Abbott Nutrition Global Microbiological Standards, ID: AN06-99-004, approved Jan 28, 2020, effective Apr. 27, 2020, Section 5.4.6.2; see also Section 5.4.5.2 ("Prior to drying, the dryer and powder handling systems must be adequately dried. Moisture within the dryer and powder handling equipment provide the environmental conditions to support microbial growth that can influence the quality of the finished product. The cleaning procedures must include steps to rapidly dry the drying and powder handling equipment. When equipment has been down (idle) and held at ambient conditions, the start-up procedures must include procedures to dry out the equipment prior to production.").

individual review the CIP records for compliant CIP and appropriately timed CIP completion, Sturgis' quality engineer at the time (who was later promoted to Compliance Manager and then to Quality Assurance Director), Keenan Gale, refused. Notably, as of early 2022, the CIP documentation was still unresolved.

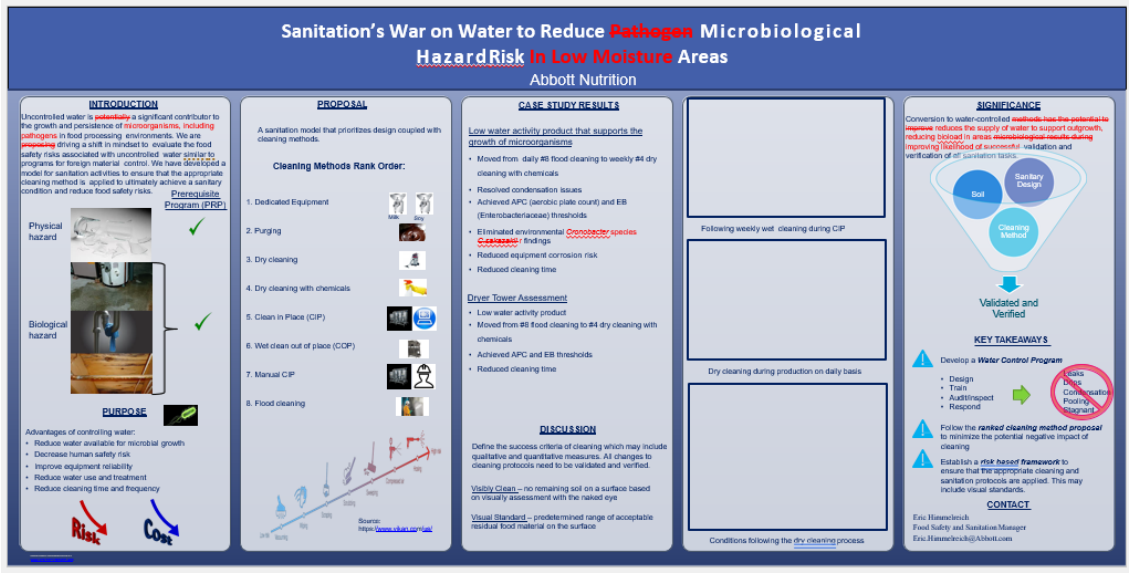
240. After FDA required Abbott to validate its dry out process in 2022 as part of its obligations under the Consent Decree, Abbott attempted to validate its existing dry out process without making any changes. Abbott failed to obtain validation. The Sturgis Quality Assurance (QA) Project Lead confirmed 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."

241. Ultimately, Abbott did not implement a validated dry out procedure until late 2022.

ii. Abbott Drowned in its "War on Water" Campaign

242. Infrastructure defects plagued Sturgis, including known roof leak issues. Sturgis was afflicted with water leaking through the roof, as well as flooding, especially after heavy rain. Abbott was aware that the presence of uncontrolled water in the manufacturing environment put powder infant and nutritional therapy formulas at increased risk of microorganism ("micro") contamination yet failed to resolve the underlying causes of the uncontrolled water.

243. 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:



244. 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."

245. The Sturgis facility frequently diverted leaks rather than permanently address their root causes. For example, rather than addressing the underlying structural issues, Abbott "specialty" roof leak umbrellas 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."

246. 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."

247. 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."

248. Despite recurring and unsuccessful campaigns to curb water exposure, leak issues persisted at the Sturgis facility until 2022. For instance, 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."

249. In the 2021 FDA Establishment Inspection Report ("EIR"), FDA documented standing water. FDA issued an 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…"

250. 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."

251. 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.

252. 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, e.g., during spray-drying the infant formula and/or filling the infant formula into containers.

253. Abbott's records describe several water leaks as necessitating repairs of the Sturgis roof. When *C. sak.* is present in a manufacturing environment, it can be further spread to other processing areas, particularly where water is poorly controlled.

254. On January 31, 2022, FDA investigators observed water on several levels of a spray-dryer tower, while the spray dryer was being used to process a batch of powder infant formula, as follows:

a. On the tower's fifth level, the FDA investigators observed water on the floor from a steam-condensate leak in the inlet steam coils; the water was dripping from the valves onto the floor of the tower's fourth level. The FDA investigators noted that, according to Abbotts' records, Sturgis had prior water leaks (on January 21, 2022, November 4, 2021, and February 1, 2021) associated with inlet steam coils;

b. On the tower's second level, the FDA investigators observed water around the floor drain near the potassium hydroxide tanks, which are used for pH adjustment in the production of powder infant formula, and at the floor-wall junction near the floor scrubber used to clean the floors of the spray-dryer tower; and

c. On the tower's basement level, the FDA investigators observed water on the floor by an eye-wash station, which is adjacent to the air-handling system of a vibratory fluid

bed used to further cool the powder infant formula as it comes out of the main chamber of the spray dryer.

255. 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.

iii. Abbott Employees and Contractors Failed to Wear Necessary Protective Apparel to Protect Against Contamination

256. In 2022, FDA investigators observed that Sturgis facility personnel working in infant formula processing areas did not wear necessary protective apparel to protect against contamination of infant formula.

257. On January 31, 2022, FDA investigators observed an employee exit the elevator in a spray-dryer tower and enter the room containing the vibratory fluid bed—and pass the shoe sanitizing station without spraying the soles of his/her shoes with sanitizer. When this inspectional observation was made, the nozzle of the sanitizer bottle was improperly set to stream instead of spray, which does not allow a uniform coating of sanitizer on the shoe soles. At the time the employee failed to sanitize his/her shoes, the spray dyer was processing a batch of powder infant formula.

258. Another example is between January 31 and February 12, 2022, FDA investigators observed that Sturgis employees and contractors were not required to spray their "captive shoes" (i.e., shoes that are to be worn only inside the facilities) with sanitizer before entering the production area. Part of that time (specifically, between January 31 and February 4, 2022, and

February 8, 2022), FDA investigators observed that Sturgis employees had been wearing their captive shoes while walking in hallways and the cafeteria and exiting the restroom.

iv. Results of Abbott's Failure to Maintain the Sturgis Facility in a Clean and Sanitary Condition

259. During 2022 inspections, FDA investigators collected samples from surfaces in Sturgis's production areas for powder infant formula. FDA laboratory analysis of those samples detected *C. sak.* on several surfaces, including:

a. The cover of a scoop hopper, which is used to feed scoops that are placed directly inside infant formula containers and come in contact with the infant formula. At the time the sample from the scoop hopper cover had been collected, a batch of infant formula was being packaged; and

b. A structural support and the immediately surrounding floor of a spray dryer, and two areas in the dehumidification room on the fourth level of that spray-dryer tower, i.e., the floor between a duct-taped spot and the wall, and the floor and seam of the first door. At the time the samples on or near the spray dryer had been collected, the spray dryer was in a cleaning cycle, which introduces water into this dry-production environment and the equipment interiors.

260. Additionally, Abbott's own environmental samples between September 25, 2019, and February 20, 2022, confirmed the presence of *Cronobacter* spp. on surfaces in Sturgis's production areas for powder infant formula.

B. Abbott Knowingly Operated Deteriorated Major Manufacturing Equipment

i. The Spray Dryers at the Sturgis Facility Were Degraded

261. Spray drying, where a liquid mixture is transformed into a dry powder, is a crucial process in manufacturing powder infant formulas and nutritional therapy products.

262. 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).

263. 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 personnel conducted inspections of Spray Dryers 3 and 4 and observed that both had cracks.

264. 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."

265. 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."

266. 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.

267. In a February 2021 company PowerPoint titled "D3 [Dryer 3] Backfill Evaluation," Abbott 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[.]"

268. 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 the FDA investigators instructed Abbott to speak with its third party dryer inspector "…about conducting a more thorough inspection of dryer #3 in the future," and suggesting that the inspector provide photos of the defects before and after repair.

269. FDA investigators observed that Abbott records documented a history of internal deterioration of the spray dryers at Sturgis, dating back to 2018. 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 bacterial contamination to persist, particularly in the presence of moisture.

270. 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."

271. Despite this well-documented and extensive history of known defects, Abbott chose to continue operating the spray dryers with known deficiencies at the Sturgis facility. For

example, in an exchange between Sturgis maintenance personnel 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."

ii. Spray Dryer Deterioration and Other Dryer Issues Were Repeatedly Identified as Potential Causes of Microorganism Contamination

272. 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. 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."

273. 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."

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

275. 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."

276. 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."

277. 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 CIP cycles, to increase production capacity. As CIP requires a period of equipment shutdown, more frequent CIP cycles result in less production.

278. 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."

279. 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."

280. 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.

iii. Abbott Prioritized Profits Over Repairing Essential Equipment

281. 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.

282. 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 decided to increase production on failing equipment at the Sturgis facility, specifically for the highly profitable Similac Alimentum and EleCare products.

283. 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.

284. Two years later, in February 2021, in spite of continued, known problems 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?"

285. 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

286. The Sturgis facility used an unvalidated dry out procedure until late 2022. The purpose of dry out 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 dry out process achieved complete dryness prior to restarting powder infant formula and nutritional therapy product processing.

287. Abbott's related Standard Operating Procedure ("SOP") did not contain a validated dry out 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."

288. Moreover, Abbott personnel acknowledged that its dry out 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."

289. After FDA required Abbott to validate its dry out process in 2022 as part of its obligations under the Consent Decree, Abbott attempted to validate its existing dry out 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."

290. Ultimately, Abbott did not implement a validated dry out procedure until late 2022.

D. Abbott's Ongoing and Systemic Violations of the FDCA and cGMP Requirements

i. Abbott's Sturgis Facility Had Inadequate Temperature Control for Bulk Finished Product ("FP") Storage Tanks and Heat Treatment Rooms

291. Abbott's own Global Microbiological Standards related to "Bulk Finished Product ("FP") Storage Tanks" require a process control to prevent biological hazards, specifically, "microbial growth due to out of specification temperature." Abbott's standards also require that

FP tank temperatures be manually monitored every four hours, be continuously monitored on the visual process report ("VPR"), and identify subsequent records that are to be produced and maintained as part of the batch record. The VPR review and verification is maintained in the VPR web-based system and is electronically signed-off, documenting the exact time and date of the review and when verification is provided. Further, after a relevant batch processes, it is transferred to the FP tank for cold storage, which is required to be maintained at 45 degrees for all products and 40 degrees for infant formula in order to be shipped to U.S. customers (up to 45 degrees permitted by regulations in certain circumstances).[7] These FP tank temperature requirements are also stated in Abbott's Global Microbiological Standards and must be followed and verified on the FP tank reports to ensure product quality.

292. Abbott's Global Microbiological Standards explain the importance of temperature control to avoid adulterated product:

> The wet blending, liquefication, of ingredients may allow outgrowth of microorganisms of health significance and those that may contribute to spoilage in the finished product. A product that is not held at temperatures to control the outgrowth of health significance microorganisms may be considered adulterated. Proper temperature and time control is important to protect the quality of the finished product. The growth of microorganisms during blending can influence the overall quality of the final product.[8]

293. Abbott failed to maintain temperature controls and the related records at Sturgis. Data loggers at Sturgis failed to record the temperature in a heat treatment room. For example, Xanthan gum (a thickening agent used in Alimentum) needs to be maintained in a room with heat treatment for 21 days before it can be used for production. After the commodity has been heat

[7] 21 C.F.R. § 106.30(e)(2)(ii), (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-106).

[8] Abbott – Abbott Nutrition Global Microbiological Standards, ID: AN06-99-004, approved Jan 28, 2020, effective Apr. 27, 2020, Section 5.4.2.

treated, the data must be reviewed to ensure the commodity has been processed as required and that the temperature and time requirements are met.

294. To illustrate, Abbott's records of a batch of Xanthan gum that was heat treated at Sturgis was found to be missing a large amount of data. Specifically, 10 of the 21 days of temperature data was missing. The violation was escalated to an Analytical Lab Manager who determined that the product should be released despite there being no supporting data verifying that proper temperature controls were in place complying with the specification for heat treatment.

ii. Abbott Systemically Violated Technical Equipment, Engineering, and Production Requirements

295. Abbott used Plant Information Reports ("PIRs") from production QS staff to report any production related deviations. The PIR identifies deviations to the master manufacturing order (referred to as a "work order").[9] The PIR also addresses corrective actions.[10] The PIR is integral to the control of the manufacturing process to prevent adulteration of products.[11] PIRs may address

[9] Under the FDCA and implementing regulations, a manufacturer must "prepare and maintain records that include complete information relating to the production and control of the production aggregate. These records shall include: (1) The master manufacturing order. . . (2) Any deviations from the master manufacturing order and any corrective actions taken because of the deviations. . . [and] (3) Documentation, in accordance with § 106.6(c), of the monitoring at any point, step, or stage in the manufacturer 's production process where control is deemed necessary to prevent adulteration." 21 C.F.R. § 106.100(e).

[10] *Id.*

[11] "The master manufacturing order shall include: (i) The significant steps in the production of the production aggregate and the date on which each significant step occurred; (ii) For a manufacturing facility that has more than one set of equipment or more than one processing line, the identity of equipment and processing lines for which the manufacturer has identified points, steps, or stages in the production process where control is necessary to prevent adulteration; (iii) The identity of each lot of ingredients, containers, and closures used in producing the production aggregate of formula; (iv) The amount of each ingredient to be added to the production aggregate of infant formula and a check (verification) that the correct amount was added; and (v) A copy of each infant formula label used on a finished production aggregate of infant formula and the results of examinations conducted during the finishing operations to provide assurance that the containers and packages have the correct label." 21 C.F.R. § 106.100(e)(3).

issues related to technical equipment and engineering issues or product that is OOS. PIR content also may be entered into ABTRAQ ("Abbott Trackwise for Quality") to create a Quality Assessment.

296. In numerous instances, PIRs or Quality Assessments were approved despite the product being out of specification ("OOS"). At Sturgis, PIRs required sign off approval by QS. Frequently, however, no one in QS possessed the knowledge to confirm whether the steps taken to address deviations from product specifications were acceptable. Abbott's Quality System Manager at Sturgis, Megan Fry, regularly instructed QS staff to improperly sign off on PIRs, effectively undermining a process that was designed to serve as an internal control measure.

iii. Abbott Approved Substandard and Adulterated Products with Unvalidated Data (SQE and ZARPAC Reports)

297. Meeting production goals and timelines assigned by Abbott leadership consistently took precedence over ensuring product safety at Abbott's facilities. As noted above, Relators know of multiple instances where Quality Assessments were approved despite the product being OOS. The OOS event was documented in a Quality Assessment, though an OOS event should have triggered a potential nonconformity ("pNCR") or a nonconformity ("NCR"). However, at Sturgis, Abbott improperly uses Standard Quality Evaluations ("SQE") specifically to avoid using pNCRs or NCRs.

298. SQEs are procedures used by Abbott to evaluate product that does not comply with specified work order requirements. SQEs are grouped by associated numbers or codes based on the type of event. For example, SQE 6.13 states that if a nutrient or mineral is OOS in-process, it must test within specification at FP or project within specification at FP. Once it is verified that the mineral or nutrient tests or projects within FP specifications, the SQE is used to "pass" the

product, and the event is determined as acceptable without submitting the product for a pNCR or NCR.

299. Abbott misuses SQEs to meet metrics and to avoid (a) additional analytical tests, sampling, reworks, or (b) creating pNCRs and NCRs that have a greater potential of leading to destroyed product. The use of SQE 6.16 instead of SQE 6.12 illustrates a common misuse of SQEs for improper purposes. These two SQEs relate to validations at the packaging/FP stage. Specifically, Abbott applies SQEs inappropriately to seam integrity inspections and OOS oxygen results.

300. To meet the criteria of SQE 6.12, product testing through sampling is needed to validate whether or not the product complies with specifications. In contrast, SQE 6.16 pertains to missed oxygen checks, "overcap" inspections, outgoing package quality checks, and similar issues. For the most part, the criteria for resolving SQE 6.16 is comparably low and can be resolved by the work order without testing or sampling the product.

301. Abbott directs QS staff to intentionally mischaracterize OOS events as SQE 6.16 and not as SQE 6.12. By applying the incorrect SQE, Abbott avoids product sampling for visually defective containers. Indeed, Abbott's management, including Susan Elgan and Megan Fry, were repeatedly confronted by employees, including Relators, about this unlawful practice.

302. On other occasions, Megan Fry directed QS employees to apply SQE 6.16 when a batch had a high oxygen test result rendering it OOS and not commercially releasable. Applying the SQE inappropriately in this manner allowed Abbott to avoid reworks, product destruction, and QRs.

303. Abbott often moves OOS batches into a category known as Quality Assessment to make it easier for OOS products to be released. To illustrate, a Quality Assessment was initiated

specifically to replace a previously created pNCR regarding a batch of infant formula with low-fill weights, which does not comply with specifications, and is a reason not to release a product. To avoid destroying a large amount of product or otherwise determining the root cause of the problem, Abbott "shuffled" the cases of product among the pallets to re-distribute the low-fill product among the acceptable weight product. In this example, a pNCR was initiated and then cancelled, effectively concealing the low-fill issue because Abbott shuffled cases.

304. In some instances, a Quality Assessment or SQE is used instead of a pNCR or NCR to avoid testing, reworks, or product destruction. In the case of over-oxygenated product cans, it would mean that product was knowingly released where the expiration date of the product may have been well before the expiration date disclosed on the container because the oxygenation would speed up the true expiration period, in addition to the product potentially being OOS.

305. In addition, Abbott used reports from a packaging line software known as ZARPAC are used to justify and approve PIRs. However, ZARPAC is a non-validated system that Abbott manipulated to alter and improve a department's performance metrics. It is not intended to be used to assess quality evaluations.

iv. Abbott Falsified Maintenance Records and Root Causes

306. Abbott and its facilities' maintenance departments are required to ensure equipment complies with FDCA and its implementing regulation standards.[12] Each maintenance department

[12] "A manufacturer shall make and retain all records of . . . (2) accuracy checks of instruments and controls. A certification of accuracy of any known reference standard used and a history of recertification shall be maintained. At a minimum, such records shall specify the instrument or control being checked, the date of the accuracy check, the standard used, the calibration method used, the results found, any actions taken if the instrument is found to be out of calibration, and the initials or name of the individual performing the test. If calibration of an instrument shows that a specification at a point, step, or stage in the production process where control is deemed necessary to prevent adulteration has not been met, a written evaluation of all affected product, and any actions that need to be taken with respect to that product, shall be made. . . (4) equipment

has dedicated tasks to complete on a scheduled basis. Once a maintenance technician completes a task, he or she is required to sign and date the completion of the task in Maximo, a software system used by Abbott. However, technicians regularly enter false records in Maximo, representing that maintenance tasks have been completed when, in reality, they have not been completed.

307. Sturgis maintenance employees openly used black books with calendar inserts to record their non-scheduled work, known as direct maintenance work orders,[13] prior to entering information into Maximo. This resulted in delayed or inaccurate maintenance records. Additionally, maintenance staff routinely discarded the calendars containing the handwritten notes.

308. Supervisory staff in the facilities' maintenance departments falsified root cause analyses ("RCAs") when participating in CAPA investigations. Long-standing seam integrity problems are just one example of these ongoing misrepresentations. Failure to maintain product seam integrity compromises the airtight seal of the infant formula and nutritional therapy product packaging because of defects such as droops, vees, false seams, knocked down flanges, and double-ended cans.[14]

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cleaning, sanitizing, and maintenance that show the date and time of such cleaning, sanitizing, and maintenance and the production aggregate number of each infant formula processed between equipment startup and shutdown for cleaning, sanitizing, and maintenance. The person performing and checking the cleaning, sanitizing, and maintenance shall date and sign or initial the record indicating that the work was performed." 21 C.F.R. §§ 106.100(f)(2), (f)(4).

[13] Preventive Maintenance is pre-scheduled work.

[14] Droop is a condition where a smooth projection of the seam extends below the normal seam. This can occur any place on the seam. Vee is an irregularity on the cover hook when the cover material does not form smoothly. The material splits causing a "V" shaped opening on the face of the cover hook. They can be caused by damaged ends at cover feed. Knocked Down Flange is a critical defect and occurs when the cover and body hooks do not interlock in a localized area of the double seam which is usually 1 to 2 inches in length.

309. For example, in February 2021, defects in the infant formula can seams were observed at Sturgis. The third shift maintenance team identified the problem causing the droop and vee defects and determined it was due to defective ends, which affected three batches. The seam defects arose because the Abbott applied sanitary can ends were produced based on faulty specifications provided to the supplier by Abbott.[15] Since the defective ends were made to Abbott's specifications (sampled only once per quarter), Abbott could not demand replacement can ends from the supplier even though it knowingly resulted in seam defects. Abbott understood that acknowledging the defective can ends would have required Abbott to recall the product. Several months of commercially released product made at Sturgis were impacted, as well as product from other Abbott facilities using the same defective can ends.

310. To avoid a product recall, Abbott's quality management and maintenance departments had an untrained technician adjust the pin height in the seamer causing the defects. A pin height adjustment generally does not cause droops or vees, and it was ruled out as the cause of the defective ends previously. However, the ensuing analysis wrongly attributed the untrained technician's pin height adjustment as the root cause of the seam problem.

311. Almost immediately, the same issue arose again with the Abbott applied can ends. Abbott failed to isolate batches they had already released (using the same defective ends and the faulty root cause). Instead, Abbott identified a different root cause, namely, the infeed chute that connects the ends into the seamer. To avoid detection (and a recall), Abbott determined that the only sampling required was a single batch at the beginning and one at the end of the bracket. Susan Elgan, Abbott's Site Quality Assurance Director at Sturgis, boasted "that's why I chose two

[15] The "sanitary can end" is often referred to as the "Abbott applied end." It is applied to the bottom of a can and the supplier end is applied to the top.

metabolic batches to be the batches stat sampled." Metabolic batches are small and typically yield only a few hundred cases, which is not a representative sample of batches run in the adulterated bracket. Elgan subsequently was promoted to the position of Abbott's Global Food Safety Director.

312. Additional defects at Sturgis were caused by one of the seamers seaming two ends per can instead of one end per can. Seaming two ends causes significant seam integrity defects and causes powdered infant formula to become oxygenated. Oxygenated infant formula creates a high risk of microbiological contamination. According to applicable specifications, infant formula containing more than two percent detectable oxygen in the sealed infant formula may not be released.

313. Still another example of a failure in manufacturing process control occurred in early 2021 when Sturgis maintenance discovered that an unvalidated Nucon rotary valve was used for more than one month before the issue was discovered. The rotary valve controls the flow of product, which means that one month's worth of batches were commercially released after being manufactured on an unvalidated system. Yet after discovering that a month's worth of product was manufactured with this defect and without submitting the product for adequate testing, Abbott released the product, never notified FDA of the commercial release of the affected infant formula, and never issued a voluntary recall of the affected batches.

v. Abbott's Systemic Seam Integrity Violations Adulterated Powdered Infant Formula

314. Powered infant formula products manufactured at Sturgis consistently experienced seam integrity defects, as noted above. For example, powdered infant formula becomes enmeshed in the seam which jeopardizes the integrity of the seal and causes powdered infant formula

contamination. Powder in the seam causes an OOS, imperfect seal allowing air, moisture, and bacteria to enter and contaminate the formula.

315. Instead of correcting and disclosing these known seam defects, Abbott materially altered the test to validate seam integrity to hide the problems. Specifically, seam integrity validation should be performed on sealed cans that actually contain powdered infant formula. However, Abbott changed the validation to only test empty cans without powdered infant formula. This fraudulent validation practice was never disclosed or documented. Further, although Sturgis has since installed new seaming equipment, seam integrity issues continue.

316. In addition to not maintaining adequate seam process control and falsifying seam integrity validations, Abbott concealed these problems from FDA and consumers. For example, Abbott recalled a single lot (No. 79696K800) of Calcilo XD in 2019 on the grounds that there was "inconsistency in aroma and color." Calcilo XDis a specialty infant formula for infants requiring a Vitamin D-free formula due to hypercalcemia, such as when an infant is diagnosed with Williams syndrome, osteopetrosis, and primary neonatal hyperparathyroidism. The root cause of the recall was powder in the seam on the Abbott-applied end of the can. This results in powdered infant formula discoloring and becoming rancid. Abbott's announcement of the recall falsely stated that "[t]his does not affect any other lots of Calcilo XD, or any other Abbott nutritional products. All other Abbott products can continue to be used with confidence."

317. In reality, several batches of Calcilo XD produced after the recall had the same defect. Relators know that the work order was altered to fraudulently misstate the true scope of the problems. For example, records were altered to appear that Abbott implemented changes to correct the seam-integrity defects. In reality, Abbott continued to perform seal check validations on empty

cans without powered infant formula in order to putatively obtain "passing" results because there was no powder in the seam.

318. Further evidence of Abbott's falsification of seam check validations are Abbott's "reworks" of powdered infant formula cans. Instead of tearing down (that is, mechanically cutting a cross section of the can, photographing, and measuring seam lengths) the powdered infant formula cans during the rework to verify whether there was any powder in the seams, Abbott directed employees to only weigh the cans. Doing this failed to account for powdered infant formula with a lower bulk density. It is well known that if powdered infant formula has a low bulk density and is too "fluffy," the sealed can may weigh within the acceptable weight range even when powdered infant formula is in the seam. In fact, Abbott knew that accurate bulk densities are a common problem with Calcilo XD, which affected both the seam integrity and the nutritional quality delivered per serving. Nevertheless, Abbott instructed that weighing the cans was all that was required. Two Abbott employees expressed concerns that they were required to perform seam check validations on empty cans that did not have powdered infant formula. Nevertheless, Abbott implemented this strategy to avoid discarding the entire batch.

319. Seam defects on powdered infant formula cans continued to be a problem. In January 2021, a PIR was issued for EleCare. The PIR noted that visual defects were observed with the seams during operator checks, leading to a part of the batch later being isolated for review.

320. Another example of seam defects at Sturgis is reflected in the 2021 seamer bracket discussed below. Forty batches were designated in the bracket. Abbott signed off on the release of the entire bracket based on a statistical sampling of just two small batches. Elgan stated that she selected the smallest batches for the sampling because they were the least likely to reveal seam

issues when the batch is run during shorter time periods – in effect, Abbott selected a non-representative sample set to release 40 batches with known seam integrity issues.

vi. Abbott Deceptively Disguised Out of Specification Products

321. Abbott has used non-validated procedures to address OOS results. In order to salvage infant formula product or commodities with OOS results, Sturgis blends OOS intermediate bulk containers ("IBC") with IBCs of in-specification product. This procedure is referred to as "bag pairing." Abbott has performed bag pairing at Sturgis when infant formula is OOS for excessive moisture, scorched particles, and OOS bulk densities.

322. For example, in or around 2016, Sturgis had a finished infant formula product that tested OOS for vitamin D. The levels were far higher than permitted under the specification to be released for infant consumption. Abbott did not want to destroy the batches and record the loss. Instead Abbott directed that the batches be stored in the warehouse to allow the vitamin D to degrade over time. Of course, as the vitamin D degraded, so would other ingredients in the product. Further, the vitamin D degradation also impacted other ingredients in the batches. Yet only vitamin D and vitamin K were tested. Once those two tests were in specification, no further testing was performed. The batches were commercially released. Some of the batches sat in the warehouse for at least one year.

323. Another example of Abbott releasing OOS infant and/or nutritional therapy formula from Sturgis occurred in approximately 2015.[16] A batch received twice the specified amount of a particular ingredient during dry blending of formula due to operator error. Upon testing, the batch showed twice the normal level of that ingredient. Nevertheless, the product was released. The

[16] The affected batch is believed to be either the infant or adult formulation of Ketonex. Ketonex is nutrition support for infants and toddlers with maple syrup urine disease ("MSUD") or beta-ketothiolase deficiency and is to be used under medical supervision.

Abbott CAPA coordinator later stated that Abbott concluded it was acceptable to ingest twice the appropriate amount of that particular commodity.

324. Further, in 2016, it was discovered that for more than a year a Sturgis microbiologist used the wrong test method. The microbiologist's errors in his analysis affected every powdered product produced for approximately one year. Relators participated in a process of reviewing records and sending data to Abbott Division during off-hours. Subsequently, Abbott took no action to recall products.

II. Abbott Knew That Its Extensive Manufacturing Safety Failures Were Being Concealed from The Government Through Misrepresentations, Concealment, And Omissions

325. At all times alleged in this Complaint, Abbott, through its employees and agents, had actual knowledge of information and facts indicating that its employees and agents were committing fraudulent acts, making false representations, and making fraudulent omissions designed to conceal from government entities (including but not limited to the FDA, CMS, and all State and federal agencies responsible for administering and paying Medicaid claims) its pervasive failures to comply with and fulfill its contractual, statutory, and regulatory obligations (as alleged in this Complaint) regarding safe practices and procedures for manufacturing, testing, packaging, holding, shipping, distributing, transferring, and selling its infant formula and nutritional therapy products paid for by each plaintiff State's Medicaid programs. In addition, or in the alternative, Abbott, through its employees and agents, acted with deliberate indifference to or reckless disregard of the aforementioned commission of fraudulent acts, fraudulent representations, fraudulent omissions, and fraudulent efforts at concealment.

326. The following paragraphs 327 through 429 evidence the aforementioned actual knowledge of, deliberate indifference to, and/or reckless disregard of the commission of these

fraudulent acts, fraudulent representations, fraudulent omissions, and fraudulent efforts at concealment. These paragraphs also demonstrate that Abbott, through its employees, and agents, acted with knowledge of, deliberate indifference to, and/or reckless disregard of the fact that these fraudulent acts, fraudulent representations, fraudulent omissions, and fraudulent efforts at concealment proximately caused and contributed to the submission of false claims for reimbursement by the plaintiff States' Medicaid Programs to pay for purchases and consumption of Abbott's infant formulas and nutritional therapy products. Abbott, through its employees and agents was, at all times alleged in this Complaint, aware that these products were distributed to and sold to Medicaid beneficiaries, pharmacies, medical providers, stores and/or distributors for ultimate consumption by Medicaid beneficiaries. Abbott, by and through its employees and agents, was, at all times alleged in this Complaint, aware that Medicaid beneficiaries, pharmacies, stores, and/or medical providers would thereafter submit claims to the States' Medicaid programs for reimbursement with Medicaid funds for the price that these Medicaid beneficiaries, pharmacies, stores, and/or medical providers paid for the original purchase of these products from Abbott.

A. Abbott's Knowledge of Fraud Related to the Failure to Identify, Document, Investigate, and Prevent the Presence of Microorganisms

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

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

329. cGMP regulations for infant formula and nutritional therapy products require 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*. at § 106.55(d). cGMP also requires 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).

330. cGMP regulations for human food also require that Abbott's manufacturing process ensure "[a]ll food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food." 21 C.F.R. § 117.80(c)(2). *See also* 21 C.F.R. § 110.80(b).

331. 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."

332. Abbott's own Global Microbiological Standards 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.

333. 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."

334. 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.

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

336. 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, sent after the Sturgis facility shut down and recall: "[j]ust don't want to give more [to FDA] than what we committed."

337. 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."

B. Abbott's Knowledge of Fraud Related to Failures to Maintain Adequate Testing Records and Investigate Positive Results

338. 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.

339. Abbott 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.

340. 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.

341. 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 and nutritional therapy products.

342. 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."

343. Communications among Sturgis personnel show why Abbott's 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."

344. 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]

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

345. 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.

346. The classification of micro contamination test results also directly impacted what Abbott represented to FDA. During FDA inspections, FDA 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."

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

C. Abbott's Knowledge of Fraud Related to Avoiding Testing for the Presence of Microorganisms

348. Before 2022, most of Abbott's environmental testing (*i.e.*, testing of the production environment, not the infant formula and nutritional therapy 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.

349. When FDA began its own environmental testing in February 2022, Sturgis employees remarked that FDA's testing 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."

350. 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…"

351. 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?"

352. 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.

353. 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.

354. 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."

355. 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. As a class, *Cronobacter* spp. are infectious agents.

356. 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. This is a Gram negative pathogen that can cause serious infections in humans, including newborns. Such infections can include meningitis, necrotizing enterocolitis, and sepsis.

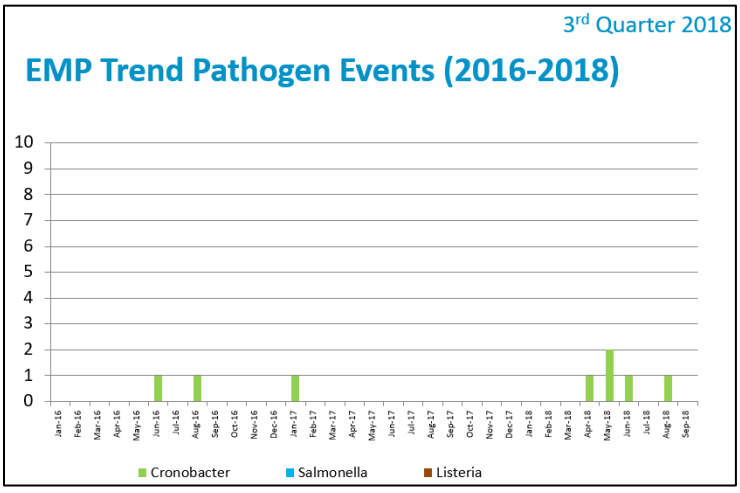
357. Despite these documented internal concerns regarding BAX's detection failure and Abbott's awareness that it was required to test for all species of *Cronobacter* spp., Abbott also misrepresented to FDA that it conducted testing at Sturgis for *all* species of *Cronobacter* spp. until 2022.

358. 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.

D. Abbott's Knowledge That the Sturgis Facility Had a Recurring Presence of Microorganisms and that Employees Failed to Disclose Positive Test Results to the FDA

359. 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.

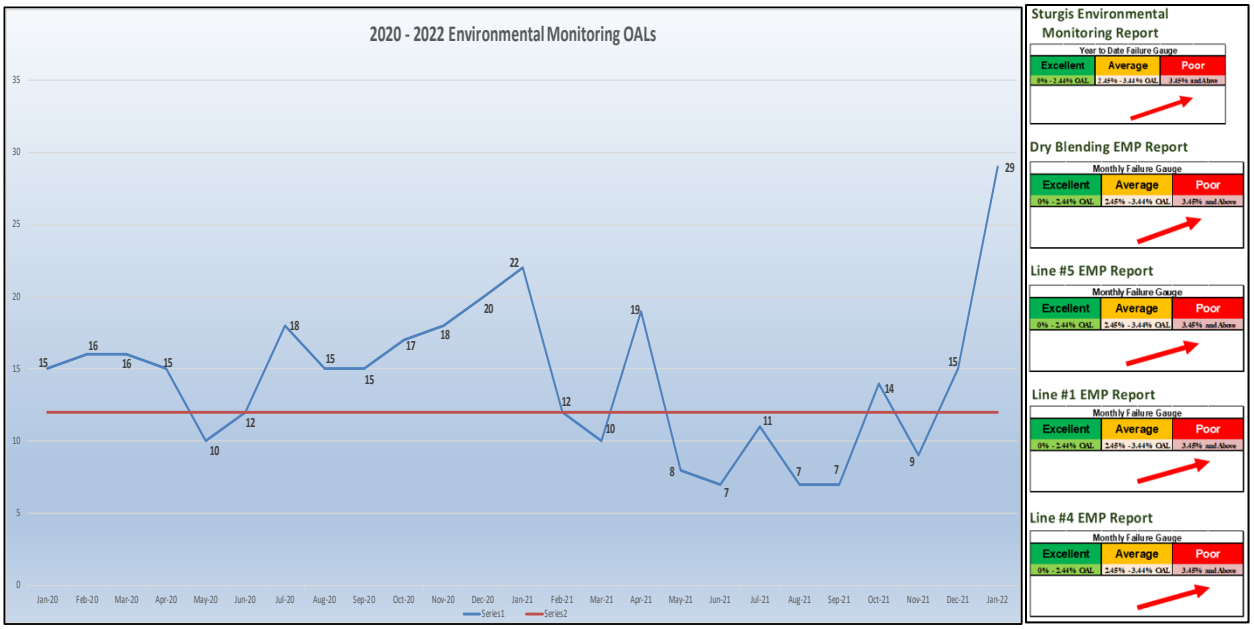
360. For example, over time, Abbott knew that the Sturgis facility had sharply increased positive *Cronobacter* environmental pathogen events:



361. 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."

362. 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 the following 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."

363. 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.



364. 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 for environmental contaminations at the Sturgis facility when they responded to requests from FDA investigators for any positive test results during the 2019 and 2022 inspections at the Sturgis facility.

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

366. 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.

E. Abbott's Knowing Falsification of Records to Conceal its Failures to Fulfill and Comply with its Contractual, Statutory, and Regulatory Duties

i. Batch Records

367. On multiple occasions, and in various ways, Abbott knowingly falsified manufacturing and batch records and provided incomplete records to FDA investigators to conceal violations of the FDCA and its implementing regulations. Batch record content evidencing violations was removed from records Abbott was required to maintain and provide to FDA upon request.

368. Batch records contain information relevant to all applicable steps in the manufacturing and testing process. For example, a batch record for a powdered infant formula or nutritional therapy product contains work orders for the Analytical Lab, the Microbiology Lab, Processing, Dryer and Packaging Departments, raw data, as well as applicable ad hoc forms, QRs, PIRs, statistical samplings, reworks, and 3x5 testing results. This data, when generated in order to satisfy cGMP requirements, becomes a permanent part of a manufacturer's cGMP data. For data integrity purposes, the FDCA and its implementing regulations require Abbott to maintain and make available to FDA "true copies" of "original records"[17] that do not alter or manipulate

[17] "A manufacturer shall maintain all records required under this part in a manner that ensures that both the manufacturer and the Food and Drug Administration can be provided with access to such records within 24 hours. The manufacturer may maintain the records required under this part as original records, as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records, or as electronic records." 21 C.F.R. § 106.100(m).

documentation[18] in the batch record to conceal violations.[19] Compliance with monitoring and documentation is required to prevent infant formula adulteration. [20]

ii. Sturgis – Purple Folders

369. At Sturgis, after batch release sign off, the batch record documentation was maintained in a single expandable file based on batch number. At least until recently, batch records contained a manila folder and a purple folder.

370. Most of the batch record documentation at Sturgis was maintained in paper as opposed to electronic format. Further, when content was maintained electronically, it was manually entered from paper notes or from one system to the next, rather than maintaining a continuous and unalterable electronic chain of information for data integrity purposes. Records manually transposed from hard copy to electronic format included QRs and testing results. At Sturgis, these records were manually entered into electronic format and then printed and put in the batch record folder.

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[18] The documentation required to be maintained includes "monitoring at any point, step, or stage in the manufacturer's production process where control is deemed necessary to prevent adulteration. These records shall include: (i) A list of the specifications established at each point, step, or stage in the production process where control is deemed necessary to prevent adulteration, in accordance with 21 C.F.R. § 106.6(c)(1), including documentation of the scientific basis for each specification; (ii) The actual values obtained during the monitoring operation, any deviations from established specifications, and any corrective actions taken; and (iii) Identification of the person monitoring each point, step, or stage in the production process where control is deemed necessary to prevent adulteration." 21 C.F.R. § 106.100(e).

[19] Abbott's Global Microbiological Standards requires, "[a]ny disposition decision made for products utilizing a decision matrix must: Be documented in the batch record…" Abbott – Abbott Nutrition Global Microbiological Standards, ID: AN06-99-004, approved Jan 28, 2020, effective Apr. 27, 2020, Section 5.5.8.

[20] "A manufacturer shall maintain all records required under this part in a manner that ensures that both the manufacturer and the Food and Drug Administration can be provided with access to such records within 24 hours. The manufacturer may maintain the records required under this part as original records, as true copies such as photocopies, microfilm, microfiche, or other accurate reproductions of the original records, or as electronic records." 21 C.F.R. § 106.100(m).

371. Every batch record at Sturgis contained a purple folder. The purple folder was used to segregate batch record content Abbott wanted to conceal from FDA because the content identified, or otherwise signaled, product deviations and FDCA violations. Sturgis personnel started using purple folders for this practice prior to 2015, and continued to do so at least through 2021.[21]

372. Abbott's internal QS auditors reviewed batch record content including work orders with reports and raw data and then placed content into purple folders.[22] The purple folder was not provided to FDA investigators even though it is a material part of the batch record.

373. When FDA investigators visited Sturgis, Abbott was provided with batch numbers to be retrieved for FDA's review. The batch records were retrieved by an Abbott employee from Record Storage, located in the basement along with both sections of QS. The batch records were brought to a "Back Room" accessible only to specific Abbott employees. FDA investigators generally remained in a separate "Front Room" on a separate floor.

374. The Back Room was set up when FDA investigators visited. It was located on the second-floor conference room with laptops, monitors, access to the engineering printer in the hallway outside the conference room, and additional office supplies. The Back Room was only

[21] Former employees with knowledge of Abbott's use of purple folders include Suzanne Sadler who held quality positions for a long time, including as Director and CAPA coordinator, and Jeff Rambadt, a long-time QS employee, who passed away in 2018.

[22] Sturgis employed four full-time and one contingent QS auditors, including John Hagner, Michael Conway, Josefina ("Josie") Miller, and Derek Blum. Prior to Blum, Maria Clementz was a QS auditor before moving to Rework Coordinator then to Complaint Coordinator, and Leah Handyside who is currently employed by Pfizer. Relators note that John Hagner maintained records spanning his 25 years at Sturgis, of all directives with which he disagreed. He described the records as "for his protection." The records were kept in two cabinets under his desk, as well as in five-six 3" binders. A lot of the records were handwritten because whoever was the leader of QS at the time did not want there to be a record of his or her directives. Additionally, Miller keeps an email folder titled by every QS supervisor with whom she has worked.

accessible to select Abbott employees, including but not limited to Deanna Denton, Analytical Lab Manager (responsible for Analytical Lab, Incoming Lab, and ELISA Lab); Brian Austin, Senior Quality Engineer; Adam Takace, Quality Engineer; and Scott Wonderly, Microbiologist.

375. Keenan Gale and Megan Fry had access to both the Back and Front Rooms. Susan Elgin and TJ Hathaway typically interacted with the FDA investigators in the Front Room. There was a scribe in the Front Room notating FDA's questions and review progress, which at least in Casa Grande, is projected into the Back Room in real-time.

376. Prior to a requested batch record being provided to FDA, the batch record was reviewed in the Back Room. Abbott employees conducting this review would move documentation selectively to the batch record's purple folder. The purple folder then was separated from the batch record and the record, absent the purple folder documentation, was provided to the FDA investigator(s).

377. All batch record folders were maintained in Record Storage at Sturgis. This room contained between 3,000 and 5,000 batch records, as it housed all batch records including work orders for oil blends, protein free CIPs, and work orders for batches that were destroyed. Folders for unreleased batches are located in QS.

iii. Falsification of Batch Records – Back Room Record Removal

378. Abbott has undertaken specific actions to hide from FDA records of FDCA and implementing regulations violations. On one hand, Abbott's internal policy acknowledges: "when microbial contamination of a health hazard is confirmed, the event must be documented and the

affected product isolated. The following actions must be taken . . . Document the event in the batch record at the time the suspected event is confirmed. . . .”[23]

5.5.7.2 Health Hazard Microorganism

5.5.7.2.1 Documentation/Isolation

When microbial contamination of a health hazard is confirmed, the event must be documented and the affected product isolated. The following actions must be taken:

Step	Action
1.	Initiate a Potential Nonconformity per current procedures.
2.	Document the event in the batch record at the time the suspected event is confirmed.
3.	Assess the potential impact of the event throughout all portions of the batch(es), i.e., bracket.
4.	Segregate and hold the batch(es) or portion of the batch(es).

379. However, for years Abbott knowingly has altered records that were presented to FDA investigators as true, accurate, and complete.

a. Sturgis 2019 Audit

380. The 2019 FDA audit of Sturgis illustrates Abbott’s scheme. At the time, Abbott was concerned that FDA would discover batches with microbiological contamination. During the audit, QA leadership kept QS staff apprised of the areas of investigation by FDA. Abbott’s Quality System Manager, Megan Fry, commented internally that FDA was on the “right trail” to identify the violations. Later, Fry expressed surprise that FDA ultimately failed to identify the violations with the batches.

381. After the audit, Elgan stated that she avoided direct answers to questions asked by FDA which caused her to be uncomfortable. This was in reference to Sturgis’ positive

[23] Documentation of the event in the batch record at the time the suspected event is confirmed is also required “when a finished product batch is over the defined process hygiene indicator trend limit or action level” according to Section 5.5.7.3.1 of Abbott’s Global Microbiological Standards. This “hygiene indicator” refers to testing for Standard Plate Count (“SPC”), *Enterobacteriaceae*/Coliform, Yeast & Mold, Bacillus *cereus*, and others.

environmental *Cronobacter* swab, the results of which were in the Environmental Monitoring Program ("EMP") data and withheld from FDA.

b. Sturgis 2021 Inspection

382. Another example of Abbott altering records at Sturgis occurred during a 2021 FDA inspection. FDA visited Sturgis and requested Alimentum batch records. The QS staff was instructed to find Alimentum batch records within the last 30 days. Many of the records were described internally as not "clean," meaning that they contained documentation of problems including reworks, blending/bag pairing, or significant documentation errors. Adam Takace, Abbott's Quality System Supervisor, told the QS staff that Elgan only wanted clean batch records provided to FDA. Elgan personally oversaw the progress of the batch records retrieval and review. QS staff told Elgan that the "cleanest" Alimentum batch records still contained evidence of OOS blending bag pairings, and all of the batches had problems. Elgan said those records were "not ideal" but could be used.

383. QS compiled the batches with the least number of issues, which were sent to the Back Room on a cart. The QS team, as they had been instructed, pulled the purple folders with the problematic documentation for each batch, placed the batch records on top of the cart and the corresponding purple folders on bottom. The cart was taken to the Back Room where the records were reviewed again. The batch records without the purple folders were provided to FDA. As FDA reviewed the batch records in the Front Room, the purple folders remained in the Back Room.

F. Abbott's Knowing Release of Inadequately Tested Infant Formula and Nutritional Therapy Products Based on Use of "Time Code Removals" and Failure to Appropriately Bracket

i. "Time Code Removals" in General

384. Abbott's withholding of documents and falsifying records is illustrated by Abbott's long-standing use of "time code removal" practices to release infant formula and nutritional therapy products with known positive contamination results or exposure to the contamination.

385. "Time code removal" is a flawed and non-validated practice widely used by Abbott when a batch of infant formula, nutritional therapy products, or equipment tests positive for contamination. "Time code removal" involves (i) identifying where in the batch the testing revealed the presence of microorganisms, (ii) blocking a period of time around the confirmed contamination test (*e.g.*, 15 minutes before and after) using the manufacturing date and time code imprinted on the cans, (iii) destroying product within the limited time code range, and (iv) releasing the remainder of the batch without confirming that the released product meets specifications.

386. When an infant formula or nutritional therapy product tests positive for contamination or is exposed to environmental contamination, the product should not be released because it is adulterated. Abbott documentation states that additional testing is required to verify the acceptability of the infant formula or nutritional therapy products following an event investigation. For example, Abbott's Global Microbiological Standards states that, for infant formula lots that are adjacent to the adulterated infant formula due to a health hazard microorganism contamination:

> [b]racketed, adjacent lots verified as acceptable could be released pending division Quality Assurance Director or designate approval provided the following criteria are met: The event investigation has been completed[;] The decision matrix allows acceptance[;] Additional testing verifies acceptance[;] and There is documented evidence supporting the product release decision.

387. Abbott – Abbott Nutrition Global Microbiological Standards, ID: AN06-99-004, approved Jan 28, 2020, effective Apr. 27, 2020, Section 5.5.7.4.

388. Notwithstanding clear FDCA and implementing regulations, as well as Abbott's own Global Microbiological Standards, it was routine at the facilities to use "time code removal" to release batches of product with confirmed contamination without testing to verify the acceptability of the adjacent products.[24] This practice was directed and implemented with the knowledge of the Directors of Quality Assurance at Sturgis and Casa Grande, Susan Elgan and Arlene Rivera Contreras, among others. Elgan and Rivera Contreras both reported to Lesa Scott, former Director, North America Quality Assurance Operations at Abbott Nutrition. Scott knew of and participated in "time code removal" practices. For example, Scott was involved in calibrating the "time code removal" range to block during one sizable "time code removal" event.

389. "Time code removal" is not scientifically validated. It is not done with testing rigor to identify the root cause and full scope of confirmed microbiological or other contamination. "Time code removal" fails to prevent known contaminated products from being released. For example, product outside the designated "time code removal" range of a batch with a positive contaminant test result (from FP or contact) is commercially released by Abbott without adequate testing verifying the product's safety. Sturgis improperly implemented the practice when Quality Assurance employees used pallet placement for "time code removal" even though the pallets contained product with non-sequential time codes.

[24] Abbott Global Microbiological Standards states that for any disposition made for products that have been bracketed due to positive final product or environmental results "[j]ustification for product acceptance is determined based on no impact to the adjacent batches and assurance that the microbial contamination was isolated and eliminated." Abbott – Abbott Nutrition Global Microbiological Standards, ID: AN06-99-004, approved Jan 28, 2020, effective Apr. 27, 2020, Section 5.5.7.3.2.

390. Even further, when a positive contamination test results in "time code removal" of product, Abbott wrongfully limits testing to unreleased products when products from the same batch with a confirmed contamination or exposure already are released. Samples from products commercially released by Abbott and later determined to be part of a "bracket" of contaminated products are not tested by Abbott. Susan Elgan (Sturgis), Megan Fry (Sturgis), Arlene Rivera Contreras (Casa Grande), and Stefanie Crum (Casa Grande), among other Abbott employees, engaged in these practices.

ii. Bracketing Contaminated Batches

391. Abbott created a "bracket" around a group of batches of infant formula or nutritional therapy products that are OOS or otherwise fail to comply with the FDCA and its implementing regulations due to, for example, a confirmed contamination. In the context of microbiological and environmental contamination, a bracket typically contains a large number of batches manufactured between equipment cleanings, including CIPs at the dryer or between wet cleans in powder filling. When the OOS event traces to a commodity or seamer, for example, the bracket would be defined by batches using that commodity or equipment.

392. According to Abbott's Global Microbiological Standards,

> [t]he following actions are required in case of unsatisfactory results...Product Safety Indicators: The tests in this category are required to be tested prior to release for each batch. If a batch is found to be defective, a complete investigation is required to determine the root cause of the contamination. If the product has been released to market, Supply Chain management should be notified immediately in order to assess the need for bracketing, containment, and recall of potentially affected products.[25]

[25] Abbott – Abbott Nutrition Global Microbiological Standards, ID: AN06-99-004, approved Jan 28, 2020, effective Apr. 27, 2020, Section 5.5.5.1.

393. Microbiological brackets are created following a positive microbiological contaminant or environmental test. Thereafter a microbiological testing schedule, a result data tracker, and a risk assessment spreadsheet are generated for the bracket.

iii. Implementation of the "Time Code Removal" Scheme

394. Following a presumptive positive contamination test result, Abbott selectively performs microbiological testing on the powder in the cans. This is called "3x5 testing," which is testing three times the number of samples and five times the volume. These tests are ***only*** performed on unreleased batches. If any portion of a batch is released, no tests are performed on it. Therefore, if a batch is implicated in a bracket (meaning the batch has been determined to have been potentially exposed to contamination), and any portion of that batch is released, Abbott ***will not*** test samples or parts of that batch still within Abbott's control because they do not want to notify FDA and issue a recall.

395. Further, this 3x5 process for microbiological testing is ***only*** performed on batches immediately adjacent to the positive test. Even then the microbiological testing is performed on an extremely small, non-representative sampling of the thousands of cans within each batch.

396. On every can produced, the Julian date and the time the can was produced is printed on the bottom of the can. Using the Julian date and time printed on the bottom of the can, cans to be removed are identified if within the coded range. The remaining product is commercially released.

397. "Time code removal" practices at Sturgis also resulted in systemic product traceability problems. Sturgis did not visibly inspect all cans within a batch designated for "time code removal." Instead, employees only inspected cans from pallets identified as having been

produced and received by the warehouse, based on pallet reports, within or around the time needed for the "time code removal."

398. Each pallet at Sturgis receives its own time code when it enters the warehouse. However, pallets are not formed based on the consecutive production time of the cans. Conducting a rework review by pallet time code renders it virtually impossible to adequately trace the product produced during the "time code removal" range. Thus, using pallet time codes to identify product with confirmed contamination or exposure that was required to be destroyed was inherently defective. Substandard, adulterated, and non-compliant infant formula and nutritional therapy products that should have been destroyed were released. At the end of the "time code removal", Sturgis could not verify that all time code designated product was detected and destroyed.

399. The ineffectiveness of "time code removal" based on pallet time codes is made worse by the various ways cans get out of order and mixed during the packaging process. Product packaging machines often experience stoppages or downtime. If equipment downstream of the filler/seamer is down, the equipment is programmed nevertheless to continuing filling the cans. As cans come out of the seamer, they are automatically moved to an accumulation table until a sensor tells the filler there is no more room. At that point, depending on the production line, the machine stops filling or cans are pushed to the other side by a conveyor belt. The effect, however, is that the cans no longer are in order by their time codes.

400. The situation is often made worse when cans are moved to a temporary pallet by a Whalon, which is a large magnetizer used to move large groups of cans from one area to another. In this situation, cans are moved to a temporary pallet, back to the accumulation table when there is room, and ultimately packed and re-palletized, resulting in pallets with mixed time codes.

401. Relators also note that in Sturgis once a pallet is designated for "rework" it is "shot out" of or, in other words, removed from the system and cannot return as the same pallet. Once these pallets are returned to the warehouse, they are assigned a new pallet ID, resulting in virtually no possibility of internal-Abbott traceability.

402. – 417. Paragraphs 402 through 417 have been intentionally omitted.

iv. Sturgis – 2019 Microbiological Batches

418. For several years, Abbott knew that equipment used in the drying process at Sturgis, including the evaporator, was unreliable and failing. As a result of these equipment defects, a number of product flow pipes were pitting and leaving pin holes. This allowed bacteria to enter the system and led to the CIP process' failure to adequately clean out bacteria. In turn, this caused product flowing through the pipes to pick up the bacteria that was trapped in the defective areas of the pipe.

419. Prior to the 2019 FDA audit, Abbott's Lesa Scott, with the knowledge of Elgan and Fry, authorized the release of infant formula that tested positive for microbiological contamination. This bracket of "micro batches" of infant formula included the batch that had triggered the internal investigations into the product flow pipes and the spray balls.

420. Since the microbiological contaminant was discovered during the standard batch testing (30 samples pulled evenly throughout the production of the batch, including the first and last can produced),[26] 3x5 testing was performed on additional samples. Of these additional samples, multiple samples tested positive for microbiological contamination. Abbott made the decision not to destroy the entire batch. Instead, a "time code removal" was performed.

[26]At the time, this was the standard microbiological sampling procedure. During the 2019 FDA audit, FDA cited Sturgis for not adequately sampling for microbiological testing. As a result, Abbott Division and Sturgis increased their microbiological sampling.

421. Abbott, with Scott's input at Abbott Division, set the time span for the "time code removal". Once the product outside the "time code removal" range was culled out, no additional testing was performed to provide evidence that all the microbiological-positive product was captured and destroyed. The infant formula outside the "time code removal" range was commercially released without supporting documentation to suggest it was compliant and safe for consumption, all based on the non-validated "time code removal" process.

v. Sturgis – Spring 2021 Seamer Bracket

422. Between December 2020 and January 2021, Sturgis created a large seamer bracket based on issues resulting from the seamers on Lines 3 and 5. There were 40 batches designated in the bracket. Abbott signed off on release of the entire 40 batches based on a statistical sampling of cans at the beginning and end of the bracket. Elgan announced that she chose metabolic product batches[27] for sampling because there are less than 500 cases in those batches. In contrast, Alimentum infant formula products can include as many as 11,000 cases in a batch. Based on this non-representative sampling, Abbott released the batches for commercial consumption.

423. This seamer bracket followed years of FP can seam defects, specifically cans produced on Line 5, which was created to package value size packages for bulk retailers. Line 5 installation was completed in 2017 with a seamer from Sweden. Relator L. Cooper later learned that the seamer was made for liquid packaging and not for powdered product, which is how Abbott was employing it. Shortly after installation, during Labor Day weekend of 2018, Line 5 at Sturgis had to be shut down.

[27] These include Abbott products such as I-Valex, Ketonex, Phenex, Propimex, Provimin, and Tyrex.

424. Aside from the Labor Day shut down, seam integrity issues caused so many brackets and corresponding reworks that Abbott employees were flown to Sturgis from across the country to assist in the reworks to meet deadlines for Costco and Sam's Club.

425. In addition to flying in Abbott employees, Elgan hired her husband, Eric Elgan, in approximately April 2019 to lead the reworks for seam issues. Though Eric Elgan was clearly doing QA work, he is believed to have been hired through the Engineering Department to avoid the appearance of impropriety.

426. The rework process addressed numerous issues, including Abbott applied seam integrity, packaging, label issues, and excessive oxygen issues (too much oxygen causes spoilage), yet no cans were opened during the rework.

G. Abbott Failed to Take Consumer Complaints Seriously

427. During the FDA's 2022 Inspection at Sturgis, FDA investigators found that Abbott failed to follow their own procedures to determine the root cause of consumer complaints associated with their products.

428. Specifically, FDA investigators reviewed Abbott's complaint investigations for consumer complaints received by FDA, identified as FDA Consumer Complaint Nos. 171222, 170177, 171771, 171087, that are associated with (but not definitively caused by) powder infant formulas manufactured at Sturgis, including reported *C. sak.* illnesses and a reported illness from *Salmonella newport*. The FDA investigators found that Abbott closed their complaint investigations without having identified a root cause for the reported illnesses associated with bacterial infection.

429. FDA investigators observed that, although Abbott's standard operating procedure ("Complaint Management and Investigations" v. 26, s. 5.2.2.8 on page 26) states that retained samples are to be evaluated for microbial analysis when "there is a potential for the distributed product not to comply with specifications," Abbott closed their complaint investigations without having evaluated any retained samples of the Consumer Complaint-related powder infant formulas for microbiological contamination.

III. Abbott Falsely Represented and or Certified Compliance with Material Statutory, Regulatory, and Contractual Requirements of The Intervening States for Powder Infant and Nutritional Therapy Formulas Manufactured at the Sturgis Facility

430. 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 Medicaid requirements for infant formula and nutritional therapy products by State contracts, the FDCA, federal regulations, and State analogues of health and food safety laws, and cGMP regulations.

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

432. As a manufacturer supplying the Medicaid programs of the Intervening States, Abbott represented that its powder infant formulas and nutritional therapy products, complied with the Medicaid statutory and regulatory requirements for infant formula and nutritional therapy products.

433. Abbott also certified compliance with Medicaid infant formula and nutritional therapy product obligations in its petitions for consideration and contracts executed with Medicaid

single state agencies, including compliance with the FDCA, federal regulations, and/or a State's analogues food safety laws and regulations.

434. Medicaid programs required Abbott's certifications to State agencies that its infant formula and nutritional therapy products manufactured at the Sturgis facility complied with applicable requirements to be eligible to supply infant formula and nutritional therapy products to the Medicaid programs of the Intervening States.

435. Abbott did not disclose to the Medicaid programs of the Intervening States that it misrepresented its compliance with infant formula and nutritional therapy product obligations and was in breach of material provisions of its State agency contracts and requirements imposed by Medicaid directed statutes and regulations.

436. Abbott sold its powder infant formulas and nutritional therapy products to Medicaid participants knowing that at least some of the formula would be purchased using Medicaid benefits from the Intervening States' Medicaid programs.

437. Medicaid participants sought payment from Medicaid for Abbott's powder infant formulas and nutritional therapy products that failed to comply with contractual, statutory, and regulatory requirements that were material to the Medicaid programs of the Intervening States.

438. As described above, Medicaid participants used Medicaid benefits to purchase non-compliant infant formula and nutritional therapy products from authorized Medicaid vendors.

439. Thus, Abbott caused authorized Medicaid vendors to present false claims for payment of Medicaid funds when Medicaid participants used Medicaid benefits to purchase these infant formulas and nutritional therapy products.

IV. Abbott's Representations and or Contract Certifications for Powder Infant and Nutritional Therapy Formulas Manufactured at the Sturgis Facility Were Material to Single State Agencies' Decisions to Purchase or Reimburse Product using Medicaid Funds

440. 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 an infant formula and nutritional therapy manufacturer supplying product to the Intervening States' Medicaid Programs.

441. As detailed above, State agency contracts and applicable statutes and regulations contain material provisions that required Abbott's infant formula and nutritional therapy products to meet standards set forth in the FDCA, federal regulations, State analogous statutes and regulations, and cGMP regulations.

442. The Intervening States' Medicaid Programs required, and State agencies relied on, Abbott's certification that its infant formulas and nutritional therapy products complied with these material contract provisions, including that the infant formula and nutritional therapy products met standards set forth in the FDCA, federal regulations, cGMP, State analogous health and food safety laws and regulations, and the quality-related terms of the State agency contracts.

443. State Medicaid programs would not have allowed any funds to be used by State agencies for the purchase or reimbursement of powder infant formulas and nutritional therapy products manufactured at the Sturgis facility by Medicaid participants had it known that the infant formulas and nutritional therapy products failed to comply with FDCA, federal regulations, cGMP, State analogous health and food safety laws and regulations, and the quality-related terms of the State agency contracts.

444. Abbott knew that its infant formula and nutritional therapy products were purchased using Medicaid funds. Abbott knew that its false certifications to compliance with contractual, statutory, and regulatory requirements for infant formula and nutritional therapy products directly affected the Intervening States' State Medicaid Program decisions to entertain Abbott's application for, and execution of, contracts with Abbott to supply products that would be purchased using Medicaid benefits.

V. Abbott's Contract Certifications for Powder Infant and Nutritional Therapy Formulas Manufactured at the Sturgis Facility Were Material to The Intervening States' Medicaid Programs' Petitions and Contract Execution Decisions

445. 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 Medicaid infant formula and nutritional therapy product manufacturer.

446. As detailed above, State agency contracts and applicable statutes and regulations contain material provisions that required Abbott's infant formula to meet standards set forth in the FDCA, federal regulations, State analogues of health and food safety laws and regulations, and cGMP regulations.

447. The Intervening States' Medicaid Programs required, and State agencies relied on, Abbott's certification that its infant formulas and nutritional therapy products complied with these material contract provisions, including that the infant formula and nutritional therapy products met standards set forth in the FDCA, federal regulations, State analogous health and food safety laws and regulations, cGMP, and the quality-related terms of the State agency contracts.

448. The Intervening States' Medicaid Programs would not have allowed any funds to be used by Medicaid for the purchase of powder infant formulas and nutritional therapy products manufactured at the Sturgis facility by Medicaid participants had it known that the infant formulas and nutritional therapy products failed to comply with the Intervening States' Medicaid Programs statutes and regulations and State agency contracts.

449. Abbott knew that its infant formula and nutritional therapy products were purchased using Medicaid benefits. Abbott knew that its false certifications to compliance with contractual, statutory, and regulatory requirements for infant formula and nutritional therapy products directly affected State agency decisions to accept Abbott's bids and execute contracts with Abbott, and the Medicaid's decision to allow State agencies to enter contracts that enabled the Intervening States' Medicaid Programs participants to purchase and participating pharmacists or physicians to prescribe Abbott's powder infant formula and nutritional therapy products using Medicaid benefits.

VI. The Intervening States' Damages/Civil Remedies

A. California's Damages

450. Abbott's violations of cGMP Regulations for Human Food render Abbott's products (including the Specialty Infant Formulas, the Standard Infant Formulas, and the other nutritional therapy products at Sturgis) adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been manufactured, prepared, packed, distributed, held, and sold under insanitary conditions whereby they may have become contaminated or been rendered injurious to health. See 21 C.F.R. § 117.1(a)(1)(ii), 21 U.S.C. § 350a(b)(2), 21 C.F.R. Part 106, Subpart B, and 21 C.F.R. Part 110 and Part 117, Subpart B. *See also* Cal. Health & Safety Code §§ 110545, 110560, 110565, 110560, 110585.

451. California's Medi-Cal Enteral Nutrition Products Program was substantially adversely impacted by the false claims resulting from Abbott's failures to comply with its contractual, statutory, and regulatory duties regarding safe manufacturing, testing, packaging, distributing, transferring, and selling its infant formula and nutritional therapy products for the intended benefit of Medi-Cal beneficiaries. As explained in Section III(A) of the Background Section. above, the Medi-Cal Program, by contracting with Abbott, bargained for and expected to pay only for the provision of safely manufactured infant formula and nutritional therapy products intended for the welfare of Medi-Cal beneficiaries. This was a material condition of the contractual arrangement and a material condition of Medi-Cal paying reimbursements for purchases of Abbott's products.

452. Had DHCS and the Medi-Cal Program known of Abbott's extensive and pervasive breaches of its safe manufacturing obligations and duties leading up to and during January 1, 2020 to on or about June 30, 2022, Abbott's products would have been removed from the *Medi-Cal Rx List* of products eligible for reimbursement with Medi-Cal funds. Yet, Abbott knowingly[28], actively, repeatedly, consistently, and continuously engaged in fraudulent misrepresentations, omissions, failures to disclose, and false certifications to conceal from the FDA, CMS, and the DHCS/Medi-Cal Program that Abbott's production process was in gross violation of the material safety expectations and requirements of the contracts and applicable statutory and regulatory requirements for cGMP. All powdered infant formula and nutritional therapy products produced by Abbott at the Sturgis facility during those years were manufactured in material breach of the bargained-for safety expectations, risking the lives and health of thousands of Medi-Cal

[28] Abbott acted at all alleged times with actual knowledge of the fraud that was being committed against the Program and/or with at least deliberate indifference to or reckless disregard of the fact that such fraud was being committed.

beneficiaries (the vast majority of which were infants and children). Once those products were distributed and sold in the chain of commerce that placed them in the hands of pharmacies, medical providers, medical facilities, or other authorized providers of these products, they were ultimately provided to Medi-Cal beneficiaries.

453. The specific powdered infant formula and nutritional therapy products that were manufactured/produced by Abbott at the Sturgis plant pursuant to its contracts with the California Medi-Cal Enteral Nutrition Product Program and which resulted in claims being made to and paid by the Medi-Cal Program during the period running from at or around January 1, 2020 to on or about June 30, 2022, include, but are not limited to, the products listed in the following chart, identified by their category type on the *Medi-Cal Rx List* , their NDC[29] numbers, the description of product line, and packaging quantity. These products (and potentially others that may be discovered in the process of discovery) were the subjects of submissions of and payment of false claims resulting from and proximately caused by Abbott's knowing and material failures to comply with its obligations under its California contracts with the Medi-Cal Program and its obligations under state and federal statutes and regulations (as alleged above in this complaint) for Enteral Products. Abbott's certifications to Medi-Cal that it was, at all times alleged herein, in compliance with its contractual requirements and state and federal statutory and regulatory requirements regarding safe manufacturing, testing, packing, holding, distributing, shipping, and selling its infant formula and nutritional therapy products was a material factor in the Medi-Cal program

[29] NDC refers to a drug or medical product's National Drug Code number. For purposes of the products at issue in this case, this is a unique 11-digit identifier assigned to drugs and medical products like infant formulas for specific identification and reporting of each drug or product. The NDC numbers are listed in the FDA's NDC Directory.

paying out claims for reimbursement for Medi-Cal beneficiaries' use and consumption of the following products.

Medi-Cal RX Enteral Nutrition Product List Category	NDC	Description
Specialty Infant	70074053511	Elecare 14.1 oz PWDR (EH)
Specialty Infant	70074064712	Similac Alimentum (343 g) PWDR (EH)
Specialty Infant	70074060850	Similac PM 60/40 (400g) (Renal)
Metabolic	70074067037	Glutarex-1 14.1 oz PWDR 6 Ct (Glutaric Acidemia Type 1)
Metabolic	70074053329	CALCILO XD CAL W/O VITD (375 g) PWDR 6 Ct (Hypercalcemia)
Metabolic	70074067047	I-VALEX-2 UNFL 14.1 oz (400 g) PWDR 6 Ct (Leucine Metabolism Disorder)
Metabolic	70074067049	Ketonex-1 14.1 oz PWDR 6 Ct (Maple Syrup Urine Disease)
Metabolic	70074067051	Ketonex-2 UNFL 14.1 oz (400 g) PWDR 6 Ct (Maple Syrup Urine Disease)
Metabolic	70074067053	PHENEX-1 14.1 oz PWDR 6 Ct (Phenylketonuria [PKU])
Metabolic	70074067055	PHENEX-2 UNFL 14.1 oz (400 g) PWDR 6 Ct (Phenylketonuria [PKU])
Metabolic	70074067057	PHENEX-2 VAN 14.1 oz (400 g) PWDR 6 Ct (Phenylketonuria [PKU])
Metabolic	70074067059	PROPIMEX-1 14.1 oz PWDR 6 Ct (Propionic & methylmalonic acidemia)
Metabolic	70074067031	PRO-PHREE 14.1 oz PWDR 6 Ct (Protein-free diet)
Metabolic	70074067033	CYCLINEX-1 14.1 oz PWDR 6 Ct (Urea Cycle Disorders [UCD])
Metabolic	70074067035	CYCLINEX-2 UNFL 14.1 oz (400 g) PWDR 6 Ct (Urea Cycle Disorders [UCD])
Elemental & Semi-Elemental	70074055254	EleCare Junior 400 g Unflavored PWDR (Amino acid-based pediatric formula)
Elemental & Semi-Elemental	70074066276	EleCare Junior Banana, 400 g PWDR (Amino acid-based pediatric formula)
Elemental & Semi-Elemental	70074066271	EleCare Junior Chocolate 400 g PWDR (Amino acid-based pediatric formula)
Elemental & Semi-Elemental	70074056586	EleCare Junior Vanilla 400 g PWDR (Amino acid-based pediatric formula)

454. For the above-listed infant formula and nutritional therapy products that were manufactured/produced by Abbott at the Sturgis plant and that were distributed and sold so as to result in and proximately cause false claims being made to and paid by the Medi-Cal Enteral Nutrition Product Program during the period running from at or around January 1, 2020 to on or about June 30, 2022, the following chart shows the currently discovered minimum number of such Medi-Cal claims made to Medi-Cal and paid by Medi-Cal funds for each NDC during that time period.

455. The total currently discovered minimum total amounts paid out by Medi-Cal for the false and fraudulent claims related to each NDC are also shown for those years. All of these paid-for claims (and potentially others that may be discovered in the process of discovery) were rendered false due to Abbott's knowing and material failures to comply with its cGMP obligations under its California contracts with the Medi-Cal Program and its obligations under state and federal statutes and regulations (as alleged above in this complaint) related to these Enteral Nutrition Products that were ultimately distributed and sold by Abbott pursuant to its California contracts and for the use and consumption by Medi-Cal beneficiaries.

456. Abbott's certifications to Medi-Cal that it was, at all times alleged herein, in compliance with its contractual requirements and state and federal statutory and regulatory requirements regarding safe manufacturing, testing, packing, holding, distributing, shipping, and selling its infant formula and nutritional therapy products was a material factor in the Medi-Cal program paying out all of the following claims for reimbursement for Medi-Cal beneficiaries' use and consumption of the following products.

457. Abbott knowingly made these false certifications. The certifications made by pharmacies, physicians, retailers, Medi-Cal members, and any other persons or entities seeking

reimbursement for the following claims as to the medical necessity, safety, and efficacy of these products were necessarily made false by Abbott's concealment from all of these persons and entities (as well as from Medi-Cal and other state and federal agencies) of the pervasive, persistent, extensive, and material violations by Abbott of its contractual requirements and state and federal statutory and regulatory requirements regarding safe manufacturing, testing, packing, holding, distributing, shipping, and selling its infant formula and nutritional therapy products (as alleged above in this complaint).

NDC	No. Claims Paid 2020-2022	Total Medi-Cal Paid Amount 2020-2022
70074053511	4,446	$1,839,317.06
70074064712	6,465	$2,119,550.12
70074060850	1,109	$182,818.82
70074067037	13	$2,374.05
70074053329	63	$11,123.84
70074067047	11	$4,737.37
70074067049	42	$16,688.54
70074067051	50	$40,324.85
70074067053	1	$47.75
70074067055	153	$66,633.52
70074067057	17	$9,013.22
70074067059	107	$21,560.09
70074067031	310	$16,685.40
70074067033	34	$6,688.41
70074067035	11	$6,998.61
70074055254	4,276	$2,868,730.15
70074066276	63	$28,168.16
70074066271	79	$40,909.91
70074056586	4,219	$2,891,982.73

458. The following charts are representative examples of details of specific false and fraudulent claims made and/or caused to be made/submitted to the Medi-Cal Program by medical providers and pharmacies and which were paid for by Medi-Cal funds, with all such claims arising from the use and consumption of Abbott's infant formula and nutritional therapy products

manufactured and sold pursuant to Abbott's contracts with Medi-Cal for the Medi-Cal Enteral Nutrition Product Program. Payments for these claims were made by Medi-Cal as the result of and were proximately caused by Abbott's knowingly false and fraudulent conduct, omissions, and certifications (as alleged above in this complaint). Such conduct, omissions, and certifications were material to Medi-Cal's retention of Abbott's products on the list of contracted products eligible for reimbursement and thereby material to Medi-Cal's ultimate payment of such claims.

i. Fee-For-Service (FFS) Claims Paid with Medi-Cal Funds

NDC	Paid Provider	Date Provided	No. of Units	Amount Billed	Amount Paid	Date Paid	Recipient Initials
70074053511	MDM Pharm. Services 2	06/09/20	3,600	$469.98	$352.69	06/29/20	J. H.
70074053511	Aids for Daily Living Inc.	08/07/20	3,200	$517.12	$313.51	08/17/20	V. E.
70074053511	Shield Cal. Health	10/27/20	5,600	$891.38	$548.63	11/09/20	A. A.
70074053511	Rady's Childrens Health	12/10/20	4,800	$766.68	$470.25	12/28/20	K. K.
70074053511	Long Beach Mem. Medical	02/24/21	5,600	$606.34	$545.71	03/15/21	J. R.
70074053511	JMC Pharm. Inc.	06/24/21	1,200	$156.94	$126.73	07/06/21	S. C.
70074053511	H & H Drug Stores, Inc.	11/02/21	5,600	$963.24	$591.41	11/15/21	A. A.
70074053511	River City Pharm., Inc.	01/03/22	5,200	$578.70	$520.83	03/11/22	S. L.

NDC	Paid Provider	Date Provided	No. of Units	Amount Billed	Amount Paid	Date Paid	Recipient Initials
70074064712	H & H Drug Stores, Inc.	03/17/20	2,744	$459.02	$232.68	03/30/20	T. V.
70074064712	Delta Drugs II Inc.	11/05/20	3,430	$390.00	$290.85	11/16/20	N. R.
70074064712	Valley Childrens Hosp. PH	05/11/21	3,773	$455.59	$335.81	06/28/21	Z. W.
70074064712	Rady Childrens Health	09/03/21	3,087	$487.86	$274.74	09/20/21	M. C.
70074064712	Express RX Inc.	01/18/22	4,116	$412.04	$366.34	02/11/22	Y. H.
70074055254	Rady Childrens Health	02/04/20	4,800	$766.68	$470.25	03/09/20	A. P.
70074055254	Rady Childrens Health	10/21/20	4,400	$702.79	$431.06	11/09/20	M. G.
70074055254	River City Pharm., Inc.	03/22/21	6,400	$706.47	$635.82	05/17/21	A. H.
70074055254	Long Beach Mem. Med.	08/27/21	5,600	$606.34	$545.71	09/13/21	J. R.
70074055254	Super Care, Inc.	01/18/22	6,000	$771.80	$633.64	04/12/22	N. H.
70074055254	Aids for Daily Living, Inc.	02/11/22	5,200	$840.32	$549.16	03/04/22	J. J.
70074056586	Rady Childrens Health	07/20/20	4,400	$702.79	$431.06	08/03/20	K. M.

NDC	Paid Provider	Date Provided	No. of Units	Amount Billed	Amount Paid	Date Paid	Recipient Initials
77074056586	Shield Cal. Health	10/26/20	3,600	$573.03	$352.69	11/09/20	S. T.
77074056586	Valley Childrens Hosp. PH	04/26/21	4,800	$739.80	$506.92	06/28/21	J. G.
70074056586	Dignity Health	01/18/22	7,200	$776.66	$699.00	02/11/22	S. C.
70074056586	Shield Cal. Health	02/04/22	6,000	$955.05	$633.64	03/01/22	G. S.
70074056586	Longs Drug Stores CA LLC	02/10/22	3,600	$393.38	$354.04	03/04/22	B. A.

ii. Managed Care Organization (MCO) Claims Paid with Medi-Cal Funds: Involved MCO was Inland Empire Health Plan, Riverside

NDC	Paid Provider	Date Provided	No. of Units	Amount Billed	Amount Paid	Date Paid	Recipient Initials
70074053511	Loma Linda Univ. Med. Cntr.	09/16/20	1,600	$140.73	$140.73	09/24/20	M. R.
70074053511	Delta Drugs II, Inc.	11/03/20	4,800	$420.54	420.54	11/08/20	S. S.
70074053511	Loma Linda Univ. Med. Cntr.	12/15/20	5,200	$456.20	$456.20	12/16/20	A. O.
70074064712	Delta Drugs II, Inc.	05/19/21	4,116	$346.49	$346.49	05/24/21	A. Q.
70074064712	Walgreen Co.	08/26/21	2,058	$173.46	$173.46	08/31/21	L. N.O.

NDC	Paid Provider	Date Provided	No. of Units	Amount Billed	Amount Paid	Date Paid	Recipient Initials
70074064712	Garfield Beach CVS	11/13/21	3,087	$273.62	$273.62	11/16/21	H. I.

B. Connecticut's Damages

459. When providers of enteral nutrition products submitted claims to the Connecticut Medicaid Program, those Medicaid claims identified Abbott products by their specific NDC. Those claims constituted specific representations that the Abbott products were medically appropriate and medically necessary for a Connecticut Medicaid beneficiary.

460. In many instances, the Abbott products for which providers billed claims to the Connecticut Medicaid program were not medically appropriate or medically necessary because those products were included within the Class I recall of infant formulas manufactured at Sturgis. After the recall took effect, the Connecticut Medicaid program stopped paying for certain infant formulas manufactured at Sturgis because providers of enteral nutrition products took steps to remove those products from their shelves.

461. However, the Connecticut Medicaid program did pay for certain powder infant formulas manufactured at Sturgis that were included within or otherwise impacted by the Class I recall. Abbott's actions and omissions caused pharmacy providers to present claims to the Connecticut Medicaid program for adulterated, substandard, and noncompliant infant formula.

462. The table below includes individual examples of Medicaid claims that were false because the Abbott infant formulas were included within or otherwise impacted by the Class I recall and, as such, the Abbott infant formulas were not medically appropriate or necessary:

State	Product Name	Product NDC	Date	Medicaid Billed Amount	Medicaid Paid Amount
Connecticut	Similac Alimentum Powder	70074-0647-18	July 2021	$323.20	$239.41
Connecticut	Similac PM 60/40 Powder	70074-0608-50	January 2021	$124.54	$114.10
Connecticut	Similac Alimentum Powder	70074-0647-18	January 2022	$140.77	$119.71

463. As pled above, a Class I recall 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. The Consent Decree Action and the temporary shutdown of Sturgis, in conjunction with the Class I recall, reflected a situation in which there was reasonable probability and an unacceptable risk that use of or exposure to the recalled Abbott products would adversely affect the health and safety of Connecticut Medicaid beneficiaries. A product that is subject to a safety-related recall is a product which a reasonable person would not willingly purchase or pay for. As such, the false representation that the Abbott infant formulas were medically appropriate and medically necessary was material to Connecticut Medicaid payment.

C. Commonwealth of Massachusetts' Damages

i. MassHealth Formula Claims

464. Between 2018 and 2022, MassHealth paid an estimated $732,898.86 for Abbott infant formulas manufactured at Abbott's Sturgis plant and for which Abbott was materially noncompliant with federal and state regulations. $425,676.28 were paid for by MassHealth directly through FFS, while the remaining $307,222.58 were paid via MCE claims.

ii. Representative Examples of Abbott's False and Fraudulent MassHealth Claims

465. The Commonwealth has identified numerous instances in which MassHealth paid for Abbott infant formulas manufactured at Abbott's Sturgis plant and implicated in the recall.

466. For example, on April 21, 2021, CVS Pharmacy #04471 located in Springfield, Massachusetts, dispensed 3,773 units of Similac Alimentum powder formula (NDC 70074064712) to MassHealth member G.S. The pharmacy billed the member's MCE, Tufts Health Together, $357.38 as an MCE pharmacy claim, of which Tufts Health Together paid $319.84 on April 21, 2021.

467. On November 6, 2021, Option Care Health, a DME-designated pharmacy located in Marlborough, Massachusetts, dispensed 281 units of EleCare Jr. unflavored powder formula (NDC 70074055254) to MassHealth member Y.G.D. Option Care Health billed the member's MCE, BMC HealthNet Plan, for $4,073.40 as a DME claim. BMC HealthNet Plan paid $845.81 on August 14, 2023.

468. On December 28, 2021, CVS Pharmacy #513 located in Raynham, Massachusetts, dispensed a prescription for 343 units of Similac Alimentum powder formula (NDC 70074064712) to MassHealth member D.F.-M. The pharmacy billed MassHealth $28.65 by way of a fee-for-service pharmacy claim, and MassHealth paid the claim in full on January 4, 2022.

469. On January 31, 2022, Option Care Health furnished to MassHealth member M.F. 319 units of EleCare Jr. chocolate-flavored powder formula (NDC 70074066271). Option Care Health submitted a fee-for-service DME claim for $4,656.30 to MassHealth, of which MassHealth paid $714.56 on May 17, 2022.

iii. Massachusetts's WIC Damages

470. During the relevant time period, Massachusetts's WIC program paid for tens of thousands of units of Abbott's non-compliant infant formula with a combination of federal and Massachusetts funds. As a result, Massachusetts was damaged in an amount expected to exceed $100,000

D. Maryland's Damages

471. The table below includes individual examples of Maryland Medicaid claims that were false because the Abbott infant formulas paid for were not in compliance with the applicable state and federal laws and regulations:

STATE	PRODUCT	NDC	DATE	BILLED AMT	PAID AMT
Maryland	Neosure	700405743	1/25/2020	$586.80	$195.69
Maryland	Neosure	700405743	1/20/2021	$332.78	$280.42
Maryland	Ensure	7007404070	9/11/2020	$319.47	$187.87
Maryland	Ensure	7007404070	1/20/2020	$1,330.56	$353.82
Maryland	Propimex-1	7007405113	5/21/2020	$200.20	$179.09
Maryland	Similac Alimentum	7007405750	6/9/2020	$897.60	$754.47
Maryland	Vital Af 1.2 Cal liquid	7007405654	1/8/2020	$1,942.59	$766.48
Maryland	Propimix-2	7007405113	1/11/2020	$321.12	$280.89
Maryland	Vital High Protein Liquid	7007406481	1/4/2021	$3,654.31	$549.20

E. New York's Damages

472. When providers of enteral nutrition products submitt claims to the New York Medicaid Program, those Medicaid claims identified Abbott products by their specific NDC. Those claims constituted specific representations that the Abbott products were medically appropriate and medically necessary for a New York Medicaid beneficiary.

473. The New York Medicaid program paid for certain powder infant formulas manufactured at Abbott's Sturgis facility that were included within or otherwise impacted by the Class I recall. The Abbott products that were included within the Class I recall of infant formulas manufactured at Sturgis were adulterated as they were produced or stored under conditions that created the potential for contamination or injury to health, as described above, and therefore were not medically appropriate or medically necessary for consumption by infants and children. It is unlawful in New York to sell, manufacture, distribute or offer for sale adulterated food or drugs. The New York Medicaid Program does not pay for DME, services, or supplies dispensed in violation of New York or Federal laws. As such, the false representation that the Abbott infant formulas were medically appropriate and medically necessary was material to New York Medicaid payment.

474. The table below includes individual examples of Medicaid claims that were false because the Abbott infant formulas were included within or otherwise impacted by the Class I recall and, as such, the Abbott infant formulas were not medically appropriate or necessary:

State	Product Name	Product NDC	Date	Medicaid Paid Amount
New York	ELECARE INFANT FORMULA POWDER	70074053511	9/18/2020	$380.31
New York	ELECARE JR POWDER	70074055254	11/24/2021	$338.21
New York	ELECARE JR POWDER	70074056586	5/4/2020	$725.64
New York	ELECARE JR POWDER	70074066271	3/22/2021	$563.21
New York	ELECARE JR POWDER	70074066276	8/16/2021	$760.07
New York	IMILAC ADVANCE ORGANIC POWDER	70074050822	2/15/2018	$193.23
New York	SIMILAC ADVANCE WITH IRON POWD	70074055958	10/19/2021	$164.88
New York	SIMILAC ALIMENTUM POWDER	70074064712	6/28/2018	$163.35
New York	SIMILAC ALIMENTUM POWDER	70074064718	1/9/2021	$155.52
New York	SIMILAC FOR SPIT-UP POWDER	70074053730	8/4/2020	$210.98
New York	SIMILAC GO-GROW SENSTV NON-GMC	70074064788	3/5/2020	$126.69
New York	SIMILAC NEOSURE POWDER	70074057431	10/18/2019	$115.62
New York	SIMILAC PM 60-40 POWDER	70074060850	1/4/2019	$118.79
New York	SIMILAC PRO-ADVANC NON-GMO PWI	70074068089	6/1/2021	$238.38
New York	SIMILAC PRO-SENSTV NON-GMO PWD	70074068091	9/8/2021	$208.39
New York	SIMILAC SENSITIVE FUSS-GAS PWD	70074050818	6/8/2021	$1,306.75
New York	SIMILAC SENSITIVE FUSS-GAS PWD	70074057541	8/10/2018	$122.54
New York	SIMILAC SENSITIVE FUSS-GAS PWD	70074062952	11/9/2018	$13.60
New York	SIMILAC SENSITIVE FUSS-GAS PWD	70074068083	1/7/2022	$314.67
New York	SIMILAC SOY ISOMIL POWDER	70074050820	9/14/2020	$131.31
New York	SIMILAC SOY ISOMIL POWDER	70074055964	7/9/2021	$139.16
New York	SIMILAC TOTAL COMFORT POWDER	70074062600	5/10/2019	$162.02

475. The Consent Decree Action and the temporary shutdown of Sturgis, in conjunction with the Class I recall, reflected a situation in which there was reasonable probability and an unacceptable risk that use of or exposure to the recalled Abbott products would adversely affect the health and safety of New York Medicaid beneficiaries. A product that is subject to a safety-related recall is a product which a reasonable person would not willingly purchase or pay for.

As a direct and proximate result of Abbott's conduct, the New York State Medicaid paid money to pharmacies who purchased product from Abbott, in an amount to be proven at trial. Abbott received and retained the money from pharmacies to which it was not entitled. Abbott's actions caused New York State to suffer direct monetary loss by paying for unsafe, ineffective, and adulterated products.

F. Tennessee's Damages

476. Abbott caused claims for payment to be submitted to TennCare that were false, fraudulent, misleading, and non-compliant with applicable federal and state laws, regulations, and TennCare program requirements, including the Tennessee FDCA, FDA regulatory compliance, product safety requirements, cGMP requirements, and Tennessee's medical necessity regulations.

477. Abbott caused false claims to be submitted by fraudulently concealing a systemic practice of knowingly releasing, to the most vulnerable of our population, substandard, adulterated, and non-compliant infant formula and nutritional therapy products that have been exposed to or that pose an undue risk of being exposed to microbiological contaminants, through the following acts or omissions:

- Inadequate Clean-in-Place Practices;
- Inadequate Temperature Control for Bulk Finished Product ("FP") Storage Tanks and Heat Treatment Rooms;
- Systemic Technical Equipment, Engineering, and Production Violations;
- Approving Substandard and Adulterated Products with Unvalidated Data (SQE and ZARPAC reports); Falsification of Maintenance Records;
- Systemic Seam Integrity Violations Adulterating Infant Formula;
- Protein In Fat ("PIF") Tank and Positive Displacement ("PD") Pump Violations; (Appears to be Casa Grande Specific)
- Out of Specification ("OOS") Products;
- Falsification of Batch Records;
- Providing Falsified Batch Records to FDA;

- Non-Validated "Time Code Removal" Practices to Release Batches of Products with Confirmed Microbiological and/or Other Contamination Verified by Internal Tests; and

- Ongoing Current Contamination Events on Released Batches at Sturgis, including Critical Process Calibration Failures.

478. Abbott's extensive efforts to intentionally conceal these and other questionable practices deceived TennCare, its providers and pharmacists, its members and caregivers, and also the FDA, HHS, CMS, and other federal and state authorities.

479. Specifically, Abbott knowingly made and used false records, statements, certifications, and representations material to TennCare's decision to pay only for safe and effective infant formula.

480. Abbott knew that its products and reimbursement submissions were false, non-compliant, unsafe, ineffective, misbranded, adulterated, and otherwise ineligible for TennCare reimbursement. [30]

481. The false statements and certifications from Abbott were material because TennCare would not have approved or paid the claims had it known the adulteration and falsification that occurred, including but not limited to the false claims and certifications that led to a Consent Decree of Permanent Injunction against Abbott. [31]

482. By causing the submission of these false and fraudulent claims, Abbott knowingly obtained money to which it was not entitled, thereby violating Tenn. Code Ann. § 71-5-182.

483. The table below includes individual examples of TennCare claims that were false because the Abbott infant formulas were not safe and effective:

[30] FDA Investigation of Cronobacter Infections: Powdered Infant Formula (February 2022) | FDA

[31] *United States v. Abbott Laboratories, et. al.*, Case No. 1:22-cv-00441-HYJ-SJB, [ECF No. 8], PageID.62 (W.D. Mich. May 15, 2022).

State	Product Name	Product NDC	Date	TennCare Billed Amount	TennCare Paid Amount
Tennessee	Phenex-2	70074067055	March 2022	$672.89	$545.54
Tennessee	Similac Pro-Advance Non-GMO	70074068089	January 2022	$260.82	$260.82
Tennessee	Ensure Original	70074053807	October 2022	$419.77	$413.10

484. As a direct and proximate result of Abbott's conduct, TennCare paid money to pharmacies who purchased product from Abbott, in an amount to be proven at trial. Abbott received and retained the money from pharmacies, to which it was not entitled. Abbott's actions caused TennCare to suffer direct monetary loss by paying for unsafe, ineffective, and adulterated products.

CAUSES OF ACTION

A. Claims of the State of California

COUNT 1

California False Claims Act: Knowingly Presenting or Causing False Claims Gov't Code § 12651(a)(1)

485. California realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1-115, 201-205, and 226 through 458(iii) above, as though fully set forth herein.

486. By virtue of the acts described above, Abbott knowingly caused false claims to be made, used and presented to the State of California by its violations of contractual agreements, federal and state laws and submitted false or fraudulent claims for payment for adulterated, substandard, and non-compliant infant formula and nutritional therapy products to which it was

not entitled. Abbott knew that these claims for payment were false, fraudulent, or fictitious, or were deliberately ignorant of the truth or falsity of the claims, or acted in reckless disregard for whether the claims were true or false in violation of Cal. Gov't Code § 12651(a)(1).

487. Each claim presented or caused to be presented for reimbursement for adulterated, substandard, and non-compliant infant formula and nutritional therapy products challenged herein represents a false or fraudulent claim for payment under the California FCA.

488. The State of California, by and through the California Medicaid program, was unaware of Abbott's fraudulent and illegal misrepresentation that it complied with required cGMP, federal and state law, and its contractual obligations in order to be added to and retained on the Medi-Cal Rx *List*.

489. Compliance with applicable Medicaid, the above-cited federal and state laws and regulations, and Abbott's contractual obligations was a condition of payment of claims submitted to the State of California. Had the State of California known that Abbott violated the laws cited herein, it would not have paid the claims caused to be submitted by Abbott when pharmacy providers filled beneficiary prescriptions that were on the *Medi-Cal Rx List*, nor would it have allowed Abbott's products to continue to be listed on the *Medi-Cal Rx List* as eligible for Medi-Cal reimbursement.

490. As a result of the false or fraudulent claims, the State of California has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim.

COUNT 2

California False Claims Act: False Statements Material to False Claims
Gov't Code § 12651(a)(2)

491. California realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1-115, 201-205, and 226 through 458(iii) above, as though fully set forth herein.

492. Abbott knowingly made, used, or caused to be made or used false records or statements that were material to false or fraudulent claims for payment to the California Medicaid program. Cal. Gov't Code § 12651(a)(2). That is, Abbott falsely represented or certified compliance with material statutory, regulatory, and contractual requirements for the manufacturing of infant formula and nutritional therapy products.

493. The fraudulent representations or certifications were material to, and California Medicaid actually relied on them in, determining California Medicaid reimbursement for claims for Abbott infant formula and nutritional therapy products.

494. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of Abbott's fraudulent acts and omissions, statements, and actions.

495. By reason of these false records or statements, the State of California has sustained actual damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each false or fraudulent claim and the cost of this civil action.

COUNT 3

Unjust Enrichment

496. California realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1-115, 201-205, and 226 through 458(iii) above, as though fully set forth herein.

497. If Abbott had not engaged in the acts alleged herein, Abbott would not have been unjustly enriched by retaining the use and enjoyment of State funds that Abbott should not have been paid.

498. As a result of their fraudulent conduct, Abbott are liable to the State for damages and any other relief the Court deems proper, in addition to all other remedies pleaded herein.

B. Claims of the State of Connecticut

COUNT 4

Connecticut False Claims Act: Knowingly Causing False Claims
Conn. Gen. Stat. § 4-275(a) (1)

499. Connecticut realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 116 through 121, 201, 206 through 207, 226 through 449, and 459 through 463 above, as though fully set forth herein.

500. In violation of the CTFCA, Abbott knowingly caused to be presented false or fraudulent claims for payment to the Connecticut Medicaid program. Conn. Gen. Stat. § 4-275(a)(1). Specifically, Abbott knowingly caused false claims for payment to be presented by pharmacy providers to the Connecticut Medicaid program for adulterated, substandard, and noncompliant infant formula.

501. Abbott's conduct was knowing because it possessed actual knowledge of information, acted with deliberate ignorance of the truth or falsity of information, and/or acted with reckless disregard of the truth or falsity of the information.

502. By virtue of the false or fraudulent claims, Connecticut suffered damages and therefore is entitled to statutory damages under the CTFCA, a civil penalty for each violation, and the costs of prosecution of this civil action.

COUNT 5

Connecticut False Claims Act: False Statements Material to False Claims
Conn. Gen. Stat. § 4-275(a) (1),(2)

503. Connecticut realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 116 through 121, 201, 206 through 207, 226 through 449, and 459 through 463 above, as though fully set forth herein.

504. In violation of the CTFCA, Abbott knowingly made, used, or caused to be made or used false records or statements that were material to false or fraudulent claims. Conn. Gen. Stat. § 4-275(a) (1), (2). Specifically, due to Abbott's false statements and omissions, Abbott knowingly caused false claims for payment to be presented by pharmacy providers to the Connecticut Medicaid program for adulterated, substandard, and noncompliant infant formula.

505. Abbott's conduct was knowing because it possessed actual knowledge of information, acted with deliberate ignorance of the truth or falsity of information, and/or acted with reckless disregard of the truth or falsity of the information.

506. By virtue of the false records or statements, Connecticut suffered damages and therefore is entitled to statutory damages under the CTFCA, a civil penalty for each violation, and the costs of prosecution of this civil action.

COUNT 6

Unjust Enrichment

507. Connecticut realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 116 through 121, 201, 206 through 207, 226 through 449, and 459 through 463 above, as though fully set forth herein.

508. Connecticut, through the Connecticut Medicaid program, paid for Abbott infant formulas that it should not have paid for because those infant formulas were not medically appropriate and were not medically necessary for Connecticut Medicaid beneficiaries. Specifically, Abbott caused Connecticut to pay pharmacy providers for adulterated, substandard, and noncompliant infant formula due to false statements and omissions by Abbott.

509. Abbott did not provide consideration for those Medicaid payments.

510. By virtue of its conduct described above, Abbott was unjustly enriched at the expense of Connecticut. Connecticut is entitled to recover all amounts by which Abbott was unjustly enriched, in addition to pre-judgment and post-judgment interest.

C. Claims of the Commonwealth of Massachusetts

COUNT 7

False Claims in Violation of Massachusetts False Claims Act
Mass. Gen. Laws ch., § 5B(a)(1)

511. The Commonwealth of Massachusetts realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 122 through 138, 172 through 200, 201, 208 through 213, 226 through 449, and 464 through 470 above, as though fully set forth herein.

512. During the relevant time period, Abbott violated Mass. Gen. Laws ch. 12, § 5B(a)(1) by knowingly causing a false or fraudulent claim for payment or approval to be presented to Massachusetts. Specifically, Abbott knowingly caused false claims for payment to be presented by DME and pharmacy providers under the MassHealth program for adulterated, substandard, and noncompliant infant formula.

513. MassHealth was unaware of Abbott's noncompliance with federal and regulatory requirements. If, however, MassHealth had known that Abbott was violating applicable law and supplying adulterated, substandard, and noncompliant infant formula to MassHealth beneficiaries through DME suppliers and pharmacy providers, MassHealth would not have paid those claims or would have taken other appropriate action, including by recouping payments through administrative processes, making adjustments in the claims data, or seeking return of overpayments.

514. During the relevant time period, Abbott also violated Mass. Gen. Laws ch. 12, § 5B(a)(1) by knowingly causing a false or fraudulent claim for payment or approval to be presented to Massachusetts's WIC program.

515. Specifically, Abbott knowingly caused false claims for payment to be presented to Massachusetts by retail sellers for infant formula that was adulterated, substandard, and noncompliant with applicable federal statutes and regulations and with the terms of the Massachusetts WIC contracts.

516. Abbott's conduct was knowing because it possessed actual knowledge of relevant information, acted with deliberate ignorance of the truth or falsity of information, and/or with reckless disregard of the truth or falsity of the information.

517. The administrators of the Massachusetts WIC program were unaware of Abbott's noncompliance with federal and regulatory requirements. If, however, they had known that Abbott was violating applicable law and supplying adulterated, substandard, and noncompliant infant formula to WIC beneficiaries through retailers, Massachusetts would not have paid those claims or would have taken other appropriate action, including by recouping payments through administrative processes, making adjustments in the claims data, or seeking return of overpayments. By virtue of Abbott's conduct, Massachusetts has suffered damages and is entitled to recover treble damages plus civil monetary penalties.

COUNT 8

False Records in Violation of Massachusetts False Claims Act
Mass. Gen. Laws ch. 12, § 5B(a)(2)

518. The Commonwealth of Massachusetts realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 122 through 138, 172 through 200, 201, 208 through 213, 226 through 449, and 464 through 470 above, as though fully set forth herein.

519. During the relevant time period, Abbott violated Mass Gen. Laws ch. 12, § 5B(a)(2) by knowingly making, using, or causing to be made or used, a false record or statement to obtain payment or approval of a claim by MassHealth, resulting in MassHealth reimbursing DME and pharmacy providers under the MassHealth program for adulterated, substandard, and noncompliant infant formula.

520. Specifically, Abbott knowingly made false representations regarding the safety of its infant formula, causing MassHealth to pay for claims presented by DME and pharmacy providers under the MassHealth program for adulterated, substandard, and noncompliant infant formula.

521. During the relevant time period, Abbott also violated Mass Gen. Laws ch. 12, § 5B(a)(2) by knowingly making, using or causing to be made or used false records or statement material to a false or fraudulent claim with respect to the WIC program.

522. Specifically, Abbott knowingly made records containing false representations regarding the safety of its infant formula, causing Massachusetts to pay for claims presented by retailers under the Massachusetts WIC program for adulterated, substandard, and noncompliant infant formula.

523. Abbott's bid documents to NEATO, which resulted in its selection as exclusive WIC supplier and were incorporated into the Massachusetts WIC contracts, were records containing false statements certifying that its formula complied with the relevant standards set forth in the FDCA and cGMP and were material to a false claim.

524. Abbott also created false records material to a false claim when it signed the Massachusetts WIC contracts incorporating its bid submissions in which it falsely certified that its formula complied with the relevant standards set forth in the FDCA and cGMP.

525. Abbott's conduct was knowing because it possessed actual knowledge of relevant information, acted with deliberate ignorance of the truth or falsity of information, and/or acted with reckless disregard of the truth or falsity of the information.

526. By virtue of Abbott's conduct, Massachusetts has suffered damages and is entitled to recover treble damages plus civil monetary penalties.

COUNT 9

Entering into a Contract Knowing Information Therein is False in Violation of Massachusetts False Claims Act
Mass. Gen. Laws ch. 12, § 5B(a)(8)

527. The Commonwealth of Massachusetts realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 122 through 138, 172 through 200, 201, 208 through 213, 226 through 449, and 464 through 470 above, as though fully set forth herein.

528. During the relevant time period, Abbott violated Mass Gen. Laws ch. 12, § 5B(a)(8) by knowingly entering into an agreement, contract or understanding with an official of the Commonwealth of Massachusetts knowing the information contained therein was false.

529. Specifically, Abbott entered into the Massachusetts WIC contracts in which it falsely certified that it would supply formula that complied with the relevant standards set forth in the FDCA and cGMP.

530. Abbott's conduct was knowing because it possessed actual knowledge of relevant information, acted with deliberate ignorance of the truth or falsity of information, and/or acted with reckless disregard of the truth or falsity of the information.

531. By virtue of Abbott's conduct, Massachusetts has suffered damages and is entitled to recover treble damages plus civil monetary penalties.

COUNT 10

Medicaid False Statements
Mass. Gen. Laws ch. 118E, § 40(1)

532. The Commonwealth of Massachusetts realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 122 through 138, 172

through 200, 201, 208 through 213, 226 through 449, and 464 through 470 above, as though fully set forth herein.

533. During the relevant time period, Abbott knowingly, willfully, and/or with willful blindness, caused false statements or representations of facts to be made in the submissions of claims to MassHealth.

534. Specifically, Abbott knowingly caused false claims for payment to be presented by DME and pharmacy providers to the MassHealth program for adulterated, substandard, and noncompliant infant formula. These claims for infant formula were not eligible for reimbursement under MassHealth regulations due to noncompliance with relevant state and federal regulations.

535. These misrepresentations were material as that term is interpreted by the courts.

536. By virtue of Abbott's conduct, the Commonwealth has suffered damages and is entitled to recover treble damages plus the costs of investigation and litigation, in accordance with Mass. Gen. Laws ch. 118E, § 44.

COUNT 11

Unjust Enrichment

537. The Commonwealth of Massachusetts realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 122 through 138, 172 through 200, 201, 208 through 213, 226 through 449, and 464 through 470 above, as though fully set forth herein.

538. During the relevant time period, Massachusetts's WIC program paid for adulterated, substandard, and noncompliant infant formula due to false statements and omissions by Abbott. Based on this unlawful submission, Abbott received payments from retailers, who paid Abbott and were reimbursed with Massachusetts WIC funds.

539. If Abbott had not impliedly misrepresented compliance with applicable state laws and regulations, Massachusetts would not have made these payments. By retaining monies improperly received from Massachusetts, Abbott has retained funds that are the property of the Commonwealth and to which Abbott is not entitled.

540. In addition, during the relevant time period, MassHealth paid for adulterated, substandard, and noncompliant infant formula due to false statements and omissions by Abbott. Based on this unlawful submission, Abbott received payments from DME and pharmacy providers, who receive payment from MassHealth.

541. If Abbott had not impliedly misrepresented compliance with applicable state laws and regulations, MassHealth would not have made these payments. By retaining these monies, Abbott has retained funds that are the property of the Commonwealth and to which Abbott is not entitled.

542. It is unfair and inequitable for Abbott to retain revenue from Massachusetts for payments that it obtained while its products were in violation of WIC program regulations.

543. By virtue of Abbott's conduct, Abbott has been unjustly enriched and is liable to account and pay such amounts to the Commonwealth.

D. Claims of the State of Maryland

COUNT 12

Maryland False Health Claims Act
Md. Health Gen. Code Ann. § 2-601 et seq.

544. Maryland realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 139 through 141, 201, 214 through 215, 226 through 449, and 471 above, as though fully set forth herein.

545. Under the Maryland False Health Claims Act, a person or company may not ""[k]nowingly present or cause to be presented a false or fraudulent claim for payment or approval"; "[k]nowingly make, use, or cause to be made or used a false record or statement material to a false or fraudulent claim"; "[c]onspire to commit a violation" of the False Health Claim Act; or "[k]nowingly make any other false or fraudulent claim against a State health plan or State health program." *Id.* at § 2-602(a)(1)-(3), (9).

546. Under the Maryland False Health Claims Act, "knowingly" means that a person "[h]as actual knowledge of the information;" "[a]cts in deliberate ignorance of the truth or falsity of the information;" or "[a]cts in reckless disregard of the truth or falsity of the information." *Id.* at § 2-601(f).

547. Abbott knowingly submitted, or caused to be submitted claims for reimbursement to Medicaid.

548. Each of the above-referenced submissions was a "false claim" within the meaning of the False Health Claims Act because each falsely certified compliance with applicable state laws and regulations.

549. These false claims were material to the Medicaid program in determining whether to pay the claims, and Medicaid would not have paid such claims had it known of their falsity.

550. In reliance on these false claims, the Medicaid program paid Abbott.

551. Under the False Health Claims Act, the State may obtain civil penalties of up to $10,000 for each violation of the Act, an award of three times the amount of damages sustained by the State as a result of the violations of the Act, and court costs and attorney's fees.

E. Claims of the State of New York

COUNT 13

New York False Claims Act

N.Y. State Fin. Law § 189(1)(a)

552. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

553. The State of New York seeks relief against Abbott under Section 189(1)(a) of the New York Finance Law.

554. Through the acts set forth above, Abbott, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, presented, either directly or indirectly, false or fraudulent claims for payment to the State.

555. Abbott, by and through its agents, officers, and employees, knowingly presented, or caused to be presented to New York State false or fraudulent claims for reimbursement of services provided to Medicaid beneficiaries that were not reasonable and necessary and were not medically appropriate. Accordingly, Abbott presented false submissions to the State of New York for reimbursement of Medicaid expenditures in violation of New York's False Claims Act, New York State Finance Law § 189(1)(a).

556. New York made payments to Abbott because of the false or fraudulent claims.

557. If New York had known that Abbott had made false claims, it would not have reimbursed Abbott for those claims.

558. By reason of the false or fraudulent claims, the State of New York has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each violation.

COUNT 14

New York False Claims Act

N.Y. State Fin. Law § 189(1)(b)

559. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

560. The State of New York seeks relief against Abbott under Section 189(1)(b) of the New York Finance Law.

561. Through the acts set forth above, Abbott, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, made, used, or caused to be made or used false records and statements material to false or fraudulent claims to the State. Specifically, Abbott, by and through its agents, officers, and employees, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, made, used, or caused to be made or used, false records or statements material to false or fraudulent claims paid or approved by New York State for reimbursement of services provided to Medicaid beneficiaries that were not medically appropriate. Accordingly, Abbott presented false submissions to the State of New York for reimbursement of Medicaid expenditures in violation of New York's False Claims Act, New York State Finance Law § 189(1)(b).

562. If New York had known that the records and statements were false, it would not have paid the claims.

563. By reason of these false records and statements, the State of New York has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each violation.

COUNT 15

New York False Claims Act

N.Y. State Fin. Law § 189(1)(b)

564. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

565. Abbott, by and through its agents, officers, and employees, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money to the state.

566. Abbott, acting with actual knowledge or with deliberate ignorance or reckless disregard of the truth, concealed or improperly avoided or decreased an obligation to pay or transmit money to the State of New York in violation of New York State Finance Law § 189(1)(g) and (h).

567. By reason of these false records and statements, the State of New York has sustained damages in a substantial amount to be determined at trial and is entitled to treble damages plus a civil penalty for each violation.

COUNT 16

New York Social Services Law

N.Y. Soc. Serv. Law § 145-b

568. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

569. New York Social Services Law § 145-b provides, in pertinent part, that: "It shall be unlawful for any person, firm or corporation knowingly by means of a false statement or representation, or by deliberate concealment of any material fact, or other fraudulent scheme or device, on behalf of himself or others, to attempt to obtain or to obtain payment from public funds for services or supplies furnished or purportedly furnished pursuant to this chapter."

570. As set forth above, Abbott knowingly, or acting with deliberate ignorance or in reckless disregard for the truth, deliberately concealed evidence of unsafe manufacturing practices to improperly obtain payments from the New York Medicaid Program.

571. By reason of the foregoing, Abbott is liable, pursuant to New York Social Services Law § 145-b, to the State of New York for treble damages, penalties, and costs.

COUNT 17

New York Repeated and Persistent Fraud

N.Y. Exec. Law § 63-(12)

572. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

573. New York Executive Law § 63(12) makes "repeated fraudulent . . . acts or . . . persistent fraud . . . in the carrying on, conducting or transaction of business" actionable by the Attorney General of the State of New York.

574. By engaging in the acts and practices described above, Abbott has engaged in repeated fraudulent acts or persistent fraud in violation of New York Executive Law § 63(12).

575. By reason of the foregoing, Abbott is liable to the State of New York for damages in an amount to be determined at trial.

COUNT 18

New York Repeated and Persistent Fraud

N.Y. Exec. Law § 63-(12)

576. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

577. New York Executive Law § 63(12) makes "repeated . . . illegal acts or . . . persistent . . . illegality in the carrying on, conducting or transaction of business" actionable by the Attorney General of the State of New York.

578. Abbott's violations of the New York False Claims Act, State Finance Law § 189(1), and of New York Social Services Law § 145-b constitute repeated and persistent illegal conduct in violation of New York Executive Law § 63(12).

579. By engaging in the acts and practices described above, Abbott has engaged in repeated illegal acts or persistent illegal conduct in violation of New York Executive Law § 63(12).

580. By reason of the foregoing, Abbott is liable to the State of New York for damages, in an amount to be determined at trial.

COUNT 19

Misappropriation of Public Property

N.Y. Exec. Law § 63-c

581. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

582. The acts and practices of Abbott complained of herein constitute a misappropriation of public property, in violation New York Executive Law § 63-c.

583. By reason of the foregoing, the State of New York is entitled to restitution from Abbott in an amount yet to be determined, but at least in the amount of the illegally retained and obtained Medicaid funds, plus the maximum amount of interest available under law.

COUNT 20

Common Law Fraud

584. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

585. Abbott made and/or caused to be made fraudulent statements to the United States and the State of New York, and specifically to the Medicaid Program, regarding the safety of their products and their adherence to Federal laws and regulations regarding manufacturing practices.

586. Abbott made and/or caused to be made these fraudulent material misrepresentations, failing to disclose material facts that they had a duty to disclose, with actual knowledge or belief of the false and fraudulent nature of those misrepresentations and/or with reckless disregard for the truth.

587. Abbott intended that the State of New York act or refrain from acting in justifiable reliance on these fraudulent misrepresentations.

588. The State of New York did, in fact, rely on Abbott's fraudulent misrepresentations. As a result, the State of New York paid Abbott amounts to which they were not entitled, by paying the Medicaid claims on the basis of Abbott's fraudulent misrepresentations.

589. As a result of Abbott's conduct, the State of New York suffered harm and is entitled to recovery of actual damages, in an amount to be determined at trial, plus prejudgment interest.

COUNT 21

Unjust Enrichment

590. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

591. Through the acts set forth above, Abbott received Medicaid payments from the State of New York to which it was not entitled and therefore have been unjustly enriched. The State of New York paid claims submitted to Medicaid for Abbott's products to be furnished to Medicaid recipients which products were recalled and thus adulterated, leaving New York State Medicaid recipients without the benefit of the medically appropriate services for which New York State paid.

592. The circumstances of these payments are such that Abbott has been unjustly enriched. In equity and good conscience, Abbott should not retain these payments, and are liable to account for and pay such amounts, which are to be determined at trial, to the State of New York.

COUNT 22

Payment Under Mistake of Fact

593. New York realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 142 through 158, 201, 216 through 222, 226 through 449, and 472 through 475 above, as though fully set forth herein.

594. The State of New York seeks relief against Abbott to recover monies paid under mistake of fact.

595. The State of New York paid money to Abbott based on the claims that Abbott caused to be submitted, under the erroneous belief that the claims were for services that were medically necessary and appropriate services that complied with federal and state law and regulations.

596. In making such payments, the State of New York relied upon and assumed the truth of those claims. This erroneous belief was material to the State of New York's decision to pay Abbott the amounts paid. In such circumstances, the State of New York's payments to Abbott were by mistake and were not authorized.

597. Because of these payments by mistake, Abbott received monies to which they are not entitled.

598. By reason of the foregoing, the State of New York was damaged in a substantial amount to be determined at trial.

F. Claims of the State of Tennessee

COUNT 23

Tennessee Medicaid False Claims Act
Tenn. Code Ann. § 71-5-182(a)(1)(B)

599. Tennessee realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 159 through 171, 201, 223 through 449, and 476 through 484 above, as though fully set forth herein.

600. In violation of the TMFCA, Abbott knowingly caused to be presented false or fraudulent claims for payment and knowingly made, used, or caused to be made or used false statements that were material to payment under TennCare. Tenn. Code Ann. § 71-5-182(a)(1)(B).

601. Abbott's conduct was knowing because it possessed actual knowledge or information, acted with deliberate ignorance of the truth or falsity of information, and/or acted with reckless disregard of the truth or falsity of the information.

602. By virtue of the false or fraudulent claims, Tennessee suffered damages and therefore is entitled to statutory damages under the TMFCA, a civil penalty for each violation, and the costs of prosecution of this civil action.

COUNT 24

Tennessee - Unjust Enrichment

603. Tennessee realleges and incorporates by reference all allegations in the Preliminary Statement and in paragraphs 1 through 92, 159 through 171, 201, 223 through 449, and 476 through 484 above, as though fully set forth herein.

604. Tennessee, through TennCare, paid for Abbott infant formulas that it should not have paid for because those infant formulas were not medically appropriate and were not medically necessary for TennCare beneficiaries.

605. Abbott did not provide consideration for those TennCare payments.

606. By virtue of its conduct described above, Abbott was unjustly enriched at the expense of Tennessee. Tennessee is entitled to recover all costs by which Abbott was unjustly enriched, in addition to pre-judgment and post-judgment interest.

PRAYER FOR RELIEF

WHEREFORE, the undersigned Intervening States respectfully request this Court to enter judgment for the Intervening States and against Defendant Abbott on each count of this Complaint, impose damages and penalties as described above and to the full extent allowed by law and in equity and award all costs and fees as applicable under state law.

DEMAND FOR JURY TRIAL

The Intervening States demand a jury trial on all claims alleged herein.

Dated: December 1, 2025

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, Tara T Vo, certify that on December 1, 2025, a copy of the foregoing Consolidated Complaint of the Intervening States Against Abbott Laboratories was electronically filed with the Court, and was served through the Court's electronic filing system on parties who have noticed their appearance, and through USPS First-Class Mail upon all parties below:

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