Exhibit 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MATTHEW STEELE, derivatively on behalf of ABBOTT LABORATORIES, Plaintiff, vs. LORI J. RANDALL, KEENAN S. GALE, TJ HATHAWAY, ROBERT J. ALPERN, M.D., ROXANNE S. AUSTIN, SALLY E. BLOUNT, PH.D., PAOLA GONZALEZ, MICHELLE A. KUMBIER, DARREN W. McDEW, ROBERT B. FORD, NANCY McKINSTRY, WILLIAM A. OSBORN, MICHAEL F. ROMAN, DANIEL J. STARKS, JOHN G. STRATTON, GLENN F. TILTON, ROBERT E. FUNCK, JR., JOSEPH MANNING, and CHRISTOPHER J. CALAMARI, Defendants, - and – ABBOTT LABORATORIES, Nominal Defendant.	Case No. _____ **VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT FOR WRONGFUL REFUSAL OF DEMAND** **JURY TRIAL DEMANDED**

VERIFIED STOCKHOLDER DERIVATIVE COMPLAINT

Plaintiff Matthew Steele ("Plaintiff"), by his undersigned attorneys, derivatively and on behalf of Nominal Defendant Abbott Laboratories ("Abbott" or "the Company"), files this Verified Stockholder Derivative Complaint against the Individual Defendants (defined below) for breach of fiduciary duties, aiding and abetting breach of fiduciary duties, unjust enrichment, waste of corporate assets, as well as violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5. Plaintiff alleges the following based upon personal knowledge as to Plaintiff and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff's

attorneys, which included, among other things, a review of documents produced by Abbott Laboratories in response to Plaintiff's inspection demand under 805 ILL. COMP. STAT. §5/7.75, the Defendants' filings with the United States Securities and Exchange Commission (the "SEC"), conference calls with analysts, wire and press releases published by and regarding Abbott, the proceedings in the lawsuit brought by the U.S. Department of Justice ("DOJ"), *United States v. Abbott Labs*, No. 1:22-cv-00441 (W.D. Mich. 2022), which resulted in Abbott entering into a consent decree with the U.S. Food and Drug Administration ("FDA"), a whistleblower report submitted to regulators, legal filings, news reports, analysts' reports, and information readily obtainable online. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a stockholder derivative action that seeks to remedy wrongdoing committed by certain officers and directors of Abbott from February 2019 through the present (the "Relevant Period").

2. Abbott is an Illinois corporation. Illinois requires stockholders to be holders of record to bring derivative actions in the name of a company. Plaintiff is a stockholder of record of Abbott and has continuously been a record owner at all relevant times.

3. Abbott manufactures a broad line of healthcare products, including baby formula. Abbott manufactures about 40 percent of the baby formula in the United States, nearly half of which was manufactured at the Company's Sturgis, Michigan facility and was sold under the brand names Similac, Alimentum, and EleCare.

4. The baby formula shortages in the U.S. in 2022 were largely caused by the FDA shutdown of Abbott's Sturgis facility and voluntary recall of products made there beginning in February 2022. In September 2019, FDA inspectors found violations of

federal food safety laws at the Sturgis Plant. Those violations were not fully corrected and other more serious violations were uncovered in September 2021.

5. On January 20, 2023, it was reported that Abbott is under ***criminal investigation*** by the United States Department of Justice for manufacturing tainted baby formula, which resulted in the death of at least nine children. *See* "Abbott Under Federal Criminal Investigation Over Baby Formula," THE WALL STREET JOURNAL, Jan. 20, 2023; *see also* "DOJ Launches Criminal Investigation Into Abbott Over Baby Formula Crisis," THE HILL, Jan. 21, 2023. *See also* Kevin Reed, "Seven More Children Died After Consuming Baby Formula Produced at Contaminated Abbott Labs Factory in Michigan," WSWS.ORG, June 12, 2022 ("According to newly released documents, nine children have died since 2021 after consuming powdered baby formula produced by Abbott Labs at its pediatric nutritionals factory in Sturgis, Michigan, seven more than had been previously acknowledged by the U.S. Food and Drug Administration (FDA).").

6. The Company's baby formula plant in Sturgis, Michigan is pictured below:

[The remainder of this page is intentionally left blank.]

7. Previously, the Food and Drug Administration (FDA) had announced in February 2022 that it found evidence of unsanitary conditions at the Sturgis plant and that multiple strains of bacteria that can be deadly to infants were present at the facility. It was also revealed that Abbott had previously identified incidents of contamination, necessitating the destruction of such contaminated products.

8. The deadly strains of bacteria found by the FDA at Abbott's Sturgis plant were Cronobacter sakazakii. Cronobacter infections are rare and can be deadly in newborns. Only about two to four cases are reported to the CDC every year, but this figure may not reflect the true number of illnesses.

9. Cronobacter germs can cause a dangerous blood infection called sepsis. They can also make the linings surrounding the brain and spinal cord swell (meningitis).

10. In light of these serious and potentially fatal risks to babies, the federal government's actions resulted in the closure of the Sturgis plant for a period of time in 2022.

11. Evidence also exists that, in connection with the FDA inspections and the subsequent recalls, Abbott's officers and directors breached their duty of loyalty by making false and incomplete statements to the public. On February 17, 2022, Abbott issued a press release recalling its baby formula from the Sturgis plant. In the February 17 press release, Abbott reported that: "During testing in our Sturgis, Mich., facility, we found evidence of Cronobacter sakazakii in the plant ***in non-product contact areas***" (emphasis added). However, the FDA inspection report released on March 22, 2022 contradicted that assertion, stating that Cronobacter was detected on a "scoop hopper" that was "***utilized to feed scoops, which are placed directly inside infant formula containers and contact product***" (emphasis added).

12. Likewise, Abbott stated on February 17, 2022, that "While ***Abbott's testing of finished product detected no pathogens***, we are taking action by recalling the powder formula manufactured in this facility with an expiration of April 1, 2022, or later" (emphasis added). Yet just a little over one month later, the FDA reported that "both FDA and [Abbott] found evidence of Cronobacter spp. in your powdered infant formula production environment. [Abbott] also identified Cronobacter spp. ***in finished powdered infant formula products***" (emphasis added).

13. Defendants' February 17, 2022 statements falsely downplayed the danger Abbott's infant formula posed to babies at a time when Abbott's infant formula was still for sale on store shelves and being used in the homes of thousands of families at the time.

Instead of disclosing the full truth of the threat posed by Abbott's products, Defendant Manning stated in the press release that: "We know parents depend on us to provide them with the highest quality nutrition formulas," said Joe Manning, executive vice president, nutritional products, Abbott. "We're taking this action so parents know they can trust us to meet our high standards, as well as theirs. We deeply regret the concern and inconvenience this situation will cause parents, caregivers and health care professionals."

14. In May 2022, Abbott was forced to enter into a consent decree with the U.S. Department of Justice. Abbott's Board – the individual defendants sued herein – thus had actual knowledge of the life-threatening problems with the Company's Sturgis facility and assumed direct responsibility for ensuring the Company's compliance with the consent decree.[1] As a sign of the Board's responsibility for compliance, Abbott's Chairman and CEO, Defendant Ford, was quoted in a May 16, 2022 press release by Abbott announcing the consent decree, in which Ford said "Our number one priority is getting infants and families the high-quality formulas they need, and this is a major step toward re-opening our Sturgis facility so we can ease the nationwide formula shortage. We look forward to working with the FDA to quickly and safely re-open the facility."[2]

[1] Under the consent decree, Abbott must retain outside expert assistance to bring its facility into compliance with the FDCA and good manufacturing practice regulations. Among other things, the expert will assist Abbott, under FDA supervision, in the development of plans designed to reduce and control the risk of bacterial contamination, and will periodically evaluate Abbott's compliance with the FDCA, regulations, and the consent decree.

[2] *See* "Abbott Enters into Consent Decree with U.S. Food and Drug Administration for its Sturgis, Mich., Plant," PR NEWSWIRE, May 16, 2022, available at https://www.prnewswire.com/news-releases/abbott-enters-into-consent-decree-with-us-food-and-drug-administration-for-its-sturgis-mich-plant-agreement-creates-pathway-to-reopen-facility-301548354.html.

15. In the complaint accompanying that consent decree, the Justice Department said Abbott and several of its employees (including Defendants Lori J. Randall, Keenan S. Gale, and TJ Hathaway) had caused "adulterated food" to enter interstate commerce. "Ongoing inadequacies in manufacturing conditions and practices at Defendants' facilities demonstrate that Defendants have 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," the Justice Department said in the complaint.

16. About two weeks after the consent decree was signed, FDA Commissioner Dr. Robert Califf gave sworn testimony in which he stated, "***We had no confidence in the integrity of the quality program at the facility***." Dr. Califf also described bacteria growing in multiple sites within the complex, cracks in key equipment, leaks in the roof, standing water and inadequate handwashing by staff.

17. Abbott was allowed to reopen the Sturgis plant in June 2022, subject to its obligation to comply with the consent decree. The Board of Directors had direct responsibility for ensuring compliance with the consent decree. The Board was also well aware of how failure to ensure sanitary conditions at Sturgis could lead to the death of babies, materially adverse fines, sanctions, and even criminal penalties. In 2020, the Justice Department filed criminal charges against Texas ice-cream company Blue Bell Creameries LP and its former chief executive following an investigation into a listeria outbreak tied to three deaths and other illnesses. Blue Bell agreed to pay $19 million and plead guilty to two misdemeanor charges related to shipments of contaminated ice cream. The former chief executive has pleaded not guilty to the charges.

18. That same year, Chipotle Mexican Grill Inc. said it would pay a record $25 million to resolve criminal charges stemming from a series of foodborne-illness outbreaks involving its restaurants that sickened more than 1,000 people.

19. In 2015, Stewart Parnell, the former owner of Peanut Corp. of America, was sentenced to 28 years in prison a year after being convicted of presiding over a coverup that led to a deadly salmonella outbreak.

20. On September 6, 2022, the New York Times published an article detailing how Abbott and its outside lawyers at Jones Day had used "scorched earth litigation tactics" for years to avoid liability in past cases brought by parents whose babies became sick from Abbott's baby formula. *See* David Enrich, "How Abbott Kept Sick Babies From Becoming a Scandal," THE NEW YORK TIMES, Sept. 6, 2022. The article noted that Abbott had also utilized confidentiality provisions and "gag orders" in past settlement agreements with families to avoid further publicity of the health hazards of Abbott's baby formula.

21. During the Relevant Period, the Individual Defendants breached their fiduciary duties to the Company and its shareholders, resulting in substantial damages and harm to the Company. Abbott's Board of Directors failed to adopt and implement an effective system of internal controls to ensure that material information known to management about key safety and health risk problems at Sturgis was elevated to the Board. The Board also misrepresented in Abbott's SEC filings that the Company had an effective and functioning system of internal controls.

22. In addition to the DOJ criminal investigation, Abbott has been named as a defendant in numerous consumer lawsuits that allege that babies developed necrotizing enterocolitis as a result of consuming Abbott's powdered baby formula.

23. In January 2022, the U.S. Judicial Panel on Multidistrict Litigation was asked to consolidate the consumer cases brought in federal court for pretrial purposes. The MDL subsequently granted the motion for consolidation and the cases are pending in this Court under the caption *In re Recalled Abbott Laboratories et al. Infant Formula Products Liab. Litig.*, Case No. 22-cv-2148, MDL No. 3037 (N.D. Ill.).[3]

24. On February 17, 2022, Abbott issued a recall of various infant formula products manufactured at the Sturgis facility, including Similac, Alimentum, and EleCare. Abbott did not disclose the existence of the FDA investigation, instead portraying the recall as a proactive measure to protect the public.

25. As a result of the FDA inspection which discovered the existence of the Cronobacter bacteria at the Sturgis plan, Abbott was forced to close the Sturgis facility. Abbott is one of four major companies that control some 90 percent of the infant formula supply in the United States. The closure of the plant worsened a nationwide shortage that left parents unsure where they would find more baby formula.

26. In May 2022, the White House invoked the Defense Production Act to help baby formula manufacturers obtain necessary ingredients and launched Operation Fly Formula, importing product from around the world to stock store shelves. Those efforts offered some help, but there were still widespread shortages on grocery shelves.

27. On March 22, 2022, the FDA released reports from three inspections of the Sturgis facility conducted in September 2019, September 2021 and, most recently, between

[3] Lawsuits were also filed, and are pending, in Canada, seeking to represent a class of Canadian infants who suffered similar injuries after ingesting Abbott's baby formula. The Canadian lawsuits seek various damages, including punitive damages from Abbott's concealment of violations of safety protocols at the Sturgis facility that resulted in the development of Cronobacter sakazakii bacteria.

January 31, 2022 and March 18, 2022. The FDA reports concluded that (a) Abbott failed to establish process controls "designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment" and (b) Abbott failed to "ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source."

28. In response to the disclosure of these reports, Abbott's stock price dropped $4.97 per share, or 4%, from a closing price of $121.89 per share on March 22, 2022, to a closing price of $116.92 per share on March 23, 2022.

29. On April 28, 2022, a redacted copy of a 34-page whistleblower complaint sent to the FDA in October 2021 was made public. ***See*** **Exhibit A**.

30. The whistleblower employee worked in Quality Systems ("QS"), a subunit of the Quality Assurance organization ("QA") in Sturgis, Michigan ("Sturgis site") as part of Abbott's Nutritional Division. The whistleblower alleged that Abbott's management was aware of health and safety issues at the Sturgis facility well before the FDA inspection, and that Abbott management falsified test records and released untested infant formula to the market. In addition, the whistleblower alleges that Abbott management attempted to mislead the FDA during a 2019 inspection audit about serious existing safety problems with the Company's baby formula. The whistleblower complaint also details additional wrongdoing by Abbott management at Sturgis, including the falsification of testing records, the release of untested baby formula to the market, and Abbott's efforts to mislead the FDA during its 2019 inspection audit.

31. In March 2022 testimony before a House of Representatives Subcommittee, FDA Commissioner Dr. Robert Califf stated that there were bacteria growing at multiple sites in the Sturgis facility, cracks in key equipment, roof leaks, and standing water which were unsanitary. Dr. Califf stated that FDA had lost confidence that the Company had "the appropriate safety and quality culture and commitment to fix these problems quickly."

32. On May 17, 2022, the Senate Finance Committee requested information on how much Abbott spent on upgrades to its Sturgis facility prior to its closure due to bacterial contamination, and whether the Company used billions in tax cuts to repurchase its stock instead of investing in the Sturgis facility. Committee Chairman, Sen. Ron Wyden, sent a letter to Abbott's Chief Executive Officer, Defendant Robert B. Ford, which stated "[a]s Abbott spent billions buying back its own stock, it appears that it failed to make necessary repairs to fix a critical manufacturing plant of infant formula located in Michigan . . . [t]he closure of the plant has contributed substantially to a national shortage of infant formula, putting families across the country at risk."

33. On May 25, 2022, Defendant Calamari testified on behalf of Abbott at a hearing concerning the baby formula shortage held by the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations. During his testimony, Calamari repeatedly stated that Abbott was unaware of the whistleblower's complaints until late April 2022, when the complaint submitted to the FDA was publicly disclosed by a member of Congress. For example, Calamari stated:

> Abbott did not find out about it [the whistleblower complaint] until it was made public in the end of April and it was the particular individual who raised the complaint . . . it was their choice to use that mechanism to raise the complaint.

34. This and similar statements made by Defendant Calamari during the May 25, 2022 congressional hearing were false and misleading when made. On June 8, 2022, it was disclosed that the Company was aware of the allegations in the whistleblower complaint in early 2021, when the complaint was filed with the U.S. Labor Department's Occupational Safety & Health Administration ("OSHA") and delivered to both Abbott and the FDA. The Company's response was submitted two months later.

35. The news that Abbott received the whistleblower's complaint in early 2021 revealed that executives at Abbott's highest levels were informed of the safety violations one year prior to the formula recall, despite statements denying any knowledge of the whistleblower's complaints prior to April 2022. This news caused a precipitous decline in the market price of Abbott common stock. Specifically, in response to these disclosures, the price of Abbott common stock declined $4.17 per share, or 3.5%, from a closing price of $116.88 per share on June 7, 2022, to a closing price of $112.71 per share on June 9, 2022. The stock continued to decline in the following months, eventually reaching as low as $93.

36. Abbott has also been sued by its stockholders for securities fraud. On August 31, 2022, a securities class action was filed in this Court -- *Pembroke Pines Firefighters & Police Officers Pension Fund v. Abbott Laboratories, et al.*, Case No. 1:22-cv-4661 (N.D. Ill.) (the "Securities Action"), exposing the Company to millions of dollars in potential liability.

II. JURISDICTION AND VENUE

37. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1332. There is complete diversity among the parties and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

38. The Court also has subject matter jurisdiction pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, over the claims asserted herein for, inter alia, violations of Section 10(b) of the Exchange Act, 15 U.S.C.§ 78(j), and the rules promulgated thereunder. This Court has supplemental jurisdiction over the state law claims asserted herein under 28 U.S.C.§ 1367.

39. In connection with the acts, conduct and other wrongs complained of herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, the United States mail, and the facilities of a national securities market.

40. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) because Nominal Defendant Abbott is incorporated in Illinois and maintains its corporate headquarters in this District, because many of the Defendants are Illinois citizens, and because a substantial part of the wrongful conduct occurred in this District.

III. PARTIES

41. Plaintiff Matthew Steele is a current shareholder of record of Abbott and has been a continuous owner of record of Abbott at all relevant times, including continuously since approximately 1992. Plaintiff owns over 6,000 shares of Abbott stock. Plaintiff is a citizen of Canada.

42. Nominal Defendant Abbott Laboratories is an Illinois corporation which is headquartered at 100 Abbott Park Road, Abbott Park, Illinois. Abbott's common stock trades on the NYSE under ticker "ABT." Abbott is a citizen of Illinois.

43. Defendant Robert B. Ford ("Ford") is Abbott's Chairman of the Board ("Chairman") and Chief Executive Officer ("CEO"). Ford was appointed as the Company's CEO in March 2020 and became Chairman in December 2021. Ford is a citizen of Illinois.

44. Defendant Robert J. Alpern, M.D. ("Alpern") is, and at all times relevant hereto has been, a director of Abbott. Alpern is a member of the Nominations and Governance Committee and the Public Policy Committee. Alpern is a citizen of Connecticut.

45. Defendant Roxanne S. Austin ("Austin") served as a Director of Abbott during the Relevant Period from 2000 to 2022. Austin served as a member of the Company's Compensation (Chair), Nominating and Governance, and Executive Committees. Austin also serves on the Boards of Abbvie and Verizon. Austin is a citizen of California.

46. Defendant Sally E. Blount, Ph.D. ("Blount") is, and at all times relevant hereto has been, a director of Abbott. Blount is a member of the Nominations and Governance Committee and the Public Policy Committee. Blount is a citizen of Illinois.

47. Defendant Paola Gonzalez ("Gonzalez") is, and at all times relevant hereto has been, a director of Abbott. Gonzalez is a member of the Audit Committee. Gonzalez is a citizen of California.

48. Defendant Michelle A. Kumbier ("Kumbier") is, and at all times relevant hereto has been, a director of Abbott. Kumbier is a member of the Audit and Compensation Committees. Kumbier is the Senior Vice President and President, Turf & Consumer Products of Briggs & Stratton, LLC. Kumbier is a citizen of Wisconsin.

49. Defendant Darren W. McDew ("McDew") is, and at all times relevant hereto has been, a director of Abbott. McDew is a member of the Nominations and Governance Committee and the Public Policy Committee, and Audit and Compensation Committees. McDew is a citizen of North Carolina.

50. Defendant Nancy McKinstry ("McKinstry") is, and at all times relevant hereto has been, a director of Abbott. McKinstry is Chair of the Audit Committee, and a member of the Compensation and Executive Committees. McKinstry is also Chief Executive Officer and Chairman of the Executive Board of Wolters Kluwer N.V. and a board member of Accenture. McKinstry is a citizen of the Netherlands.

51. Defendant William A. Osborn ("Osborn") is, and at all times relevant hereto has been, a director of Abbott. Osborn is Chair of the Nominations and Governance Committee, and a member of the Compensation and Executive Committees. Osborn is a citizen of Illinois.

52. Defendant Michael F. Roman ("Roman") is, and at all times relevant hereto has been, a director of Abbott. Roman is a member of the Audit and Compensation Committees. Roman has also been Chairman of the Board, President and Chief Executive Officer of 3M Company since May 2019. Roman is a citizen of Minnesota.

53. Defendant Daniel J. Starks ("Starks") is, and at all times relevant hereto has been, a director of Abbott. Starks is a member of the Public Policy Committee. Starks is a citizen of Minnesota.

54. Defendant John G. Stratton ("Stratton") is, and at all times relevant hereto has been, a director of Abbott. Stratton is a member of the Audit and Public Policy Committees, and a member of the Compensation and Executive Committees. Stratton has also served as the Executive Chairman of Frontier Communications Parent, Inc. since April 2021. Stratton is a citizen of Connecticut.

55. Defendant Glenn F. Tilton ("Tilton") is, and at all times relevant hereto has been, a director of Abbott. Tilton is Chair of the Public Policy Committee, the Audit Committee, and the Executive Committee. Tilton also serves as Chairman, President and Chief Executive Officer of UAL Corporation, an airline holding company, and sits on the Boards of Abbvie and Phillips 66. Tilton also serves on the board of trustees for the Field Museum and the Museum of Science and Industry, and the board for the Economic Club of Chicago, the Executives' Club of Chicago, and After School Matters, as well as on the civic committee of the Commercial Club of Chicago. Tilton is a citizen of Illinois.

56. The defendants in ¶¶43-55 are collectively referred to herein as the "Director Defendants."

57. Defendant Lori J. Randall ("Randall") is Abbott Nutrition's Division Vice-President of Quality Assurance. Defendant Randall has overall responsibility for quality operations for global Abbott Nutrition, which includes, but is not limited to, oversight of manufacturing locations and food safety, product quality, supplier quality, compliance, complaint management, and corrective and preventive actions. Defendant Randall was

responsible for approving the decision made during the FDA's inspection at Sturgis to initiate a recall of certain infant formulas manufactured at Sturgis. Defendant Randall performs her duties at Abbott Laboratories' corporate office located in Abbott Park, Illinois, where she conducts her oversight duties for Abbott Laboratories' manufacturing sites including, but not limited to, the Sturgis facility. Randall is a citizen of Michigan.

58. Defendant Keenan S. Gale ("Gale") holds the title of Director of Quality at Sturgis and oversees all quality assurance including, but not limited to, sanitation, compliance, and corrective and preventive actions. Defendant Gale has the authority to detect, correct, and prevent violations of the FDA and its implementing regulations. Defendant Gale performs his duties at Sturgis's location. Gale is a citizen of Michigan.

59. Defendant TJ Hathaway ("Hathaway") is the Site Director at Sturgis. Defendant Hathaway has identified himself as the most responsible individual at the Sturgis facility. Defendant Hathaway is responsible for ensuring the safety and quality of products made at Abbott's Sturgis plant. Defendant Hathaway performs his duties at Abbott's Sturgis plant. Hathaway is a citizen of Michigan.

60. Defendant Robert E. Funck, Jr. ("Funck") is, and at all times relevant hereto has been, Abbott's Chief Financial Officer ("CFO") and Vice President, Finance since March 2020. Funck is a citizen of Illinois.

61. Defendant Joseph Manning ("Manning") is, and since December 2021 has been, Abbott's Executive Vice President, Nutritional Products. Manning is a citizen of Illinois.

62. Defendant Christopher J. Calamari ("Calamari") is, and at all times relevant hereto has been, Abbott's President of Nutrition, North America and Senior Vice President for U.S. Nutrition. Calamari is a citizen of Illinois.

63. The defendants in ¶¶57-62, along with Defendant Ford, are collectively referred to herein as the "Officer Defendants." The Officer Defendants and the Director Defendants are collectively referred to herein as the "Individual Defendants."

FIDUCIARY DUTIES OF THE DEFENDANTS

64. By reason of their positions as officers, directors and/or fiduciaries of Abbott and because of their ability to control the business and corporate affairs of the Company, the Individual Defendants owe Abbott and its shareholders fiduciary obligations of trust, loyalty, good faith and due care, and were and are required to use their utmost ability to control and manage Abbott in a fair, just, honest and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of the Company and its shareholders so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.

65. Each director and officer of the Company owes to Abbott and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the affairs of the Company and in the use and preservation of its property and assets, and the highest obligations of fair dealing.

66. The Individual Defendants, because of their positions of control and authority as directors and/or officers of the Company, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

67. To discharge their duties, the officers and directors of the Company were required to exercise reasonable and prudent supervision over the management, policies, practices and controls of the affairs of the Company. By virtue of such duties, the officers and directors of the Company were required to, among other things:

(a) ensure that the Company complied with its legal obligations and requirements;

(b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(c) remain informed as to how the Company conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices; and

(d) ensure that the Company was operated in a diligent, honest and prudent manner in compliance with all applicable federal, state and local laws, rules and regulations.

68. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of

Case 1:21-cv-05013 Document #: 1-2 Filed: 04/18/25 Page 21 of 146 PageID #:59

the Company, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company. The conduct of the Individual Defendants who were also officers and/or directors of the Company has been ratified by the remaining Individual Defendants who collectively comprised all of the Company's Board at all relevant times.

69. At times relevant hereto, defendants were the agents of each of the other defendants and were at all times acting within the course and scope of such agency.

CONTROL, ACCESS, AND AUTHORITY

70. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Abbott, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by the Company.

71. Because of their advisory, executive, managerial, and directorial positions with the Company, each of the Individual Defendants had access to adverse, non-public information about the financial condition, operations, and improper representations of the Company, including information regarding Abbott's Sturgis facility.

72. At all times relevant hereto, each of the Individual Defendants was the agent of each of the other Individual Defendants and of the Company, and was at all times acting within the course and scope of such agency.

REASONABLE AND PRUDENT SUPERVISION

73. To discharge their duties, the officers and directors of the Company were required to exercise reasonable and prudent supervision over the management, policies,

practices and internal controls of the Company. By virtue of such duties, the officers and directors of the Company were required to, among other things:

(a) adopt and implement an effective system of internal controls to elevate known safety and regulatory problems at the Company's manufacturing facilities to the Board's attention;

(b) ensure that the Company complied with its legal obligations and requirements, including acting only within the scope of its legal authority and disseminating truthful and accurate statements to the investing public;

(c) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets, and to maximize the value of the Company's stock;

(d) properly and accurately guide investors and analysts as to the true financial condition of the Company at any given time, including making accurate statements about the Company's internal controls and financial results;

(e) remain informed as to how the Company conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith, and take steps to correct such conditions or practices and make such disclosures as necessary to comply with securities laws; and

(f) ensure that the Company was operated in a diligent, honest, and prudent manner in compliance with all applicable laws, rules, and regulations.

BREACHES OF DUTIES

74. Each Individual Defendant, by virtue of his or her position as a director and/or officer, owed to the Company and to its shareholders the fiduciary duty of loyalty and good faith and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its

property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and officers of the Company, the absence of good faith on their part, and a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

75. The Individual Defendants each breached their duty of loyalty and good faith by allowing Defendants to cause, or by themselves causing, the Company to make false and/or misleading statements and or failing to disclose: (1) the Company lacked effective internal controls regarding safety and regulatory compliance at the Company's Sturgis plant; (2) the Company's financial statements were inaccurate because the Company failed to disclose the known health and safety problems at the Sturgis plant, and misrepresented that the Company's internal controls were adequate and functioning effectively; and (3) the Individual Defendants lacked a basis for their positive statements about the Company's prospects and growth. In addition, as a result of the Individual Defendants' illegal actions and course of conduct, the Company is now the subject of a criminal investigation by the DOJ and class action lawsuits by consumers and investors. As a result, the Company has expended, and will continue to expend, significant sums of money to rectify the Defendants' wrongdoing.

CONSPIRACY, AIDING AND ABETTING, AND CONCERTED ACTION

76. In committing the wrongful acts alleged herein, the Individual Defendants have pursued, or joined in the pursuit of, a common course of conduct, and have acted in concert with and conspired with one another in furtherance of their wrongdoing. The

Individual Defendants further aided and abetted and/or assisted each other in breaching their respective duties.

77. During all times relevant hereto, the Individual Defendants collectively and individually initiated a course of conduct that was designed to and did conceal the fact that: (1) the Company lacked effective internal controls regarding safety and regulatory compliance at the Company's Sturgis plant; (2) the Company's financial statements were inaccurate because the Company failed to disclose the known health and safety problems at the Sturgis plant, and misrepresented that the Company's internal controls were adequate and functioning effectively; and (3) the Individual Defendants lacked a basis for their positive statements about the Company's prospects and growth. In furtherance of this plan, conspiracy, and course of conduct, the Individual Defendants collectively and individually took the actions set forth herein.

78. The Individual Defendants engaged in a conspiracy, common enterprise, and/or common course of conduct. During this time, the Individual Defendants caused the Company to issue false financial results based upon sales of the Company's baby formula despite knowledge of health and safety violations and bacterial contamination at the Company's Sturgis plant that had been brought to their attention by a whistleblower and which were reasonably likely to lead to a product recall, governmental investigations, and consumer lawsuits for personal injury and death.

79. The purpose and effect of the Individual Defendants' conspiracy, common enterprise, and/or common course of conduct was, among other things, to: (i) disguise the Individual Defendants' violations of law, including breaches of fiduciary duty and unjust

enrichment; and (ii) disguise and misrepresent the Company's existing and future business prospects.

80. The Individual Defendants accomplished their conspiracy, common enterprise, and/or common course of conduct by causing the Company to falsely represent that the Company had adequate internal controls in place, by failing to disclose adverse, known, material health and safety problems at the Company's Sturgis plant that endangered the health of infants, and by purposefully, recklessly, or negligently causing the Company to release improper statements. Because the actions described herein occurred under the authority of the Board, each of the Individual Defendants was a direct, necessary, and substantial participant in the conspiracy, common enterprise, and/or common course of conduct complained of herein.

81. Each of the Individual Defendants aided and abetted and rendered substantial assistance in the wrongs complained of herein. In taking such actions to substantially assist the commissions of the wrongdoing complained of herein, each Individual Defendant acted with knowledge of the primary wrongdoing, substantially assisted the accomplishment of that wrongdoing, and was aware of his or her overall contribution to and furtherance of the wrongdoing.

IV. FACTUAL ALLEGATIONS

A. Abbott's Baby Formula Products and the Highly Regulated Nature of Abbott's Operations

82. Abbott Laboratories is an American multinational medical devices and health care company with its headquarters in Abbott Park, Illinois, United States. Abbott's products are currently distributed and sold in over 160 countries. In 2021, Abbott Laboratories' gross sales were $43.1 billion.

83. Abbott operates in a highly regulated field and its products are subject to oversight and regulation by numerous federal agencies, including the FDA.

84. Because its products, if adulterated, can pose a threat of sickness or death to persons who consume the products, Abbott's compliance with federal and state regulations concerning its products is of the utmost importance. Abbott's directors thus have a paramount obligation to ensure that Abbott adheres to all safety and health regulations. The bacterial risk in powdered infant formula — which is not sterile, unlike liquid formula — has been well known among formula producers, food safety scientists and federal regulators for years.

85. While Cronobacter is harmless to most, it can be debilitating or deadly for newborns and others with weak immune systems, where it can cause fatal courses of meningitis.

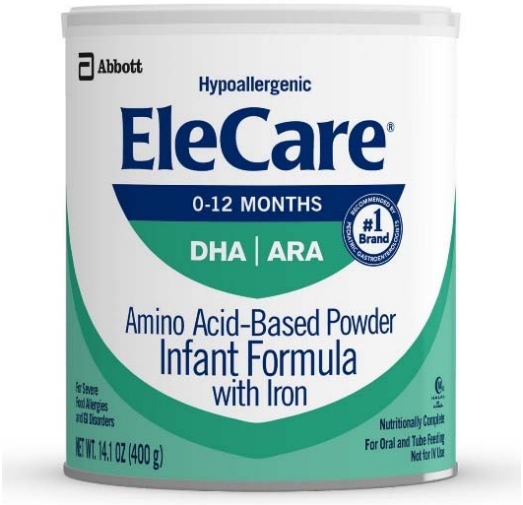
86. Abbott's directors had a fundamental obligation to design and implement a robust system of internal controls to ensure that the directors received detailed, regular reports from management on the key safety and regulatory risks facing the Company, including the safety and regulatory risks existing at the Company's Sturgis plant. The Director Defendants failed to do so, as alleged herein.

87. During the Relevant Period, Abbott, through Abbott Nutrition, was and is engaged in the manufacture, distribution, marketing, and sale of several powdered infant formula brands, including the contaminated product brands Similac®, Similac PM 60/40 ®, Alimentum® and EleCare®.

88. In addition to Similac, Abbott manufactures, markets, and distributes several different types of specialty infant formula products. Abbott advertises that its

specialty infant formulas are a safe alternative for infants who suffer from pre-existing health conditions or severe food allergies, and, in doing so, targets an especially at-risk subset of an already vulnerable class of consumers. EleCare Powdered Infant Formula on Abbott's website and the product's front label advertise that EleCare is "#1 Recommended by Pediatric Gastroenterologists" and safe for "Severe Food Allergies and GI Disorders." Abbott also states that the product is "clinically shown to support the growth of exclusively formula-fed infants . . . EleCare helps manage symptoms of severe food allergies and various gastrointestinal (GI) conditions." EleCare is advertised as "Hypoallergenic" and safe for infants with gastrointestinal conditions, and severe food allergies.

89. For example, Abbott's promotional materials state: "Help your child—help yourself—feel better. Talk to your doctor about EleCare or EleCare Jr. They are amino acid-based, hypoallergenic formulas for infants and children with severe food allergies and various GI disorders. If your child has severe food allergies or a gastrointestinal (GI) disorder, mealtime isn't always a comforting occasion. Help your child — and yourself — feel better." The following is a picture of the Company's EleCare formula:



90. Abbott also advertises that its Similac baby formula is good for babies with health issues. Abbott represents that the product is designed "[f]or infants who would benefit from lowered mineral intake, including those with impaired renal function. Calcium-to-phosphorus ratio and content designed to manage serum calcium disorders - both hypercalcemia and hypocalcemia due to hyperphosphatemia."[4]

91. The following is a picture of the Company's Similac baby formula:

92. Abbott's Similac Alimentum is advertised and promoted as "suitable for lactose sensitivity and has broken-down protein that is easy to digest for babies with food allergies or colic due to protein sensitivity;" containing "an immune-nourishing ingredient" and as reducing "excessive crying and colic symptoms due to protein sensitivity within 24 hours."

93. The following is a picture of the Company's Similac Alimentum baby formula:

[4] *See* https://abbottstore.com/infant-and-child/similac/similac-pm-60/similac-pm-60-40-infant-formula-powder-14-1-oz-can-case-of-6-00850.html (last visited Feb. 6, 2023).

94. Abbott's baby formula is a food product subject to federal regulation, and must be manufactured in compliance with the current good manufacturing practice requirements ("CGMP") established by FDA regulations. Those regulations require Abbott to design and implement a system of controls to safeguard all stages of manufacturing, including specific controls to prevent adulteration of infant formula from microorganisms and bacteria.

95. Abbott is also subject to detailed record-keeping requirements, which include the obligation to maintain procedures for handling all written and oral complaints. The FDA regulations require Abbott to conduct an investigation when it receives any complaint regarding a potential health hazard. A failure to investigate any complaint renders infant formula produced under those conditions "adulterated" under the terms of the controlling statute.

B. The Director Defendants Learned of Life-Threatening Health and Safety Violations at the Sturgis Facility From Past Warnings From the FDA, Lawsuits and Whistleblower Complaints

96. In February 2021, the Individual Defendants were aware of numerous violations of FDA regulations governing the manufacture of infant formula products at Abbott's Sturgis facility that posed significant health and safety risks to infants.

97. Federal food safety scientists met as early as 2003 with representatives of the major formula companies, including Abbott, to discuss Cronobacter risk. An Abbott representative acknowledged to the FDA and Center for Disease Control and Prevention officials that Cronobacter had proven to be "a little bit more ubiquitous" in the powdered formula production process than previously thought, according to a transcript obtained by The Washington Post.[5]

98. After representatives of all three major companies said there was no way to sterilize the powder, the FDA issued a requirement that every batch of powdered infant formula be tested for Cronobacter and salmonella, according to an FDA spokeswoman.

99. In 2012, after another formula-related Cronobacter outbreak, federal officials discussed the risk to newborns whose families were enrolled in the federal food assistance program known as WIC.

100. In February 2021, a whistleblower at Abbott filed a complaint about these health and safety violations with OSHA. The Company filed a non-public response to the complaint two months later. Thus, the Individual Defendants had actual knowledge of the

[5] *See* Jacob Bogage, "Justice Department Opens Investigation Into Abbott Over Baby Formula," THE WASHINGTON POST, Jan. 20, 2023.

material problems at Sturgis that posed a risk of sickness and death to infants who consumed its baby formula manufactured at Sturgis.

101. In October 2021, a whistleblower sent a 34-page report to the FDA alleging a host of unsanitary conditions at Abbott's Sturgis facility, months before the first baby became sick with bacterial infections after ingesting formula made at the plant.

102. The former employee detailed instances of falsification of records and safety violations, including the release of batches of formula after the discovery of microorganisms. ***The whistleblower claimed there were active efforts to keep FDA inspectors from learning about the microorganisms in the formula and that Abbott employees "even celebrated during and after the 2019 FDA audit."***

103. The whistleblower also alleged that in 2020 there were significant problems with the seams on cans of Similac, which left the contents vulnerable to pathogens.

104. Rather than work to remediate these issues, the Individual Defendants attempted to silence and discredit the whistleblower and other concerned employees and mislead the FDA and the public regarding the safety issues arising from the problems at the Sturgis facility.

105. It was not until a year later, when the report of infant deaths connected to Abbott's baby formula was reported to the FDA, and the FDA finally acted on the whistleblower's allegations, that the Company was forced to recall its infant formula in February 2022, and later discontinue operations at the Sturgis facility. The Individual Defendants' wrongdoing and failure to immediately address the life-threatening conditions at Sturgis ultimately forced Abbott to enter into a consent decree with the United States Department of Justice.

106. The Director Defendants' knowledge of material problems at Sturgis in fact pre-dated by many years the whistleblower's complaint that was filed in February 2021 with OSHA. For years prior to this, Abbott had been sued by the families of infants who had been gravely sickened from consuming its baby formula due to unsanitary conditions at Abbott's manufacturing operations.

107. On September 6, 2022, the New York Times published an article detailing how Abbott and its outside lawyers at Jones Day had been using "scorched earth litigation tactics" for years to avoid liability in cases brought by parents whose babies became sick from Abbott's baby formula. *See* David Enrich, "How Abbott Kept Sick Babies From Becoming a Scandal," THE NEW YORK TIMES, Sept. 6, 2022. The article noted that Abbott had also utilized confidentiality provisions and "gag orders" in past settlement agreements with families to avoid further publicity of the health hazards of Abbott's baby formula.

108. For over a decade prior to the February 2022 recall of its baby formula due to Cronobacter contamination, Abbott had been fighting lawsuits alleging that infants had contracted life-threatening illnesses and suffered brain damage from consuming its powdered baby formula. In one such case involving a girl named Jeanine Kunkel that was pending in 2013 in Ohio, Abbott's lawyers at Jones Day were alleged to have engaged in such scorched earth litigation tactics. Judge Mark Bennett, who presided over the trial, described the conduct of Abbott's lawyers as "the worst by a factor of ten" that he had seen in his twenty years on the bench.[6] After consuming Abbott's baby formula, Ms. Kunkel suffered severe brain damage and was left unable to feed or dress herself, speak, or swallow.

[6] *Id.*

109. Another past lawsuit against Abbott involved Slade Sisk, who developed severe brain damage in 2004 after consuming Abbott's Similac powdered baby formula. The family hired an attorney, who filed suit in North Carolina in 2007. Slade's mother, who lived in a mobile home and worked as a house cleaner, faced a lifetime of medical costs to care for Slade. Once again, Abbott's lawyers allegedly employed scorched earth litigation tactics to grind down the plaintiff through numerous motions having nothing to do with the merits of the case, thereby increasing the costs and delaying the case. For example, Jones Day filed a motion to disqualify the plaintiff's lawyers on the basis that the lawyers had unknowingly contacted an expert in a different case in a different state that had an ongoing relationship with Abbott. Even though the other case had nothing to do with Mr. Sisk's case, the judge disqualified the plaintiff's lawyers and Slade was left without a lawyer.[7] After Slade's mother was finally able to retain another lawyer and the complaint was re-filed, Abbott removed the case to federal court, essentially restarting the case.[8]

110. Jones Day's tactics allowed Abbott to drag out Slade's case until 2014, a full decade after it was filed. Immediately after trial, Abbott's lawyers moved to seal certain documents and trial testimony about Abbott's testing and food safety protocols and about its "sanitation, housekeeping and hygiene" on the grounds that the information involved confidential information. The judge granted the motion, thus sealing information about Abbott's Sturgis facility.[9]

---

[7] *Id.,* David Enrich, "How Abbott Kept Sick Babies From Becoming a Scandal," THE NEW YORK TIMES, Sept. 6, 2022.

[8] *Id.*

[9] *Id.*

111. In addition to being presented with updates during their tenure on the Board of Directors of these past lawsuits alleging that infants were gravely sickened after consuming Abbott's powdered baby formula manufactured at Sturgis, the Board of Directors was also aware of a past Corporate Integrity Agreement that Abbott had been forced to enter into which imposed heightened, direct obligations on the Board itself to ensure Abbott's compliance with FDA regulations. In 2012, the Department of Justice announced that Abbott Laboratories pleaded guilty and agreed to pay $1.5 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of the prescription drug Depakote for uses not approved as safe and effective by the FDA.

112. The FDA is responsible for approving drugs as safe and effective for specified uses. Under the Food, Drug and Cosmetic Act (FDCA), a company in its application to the FDA must specify each intended use of a drug. A company's promotional activities must be limited to only the intended uses that are FDA approved. In fact, promotion by the manufacturer for other uses – known as "off-label" uses – renders the product misbranded.

113. The FDA approved Depakote for only three uses: epileptic seizures, bipolar mania and the prevention of migraines. The FDA never approved the drug as safe and effective for the off-label use of controlling behavioral disturbances in dementia patients. In 1999, Abbott was forced to discontinue a clinical trial of Depakote in the treatment of dementia due to an increased incidence of adverse events, including somnolence, dehydration and anorexia experienced by the elderly study participants administered Depakote.

114. Abbott pleaded guilty to misbranding Depakote by promoting the drug to control agitation and aggression in elderly dementia patients and to treat schizophrenia when neither of these uses was FDA approved. In an agreed statement of facts filed in the criminal action, Abbott admitted that from 1998 through 2006, the company maintained a specialized sales force trained to market Depakote in nursing homes for the control of agitation and aggression in elderly dementia patients, despite the absence of credible scientific evidence that Depakote was safe and effective for that use. In addition, from 2001 through 2006, the company marketed Depakote in combination with atypical antipsychotic drugs to treat schizophrenia, even after its clinical trials failed to demonstrate that adding Depakote was any more effective than an atypical antipsychotic alone for that use.

115. Abbott agreed to a plea agreement, pursuant to which Abbott paid a criminal fine of $500 million, forfeited assets of $198.5 million, and submitted to a term of probation for five years. In addition, Abbott also paid $1.5 million to the Virginia Medicaid Fraud Control Unit.

116. As a condition of probation, Abbott was required to report any probable FDCA violations to the probation office, its CEO was required to certify compliance with this reporting requirement, and the Board of Directors was required to report annually on the effectiveness of the company's compliance program. In addition to the criminal and civil resolutions, Abbott also executed a Corporate Integrity Agreement (CIA) with the Department of Health and Human Services, Office of Inspector General (HHS-OIG). The five-year CIA required that Abbott's board of directors review the effectiveness of the

company's compliance program, that high-level executives certify to compliance, and that Abbott maintain standardized risk assessment and mitigation processes.

117. During the five-year term of the CIA, Abbott was subject to exclusion from federal health care programs, including Medicare and Medicaid, for a material breach of the CIA and subject to monetary penalties for less significant breaches. Abbott's settlement with the DOJ also required it to appoint a Chief Compliance Officer with direct reporting to the Board on the Company's compliance with FDA regulations.

118. Defendant Funck, who was Abbott's V.P., Chief Ethics and Corporate Compliance officer at the time, signed the CIA on May 4, 2012. Defendants Alpern, Blount, McKinstry, Osborn, and Tilton were on the Board at the time and also had to approve the CIA and had direct responsibility for ensuring compliance with the CIA. Defendant Starks also joined the Board in 2017, during the term of the CIA, and thus also assumed direct responsibility for compliance.

119. These facts serve to highlight the enhanced scrutiny that Abbott's Board was required to exercise over the Company's compliance programs, internal controls, and FDA regulations.[10]

C. The FDA's Inspections of Abbott's Sturgis, Michigan Plant and the Violations Cited by the FDA, Resulting in the Temporary Cessation of Operations at Sturgis

120. Between September 2021 and January 2022, the U.S. Food and Drug Administration received information about four cases of illness or death in infants who

[10] Plaintiff does not assert any claims or seek any damages for any conduct related to the events that gave rise to the 2012 settlement. The facts recited are provided to underscore the direct and enhanced responsibility that Abbott's Board assumed beginning in 2012 for compliance with FDA regulations and compliance with federal laws governing Abbott.

consumed powdered infant formula. After learning that each of these infants consumed powdered infant formula products manufactured by Abbott Nutrition in Sturgis, Michigan and initiating an investigation at the facility that revealed insanitary conditions, the FDA warned consumers not to use certain products manufactured at this facility.

121. On February 17, 2022, Abbott Nutrition issued a voluntary recall of certain infant formula products manufactured in Sturgis, Michigan, and temporarily ceased production. The same day, Abbott issued a press release announcing the recall. In the February 17, 2022 press release, Abbott reported that: "During testing in our Sturgis, Mich., facility, we found evidence of Cronobacter sakazakii in the plant ***in non-product contact areas***" (emphasis added). However, the FDA inspection report released on March 22, 2022 contradicted that assertion, stating that Cronobacter was detected on a "scoop hopper" that was "***utilized to feed scoops, which are placed directly inside infant formula containers and contact product***" (emphasis added).

122. Likewise, Abbott stated on February 17, 2022, that "While ***Abbott's testing of finished product detected no pathogens***, we are taking action by recalling the powder formula manufactured in this facility with an expiration of April 1, 2022, or later" (emphasis added). Yet just a little over one month later, the FDA reported that "both FDA and [Abbott] found evidence of Cronobacter spp. in your powdered infant formula production environment. [Abbott] also identified Cronobacter spp. ***in finished powdered infant formula products***" (emphasis added).

123. Defendants' February 17, 2022 statements falsely downplayed the danger that Abbott's infant formula posed to babies at a time when Abbott's infant formula was still for sale on store shelves and being used in the homes of thousands of families at the

time. Instead of disclosing the full truth of the threat posed by Abbott's products, Defendant Manning stated in the press release that: "We know parents depend on us to provide them with the highest quality nutrition formulas," said Joe Manning, executive vice president, nutritional products, Abbott. "We're taking this action so parents know they can trust us to meet our high standards, as well as theirs. We deeply regret the concern and inconvenience this situation will cause parents, caregivers and health care professionals."

124. These false and contradictory statements suggest that, in connection with the FDA inspections and the subsequent recalls, Abbott's officers and directors breached their duty of loyalty by making false and incomplete statements to the public.

D. The Defendants Caused the Company to Conceal Risks to Infants From Cow-Milk Based Formula

125. Abbott has consistently advertised its cow-milk-based infant formulas as "safe" for pre-term infants to consume. Clinical studies and medical literature demonstrate, however, that cow-milk-based formulas are unsafe and unreasonably dangerous for feeding premature infants and make babies susceptible to a dangerously high risk of developing NEC, which is potentially fatal. NEC occurs when tissue in the colon becomes inflamed. The inflammation leads to necrosis of colon tissue, causing bacterial infections and cellular damage, cellular death, and necrosis of the colon and intestine. Even if an infant survives NEC, he or she is left with a lifetime of debilitating health problems that can severely restrict their long-term quality of life.

126. Abbott's failure to warn consumers about the potential for premature infants to contract NEC when ingesting its cow-milk based infant formulas has led to a large number of lawsuits against Abbott by the parents of deceased or disabled infants, who developed NEC after they drank Abbott's baby formula. In February 2023, in its annual

report filed as Form 10-K to the SEC, Abbott disclosed that 399 of those lawsuits were pending in federal and state court, and Abbott also faced international lawsuits. Since then, the number of NEC-related lawsuits has more than doubled. In its Annual Report filed on Form 10-K on February 16, 2024, Abbott disclosed that "As of January 31, 2024, there were ***993 lawsuits*** pending in federal and state courts in which Abbott is a party. The plaintiffs seek various damages, including punitive damages."

127. In July 2023, in denying a motion to dismiss one of the MDL cases, Chief Judge Pallmeyer held that the plaintiffs had plausibly alleged that "Defendants knew of and disregarded the risks of using cow's milk in preterm infant formula[,]" and, therefore, could seek punitive damages from Abbott. *In re: Abbott Lab. Preterm Infant Nutrition Products Liability Litig.*, MDL No. 3026, No. 22-c-5325, 2023 WL 4564630, at *3 (N.D. Il. July 17, 2023). Thus, Abbott faces potentially hundreds of millions of dollars, or even billions of dollars of liability, when accounting for punitive damages related to world-wide litigation involving NEC.

128. The Company's Directors also likely violated Section 14(a) of the Exchange Act and SEC Rule 14a-9 by causing Abbott to issue proxy statements in 2021, 2022, and 2023 that failed to disclose, among other things, (1) the Company manufactured and sold its infant formula products in the U.S. in violation of federal health and safety laws and regulations; and (2) the seriously deficient internal risk management and controls that allowed those unsafe and illegal conditions to proliferate at Abbott, exposing Abbott to significant legal, regulatory, and reputational risks.

V. THE DIRECTOR DEFENDANTS CAUSED THE COMPANY TO MAKE MATERIALLY FALSE AND MISLEADING STATEMENTS

129. During the Relevant Period, the Individual Defendants issued materially false and misleading statements about the Company's baby formula and condition of the Sturgis, Michigan facility.

130. On February 19, 2021, Abbott filed its annual report for the year ended December 31, 2020, with the SEC on Form 10-K (the "2020 Annual Report"). The 2020 Annual Report was signed by Defendants Ford, Funck, Alpern, Blount, Kumbier, McKinstry, Roman, Stratton, Austin, Gonzalez, McDew, Osborn, Starks, and Tilton. In the Annual Report, the Director Defendants stated that:

> Significant safety concerns could arise for Abbott's products, which could have a material adverse effect on Abbott's revenues and financial condition.
>
> Health care products typically receive regulatory approval based on data obtained in controlled clinical trials of limited duration. Following regulatory approval, these products will be used over longer periods of time in many patients. Investigators may also conduct additional, and perhaps more extensive, studies. If new safety issues are reported, Abbott may be required to amend the conditions of use for a product. For example, Abbott may be required to provide additional warnings on a product's label or narrow its approved intended use, either of which could reduce the product's market acceptance. If serious safety issues arise with an Abbott product, sales of the product could be halted by Abbott or by regulatory authorities. Safety issues affecting suppliers' or competitors' products also may reduce the market acceptance of Abbott's products.
>
> In addition, in the ordinary course of business, Abbott is the subject of product liability claims and lawsuits alleging that its products or the products of other companies that Abbott promotes have resulted or could result in an unsafe condition for, or injury to, patients. Product liability claims and lawsuits, safety alerts or product recalls, and other allegations of product safety or quality issues, regardless of their validity or ultimate outcome, may have a material adverse effect on Abbott's business and reputation and on Abbott's ability to attract and retain customers. Consequences may also include additional costs, a decrease in market share for the products, lower income or exposure to other claims. Product liability losses are self-insured. Product liability claims could have a material adverse effect on Abbott's profitability and financial condition.

131. This statement was false and misleading because it failed to disclose that Abbott was, at the time, aware of known, existing health and safety problems at the Sturgis facility. Instead of disclosing the known, existing problems at Sturgis, the Annual Report misleadingly stated that health and safety problems related to its products "could" occur in the future.

132. In the Annual Report, Defendant Ford also represented in a signed attestation that:

> Abbott's management assessed the effectiveness of the company's internal control over financial reporting as of December 31, 2020. In making this assessment, it used the criteria set forth in Internal Control — Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our assessment, we believe that, ***as of December 31, 2020, the company's internal control over financial reporting was effective based on those criteria***.

133. The Annual Report also stated:

> ***Evaluation of disclosure controls and procedures***. The Chief Executive Officer, Robert B. Ford, and the Chief Financial Officer, Robert E. Funck, Jr., evaluated the effectiveness of Abbott Laboratories' disclosure controls and procedures as of the end of the period covered by this report, and ***concluded that Abbott Laboratories' disclosure controls and procedures were effective to ensure that information Abbott is required to disclose in the reports that it files or submits with the Commission under the Securities Exchange Act of 1934 (the Exchange Act) is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms***, and to ensure that information required to be disclosed by Abbott in the reports that it files or submits under the Exchange Act is accumulated and communicated to Abbott's management, including its principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

134. Defendant Ford also signed a Sarbanes Oxley certification which was attached to the Annual Report and which stated that "(1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and (2)

The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company."

135. In the Annual Report, Abbott stated that Total Nutritional Products sales (which includes infant formula manufactured at Sturgis) increased 4.7% in 2020 and its U.S. Pediatric Nutritional business sales (also including the formula produced at Sturgis) increased 5.8% in 2020. In the 2020 Annual Report, Abbott acknowledged:

> **Abbott is subject to numerous governmental regulations and it can be costly to comply with these regulations and to develop compliant products and processes.**
>
> Abbott's products are subject to rigorous regulation by the FDA and numerous international, supranational, federal, and state authorities. The process of obtaining regulatory approvals to market a drug, medical device, or diagnostic product can be costly and time-consuming, and approvals might not be granted for future products, or additional indications or uses of existing products, on a timely basis, if at all. Delays in the receipt of, or failure to obtain, approvals for future products, or new indications and uses, could result in delayed realization of product revenues, reduction in revenues, and substantial additional costs.
>
> In addition, no assurance can be given that Abbott will remain in compliance with applicable FDA and other regulatory requirements once approval or marketing authorization has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices, product labeling, and advertising and postmarketing reporting, including adverse event reports and field alerts. Many of Abbott's facilities and procedures and those of Abbott's suppliers are subject to ongoing regulation, including periodic inspection by the FDA and other regulatory authorities. Abbott must incur expense and spend time and effort to ensure compliance with these complex regulations. Possible regulatory actions for non-compliance could include warning letters, fines, damages, injunctions, civil penalties, recalls, seizures of Abbott's products, and criminal prosecution.

136. On April 20, 2021, Abbott held its first quarter 2021 earnings conference call. During the call, Defendant Ford stated: "In the US and several international markets, we continue to capture share with our leading portfolio of infant formula and toddler

brands." Ford failed to disclose known, existing problems at Abbott's Sturgis facility where the baby formula was manufactured that threatened the health and safety of babies and thus posed a material threat to the Company's revenues from sales of such formula.

137. On July 16, 2021, Abbott issued its 2020 ESG Global Sustainability Report to shareholders. That report stated, among other things, that "Abbott's nutrition business ensures food safety through a tightly controlled manufacturing process that encompasses all steps from accepting materials from suppliers through to final product distribution. We monitor and verify microbiology, packaging integrity, and nutrient and lot control. We complete extensive finished product testing before releasing it for commercial distribution." Abbott's 2020 ESG Global Sustainability Report also touted the Company's Code of Business Conduct and strict compliance procedures that enabled employees to "report any concerns" because "Abbott does not tolerate illegal or unethical behavior in any aspect of our business and that employees are required to ask questions and/or report any concerns."

138. The Global Sustainability Report further stated that Abbott conducts quality control to "ensure that [its quality-system performance model and metrics] continue to assess relevant quality and compliance risks." It also stated:

> Our global internal audit programs assess compliance with both regulatory standards and our own internal standards and processes. Our audits assess internal processes, such as design, production processes, supply chain, data integrity, corrective and preventive actions (CAPA), and complaint handling. Each of our operating businesses also performs internal quality audits in line with local regulatory requirements and then highlights any

findings in management reviews. We develop correction plans to address any compliance issues our audits identify.

139. These statements were false or misleading because the Company did not ensure timely and accurate quality and compliance risk assessment, as demonstrated by the failure to rigorously test infant formula before distribution and to have an information reporting system for elevating critical information including Form 483s and whistleblower complaints to the Board.

140. On July 22, 2021, the Company held its second quarter 2021 earnings conference call in which Defendants Ford and Funck participated. During the call, Ford stated: "In Pediatric Nutrition, sales grew nearly 4.5% in the quarter, led by growth of nearly 9% in the US, where we continue to capture share with our leading portfolio of infant formula and toddler brands."

141. On October 20, 2021, the Company held its third quarter 2021 earnings conference call. During the call, Ford stated:

> I'll now summarize our third quarter results . . . I'll start with Nutrition where sales increased 9% compared to last year. Strong growth in the quarter was led by US Pediatric and International Adult Nutrition. In Pediatric Nutrition, sales grew over 8.5% in the quarter, led by strong growth in the US from continued share gains in our infant formula and toddler portfolio.

142. On November 15, 2021, Abbott issued a "2020 Sustainability Report Summary" which contained similar representations to those in its July 2021 Sustainability Report, including that Abbott conducts quality control to "ensure that [its quality system performance model and metrics] continue to assess relevant quality and compliance risks." It also stated:

> Our global internal audit programs assess compliance with both regulatory standards and our own internal standards and processes. Our audits assess internal processes, such as design, production processes, supply chain, data integrity, corrective and preventive actions (CAPA), and complaint handling. Each of our operating businesses also performs internal quality audits in line with local regulatory requirements and then highlights any findings in management reviews. We develop correction plans to address any compliance issues our audits identify.

143. These statements were false or misleading because the Company did not ensure timely and accurate quality and compliance risk assessment, as demonstrated by the failure to rigorously test infant formula before distribution and to have an information reporting system for elevating critical information, including Form 483s and whistleblower complaints, to the Board.

144. On January 26, 2022, the Company held its fourth-quarter and year-end 2021 earnings conference call in which Defendants Ford and Funck participated. During the call, Defendant underscored the significance of the Company's infant formula business:

> In Pediatric Nutrition, US sales growth of more than 10% for the year was led by strong growth of Pedialyte, our oral rehydration brand, and market share gains for Similac, our market leading infant formula brand. During the past year, we continued to expand our Nutrition portfolio with several new product and line extensions including the launch of Similac 360 Total Care in the US and continued global expansion of our PediaSure, Glucerna and Ensure brands with line extensions such as plant-based, lower sugar and high protein products.

145. The statements set forth above were materially false and misleading and/or contained material omissions. The Individual Defendants were aware of, but failed to

disclose, the existence of violations of FDA regulations, manufacturing problems, and contamination afflicting Abbott's infant formula at Sturgis which were related to infant deaths. In addition, the Defendants failed to disclose known violations of applicable health and safety regulations at the Sturgis facility which exposed the Company to recalls and regulatory investigations and fines. The Defendants were also aware of and failed to disclose known material defects in the Company's internal controls.

146. In addition, the statements in the Company's February 17, 2022 press release announcing the recall of Abbott's powdered infant formula were materially false and misleading. That press release stated that Abbott was "initiating a proactive, voluntary recall of powder formulas, including Similac, Alimentum and EleCare manufactured in Sturgis, Mich., one of the company's manufacturing facilities." In addition, in the press release, Defendant Manning stated: "We know parents depend on us to provide them with the highest quality nutrition formulas. We're taking this action so parents know they can trust us to meet our high standards, as well as theirs. We deeply regret the concern and inconvenience this situation will cause parents, caregivers and health care professionals." The Company failed to disclose, however, that the recall was made at the insistence of the FDA based on information that was known to the Individual Defendants for at least a year.

147. Moreover, the February 17, 2022 press release stated that evidence of Cronobacter contamination was found in "nonproduct contact areas" when, in fact, the FDA reported that the contamination was found in areas directly contacting infant formula containers and the formula product.

148. This statements in the Company's February 17, 2022 press release were also false or misleading because they omitted that the FDA had pushed for the recall and

was conducting an ongoing investigation, as well as that the FDA inspection report dated March 18, 2022 and released publicly on March 22, 2022 stated that Cronobacter was found not only "in non-product contact areas" as asserted by Abbott but also on the "scoop hopper" that is "placed directly inside infant formula containers that contain product." As former FDA Deputy Commissioner Yiannis later testified on March 28, 2023 at a Congressional hearing, the "weight of the evidence" "supported a conclusion that [powdered infant formula] made at Abbott's Sturgis plant was produced under insanitary conditions and [was] a likely source of ongoing, sporadic contamination of [powdered infant formula] with multiple strains [of Cronobacter] over time."

149. On February 18, 2022, Abbott filed a Form 8-K with the SEC, signed by Defendant Ford, claiming: "On February 17, 2022, Abbott initiated a proactive, voluntary recall of Similac brand powder infant formulas manufactured in Sturgis, Michigan." That statement was false or misleading because it omitted that the FDA had pushed for the recall and was conducting an ongoing investigation.

150. In May 25, 2022 testimony before the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, regarding the baby formula shortage, Defendant Calamari stated that Abbott was unaware of the whistleblower's complaints until late April 2022, when the complaint submitted to the FDA was publicly disclosed by a member of Congress:

> Abbott did not find out about it [the whistleblower complaint] until it was made public in the end of April and it was the particular individual who raised the complaint . . . it was their choice to use that mechanism to raise the complaint.

This statement was materially false and misleading because, as disclosed two weeks later, the whistleblower had filed a similar complaint with OSHA in February 2021. Abbott not only received a copy of the complaint, but the Company filed a non-public response to it in April 2021.

151. On February 17, 2022, the FDA publicly announced that it was investigating four consumer complaints of infant illness related to powdered infant formula manufactured by Abbott at the Sturgis facility. The FDA stated that during its onsite inspection of the facility, it had found Cronobacter contamination in several environmental samples that was linked to infant illness and death. The FDA also disclosed that Abbott's internal records indicated "environmental contamination with Cronobacter and the firm's destruction of product due to the presence of Cronobacter." On the same day, Abbott issued a recall of certain infant formula products manufactured in Sturgis, including Similac, Alimentum, and EleCare.

152. On March 22, 2022, after the markets closed, the FDA released reports from three inspections of the Sturgis facility conducted in September 2019, September 2021 and, most recently, between January 31, 2022, and March 18, 2022. Among other things, the FDA concluded that (a) Abbott failed to establish process controls "designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment" and (b) Abbott failed to "ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source."

153. On April 28, 2022, a redacted copy of a 34-page detailed whistleblower complaint sent to the FDA in October 2021 was made public. The whistleblower complaint

revealed that Abbott was previously aware of the issues disclosed in February and March 2022. In addition, the complaint alleged that Abbott's management at the Sturgis facility had falsified test records; released untested infant formula to the public; continued the use of testing procedures known to be deficient; was unable to trace products in order to properly implement product recalls; and attempted to mislead the FDA during a 2019 inspection audit.

154. On June 8, 2022, it was publicly disclosed that Abbott was aware of the whistleblower's formal allegations in early 2021, when a complaint was sent to OSHA and then forwarded to the FDA and Abbott. Investors also learned that Abbott submitted a response to the OSHA complaint two months later.

VI. THE OFFICER DEFENDANTS ACTED IN BAD FAITH AND BREACHED THEIR DUTY OF LOYALTY TO ABBOTT, RESULTING IN A CONSENT DECREE BEING IMPOSED ON THE COMPANY

155. The Officer Defendants had direct responsibility for operation of the Sturgis facility and/or supervision and public reporting obligations about Sturgis. As a result, when the FDA, through the Justice Department, filed suit against Abbott as part of the negotiated consent decree, it also sued Defendants Randall, Hathaway, and Gale because their breaches of duty to Abbott led directly to the contamination of baby formula at Sturgis.

156. Defendant Randall is Abbott Nutrition's Division Vice-President of Quality Assurance. Defendant Randall has overall responsibility for quality operations for global Abbott Nutrition, which includes, but is not limited to, oversight of manufacturing locations and food safety, product quality, supplier quality, compliance, complaint management, and corrective and preventive actions. Defendant Randall was responsible for approving the decision made during the FDA's inspection at Sturgis to initiate a recall

of certain infant formulas manufactured at Sturgis. Defendant Randall performs her duties at Abbott Laboratories' corporate office located in Abbott Park, Illinois, where she conducts her oversight duties for Abbott Laboratories' manufacturing sites including, but not limited to, the Sturgis facility.

157. Defendant Gale holds the title of Director of Quality at Sturgis and oversees all quality assurance including, but not limited to, sanitation, compliance, and corrective and preventive actions. Defendant Gale has the authority to detect, correct, and prevent violations of the FDA and its implementing regulations. Defendant Gale performs his duties at Sturgis's location.

158. Defendant Hathaway is the Site Director at Sturgis. Defendant Hathaway has identified himself as the most responsible individual at the Sturgis Facility. Defendant Hathaway is responsible for ensuring the safety and quality of products made at Abbott's Sturgis plant. Defendant Hathaway performs his duties at Abbott's Sturgis plant.

159. As alleged by the DOJ, Hathaway, Gale, and Randall, through their acts and omissions as officers of Abbott, violated 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food, namely baby formula, that were adulterated within the meaning of 21 U.S.C. § 342(a)(4).

160. Defendants Hathaway, Gale, and Randall also violated 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

161. Through their conduct, Defendants Hathaway, Gale, and Randall breached their duties of good faith, loyalty, and honest services to Abbott, causing substantial harm and damage to Abbott. Abbott was forced to enter into a consent decree with the FDA and DOJ which imposes burdensome and expensive obligations on Abbott, including retaining an expert and making periodic reports to the government. *See* May 16, 2022 Consent Decree, attached hereto as **Exhibit B**.

162. Defendant Funck is, and at all times relevant hereto has been, Abbott's Chief Financial Officer ("CFO") and Vice President, Finance since March 2020. As alleged above, Funck caused Abbott to issue false and misleading statements about its operations during the time he was aware of material problems at the Sturgis facility.

163. Defendant Manning is, and since December 2021 has been, Abbott's Executive Vice President, Nutritional Products. As alleged *supra*, Manning made false and misleading statements about the recall and the operations at Sturgis, and failed to reveal the full extent of problems at Sturgis.

164. Defendant Calamari is, and at all times relevant hereto has been, Abbott's President of Nutrition, North America and Senior Vice President for U.S. Nutrition. As alleged *supra*, Calamari made false and misleading statements about problems afflicting Sturgis as well as when the Company learned of the problems, including false statements he made on May 25, 2022 on behalf of Abbott at a hearing concerning the baby formula shortage held by the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations.

VII. THE DIRECTORS ABDICATED THEIR FIDUCIARY DUTIES BY FAILING TO ADOPT AND IMPLEMENT A BOARD-LEVEL COMPLIANCE SYSTEM DESIGNED TO ENSURE THE SAFETY OF THE COMPANY'S BABY FORMULA MANUFACTURING OPERATIONS

165. During the Relevant Time Period, none of Abbott's Board Committees had direct responsibility for manufacturing or product safety for infant formula. The purpose of the Public Policy Committee is to assist the Board's oversight over public policy, regulatory (including regulation by the Federal Food and Drug Administration (FDA), as well as other domestic, foreign and international regulatory bodies) and government affairs and healthcare and other compliance issues.

166. This included among other things, requiring the Committee to review and discuss with management healthcare and regulatory compliance matters, including product cybersecurity and data privacy and review annually Abbott's compliance program with respect to legal and regulatory requirements, including FDA regulations, and receive a report from the corporate officer responsible for quality assurance as needed, but at least two (2) times a year, regarding any FDA warning letters and Abbott's responses, as well as any upcoming compliance initiatives.

167. The documents produced to Plaintiff by Abbott in response to Plaintiff's shareholder inspection demand reveal that the Public Policy Committee [redacted] Further, the duties listed in the charter do not include oversight over maintaining product safety, much less infant formula safety. Moreover, the [redacted]

[redacted]

168. Any references to regulatory compliance in the Abbott board minutes are devoid of [redacted] Because Abbott operates in a highly regulated industry, any reference to regulatory compliance cannot immediately be interpreted as referring to product safety. The Public Policy Committee's meeting minutes do not reflect [redacted] Thus, Abbott's directors breached their fiduciary duties by failing to implement a system to monitor product safety at the board level.

169. Similarly, while Abbott had an Audit Committee, the Audit Committee was not responsible for product safety oversight. The purpose of the Audit Committee was to assist with oversight with respect to legal and regulatory compliance as it relates to financial matters, including accounting, auditing, financial reporting, and securities law issues; and Abbott's enterprise risk management, including major financial, information security, and enterprise cybersecurity risk exposures. Its responsibilities did not include oversight over product safety, despite specifically calling out other types of risks like cybersecurity. The documents produced to Plaintiff by Abbott in response to Plaintiff's shareholder inspection demand reveal that the Audit Committee [redacted] but failed to address product or food safety manufacturing risks. The Audit Committee did not have responsibility for monitoring product safety. Further, there is no evidence of a discussion about safety issues or risks in the Audit Committee meeting minutes.

170. In addition to the fact that no Abbott board committee was vested with responsibility for product safety, the entire board of directors itself did not receive any information that could allow it to oversee the safety of Abbott's manufacturing of infant formula. The Board meeting minutes produced to Plaintiff by Abbott in response to Plaintiff's shareholder inspection demand make no reference to infant formula safety or product safety in general. The Board did not discuss the Sturgis Plant until its regularly scheduled meeting, which happened to coincide with the day the recall was announced. Specifically, the Board met on February 17-18, 2022 [redacted].[12] However, [redacted] Instead, [redacted].[13] The Board meeting minutes [redacted].[14]

171. Similarly, the entire Board met on June 10, 2022 [redacted].[15] At that June 2022 meeting, the Board's focus was on [redacted]

[11] [redacted]

[12] [redacted]

[13] *Id.*

[14] *Id.*

[15] [redacted]

[redacted] Defendant [redacted] made a presentation regarding [redacted], including [redacted].[17]

172. Thus, Abbott's board minutes demonstrate that the Board as a whole did not monitor, discuss, or address manufacturing or product safety on a regular basis. The Board did not regularly discuss, and therefore did not allocate time to, product safety. Likewise, the Board discussions were focused on [redacted]. Thus, the board minutes support an inference that the Board was not monitoring product safety.

173. The Board minutes produced to Plaintiff also reflect that the Board did not have a regular process or protocol requiring management to [redacted] and that the Board meetings were devoid of any suggestion that [redacted] To the extent the Board or subcommittees received reports related to infant formula products, it was on an *ad hoc* basis.

174. In addition, the Abbott Directors did not adopt or implement any system to [redacted] to the Board. For example, Abbott's [redacted]

---

[16] [redacted]

[17] *Id.*

[redacted]

175. Abbott has received inspection reports from the FDA since at least 2019 that show the presence of listeria, salmonella, or Cronobacter in the Sturgis Plant, but Abbott's Board minutes [redacted]. Further, the minutes [redacted]

176. In 2019, the FDA issued a Form 483 and followed up with an EIR, and there were communications with the FDA about Abbott's conduct at the Sturgis Plant, findings of Cronobacter and Listeria at the plant, and complaints of Cronobacter or other bacterial infections in infants who consumed Similac formula. However, there is no indication in the Board or Board committee minutes that [redacted] The Board and Board committee minutes also reveal that there was [redacted].

177. In addition, there were numerous red flags that were waved in front of management by regulators and the Company's own internal testing about formula safety issues at its plants, but the Board was not aware of them because of its failure to implement a monitoring system. For example, the FDA inspectors found violations of federal food safety laws as far back as September 2019. Then, in 2021, the violations escalated. In February 2021, Defendant Allen was sent a whistleblower's OSHA complaint detailing illegal activity at the Sturgis Plant. In April 2021, Abbott responded to the whistleblower's

OSHA complaint. Officer Defendants Allen, Randall, and Calamari had direct oversight over the Sturgis Plant and were or should have been involved in the response. Later in September 2021, the FDA found more serious violations, some of which related to Cronobacter.

178. At the end of 2021, the FDA demanded Abbott allow a "for-cause" inspection of the Sturgis Plant. In early 2022, the FDA conducted its for-cause inspection and found the conditions at the Sturgis Plant were "unsanitary." As a result of these findings, whistleblower reports, and several infant deaths purportedly linked to consuming formula produced at the Sturgis Plant, the FDA encouraged Abbott to conduct a voluntary recall of certain infant formula produced at that Plant. Abbott ceased production at the Sturgis Plant on February 15, 2022.

179. Yet, as noted *supra*, the regularly scheduled Board meeting held two days later on February 17, 2022 was the first time management informed the Board [redacted].[18] By this point, the FDA had made three recommendations to Abbott on successive days to issue the recall and had submitted a report to its government partners on the potential recall and resulting supply chain impacts. Yet, all the Board meeting minutes reflect is that the Board [redacted] The minutes do not reflect that [redacted]

[18] [redacted]

180. Abbott's Public Policy Committee also met on February 17, 2022, but did not [redacted].[19]

181. The Director Defendants also did not receive a report about [redacted].[20]

182. Thus, safety concerns known to management failed to make their way to the Board, supporting the conclusion that the Board failed to establish a reporting system. Further, some of Abbott's officers were aware of issues as early as spring 2021, yet the Board was not notified of the problems.

183. These facts also raise an inference of scienter on the part of the Defendants. The lack of any Board committee focused on safety, any regular process or protocols requiring management to report on safety risks, any regular schedule for the Board to address safety, any Board minutes or documents suggesting that they regularly discussed safety, and the lack of any evidence that red, or at least yellow, flags, were disclosed to the Board demonstrate recklessness or conscious indifference by the Director Defendants. Here, Abbott's Board lacked a Board committee focused on product safety, the broader Board failed to monitor and discuss product safety on a regular schedule, the Board lacked any regular process requiring management to report product safety risks, and there were red flags that were not disclosed to the Board. These facts support an inference of scienter because they demonstrate the Director Defendants acted inconsistently with their fiduciary

19 [redacted]

20 [redacted]

duties. As a result, the Director Defendants face a substantial likelihood of liability on the breach of fiduciary duty claim.

VIII. THE DIRECTOR DEFENDANTS WRONGFULLY CAUSED ABBOTT TO REPURCHASE ITS STOCK AT INFLATED PRICES DESPITE THEIR KNOWLEDGE OF THE SERIOUS PROBLEMS AFFLICTING THE COMPANY

184. On October 15, 2019, Abbott's Board authorized up to $3 billion in repurchases of its stock. On December 10, 2021, the board of directors authorized the repurchase of up to $5 billion of Abbott common shares, from time to time (the "2021 Plan").

185. The Director Defendants knew that public disclosure of the material problems at Sturgis would likely lead to recalls, governmental investigations, consumer class action lawsuits, and a precipitous decline in Abbott's stock price. The Individual Defendants thus knew that it was not in Abbott's best interests to continue to repurchase its stock in massive quantities as they had been doing and intended to continue to do. Yet they did exactly that, voting to approve massive quantities of company stock under the plan throughout the Relevant Period.

186. From April 2020 through December 2020, the Director Defendants approved the following repurchases of Abbott stock:

Date	**No. Shares**	**Weighted Average Price Per Share**	**Total Amount**
April 2020	76,831	$98.00	$7,529,438
May 2020	9,188	$92.10	$846,215
June 2020	791	$90.90	$71,902

Sept. 2020	28,423	$109.47	$3,111,466
Dec. 2020	1,600,411	$107.99	$172,842,788
Total (2020)	**1,715,644**	**$107.48**	**$184,401,809**

187. During Q1 2021, the Director Defendants caused Abbott to make the following repurchases of company stock at the indicated prices:

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
January 1, 2021 – January 31, 2021	1,785 (1)	$ 109.110	0	$ 3,097,391,913
February 1, 2021 – February 28, 2021	10,000 (1)	122.543	0	3,097,391,913
March 1, 2021 – March 31, 2021	0 (1)	0	0	3,097,391,913
Total	11,785 (1)	$ 120.509	0	$ 3,097,391,913

188. During the second quarter of 2021, the Director Defendants caused Abbott to significantly increase its stock buyback efforts, resulting in the following repurchases of company stock at the indicated prices:

Issuer Purchases of Equity Securities

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
April 1, 2021 – April 30, 2021	18,202	$ 120.900	0	$3,097,391,913
May 1, 2021 – May 31, 2021	0	0	0	3,097,391,913
June 1, 2021 – June 30, 2021	4,500,000	111.575	4,500,000	2,595,306,483
Total	4,518,202	$ 111.612	4,500,000	$2,595,306,483

189. During the third quarter of 2021, the Director Defendants authorized Abbott to further increase the number of shares repurchased, causing Abbott to make the following repurchases of company stock at the indicated prices:

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
July 1, 2021 – July 31, 2021	450,000	$ 120.849	450,000	$2,540,924,508
August 1, 2021 – August 31, 2021	2,175,000	123.265	2,175,000	2,272,822,841
September 1, 2021 – September 30, 2021	3,002,035	120.814	3,000,000	1,910,394,012
Total	5,627,035	$ 121.764	5,625,000	$1,910,394,012

190. During the fourth quarter of 2021, the Director Defendants authorized Abbott to make, and it did make, the following repurchases of company stock at the indicated prices:

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
October 1, 2021 — October 31, 2021	1,767,000	$ 127.811	1,750,000	$ 1,686,728,997
November 1, 2021 — November 30, 2021	4,750,000	$ 127.486	4,750,000	$ 1,081,169,672
December 1, 2021 — December 31, 2021	135	$ 141.000	0	$ 6,081,169,672
Total	6,517,135	$ 127.575	6,500,000	$ 6,081,169,672

191. Thus, during Q4 2021, Abbott repurchased its stock for an average of over $127 per share. When the wrongdoing came to light, Abbott's stock plunged and continued to decline, falling to as low as $93.25 per share by the fall of 2022. As a result, Abbott repurchased its stock at significantly inflated prices, causing hundreds of millions of dollars in harm to Abbott.

192. In the first quarter of 2022, the Director Defendants authorized Abbott to significantly increase the number or shares repurchased, ***more than tripling the number of shares purchased in prior quarters and resulting in Abbott repurchasing over 17.3 million shares***, again at inflated prices, as follows:

Period	(a) Total Number of Shares (or Units) Purchased	(b) Average Price Paid per Share (or Unit)	(c) Total Number of Shares (or Units) Purchased as Part of Publicly Announced Plans or Programs	(d) Maximum Number (or Approximate Dollar Value) of Shares (or Units) that May Yet Be Purchased Under the Plans or Programs
January 1, 2022 – January 31, 2022	650,000	$ 127.262	650,000	$5,998,449,112
February 1, 2022 – February 28, 2022	8,550,000	123.643	8,550,000	4,941,301,237
March 1, 2022 – March 31, 2022	8,113,060	118.344	8,113,060	3,981,169,070
Total	17,313,060	$ 121.296	17,313,060	$3,981,169,070

193. In the second quarter of 2022, Abbott abruptly discontinued its stock buyback program, and no shares were repurchased in April, May or June 2022.

194. However, during the Relevant Period, the Director Defendants had caused Abbott to repurchase 35,702,861 of its own shares at inflated prices, as indicated *supra*. Based on the average price paid by Abbott for such shares, and the lower $93.25 price that Abbott's stock declined to once the truth was revealed, the Director Defendants' breach of fiduciary duty in authorizing the stock repurchases during the Relevant Period resulted in damages of approximately $977,415,117, as reflected in the attached chart:

[The remainder of this page is intentionally left blank.]

Damages Caused to Abbott By the Director Defendants Causing the Company to Repurchase Tens of Millions of Its Shares at Substantially Inflated Prices

Time Period	No. of Shares Repurchased	Average Price per share paid	Damages[21]
2020	1,715,644	$107.48	$24,413,614
Q1 2021	11,785	$120.50	$321,141
Q2 2021	4,518,202	$111.61	$82,954,188
Q3 2021	5,627,035	$121.76	$160,426,768
Q4 2021	6,517,135	$127.57	$223,668,073
Q1 2022	17,313,060	$121.29	$485,631,333
TOTAL:	35,702,861		$977,415,117

Reliance and Causation

195. From 2019 to 2022, Abbott justifiably expected Defendants to disclose material information as required by law and SEC regulations in the Company's periodic filings with the SEC. Abbott would not have repurchased its securities at artificially inflated prices had Defendants disclosed all material information known to them, as detailed in this Complaint.

[21] Number of shares repurchased times difference between average price paid and $93.25.

196. The market for Abbott's common stock was efficient during the relevant period because, among other reasons, Abbott's stock met the requirements for listing, and was listed and actively traded on the New York Stock Exchange, which is widely considered to be the most efficient market in the world. In addition, Abbott filed periodic reports with the SEC, Abbott regularly communicated with public investors including by disseminating press releases over major newswire services and communicating with the financial press and widely available media outlets, and Abbott was followed by numerous analysts employed by major brokerage firms, including, but not limited to Barclays, Cowen and Company, Credit Suisse, J.P. Morgan, Morgan Stanley, RBC Capital Markets, UBS, and Wells Fargo, all of whom wrote reports about Abbott that were disseminated in the public domain.

197. In repurchasing shares in connection with the stock repurchase program, Abbott relied on Defendants' false or misleading statements and/or the integrity of the market price. In addition, Abbott is entitled to a presumption of reliance as to material omissions as set forth in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972).

198. Because the directors are not disinterested or independent, the directors were required to make a full disclosure to the shareholders, or else their knowledge cannot be imputed on the corporation. Because no disclosure was made to the shareholders, the knowledge of the interested directors cannot be imputed on Abbott. Abbott therefore relied on the false and misleading statements.

199. On February 10, 2022, barely a week before the scandal began to be revealed, Abbott's common stock closed at $127.76 per share. On February 16, 2022, the last trading day before Defendants' fraud was partially revealed, Abbott common stock closed at $123.68 per share.

200. Between February 17, 2022 and October 19, 2022, the revelation of the truth through a series of disclosures caused Abbott's stock price to plummet.

201. The decline in Abbott's share price was a direct result of the nature and extent of Defendants' fraud being revealed to the market. The timing and magnitude of the decline in the Company's share price negates any inference that the losses suffered by Abbott were caused by market conditions, macroeconomics or industry factors, or Company-specific facts unrelated to the fraudulent conduct.

IX. DAMAGES SUFFERED BY ABBOTT LABORATORIES

202. As a direct and proximate result of the Individual Defendants' misconduct, Abbott has sustained millions of dollars in damages. Abbott has been named as a defendant in dozens of consumer class actions alleging wrongful death and economic damages. Those cases have been consolidated for pre-trial purposes by the MDL in this Court under the caption *In re Recalled Abbott Laboratories et al. Infant Formula Products Liab. Litig.*, Case No. 22-cv-2148, MDL No. 3037 (N.D. Ill.). In a trial held in July 2024, a jury in a Missouri state court awarded a plaintiff ***$495 million*** in damages. In its most recent annual report filed on February 21, 2025, Abbott stated that "Given the uncertainty as to the possible outcome in each of these lawsuits, Abbott is unable to reasonably estimate a range of possible loss related to these lawsuits."

203. Abbott has also already paid hundreds of thousands of dollars in legal and expert fees as a result of the consent decree it was forced to enter into with the government in 2022. Abbott must retain outside expert assistance to bring its Sturgis facility into compliance with the FDCA and good manufacturing practice regulations. Among other things, Abbott has already paid the expert significant fees to assist Abbott, under FDA

supervision, in the development of plans designed to reduce and control the risk of bacterial contamination. Abbott is also obligated under the consent decree to pay the expert to periodically evaluate Abbott's compliance with the FDCA, regulations, and the consent decree.

204. The Company reported a 60% decrease in operating earnings for its Nutritional Products segment and recorded $176 million in charges related to the 2022 infant formula recall. Between February 17, 2022, the day the recall was announced, and June 8, 2022, when investors learned that Abbott was aware of the whistleblower's complaint months earlier than previously reported, Abbott's stock price declined $8.30, or 6.7%, for a total market capitalization loss of more than $13 billion.

205. Abbott faced a 31.75% decline in net earnings in its third quarter 2022 financial results. On October 19, 2022, the Form 8-K filed by Abbott attributed this decline in part to the Sturgis Plant shutdown, entry into a DOJ Consent Decree requiring significant remediation efforts, and numerous lawsuits, including personal injury lawsuits -- *In re Recalled Abbott Infant Formula Prods. Liability Litig*., No. 22-cv-02148, MDL No. 3037, related to the wrongful deaths and related damages allegedly caused by Abbott's contaminated infant formula products produced at the Sturgis Plant.

206. In its annual report on Form 10-K for 2024, filed February 21, 2025, Abbott disclosed additional legal costs and potential losses, stating that "Abbott estimates the range of possible loss for its legal proceedings and environmental exposures to be from approximately $25 million to $35 million. The recorded accrual balance at December 31, 2024 for these proceedings and exposures was approximately $30 million."

207. In addition, Abbott has already incurred substantial legal fees to defend itself in the MDL consumer class actions and in the Securities Action. The Company has also incurred costs and expenses in connection with the whistleblower complaint and the regulatory proceedings.

208. Finally, Abbott has been damaged by approximately $953,001,503 because the Individual Defendants caused Abbott to repurchase 33,987,217 shares of its stock at inflated prices during the Relevant Period.

X. DERIVATIVE AND WRONGFUL REFUSAL OF DEMAND ALLEGATIONS

209. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breaches of fiduciary duties by the Individual Defendants.

210. Abbott is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would otherwise not have.

211. Plaintiff is a current shareholder of record of Abbott and has continuously owned Abbott stock at all relevant times, including since at least 1992. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights and has retained counsel competent and experienced in derivative litigation.

212. By letter dated January 30, 2025, Plaintiff made a litigation demand on the Board of Directors. Among other things, the demand noted that Illinois law does not permit the formation of a special litigation committee of the Board ("SLC").

213. By letter dated February 14, 2025, the Company, through its attorneys at Latham & Watkins, refused Plaintiff's demand.

214. The Company and/or Board's refusal was wrongful and contrary to law. Among other things, the Company's February 14, 2025 letter erroneously stated that Illinois law permits the formation of SLCs, citing to 805 ILL. COMP. STAT. §5/8.40. However, 805 ILL. COMP. STAT. §5/8.40 does not refer to SLCs at all, instead merely referring to the ability of boards to form "one or more committees."

215. Moreover, 805 ILL. COMP. STAT. §5/8.40 explicitly states that a board may only form a committee "If the articles of incorporation or by-laws so provide." Abbott's bylaws, however, do not permit committees to have plenary authority. Instead, Article IV, Section 1 of Abbott's bylaws explicitly state that "Each committee shall have one or more members, ***who serve at the pleasure of the Board of Directors***." As a result, members of any committee of the Abbott Board are subject to dismissal by the entire board, thus precluding them by definition from having plenary authority and making them at all times subject to the "pleasure of the Board of Directors."

216. In fact, Abbott's bylaws explicitly state that only one committee – the Executive Committee – may exercise plenary authority, and then only when the full Board is not in session. *See* Abbott Bylaws, Article IV, Section 3 ("The Executive Committee may, when the Board of Directors is not in session, exercise the authority of the Board of Directors in the management of the business and affairs of the Corporation."). Abbott's website also states: "The Executive Committee may exercise all the authority of the board in the management of Abbott, except for matters expressly reserved by law for board

action" and stating that its current members are: R.B. FORD, CHAIR, N. MCKINSTRY, M.F. ROMAN, D.J. STARKS, and J.G. STRATTON.[22]

217. Here, the SLC is not the Executive Committee and thus may not exercise the plenary authority of the full Board.

218. Contrary to Abbott's bylaws and 805 ILL. COMP. STAT. §5/8.40, however, Abbott's board appointed a one-member SLC consisting of Director Michael O'Grady to investigate all pending and potential derivative claims.

219. Upon receiving the Litigation Demand, the Board had an affirmative duty under Illinois law to conduct a good faith, reasonable, and objective investigation into the allegations in the Litigation Demand and to reach a good faith, reasonable, and objective conclusion. Instead of doing so, the Board stated that it had divested itself of authority to investigate the claims due to the formation of the improperly-constituted SLC. The Board also stated in its wrongful refusal letter dated February 14, 2025 that "now is not an appropriate time to do so [investigate the facts and potential claims set forth in Plaintiff's litigation demand] given the pendency of the SLC's investigation."

220. Because Abbott's bylaws do not permit it to grant plenary authority to an SLC, the single-member SLC consisting of O'Grady is impermissibly constituted. As a result, the Directors have breached their fiduciary duties and violated Abbott's bylaws by forming the SLC and giving it plenary authority. The Board's February 14, 2025 refusal of Plaintiff's demand is therefore wrongful and contrary to law.

---

[22] *See* https://www.abbott.com/investors/governance/board-of-directors-and-committees.html, last visited Feb. 18, 2025.

221. Because the Board has constructively and wrongfully refused the Litigation Demand, Plaintiff now commences this derivative action in order to protect the Company, rectify the wrongs detailed herein, and hold the wrongdoers accountable for the damages they caused the Company.

222. In addition to wrongfully refusing the litigation demand, Defendants knew about the false statements alleged in this Complaint and did nothing to stop them. Defendants therefore violated their own fiduciary duties and are not independent or disinterested.

223. Prosecution of this action, independent of the current Board, is in the best interest of the Company.

224. The wrongful acts complained of herein subject, and will continue to subject, Abbott to continuing harm because the adverse consequences of the actions are still in effect and ongoing.

XI. CAUSES OF ACTION

COUNT I
Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Promulgated Thereunder (Against Defendants Alpern, Austin, Blount, Calamari, Ford, Funck, Gonzalez, Kumbier, McDew, McKinstry, Osborn, Starks, Stratton, and Tilton)

225. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth in this paragraph.

226. From 2019 through 2022, in connection with Abbott's repurchases of its stock, Defendants disseminated or caused to be issued false or misleading statements about the Company, which they knew or recklessly disregarded were false or misleading and were intended to deceive, manipulate, or defraud. Those false or misleading statements and

Defendants' course of conduct were designed to artificially inflate the price of the Company's common stock.

227. At the same time that the price of the Company's common stock was inflated due to the false or misleading statements, Defendants caused Abbott to repurchase millions of shares of its own common stock at prices that were artificially inflated due to Defendants' false or misleading statements. Defendants engaged in a scheme to defraud Abbott through their misconduct.

228. Defendants violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts or omitted to state necessary facts in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit on Abbott in connection with the Company's purchase of Abbott stock during 2019 through 2022.

229. Defendants, individually and in concert, directly and indirectly, by the use of means or instrumentalities of interstate commerce or of the mails, engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon the Company; made various false or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; made the above statements intentionally or with a severely reckless disregard for the truth; and employed devices and artifices to defraud in connection with the purchase of Abbott stock.

230. Defendants acted with scienter throughout 2019 through 2022, in that they acted either with intent to deceive, manipulate, or defraud, or with severe recklessness.

231. The misstatements and omissions of material facts set forth in this Complaint were either known to Defendants or were so obvious that Defendants should have been aware of them. Throughout 2019 to 2022, Defendants also had a duty to disclose new information that came to their attention and rendered their prior statements to the market materially false or misleading.

232. Defendants' false or misleading statements and omissions were made in connection with the Company's purchase of its own stock.

233. As a result of Defendants' violations of Section 10(b), Abbott has and will suffer damages in that it paid artificially inflated prices for its common stock purchased as part of the repurchase program and suffered losses when the previously undisclosed facts relating to the Company's unsafe and illegal manufacture and sale of infant formula products in the U.S. were disclosed beginning on February 17, 2022, continuing through at least October 20, 2022.

234. By reason of such conduct, Defendants are liable to the Company pursuant to Section 10(b) of the Exchange Act and SEC Rule 10b-5.

COUNT II
Against the Individual Defendants for Breach of Fiduciary Duty

235. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

236. The Individual Defendants owed the Company fiduciary obligations of loyalty, good faith, candor, and care. By reason of their fiduciary relationships, the

Individual Defendants owed the Company the highest obligation of good faith, fair dealing, loyalty, and due care.

237. As alleged herein, the Individual Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, candor, and good faith.

238. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary obligations, the Company has sustained significant damages.

239. Plaintiff on behalf of Abbott has no adequate remedy at law.

COUNT III
Against the Individual Defendants for Aiding and Abetting Breach of Fiduciary Duty

240. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

241. The Individual Defendants owed and owe fiduciary duties of good faith, candor, loyalty, and care to Abbott.

242. By the conduct alleged herein, the Individual Defendants breached those fiduciary duties.

243. By encouraging and accomplishing the illegal and improper transactions alleged herein and concealing them from the public, the Individual Defendants have each encouraged, facilitated, and advanced the breaches of their fiduciary duties committed by each other. In so doing, the Individual Defendants have each aided and abetted, conspired, and schemed with one another to breach their fiduciary duties, waste the Company's corporate assets, and engage in the *ultra vires* and illegal conduct complained of herein.

244. The Individual Defendants had actual knowledge of the breaches of fiduciary duty being committed by the other defendants and provided substantial assistance to them with respect to the breaches of fiduciary duty.

245. Plaintiff on behalf of Abbott has no adequate remedy at law.

COUNT IV
Against the Individual Defendants for Unjust Enrichment

246. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

247. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Abbott.

248. The Individual Defendants either benefitted financially from the improper conduct, or received bonuses, stock options, or similar compensation from Abbott that was tied to the performance or artificially inflated valuation of Abbott, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct. The information necessary to determine the exact amount of unjust enrichment received by the Individual Defendants is exclusively within the control of Abbott, and thus discovery is necessary to more particularly allege the amount of the unjust enrichment.

249. Plaintiff, as a shareholder and a representative of Abbott, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, benefits and other compensation procured by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.

250. Plaintiff on behalf of Abbott has no adequate remedy at law.

/ / /

/ / /

COUNT V
Against the Individual Defendants for Waste of Corporate Assets

251. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

252. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the time period in issue. It resulted in continuous, connected, and ongoing harm to the Company.

253. As a result of the misconduct described above, the Individual Defendants wasted corporate assets by, *inter alia*: (i) paying and collecting excessive compensation and bonuses; (ii) causing the Company to repurchase millions of dollars of its stock at inflated prices; and (iii) incurring potentially millions of dollars of legal liability and/or legal costs in the consumer lawsuits and Securities Class Action, including defending the Company and its officers against the Securities Class Action.

254. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.

255. Plaintiff on behalf of Abbott has no adequate remedy at law.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff, demands judgment as follows:

A. Awarding money damages against all Individual Defendants, jointly and severally, for all losses and damages suffered as a result of the acts and transactions complained of herein, together with pre-judgment interest, molded in a fashion to ensure the Individual Defendants do not participate therein or benefit thereby;

B. Directing all Individual Defendants to account for all damages caused by them and all profits and special benefits and unjust enrichment they have obtained as a result of their unlawful conduct, including all salaries, bonuses, fees, stock awards, options and common stock sale proceeds, and imposing a constructive trust thereon;

C. Awarding punitive damages;

D. Awarding costs and disbursements of this action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: April 4, 2025

Respectfully submitted,

s/Francis A. Bottini, Jr.
Francis A. Bottini, Jr.

BOTTINI & BOTTINI, INC.
7817 Ivanhoe Avenue, Suite 102
La Jolla, CA 92037
Telephone: (858) 914-2001
Facsimile: (858) 914-2002
fbottini@bottinilaw.com

THE LAW OFFICES OF EDWARD T. JOYCE & ASSOCIATES P.C.
Rowena Parma
300 South Wacker Drive, Suite 3250
Chicago, IL 60606
(312) 641-2600
rparma@joycelaw.com

Counsel for Plaintiff

VERIFICATION

I, Matthew Steele, verify that I am a shareholder of record of Abbott Laboratories, Inc. I have reviewed the allegations in this Verified Stockholder Derivative Complaint. As to those allegations of which I have personal knowledge, I believe them to be true; as to those allegations of which I lack personal knowledge, I rely upon my counsel and counsel's investigation, and believe them to be true. Having received a copy of the complaint and reviewed it with counsel, I authorize its filing.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on 3/20/2025 | 4:43 PM PDT.

Matthew Steele

Matthew Steele

EXHIBIT A

EXHIBIT A

CONFIDENTIAL DISCLOSURE RE ABBOTT LABORATORIES' PRODUCTION SITE IN STURGIS, MICHIGAN

I. OVERVIEW[1]

What is alleged in the within complaint is believed to be a series of violations of regulatory requirements relative to the manufacture of infant formula and related products by Abbott Laboratories ("Abbott"). Most of what is alleged is based upon first-hand knowledge [redacted] In a few instances, what is alleged stems from highly credible sources. Complainant stands ready to elaborate on what is alleged, to provide additional information, and to fully cooperate with any federal or state regulatory agency.

It should be emphasized that this complaint is not being filed to retaliate against Abbott.[3] To the contrary, over an extended period the Complainant properly and consistently raised product safety concerns. His protected activity ultimately led to his termination. That wrongful conduct is being appropriately investigated by OSHA.[4] Rather, this complaint stems from his personal knowledge of a litany of violations as well as the knowledge that countless current employees want this information disclosed to enforcement officials. They are rightly fearful of retaliation.

A. BACKGROUND

The Complainant is a former employee of Abbott. During the relevant period, he worked in Quality Systems ("QS"), a subunit of the Quality Assurance organization ("QA") in Sturgis, Michigan ("Sturgis site") as part of Abbott's Nutritional Division ("division"). The Sturgis site was previously a part of Ross Laboratories, a Columbus-based company that was acquired by Abbott. For a number of years, Ross Laboratories remained a separate division of Abbott.

Even though the acquisition took place many years ago, the Sturgis site has never been fully integrated into Abbott's system of internal controls. Unlike other Abbott units, active resistance to a full implementation of electronic records persists. Reliance on paper records for work orders continues to this day. Many of the same people remain in place. Long-term social

[redacted]

friends remain in positions overseeing product safety issues associated with each other.

Against this backdrop, Complainant observed and became increasingly aware of incidents and practices that caused him to be concerned as to the Sturgis site's compliance with the Food and Drug Administration's ("FDA") regulations. As long as one was not inclined to "rock the boat," lax practices, including regulatory violations, were consistently overlooked. Others also raised concerns, some with management but more often among colleagues at the Sturgis site.[5] Given the overriding fear of retaliation, few were as outspoken as the Complainant.[6]

Ultimately, despite an admirable employment record at Abbott and elsewhere,[7] Complainant was terminated based upon his repeated elevation of compliance concerns. That termination is being investigated by OSHA after filing a whistleblower complaint under Section 42 of the Food Safety Modernization Act ("FSMA complaint").[8] The timing of this complaint is prompted by the ongoing nature of the questionable practices and the fear of retaliation by current employees who have raised concerns.[9]

B. THE NATURE OF THE VIOLATIONS

As noted, most of what is reported is based upon Complainant's first-hand observations. In virtually all of these situations, he raised concerns as to regulatory violations with management at the Sturgis site. Most of what he reports has been corroborated through credible sources.

1. ***The Falsification of Records*** – On multiple occasions, and in various ways, records have been knowingly falsified. In most but not all of the situations, information of a material nature was not disclosed. This included testing seals on empty cans; signing verifications without adequate knowledge;

[5]Though far less frequently, officials at the division level were also made aware of Complainant's concerns relative to compliance with relevant FDA regulations.

[6]It must be kept in mind that Abbott's Sturgis site is, in general, the highest paying and largest employer in the immediate area. The loss of one's job is apt to have significant consequences requiring relocation to secure a position with equivalent income and benefits. In an environment where whistleblowers are not protected, raising concerns could put the well-being of families at risk.

[7]Prior to joining Abbott, Complainant's record was stellar both in terms of his academic record and in terms of his employment record. During his time at Abbott, he was never given a bad evaluation. On more than one occasion, he was awarded for being the "Best in Abbott" for carrying out certain aspects of his responsibilities. It was reported that officials at the division level repeatedly complimented him. His situation changed as he became more vocal, especially in challenging the leadership of QS and QA.

[8]21 U.S. Code § 399d.

[9]After the filing of the FSMA complaint, it is understood that officials at the corporate level seem to be more concerned about identifying employees who have raised concerns than addressing the underlying bases for the concerns. Management officials at the Sturgis site have already engaged in the harassment of individuals known to be friendly with the Complainant as well as those who were likely to provide damaging information arising out of a state investigation relative to shooting a stun gun within a facility at the Sturgis site.

understating or inaccurately describing events so as to limit or avoid oversight; issuing certifications of projection pages bereft of pertinent data; shipping packages with fill weights lower than represented on the labels; failing to maintain accurate maintenance records; and prematurely removing holds in the absence of all requisite approvals.

2. ***Releasing Untested Infant Formula*** – The Sturgis site performed a time code removal after the discovery of microorganisms ("micros") in a batch of infant formula. The remaining portion of the batch outside the time code removal was released without additional testing. On another occasion product was not re-called from the market even after management became aware of a nonconformity ("NC").

3. ***The 2019 FDA Audit*** – Active efforts were undertaken and even celebrated during and after the 2019 FDA audit to keep the auditors from learning of certain events believed to be associated with the discovery of micros in infant formula at the Sturgis site.

4. ***Clean-in-Place Staffing and Practices*** – The Sturgis site has continued to permit lax practices associated with clean-in-place ("CIP") procedures. The Sturgis site failed and continues to fail to have staff in place with sufficient training and experience to review CIP charts. Nor are CIP charts regularly reviewed prior to the release of a batch. CIP checklists do not require signatures of those performing the tasks and are not otherwise subject to audit by QS staff.

5. ***Failure to Take Corrective Measures –*** The Sturgis site has repeatedly failed to undertake reasonable measures to reduce natural or unavoidable defects to the level feasible as mandated by the current Good Manufacturing Practices ("cGMPs").[10] Deficient testing procedures known to be prone to causing mistakes have not been corrected. The Sturgis site continues to rely on staff with insufficient training and experience to interact with third-party labs ("TPL").

6. ***Lack of Traceability*** – The Sturgis site has ongoing problems associated with the traceability of its products. The automatic labeler frequently failed to work properly and led to significant difficulties in retracing product. QS staff never knew with certainty if an affected pallet was retrieved.

[10] *See*, e.g., 21 CFR § 117.110(a).

A remaining and overriding concern is the rather dramatic evidence of inadequate internal controls. The delay in transitioning to electronic records; the absence of adequate procedures to protect employees raising concerns; the pervasive lack of accountability; the questionable incentive structure; and the ongoing failure to address a material contingent liability, among others, are endemic to inadequate internal controls where food safety is paramount. Abbott's financial statements may also suggest regulatory concerns with respect to the inadequacy of its internal controls.[11]

C. THE ONGOING CONCERNS

Most if not all of the concerns raised by the Complainant in his FSMA complaint have been corroborated by others. Complainant also understands that Abbott has been made aware of credible information that corroborates the concerns raised. However, to date, no serious effort has been undertaken to address these concerns. One report suggests a greater interest at the corporate level of identifying the sources of complaints as opposed to addressing the underlying concerns raised.[12]

Aside from the compelling need to protect consumers, Complainant believes that other employees at the Sturgis site are currently at risk.[13] To protect those currently employed at Abbott, Complainant respectfully requests that, for the time being, this report be kept confidential and exempt from disclosure under the Freedom of Information Act ("FOIA"). He is prepared to fully cooperate and provide more specifics, including identifying individuals who can corroborate what is disclosed in this complaint.[14]

II. THE SUSPECTED VIOLATIONS

The suspected violations may be categorized in a variety of ways. But regardless of category, the common thread was and is to conceal the reality of what is taking place at the Sturgis site. The violations are neither inadvertent nor minor in nature. They constitute acts of commission and omission by management. In either case, what has been concealed is, in a number of instances, material information and holds the prospect of putting the ultimate consumer at risk.

[11] 15 U.S.C § 7262.

[12] In a related investigation arising out of the shooting of a stun gun within the facilities at the Sturgis site, it is known that the corporate officials disclosed the identity of the source of the complaint. [redacted]

[14] Given the credible fear of retaliation, Complainant emphasizes that a number of employees will be reluctant to come forward or speak candidly in the presence or even the knowledge of Abbott officials.

A. FALSIFICATION OF RECORDS

Complainant has first-hand knowledge of practices associated with the falsification of records on a regular and ongoing basis. He has reason to believe that these practices are not limited to what he personally observed. Most often the falsification took the form of material omissions. Sometimes a situation was incorrectly categorized. Other times, the records were simply falsified. In virtually all of the situations, the conduct was intentional and designed to conceal the reality of what was actually taking place at the Sturgis site.

1. Seam Testing of Empty Cans

The cGMPs and 21 CFR § 106.40(f)(3), in particular, provides:

> Any ingredient, container, or closure that has not been manufactured, packaged, labeled, or held under conditions to prevent adulteration under section 402(a)(1) through (a)(4) of the Federal Food, Drug, and Cosmetic shall not be approved and released for use.

The Sturgis site has had ongoing problems with seam integrity with powdered products. On an episodic basis, powder would become enmeshed in the seam thereby jeopardizing the integrity of the seal and product safety. Instead of addressing the underlying problem, the testing process was altered to test empty cans instead of sealed cans containing the product. To the Complainant's knowledge, this questionable practice was never disclosed or referenced in records that came to his attention.[15] He has reason to believe that the questionable practice has *not* ceased and, as well, has not been disclosed to FDA officials.

a. Recall of Calcilo XD

The cGMPs for infant formula and 21 CFR § 106.100, in particular, provides in pertinent part:

* * * * *

> (e) For each production aggregate of infant formula, a manufacturer shall prepare and maintain records that *include complete information* relating to the production and control of the production aggregate.

* * * * *

[15] In addition, the practice also appears to have violated 21 CFR § 106.40(d)(4), which requires in pertinent part that a manufacturer "[e]nsur[e] that each container of finished product is properly sealed."

> (2) Any deviations from the master manufacturing order and any corrective actions taken because of the deviations.
>
> * * * * *
>
> (o) *The manufacturer shall maintain quality control records that contain sufficient information to permit a public health evaluation of any production aggregate of infant formula*.[16]

In 2019, Abbott recalled a batch of Calcilo XD for discolored powder and rancid smell. It was caused by powder being in the seam on the Abbott-applied end of the can.[17] A large portion of several batches of Calcilo XD produced after the recall had the same problem.[18] Complainant has direct knowledge that the work order was changed to suggest that the Sturgis site was doing everything necessary to prevent powder from getting into the seams.

As an example, the frequency of the seam checks was increased by the terms of the work order. It was made to appear that the Sturgis site had increased its oversight to correct for the deficiency that had been discovered with respect to seam-integrity issues. But what actually took place in terms of testing was not fully disclosed. Critically, instead of directly addressing the underlying problem, seam checks were performed on empty cans. Performing seam checks on empty cans was the only way to achieve passing results without finding powder in the seam. Management at the Sturgis site directed that the checks be performed in this manner.

In addition, during the rework, instead of "tearing down" the cans to verify whether there was any powder in the seams, the operators were directed to weigh each can to show that the correct amount of powder was in the can. However, it was well known that if the powder is too fluffy, the can may fall within the acceptable weight range and powder can still be in the seam.

These decisions were made because leadership knew powder would be found in the seam. They did not want to discard the entire batch. A number of production operators raised concerns with Complainant and others. They reported that they were being directed to perform seam checks

[16]Emphasis added.

[17]When powder gets in the seam, the seal is not as tight as it should be. Air, moisture, and bacteria can get into the can thereby leading to the powder becoming discolored and rancid.

[18]It is understood that this continues to be an ongoing problem.

on empty cans.[19] He has reason to believe that the practice of testing empty cans continued after his departure.[20] He also believes that the FDA has never been apprised of this practice.

b. Similac

The cGMPs and 21 CFR § 106.70(d), in particular, provides:

> A production aggregate of infant formula, including a reprocessed or reconditioned production aggregate, that does not meet the nutrient requirements of section 412(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a(i)) or that has not been manufactured, packaged, labeled, and held under conditions to prevent adulteration under sections 402(a)(1) through (a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 342(a)(1) through (a)(4)) *shall not be approved and released for distribution*.[21]

During the week of August 17, 2020, and possibly earlier, seam integrity issues were discovered in multiple batches of Similac Sensitive for Spit Up ("Similac"). Roughly half of the affected product remained within the control of the Sturgis site. The other half had been shipped. Even though management was aware of what occurred, product was not called back for inspection.

Complainant raised his concerns as to what was taking place with other members of QA leadership. Complainant was told that the Sturgis site was required to notify officials at the division level that a nonconforming product had been released. It is Complainant's understanding that there is a "grading" scale based on severity that Abbott uses in these situations. However, despite the objections of staff, he was told by those directly involved that the Sturgis site intentionally misrepresented the severity of the issue to division officials.[22]

---

[19]Complainant recalls that during the production of the Calcilo XD batch(es), two powder packaging operators came to QS and raised concerns as to the seam checks being performed without any powder in the cans. [redacted] Complainant confirmed the accuracy of what was reported with a colleague in the powder packaging unit. He received conflicting information as to whether this was an isolated event. [redacted] Including himself, Complainant is aware of at least six individuals outside of management who were knowledgeable as to what occurred. Complainant saw the work order associated with the Calcio XD batch(es) and knows that the work order did not disclose that the testing was performed on empty cans.

[redacted]

[21]Emphasis added.

[redacted]

More than three months after the problem was discovered, the product still under Abbott's control was destroyed.[23] However, no recall was issued for the shipped product that was already in the marketplace. Generally, products are destroyed only when deemed to be non-compliant or unsafe for the consumer. Yet no action of any kind was taken for the product already in the marketplace.

2. Signing Verifications without Adequate Knowledge

At various stages of the production process, a need arises to verify that certain steps were taken or to explain corrective actions taken. At times two signatures are required. At other times, only one signature is required. However, in each instance, it was Complainant's understanding that a verification required first-hand knowledge or an independent and credible basis upon which to sign the verification. Relying exclusively on the word of others was insufficient.

a. Line Clearance

The cGMPs for infant formula and, 21 CFR § 106.100(f)(4), in particular, provides that the manufacturer of infant formula shall maintain

> [r]ecords, in accordance with § 106.30(f), on equipment 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*.[24]

What is referred to as "line clearance" is the process of clearing a packaging line at the end of a batch. At the Sturgis site, the process begins by placing a colored can on the line at the beginning of the packaging line and then following the can through every process or stage of the packaging process. Once the colored can arrives at the end of the packaging line, it can be assumed that the product and cans, or both, from the previous batch have been removed from the line. The risk of any product (powder) making it into the next batch is largely eliminated.

Along with clearing the line, other items are checked as well. Among others, can size, label, cap, shipping container, scoop (these are all commodities) can differ from batch to batch. Changes may need to be made to ensure that whatever is required for the next batch can be accommodated. In every work order for each batch, a "line clearance" section is included with critical subparts requiring verification/signatures by two operators or managers.

---

[23]It is understood that much of the shipped product was at Abbott-owned or affiliated distribution centers.

[24]Emphasis added.

Often, an operator or manager did not sign his or her portion verifying the line clearance. Some portions of the work order are required to be double verified. Complainant regularly resisted management efforts to pressure him to sign the second verification for which he had no personal knowledge as to whether the task had been actually performed. QS staff were told by management that the sole purpose of the second signature was to verify the existence of the first signature. No independent verification was required.[25]

b. Technical Equipment/Engineering Issues

The cGMPs for infant formula and 21 CFR § 106.40(d), in particular, 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*.[26]

From time to time, Plant Information Reports ("PIR") from production were sent to QS to report an issue with a piece of machinery. The purpose of the PIR is to identify any deviations from the work order that occur during the manufacturing of a batch and, if applicable, the steps taken to correct the deviation. Frequently, no one in QS had the requisite knowledge to know whether the steps taken were acceptable.

In order to address the PIR, someone with QA had to explain why the corrective action was acceptable or, if not, what steps needed to be taken to appropriately address the issue. Complainant's supervisor would typically not address the PIR. Instead, she would relay the information to Complainant and ask him to sign the PIR without affording him an opportunity to undertake his own review before signing the PIR.

[25]Complainant was directly involved with the line clearance verifications as he repeatedly refused to verify what occurred without adequate information. [redacted] Members of management were well of aware of this practice of having verifications completed by individuals who lacked the requisite knowledge.

[26]Emphasis added.

These situations usually resulted in an argument where Complainant refused to sign the PIR due to his lack of personal knowledge.[27] Complainant had no fundamental objection to the verification or certification process.[28] The issue was whether he and others had sufficient knowledge to attest to the appropriateness of the action taken. Asking others to sign off as a matter of course was pervasive at the Sturgis site with the full knowledge and participation of management. Complainant has reason to believe the practice remains ongoing.

c. Signing Off on Nonconforming Product

The cGMPs for infant formula and 21 CFR § 106.60(a), in particular, provides:

> 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.[29]

Meeting metrics frequently took precedence over product safety at the Sturgis site. Complainant is aware of multiple situations where PIRs were approved despite the product being out of specification ("OOS"). The OOS information was documented in a PIR. This should have initiated a potential nonconformity ("PNC") or an NC. However, officials at the division level would have been almost assuredly made aware of the designation of a PNC or NC.

To make a problematic situation less likely to be tracked and monitored by officials at the division level, management at the Sturgis site often moved OOS batches into a category known as "quality assessment." A PNC or a NC required certain individuals from the division level to sign off. Once division signed off, then the Sturgis site could move forward. However, by categorizing a problem or situation as a quality assessment, those within the QA organization at the Sturgis site could resolve an issue without the approval of division officials.[30]

In some instances, this meant that further testing or some sort of rework was not performed. It also meant that product was knowingly released where the expiration date of the product may

[27] In addition to members of management, Complainant [redacted] have direct knowledge of this practice. [redacted]

[28] For example, when his supervisor was unavailable, he did participate in the process. At those times, he was able to make an independent determination based on his own inquiry as to whether the actions taken were appropriate.

[29] Emphasis added.

[30] The "Low-Fill Weights" scenario described on pages 12-13 is a prime example of this practice. In that situation, in addition to management, the Complainant, [redacted] other individuals have direct knowledge of what occurred. ABTRAQ should show an audit trail whereby the PNC was initiated for the low-fill weights and then cancelled with a quality assessment being initiated to replace the PNC. ABTRAQ requires justification for each of these steps.

have been well before the date disclosed on the label.[31] Complainant has reason to believe that this practice has not ceased and continues to this day.

d. Overriding Quality Assessments to Meet Metrics

The mandate of the cGMPs and 21 CFR § 117.110(a), in particular, require that "[t]he 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.[32] Furthermore, 21 CFR § 117.305 requires that records must:

> (b) *Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities*;
>
> (c) Be *accurate*, indelible, and legible; . . . .[33]

In addition, 21 CFR § 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*.[34]

For the majority of the adverse events that arise during production, Abbott has a procedure known as the Standard Quality Evaluation ("SQE") procedure. The procedure covers a multitude of scenarios. It directs how certain issues are to be addressed. Each scenario has a number or code associated with it. As part of evaluating the PIRs and the Quality Assessments,

[redacted]

[32]Emphasis added.

[33]Emphasis added.

[34]Emphasis added.

Complainant and others would apply these codes referencing the SQE procedure as justification for the adverse event being acceptable.[35]

Increasingly over the last 12 months of Complainant's time at Abbott, management directed him and others to misuse the SQE procedure in order to meet metrics for the Sturgis site. The misuse primarily occurred with the application of SQE 6.16 in lieu of SQE 6.12. Both of these SQEs relate to missed checks at the packaging/finished product stage.

SQE 6.12 pertains primarily to missed visual inspections and seam integrity checks. Often, in order to meet the criteria of SQE 6.12, it is time consuming and costly as reworking the product tends to be the resolution. SQE 6.16 pertains to, among others, missed oxygen checks, "overcap" inspections, and outgoing package quality checks. For the most part, the criteria for resolving SQE 6.16 is found within the work order.

In order to meet metrics and, at times, over the objection of Complainant and others, management started directing Compliment and others to document SQE 6.12 events as SQE 6.16 events. At times, Complainant and others objected.[36] Indeed, on occasion, managers were repeatedly confronted and questioned as to the appropriateness of the directive being given.

3. Low-Fill Weights

FDA regulations and 21 CFR § 101.7(g), in particular, provides, in pertinent part, that

> [t]he declaration shall *accurately* reveal the quantity of food in the package exclusive of wrapper and other material packed therewith . . . .[37]

Sometime during 2019, the eight-ounce liquid packaging line had issues with low-fill weights. Over the course of several hours, the fill weights of cans were below the weight listed on the label. Instead of shutting down the line to correct the problem, the decision was made to keep filling the cans.

The initial plan was to destroy the cans where the weight was not consistent with the label.

---

[35]For example, based on his recollection, Complainant recalls that SQE 6.13, in effect, states that if a nutrient or mineral is OOS in-process, it must test within specification at finished product or project within specification at finished product. Once it is verified that the mineral or nutrient tests or projects within finished product specifications, then the SQE can be applied and the event is determined as acceptable.

[36]In addition to at least two members of management, Complainant [redacted] were knowledgeable of this practice. [redacted]

[37]Emphasis added. It is suspected that conduct may have violated other provisions of 21 CFR part 101.

The Sturgis site initiated a PNC for the incident. This was required by Abbott's Corrective Action Preventative Action ("CAPA") policy. However, management at the Sturgis site later cancelled the PNC and initiated a quality assessment to keep the situation less visible from officials at the division level.

Management at the Sturgis site then made the decision to "shuffle the deck." Cases of under-filled product were spread throughout the batch. Pallets were unstacked and restacked with the correct number of under-filled cases to get each pallet to the same weight. The object was to avoid any discrepancies in weight so that distribution centers would not be able to detect whether they were receiving noncomplying product.[38]

Complaints were made to management at the Sturgis site. Even members of QA leadership were also reported to have expressed concerns to the Complainant. One member of QA leadership went so far as to suggest to Complainant the "criminality" of the decision to proceed in this manner.

4. <u>False Certifications</u>

The cGMPs and, 21 CFR § 117.305, in particular, requires that records must:

* * * * *

(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

[38]Complainant has knowledge of this incident as he was directly involved with the batch. In addition to at least two members of management, [redacted] As noted in footnote 30, ABTRAQ should show an audit trail with respect to this incident.

> (4) Where appropriate, the identity of the product and the lot code, if any.[39]

It was not unusual for management to disregard situations involving severe breaches of the most basic regulatory requirements. In July of 2020, Complainant became aware of projection pages missing test results associated with nine batches of product. For each batch, a projection page missing test results was approved by three analytical lab chemists and one QS auditor. In essence, the certifications as to the test results were patently false as the test results were not included.

What occurred represented a major and serious breakdown in the controls designed to ensure that the product met specification.[40] Management at the Sturgis site was aware of what occurred, that is, 36 serious performance errors for nine batches of product in a short period of time. Signing off on projection pages with missing test results was repeated multiple times. This was neither inadvertent nor isolated. It meant that a complete breakdown had occurred.

Despite the blatant nature of what occurred, and its egregiousness in terms of putting consumer safety at risk, management took no corrective action in terms of discipline. Nor were remedial measures put in place to reduce the likelihood of a recurrence.

5. Inaccurate Maintenance Records

The cGMPs and 21 CFR § 106.30(f), in particular, provides in pertinent part that:

> [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.
>
> > (1) 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.
> >
> > (2) A manufacturer shall make and retain records on equipment cleaning, sanitizing, and *maintenance*, in accordance with § 106.100(f)(4).

[39]Emphasis added.

[40]Complainant discovered this situation. A very large number of individuals were made aware as it affected multiple job functions. Most of the QS staff was aware. A large number of members of the analytical lab were made aware. In addition to management, at least 10 people, including the Complainant, have knowledge of this episode. If proper procedures were followed for making corrections to the projection pages, a record should exist showing a signature for a previous date. If the projection pages signed in this manner are no longer in the batch records, then the batch records were falsified to conceal what occurred.

In terms of records, 21 CFR § 106.100(f)(4) requires that

> [r]ecords, in accordance with § 106.30(f), on equipment 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.*[41]

In addition, the cGMPs for infant formula and 21 CFR § 106.35, in particular, provides in pertinent part that:

> (b) 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.
> >
> > * * * * *
> >
> > (3) A manufacturer shall ensure that each system is validated prior to the release for distribution of any infant formula manufactured using the system.[42]
>
> (c) A manufacturer shall make and retain records, in accordance with § 106.100(f)(5), concerning mechanical or electronic equipment.

In terms of records, 21 CFR § 106.100(f)(5) requires that

> [r]ecords, in accordance with § 106.35(c), on all mechanical and electronic equipment used in the production or quality control of infant formula. These records shall include:
>
> * * * * *

[41]Emphasis added. It should be noted and emphasized that the Sturgis site *did not and does not* require "the person performing and checking the cleaning, sanitizing, and maintenance" to "date and sign or initial the record indicating that the work was performed."

[42]Emphasis added.

(iii) Records that document installation, calibration, testing or validation, and maintenance of the systems used;

The maintenance department at the Sturgis site is responsible for making sure the equipment at the Sturgis site is maintained and functioning properly. In order to do this, the maintenance department has their own tasks to complete on a scheduled basis. Once a maintenance technician physically completes a task, he or she is required to indicate the completion of the task in the web-based program. Complainant was advised on multiple occasions by credible sources that certain maintenance technicians regularly indicate on the web-based program that tasks have been completed when in reality they have not been completed.

It has also been reported to the Complainant that supervisory staff in the maintenance department have been known to falsify root causes when participating in CAPA investigations.[43] One credible source reported that an incident was blamed on an operator when further investigation demonstrated a mechanical issue. Management and maintenance officials looked the other way despite evidence of a mechanical failure.[44] As opposed to accepting responsibility for mechanical and other failures associated with equipment, it is not uncommon for maintenance supervisors to blame others instead of addressing the root cause.

6. Premature Release of Holds

The mandate of the cGMPs and 21 CFR § 117.110(a), in particular, require that "[t]he 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.[45] Furthermore, 21 CFR § 117.305 requires that records must:

[43]As an example, Complainant became aware of a situation where one of the seamers was seaming two ends to a can instead of seaming one end to a can. When two ends are seamed to a can this causes significant seam integrity issues. Maintenance technicians were able to prove this was directly caused by the feeder that feeds can ends to the seamer. Maintenance management did not want to take the blame as they were responsible for the seamer functioning properly. Maintenance management blamed the issue on the powder packaging operator who set up the seamer. The particular seamer was able to seam two different can diameters. When changing can sizes, the seamer had to be reconfigured. If not done properly, it would cause seam integrity issues. However, it would not cause the seamer to apply two ends to a can. Both QA and maintenance management knew that the operator did not make a mistake, but they chose to blame him/her anyway.

[44]Complainant has reason to believe that management was aware of the original findings of an equipment failure. However, to appease the maintenance manager, management changed the root cause. [redacted] However, it was also the Complainant's experience, which was shared by colleagues, that management sought to avoid calling into question the performance of others as they feared that there would be retaliatory disclosures as to improprieties associated with their own conduct. This was particularly prevalent among senior members of management and long-term employees.

[45]Emphasis added.

* * * * *

> (b) *Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities*;
>
> (c) Be *accurate*, indelible, and legible; . . . .[46]

In addition, 21 CFR § 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*.[47]

When a PNC or an NC was initiated for a batch, what were referred to as isolation reports, essentially holds, were created for the batch. The holds associated with isolation reports were not to be removed until the PNC or NC was adequately addressed. This meant that there had to be signoffs by management and pertinent specialists as to the various factors that prompted the PNC or NC. In other words, documentation must be in the batch record to establish that the basis for the PNC or NC had been adequately addressed.

However, Complainant consistently encountered situations where he and others were directed by management to prematurely sign off on isolation reports without having the requisite documentation demonstrating that it was acceptable to remove the hold and release the batch. In order to release the batch, all affected product has to be acceptable for release, that is, all release criteria had been met with supporting documentation establishing that all the requisite approvals had been secured.

Quite simply, the representation that Complainant and others were directed to make was false. All of the criteria had not been met. The approval for the release of the hold was premature. The sign off on the holds were premature. All release criteria had not been met. Management was aware of the absence of adequate supporting documentation but nonetheless directed that the hold

[46]Emphasis added.

[47]Emphasis added.

be released. Most of the time when this occurred, the requisite supporting documentation was provided in the evening after the release of the hold.[48]

B. RELEASE OF INFANT FORMULA

The cGMPs and 21 CFR § 106.30, in particular, provides in pertinent part that:

> (a) 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.
>
> (b) 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.*[49]

For several years, some of the equipment associated with the drying process at the Sturgis site was failing and in need of repair.[50] As a result, a number of product flow pipes were pitting and leaving pin holes. This allowed bacteria to enter the system and, at times, led to bacteria not being adequately cleaned out in clean-in-place ("CIP") washes. This, in turn, caused product flowing through the pipes to pick up the bacteria that was trapped in the defective areas of the pipe.

The Micro Batches

Prior to the 2019 FDA audit, management authorized the release of infant formula that tested positive for micros. The batch of infant formula in question was the batch that had triggered

[48]At least two members of management were aware of this practice as they directed the Complainant and, at times, others to direct the premature closure of a hold. In addition to the Complainant, [redacted] Documentary evidence should be available in the form of work orders where the Complainant's signature approving the closing of the hold was crossed out and then signed on a subsequent day. Most often it was on the following day.

[49]Emphasis added.

[50]In terms of the flow pipes, Complainant was advised by an operator that leadership at the Sturgis site was aware of the failing equipment anywhere from five to seven years from the event occurring. *See*, e.g., 21 CFR §§ 106.35(b); 106.55; 117.80(c)(2); 117.80(c)(7).

the internal investigations into the product flow pipes and the investigation into the spray balls. This episode was generally referred as "the micro batches" at the Sturgis site.

Since the micros were discovered during the standard batch testing (10 samples pulled evenly throughout the production of the batch, not including the first and last can produced),[51] 15 additional samples were taken and tested. Of these additional samples, multiple samples tested positive for micros. At that point, the decision was *not* made to destroy the entire batch. Instead, a time code removal was performed.[52]

Management decided to add so many minutes prior to and following each timeframe to "ensure" that they had eliminated all the product with micros. However, once the product was culled out, an additional set of testing was *not* performed to provide evidence that all the micro-positive product was captured and destroyed.[53] The infant formula was released commercially without supporting documentation to suggest it was compliant and safe for consumption.[54]

C. THE 2019 FDA AUDIT

During the 2019 FDA audit, it was generally known that the Sturgis site was worried what the FDA would find about the micro batches. Throughout the audit, QA leadership kept QS staff apprised. One member of management stated that the FDA was on the "right trail." She even volunteered that she was amazed that the FDA was unable to discover what occurred with the micro batches.

Once the FDA audit was over, staff and department managers congratulated each other on a successful FDA audit. Complainant came to learn of a meeting where a senior QA official was understood to have admitted the awkwardness of having to avoid providing direct answers to

[51]At the time, this was the standard micro sampling procedure. During the 2019 FDA audit, the FDA cited the Sturgis site for not sampling adequately for micro testing. As a result, the division and the Sturgis site have increased their micro sampling. It is Complainant's recollection that each division site now pulls 30 samples, not including the first and last can produced.

[52]On every can produced, the Julian date and the time the can was produced is printed on the bottom of the can. When a time code removal is performed, every can that contains a time that falls within the affected time frame is culled out and discarded.

[53]Complainant has direct knowledge of this situation as this was a batch for which he was directly involved. He became aware of the situation from records provided to him. [redacted] Excluding members of management, including at the division level who were also aware of what occurred, at least five individuals, including the Complainant were aware of what occurred. The records associated with the batch should reflect the time code removal and the failure to undertake a follow-up test.

[54]At the time, Complainant told his supervisor that he was not comfortable with the decision to release the product. It is the Complainant's understanding that senior management was under significant pressure to meet its "numbers" as the Sturgis site had already had to destroy $8 million in product.

questions asked by the FDA.[55] While Complainant does not know what precisely was withheld from FDA officials, he is aware of a conscious effort to avoid disclosure.[56]

"Preparing" files for Auditors

In addition, in conjunction with FDA and corporate audits, Complainant became aware of what he reasonably believed was a practice of "sanitizing" files before furnishing them to auditors. It involved records being pulled and reviewed by management officials apart from where the auditors were located. He was also led to believe that some records were culled before furnishing a file to the auditors. Complainant does not know what actually took place. But he had and has concerns based upon what he observed in other contexts during his time at the Sturgis site.[57]

D. CLEAN-IN-PLACE (CIP) STAFFING AND PRACTICES

The CIP practices at the Sturgis site were inadequate in countless ways. Aside from being dangerously lax in terms of product safety, they suggest countless violation of cGMPs. Despite concerns raised with management by the Complainant and others, the questionable practices were allowed to proliferate.

1. No Regularized Practice of Verifying that CIP Work Was Performed

The cGMPs and 21 CFR § 106.30(f), in particular, provides that:

> [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.
>
> > (1) 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.
> >
> > (2) A manufacturer shall make and retain records on equipment cleaning, sanitizing, and maintenance, in accordance with § 106.100(f)(4).

[55] It was generally known that this official is reported to have stated something along the lines of "All I could do was smile. I couldn't answer their questions without incriminating the site."

[56] All of QS was aware of the Sturgis site being worried what the FDA would find. A far greater number of employees were present when a member of management admitted to withholding information from the FDA.

[57] The Sturgis site has a history of misleading Abbott's corporate audit team. After the Sturgis site covered up the 2010 beetle infestation such that within a month or so after the corporate audit, Abbott recalled numerous batches affected by the infestation and shut the plant down temporarily for cleaning.

In addition, 21 CFR 106.100(f)(4) provides that

> [r]ecords, in accordance with § 106.30(f), on equipment 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.*[58]

The Sturgis site relies on what is generally referred to as a checklist for its CIP ("CIP checklist") process for equipment. It is essentially a document that directs the operators on how to perform the CIP. It lists all the steps that need to be performed as part of the CIP process such as what needs to be done to prepare the equipment for the CIP; what needs to be done while the CIP is running; and what needs to be done after the CIP is finished.[59] At the Sturgis site, the CIP checklist is not part of the records of a batch and therefore is not subject to review by QS.

The CIP checklists are controlled by the manufacturing departments: processing, drying, and dry blending. Each department creates its own CIP checklist. A committee associated with each department controls all changes to their CIP checklist. The committee decides if a suggested change is needed. For every task in the CIP checklist, there is a provision for an operator to sign and date for completing that task. However, no one reviews the checklists to determine whether the steps were taken, including providing the requisite signature.

At the Sturgis site, there is no requirement for those performing the CIP work to sign and date any document verifying the performance of the work. No review or enforcement takes place by QS or anyone at the Sturgis site. If an operator is not inclined to sign the CIP checklist, no one is held accountable. The checklists are maintained by each department and are not part of the batch records.

Management was well aware of the inadequacy of the monitoring of the CIP checklists.[60] On numerous occasions, Complainant, as well as others, specifically requested that the CIP

[58]Emphasis added. Again, it should be noted and emphasized that the Sturgis site *did not and does not* require "the person performing and checking the cleaning, sanitizing, and maintenance" to "date and sign or initial the record indicating that the work was performed."

[59]Some examples would include spraying down the inside of the equipment; ensuring the chemical hoses are properly connected to the equipment; and verifying the absence of any remaining product or water in the equipment after the completion of the CIP.

[60]This was common knowledge throughout these production departments (processing and dry blending). Complainant became directly aware of this failure when he was a dry blending operator. In addition to management, at least seven in QS knew that the CIP checklists exist and the absence of any meaningful monitoring. Over 20 people in the two production departments are aware of the CIP checklists and the inadequate monitoring of the checklists.

checklists be converted to a work order, be subject to Abbott's change control processes, and be audited to ensure compliance with FDA protocols. Their requests were repeatedly rejected.

2. Lack of Adequate Education, Training, or Experience

The cGMPs for infant formula and 21 CFR § 106.10(a), in particular, provides that:

> [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.[61]

The cGMPs for infant formula and 21 CFR § 106.30(f), in particular, also provides that:

> [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.
>
> > (1) 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.[62]

What is often referred to as a "CIP chart" is a chart that records the mechanical testing as part of the CIP process and the chemical concentrations used in the CIP process. For example, the CIP Chart also shows when one piece of equipment turns on and off. The chart shows at the cleaning stage and at the sanitization stage how much of each chemical is being used for cleaning.

In 2019, management at the Sturgis site decided to no longer have the CIP engineer or a quality engineer review CIP charts after a cleaning was performed on stationary equipment. The recommendation was made to create a position and hire an individual who would undergo the proper training to be able to understand and review these charts. However, the two ranking members of the committee, the QS manager and the site compliance manager, rejected the recommendation and chose to have a contingent employee "review" the charts instead.

On a number of occasions, Complainant raised concerns with management as to the inadequacy of the training and experience of those individuals conducting the CIP review process.[63] Since the contingent worker did not have the experience, knowledge base, or training,

[61]Emphasis added.

[62]Emphasis added.

[63]All of which was consistent with the mandate of the cGMPs and 21 CFR §§ 106.30(f)(1); 117.4(b) in particular. Two of Complainant's colleagues brought the situation to Complainant's attention. In addition to

he or she could only audit the chemical concentration information in the CIP chart.[64] It was and remains the Complainant's view, which was shared by others, that the Sturgis site did not,[65] and still does not, have someone of sufficient experience or training conducting the review process of the CIP charts.[66]

3. Inadequate Review of CIP Charts

The cGMPs for infant formula and 21 CFR § 106.35(b), in particular, provides in pertinent part that:

> [a]ll 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.
> >
> > * * * * *
> >
> > *(3) A manufacturer shall ensure that each system is validated prior to the release for distribution of any infant formula manufactured using the system.*
>
> (c) A manufacturer shall make and retain records, in accordance with § 106.100(f)(5), concerning mechanical or electronic equipment.

management, the leadership of the three departments were well aware of the decision to hire an untrained individual lacking in relevant experience and education.

[64]At the time of Complainant's termination, no one in QS had the appropriate training or knowledge base needed to review the CIP charts. The knowledge base for this task would require substantial training and experience.

[65]During one of the 2019 micro events, one of the root causes was an electrical shortage that caused some of the spray balls (cleaning chemicals are shot through the system via the spray balls) inside the processing equipment to malfunction. As a result, the spray balls were covered in caked-on moldy product. This malfunction could have been caught simply by a review of the CIP chart by experienced and properly trained CIP staff. Indeed, this issue was discovered on a CIP chart several weeks later once QA leadership asked a CIP engineer, who had the requisite training, to take a look at the chart pertaining to this CIP.

[66]Prior to August of 2020, the absence of sufficiently trained and experienced personnel had been ongoing for well over a year. This was not an oversight on the part of management. Management fully understood the importance of having someone with adequate experience and training.

It is the Complainant's understanding that the Sturgis site has been reporting to the FDA that CIP charts were reviewed prior to the release of each batch.[67] Such an assertion was false and, importantly, materially false. The only time someone would review the CIP charts was when problems arose. The contingent worker was basically gathering and filing the charts. Given their lack of experience and inadequate training, they were unable to undertake a credible review of the CIP charts.

But aside from a lack of training and experience, the audit of the CIP charts was inadequate. No audit or review of the CIP checklists takes place to ensure that the requisite steps were taken. The CIP checklists tell operators what to do or how to perform the CIPs. The CIP chart only shows whether everything mechanically worked correctly and whether or not the correct chemical concentration was used.

The CIP chart does not state whether or not the equipment is actually clean or whether a CIP is performed properly. For example, unlike the CIP chart, the CIP checklists literally direct an operator, after the CIP is complete, to open the equipment and visually inspect for any missed product. If there is still product in the equipment after the CIP, the check list directs the CIP to be redone.

4. Spot Cleaning Instead of Entire Area Cleaning

The cGMPs for infant formula and 21 CFR § 106.20(a), in particular, provides that:

> [b]uildings 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.

Spot cleaning is usually done after a protein-free CIP takes place. In order to provide data stating an environment is truly protein free, the lab takes environmental swabs. If one of the swabs comes back positive for protein, that specific spot is re-cleaned and re-tested. If an environmental swab tests positive for protein, Abbott policy requires that the entire environment be re-cleaned and re-swabbed. But again, meeting metrics took precedence. The practice at the Sturgis site was to re-clean the localized area and then re-test. The policy was repeatedly disregarded during Complainant's time at the Sturgis site.[68]

[67]Indeed, a member of management stated to others on several occasions that this is what was being told to FDA officials.

[68]Complainant first experienced this ongoing practice as a dry blending operator. It was a common practice in the processing, drying, and dry blending departments. Several people from QS previously worked in production, and they too were aware of these practices as it was discussed with Complainant from time to time. In addition to management, the lab performing the swabs was also aware of the practice.

E. FAILURE TO TAKE CORRECTIVE MEASURES

The mandate of the cGMPs and 21 CFR § 117.110(a), in particular, require that

> [t]he 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.[69]

a. Failure to Correct a Notoriously Deficient Testing Procedure

Complainant was responsible for a testing procedure relating to the export of product that was widely known to be prone to lead to mistakes by highly competent employees. This was common knowledge within the division and the Sturgis site.[70] Complainant was even told by division headquarters that some sites were not using the testing procedure because of the extreme difficulties it posed in leading to errors.

The Sturgis site produces more products affected by this procedure than any other site in the division. In February of 2020, Complainant was explicit in raising concerns as to the efficacy of the testing procedure. He suggested that steps be taken to address the problems with the procedure so as to avoid a recurrence of what had happened to him as well as countless others within Abbott's operations.

Despite the widely acknowledged deficiencies of the testing procedure, Complainant's suggestion for taking remedial action was rejected by management at the Sturgis site.[71] No remedial action of any kind was suggested or even encouraged. Despite its widely-recognized deficiencies, the testing procedure continues to be used.[72]

b. Inadequate Training and Experience to Interact with Third-Party Labs

Aside from failing to comply with the mandate of 21 CFR § 117.110(a) to reduce natural or unavoidable defects, the Sturgis site failed to comply with the requirements of the cGMPs of

[69]Emphasis added.

[70]It was even acknowledged at a 2019 Abbott Nutrition conference attended by the Complainant with other QA representatives.

[71]As further evidence of the nature of the retaliation against those who raised concerns, Complainant's isolated mistake associated with the procedure was used against him. It was his first and only mistake associated with the procedure. The irony was that the Complainant became the "go to" expert within the division as to the testing procedure.

[72]Complainant repeatedly raised his concerns with management at the Sturgis site as well as others at the division level. The deficiencies were widely known despite risk to product safety and quality assurance in the export of product.

having "an individual qualified by education, training, or experience" in a position to make such determinations in interacting with the TPLs. Indeed, 21 CFR § 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.[73]

Every division site in the United States utilizes TPLs to test items they are not capable of testing. Sometimes TPLs are also used where it may be more efficient. Except for the Sturgis site, the analytical labs at each site work directly with the TPLs. This can involve highly technical issues requiring significant training and expertise.

The Sturgis site moved the responsibility for interacting with the TPLs to QS. No one within QS had the same level of expertise as the staff of the analytical lab at the Sturgis site. Nor did the Complainant who was made responsible for interacting with the TPLs. He was repeatedly put in situations where he lacked adequate training and experience.

While Complainant tried to compensate for his lack of expertise by seeking input from the analytical lab, he was not qualified to address many of the complexities associated with the TPL. He repeatedly raised concerns with management as to his lack of training and experience. He suggested that, like the other division sites, it should be more competently handled by properly trained staff of the analytical labs.[74]

F. LACK OF TRACEABILITY

The cGMPs for infant formula and 21 CFR § 106.80, in particular, provides that:

> [e]ach production aggregate of infant formula shall 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

[73] Emphasis added.

[74] In addition to management and members of the analytical lab, [redacted]

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.

The Sturgis site has had significant issues regarding the traceability of its products.[75] QS Sturgis frequently received notification from its warehouse that pallets were found to be either mislabeled or not labeled.[76] Often the batch to which the pallet belonged had already been released and shipped.

The Sturgis site uses an automated pallet labeler. The labeler is supposed to be able to read the pallet, print a label with the correct batch specific information, and apply the label to the pallet. However, the labeler did not always work properly. This was more apt to occur when multiple batches of different products were running. Management at the Sturgis site was well aware of this recurring problem.

Whenever an issue arises during production and a rework is required, every pallet in the affected time frame gets pulled back to the production floor and inspected. To ensure the correct pallets are being selected, lists of pallet identification numbers associated with that batch are reviewed and the pallets pulled. Due to the mislabeled or unlabeled pallets in the warehouse, QS staff never knew with certainty if every affected pallet was retrieved.[77]

III. INADEQUATE INTERNAL CONTROLS

In countless ways, Abbott has failed to implement and actively enforce adequate internal controls with respect to the Sturgis site. This failure does not appear to be limited to the Sturgis site. Officials at the division level were aware of many of the problems and failed to take corrective measures. Corporate policies and practices were and are clearly inadequate. Indeed, there is evidence that some officials at the division and corporate levels may also be complicit.

---

[75] In addition, 21 CFR § 106.60 provides that

(a) 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.

(b) 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.

[76] Abbott was under a legal duty to ensure that the equipment "be designed, installed, tested, and maintained" so that it will perform as intended. *See*, e.g., 21 CFR § 106.35(b). This includes being routinely inspected and calibrated. *See*, e.g., 21 CFR §106.35(b)(1).

[77] It could also extend to situations where the wrong product could be shipped. [redacted]

A. CONTINUED RELIANCE ON PAPER RECORDS

It is generally recognized that electronic records enhance an entity's ability to monitor activities at more remote locations. The integrity of record-keeping is enhanced as is the ability to track and audit entries and modifications. The continued reliance on paper records at the Sturgis site raises questions, especially with the conversion to electronic records being budgeted.

For reasons not entirely transparent, the proposed conversion has been repeatedly deferred. One reason volunteered by one member of management to the Complainant is that electronic records would make the Sturgis site more accountable to others at the division and corporate level. This same member of management has made the same comment to others, including well after the Complainant's departure.

The ongoing reliance on paper records is suggestive of inadequate internal controls. This is especially so when management at the Sturgis site has repeatedly admitted a desire to keep division and corporate officials from being able to monitor its compliance with regulatory requirements.[78] This need is ever-present with there being multiple episodes where management has consciously misled division officials as to PNCs or NCs or the seriousness of a situation.[79]

B. LACK OF CONFIDENTIAL MEANS OF REPORTING CONCERNS

As the Justice Department has deemed in its guidance for evaluating a company's compliance program, a "hallmark of a well-designed compliance program is the existence of an efficient and trusted mechanism by which employees can anonymously or confidentially report allegations of a breach of the company's code of conduct, company policies, or suspected or actual misconduct."[80]

Proactive measures should be instituted "to create a workplace atmosphere without fear of retaliation, appropriate processes for the submission of complaints, and processes to protect whistleblowers."[81] As exemplified by the Sturgis site, Abbott's practices fail to meet one of the

[78]Every year Complainant was in QS he was told of there being the availability of funding to transition from paper to electronic work orders. Yet the transition never occurred. On several occasions, a member of management told Complainant and [redacted] that the Sturgis site not wanting division officials "to see everything we do at Sturgis." [redacted]

[79]As previously noted, *see* page 10, PNCs and NCs were re-characterized as a quality assessment to avoid the need for approval by division. A quality assessment allowed the Sturgis site to proceed without input and approval from division officials.

[80]U.S. Dep't of Justice, *Evaluation of Corporate Compliance Programs* ("Compliance Program Guidance"), at 6 (June 2020)("Confidential reporting mechanisms are highly probative of whether a company has 'established corporate governance mechanisms that can effectively detect and prevent misconduct.'")(citing U.S. DEP'T OF JUSTICE, U.S. ATTORNEYS' MANUAL, § 9-28.800; U.S.S.G. § 8B2.1(b)(5)(C)).

[81]*Compliance Program Guidance, supra* note 80, at 6.

basic hallmarks of an effective compliance program. It is a workplace where fear of retaliation is palpable. The basis for that fear is well founded.

1. A Palpable Fear of Retaliation Pervades the Sturgis Site

The Complainant can attest to a number of instances in which his identity as the source of elevating concern was disclosed by management at the Sturgis site. Employees are not free to raise concerns without fear of retaliation. In a recent whistleblower investigation conducted by MIOSHA, the Michigan equivalent of OSHA, management identified in the presence of other staff the names of the individuals being questioned. Even at the corporate level, no meaningful steps were taken to protect the identity of witnesses or to protect against retaliation.[82]

As a further example, the Complainant brought an incident involving a stun gun to the attention of Abbott's office of Employee Relations ("ER"). As a matter of corporate policy, complaints to ER are to be considered protected activity. Employees are led to believe that disclosures to ER will be treated as confidential. At the time he made the complaint to ER, he and his colleague actually discussed the likelihood of retaliation. Despite Abbott's ostensible policy, his identity was disclosed to others at that Sturgis site and retaliation soon followed.[83]

2. No Independent Investigations

In addition, the "independent" investigation conducted by ER that led to Complainant's termination was fabricated. It was, in part, drafted by the supervisor seeking his termination. No follow-up inquiry took place despite an explicit assurance that his side of the allegations made against him would be sought. Instead, the investigator allowed the supervisor to literally draft or re-draft portions of the so-called investigative report.

The investigation was neither "properly scoped" nor "independent, objective, appropriately conducted, and properly documented" as prescribed by the Department of Justice's guidance for corporate compliance programs.[84] Aside from not fully investigating what occurred, the investigator demonstrated a remarkable lack of knowledge of the relevant issues. She was in no position to make a determination.

[83]It should be further noted that Abbott refused to place a litigation hold on all records relating to the Complainant when notified in writing that a complaint had been filed with federal and state authorities. The refusal was made in writing and a copy will be provided on request. Counsel has ongoing concerns as to whether records have been altered or destroyed.

[84]*Compliance Program Guidance, supra* note 80, at 16.

C. LACK OF ACCOUNTABILITY

As Complainant grew in experience and understanding of the operations at the Sturgis site, he became increasingly concerned as to the absence of accountability in terms of regulatory compliance. He spoke out. He believed the breadth of the lax practices put in jeopardy the safety of the product being produced. Consistent with 21 CFR § 117.110(a) and other regulatory provisions, he and others reasonably believed that Abbott was under a duty to minimize the likelihood of adulterated product.

1. Overlooking the Failure to Follow cGMPs

Discipline for failing to follow Abbott policies and cGMPs was selective.[85] It was selectively employed to chill outspoken employees. It was almost always overlooked when favored employees were involved.[86] Certainly, employees who were part of management's social network were largely if not entirely exempt from discipline. More than any other site, the Sturgis site was reputed to have the largest number of certificates of analysis ("COA") returned for incompleteness or false information. Yet no one was held accountable for this ongoing practice.

2. Calling Regulatory Concerns "Petty"

Most often, Complainant directed his concerns as to a lack of accountability to his supervisor. But other members of management were involved, including officials at the division level. His concerns were summarily dismissed as "petty." This extended to situations where unaddressed PIRs were intentionally placed in batch files after the release of a batch, thereby suggesting a regulatory violation.[87]

In these instances, the batch files were effectively falsified to suggest a regulatory violation when none existed. It was largely due to lax practices that PIRs were allowed to be submitted late

[85]A classic example is one of the bases for the Complainant's termination. He is alleged to have made a mistake on one of nine batches of product. However, he spotted the oversight, disclosed it, and then had the incomplete projection pages corrected for each batch. Four employees had verified or certified the projection pages on nine batches. Yet none of the latter were terminated. Moreover, whether the Complainant was responsible for the sole oversight is highly questionable as he was following his training when the alleged oversight occurred.

[86]When a favored employee brought a stun gun into the facility at the Sturgis site and shot it twice, management disregarded Abbott policy in failing to bring the incident to the attention of ER. Previously, employees were terminated when employees had guns in their car in the parking lot. In this particular situation, the supervisor admitted that the employee was given a "free pass."

[87]This was in part retaliation directed toward the Complainant for being outspoken in terms of compliance issues. In these situations, Complainant was able to catch the unaddressed PIR and take the necessary measures to ensure that the issue had been adequately addressed. Yet management was aware of the practice and took no action despite putting the Sturgis site at risk for regulatory violations. This practice was limited to the Complainant and suggestive of management's complicity in the retaliation for his efforts in having raised regulatory concerns.

by management. Complainant suspects that some of what occurred was intended as retaliation for his efforts to insist upon timely submission of PIRs. Management looked the other way, including officials at the division level.

3. Inconsistent and Disparate Treatment

Disciplinary actions and incentives have not been consistently applied as prescribed by the Department of Justice's guidance for evaluating compliance programs.[88] At the Sturgis site, discipline is not applied consistently. Favored employees are not disciplined in the same manner as those viewed as being outspoken as to compliance issues. Enforcement is selective and inconsistent thereby signaling retaliation to those who raise concerns.

More serious is the fact that members of management who are intimately involved with circumventing what exist in terms of internal controls are not subject to any discipline other than for failures to meet their metrics. These are individuals who also repeatedly misled officials at the division and corporate level. These are individuals who knowingly direct and approve of actions in direct violation of FDA regulations. A culture of compliance does not exist at the Sturgis site as mandated by the FDA and the Department of Justice's guidance.[89]

D. Highly Questionable Incentive Structure

It is Complainant's understanding that management at the Sturgis site is rewarded in terms of bonuses of some sort for meeting metrics vis-à-vis other production sites. Productivity is tracked based upon meeting certain data points. Each site provides the information. It was well known to the Complainant and others at the Sturgis site that the information provided to evaluate productivity is frequently and, at times, blatantly false.

Electronic reports were completed where boxes were checked. Despite the reality of what occurred, the Sturgis site would routinely check the boxes saying in effect "yes" to questions addressing, among others: "no discrepancy in work order"; "everything correct in work order"; "did correctly test every time"; and "perfect batch." To all of the questions, the Sturgis site would answer "yes" every time.[90] It was generally recognized among employees at the Sturgis site that management simply "lied" on these reports.

---

[88] *Compliance Program Guidance, supra* note 80, at 13.

[89] *Id.*, at 4.

[90] To be more specific, this information was tracked through a "perfect batch" form. On this form were tracked, among others, discrepancies (missing signatures/dates or data entries), quality assessment/PNC/NC information, and destruct information. A member of the QS staff tracked the information. For certain periods, this included the Complainant. Despite the information being tracked, the QS manager disregarded the tracked information and dictated what to report so that the Sturgis site would have a perfect batch metric each month. Rarely would the underlying data support a perfect batch metric.

Complainant firmly believes that the unrelenting pressure to meet metrics was a factor in overriding product safety concerns. The failure to meet metrics was weaponized against employees. When product safety concerns were raised, employees were told that they would be singled out and held personally responsible for failing to meet certain metrics in terms of production.[91] Meeting metrics was an all-consuming consideration in almost every decision.

As the Justice Department has also deemed in its guidance for evaluating a company's compliance program that "[a]nother hallmark of effective implementation of a compliance program is the establishment of incentives for compliance and disincentives for non-compliance."[92] The incentives relative to compliance are insignificant if not nonexistent at the Sturgis site. Despite the incredible risks associated with failing to meet FDA regulations, meeting quantitative metrics was and is the governing consideration at the Sturgis site.

E. MATERIAL CONTINGENT LIABILITY

Certifications of compliance with FDA regulations, including cGMPs, are required to secure rebates under the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC Program"). The WIC Program provides federal grants to states for supplemental foods, health care referrals, and nutrition education for low-income pregnant, breastfeeding, and non-breastfeeding postpartum women, and to infants and children up to age five who are found to be at nutritional risk. Abbott is a major participant in the WIC Program.

Rebates are provided to manufacturers who supply infant formula for the program and are otherwise eligible. Eligibility for the WIC program is governed by 42 U.S.C. § 1786(f)(15):

> To be eligible to participate in the program authorized by this section, a manufacturer of infant formula that supplies formula for the program shall—
>
> > (A) register with the Secretary of Health and Human Services under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.); and
> >
> > (B) before bidding for a State contract to supply infant formula for the program, *certify with the State health department that the formula complies with such Act and regulations issued pursuant to such Act*.[93]

[91] Indeed, for a period of time, an employee who caused the site to miss a metric had a one-on-one performance review with the site Director.

[92] *Compliance Program Guidance, supra* note 80, at 13.

[93] Emphasis added.

The regulations for the WIC Program and 7 CFR § 246.2, in particular, states that "[i]nfant formula means a food that meets the definition of an infant formula in section 201(z) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(z)) and that meets the requirements for an infant formula under section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a) and the regulations at 21 CFR parts 106 and 107." As has been laid out in some detail in the foregoing, credible evidence exists to suggest that Abbott has for some time not fully complied with FDA regulations and 21 CFR part 106 in particular.

The regulations relating to the cGMPs appear to directly apply to many of the violations observed and reported by the Complainant and others at the Sturgis site. Abbott is a major beneficiary of rebates under the WIC program. To what extent it benefits from the five-to-six-billion-dollar a year program is unclear. Yet the prospect of being terminated from the WIC program poses a material contingent liability. Given what the Complainant has reported, the veracity of certifications provided to federal and state officials are suspect.

F. ***Fraud Against Shareholders.***

Fundamental to federal law relative to fraud against shareholders is the issue of materiality. However, materiality is not limited to quantitative materiality. "The omission or misstatement of an item in a financial report is material if, in the light of surrounding circumstances, the magnitude of the item is such that it is probable that the judgment of a reasonable person relying upon the report would have been changed or influenced by the inclusion or correction of the item. This formulation in the accounting literature is in substance identical to the formulation used by the courts in interpreting the federal securities laws. The Supreme Court has held that a fact is material if there is –

> a substantial likelihood that the . . . fact would have been viewed by the reasonable investor as having significantly altered the "total mix" of information made available."[94]

"[A]n intentional misstatement of immaterial items in a registrant's financial statements may violate Section 13(b)(2) of the Exchange Act and thus be an illegal act."[95] Among the considerations that may well render material a quantitatively small misstatement of a financial statement item are –

[94] 17 CFR Part 211, Staff Accounting Bulletin No. 99 – Materiality ("SAB No. 99") (citing *TSC Industries v. Northway, Inc.*, 426 U.S. 438, 449 (1976). *See also Basic, Inc. v. Levinson*, 485 U.S. 224 (1988). "As the Supreme Court has noted, determinations of materiality require "delicate assessments of the inferences a 'reasonable shareholder' would draw from a given set of facts and the significance of those inferences to him . . . ." *TSC Industries*, 426 U.S. at 4) (internal citation omitted).

[95] *Id.*

- whether the misstatement affects the registrant's compliance with regulatory requirements

It is unknown whether and, if so, to what degree, the situation with respect to the suspected regulatory violations outlined above may bear on Abbott's financial statements. But from the standpoint of investors, the implications of the violations are apt to be material in ways that may not be fully appreciated at this point in time. Certainly, the degree to which Abbott has falsely certified its compliance with the cGMPs is apt to heighten the materiality to shareholders.

IV. CONCLUSION

Even though Abbott's senior management is now aware of many of the alleged regulatory violations referenced in the foregoing, no serious effort to remedy the violations have been reported to date. Instead, the emphasis appears to be more focused on identifying current employees at the Sturgis site who may have reported concerns to the Complainant. Aside from the mandate of FDA regulations, Abbott's inaction is directly at odds with the mandate of Sarbanes-Oxley mandating adequate internal controls and the Department of Justice's policy mandating effective compliance programs.

Abbott's inaction is also inconsistent with the Corporate Integrity Agreement that it entered into with the Office of Inspector General of the Department of Health and Human Services in May of 2012 as part of a plea agreement. *United States v. Abbott Laboratories*, No. 12-cr-00026 (W.D. Va., filed May 7, 2012). At the same time, Abbott also entered into settlement agreements with various states. Though not directly applicable to Abbott Nutrition, the core concepts apply in terms of the ongoing obligations on the part of Abbott's management and board of directors.

It is further submitted that what is being reported is based upon the Complainant's direct knowledge and, in a few instances, highly credible sources. Throughout his time at Abbott, and even since his departure, others have reported additional concerns that he was unable to verify. In countless situations, he was told by employees that the Sturgis site was like a "house of cards" if employees could speak freely. But the consensus remains that only with the intervention and protections of responsible enforcement officials would employees be inclined to speak freely.

EXHIBIT B

EXHIBIT B

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v. Case No.

ABBOTT LABORATORIES, a corporation doing business as ABBOTT NUTRITION, and KEENAN S. GALE, TJ HATHAWAY, and LORI J. RANDALL, individuals, Hon.

Defendants.
_______________________________________/

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel and on behalf of the United States Food and Drug Administration ("FDA"), having filed a Complaint for Permanent Injunction ("Complaint") against Abbott Laboratories, a corporation doing business as Abbott Nutrition, and Keenan S. Gale, TJ Hathaway, and Lori J. Randall, individuals, (collectively, "Defendants"), and Defendants having appeared and having consented to the entry of this Consent Decree of Permanent Injunction (the "Decree") without contest and before any testimony has been taken, and the United States of America having consented to this Decree,

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter and over all parties to this action under 28 U.S.C. §§ 1331 and 1345, 21 U.S.C. § 332, and its inherent equitable authority.

2. The Complaint states a cause of action against Defendants under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et seq*. ("Act").

3. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into

interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4).

4. The Complaint alleges that Defendants violate 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3), 21 U.S.C. § 350a(b)(2), and 21 C.F.R. Part 106.

5. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4).

6. The Complaint alleges that Defendants violate 21 U.S.C. § 331(k) by causing articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 350a(a)(3).

7. For purposes of this Decree, the following definitions shall apply:

A. "Associated Persons" shall refer collectively to each and all of Defendants' officers, agents, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them (including individuals, partnerships, corporations, subsidiaries, and "doing business as" entities) who are involved with the manufacture, processing, preparing, packing, labeling, holding, or distribution of articles of food covered by paragraph 7(F) or paragraph 7(G) at or from the Sturgis Facility;

B. "CGMP Regulations for Human Food" shall refer to the current good manufacturing practice requirements in Subpart B of 21 C.F.R. Part 117 (Current Good

Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food);

C. "Days" shall refer to business days;

D. "Infant Formula CGMP Regulations" shall refer to the current good manufacturing practice requirements in Subpart B of 21 C.F.R. Part 106 (Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications);

E. "Inventory Products" shall refer only to the non-recalled powdered finished products manufactured at the Sturgis Facility and in Defendants' possession, custody, or control as of March 18, 2022, the close of FDA's inspection at Defendants' facilities located at 901 North Centerville Road, Sturgis, Michigan 49091;

F. "Other Operations" shall refer to Defendants' manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any infant formula, as that term is defined in 21 U.S.C. § 321(z), in powdered form, except for Inventory Products defined in paragraph 7(E) and products subject to Specialty Operations described in paragraph 7(G);

G. "Specialty Operations" shall refer to Defendants' manufacture, processing, preparing, packing, labeling, holding, and/or distribution at or from the Sturgis Facility of any article of food that is:

(1) Any powdered infant formula covered by 21 U.S.C. § 350a(h)(1); or

(2) Any powdered product for non-infants (older than 12 months of age) that serves similar nutritional purposes as any formulation of powdered infant formula covered by 21 U.S.C. § 350a(h)(1); and

H. "Sturgis Facility" shall refer to the facilities located at 901 North Centerville Road, Sturgis, Michigan 49091.

Specialty Operations

8. Subject to paragraph 11(A), upon entry of this Decree, Defendants and each and all of their Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from conducting Specialty Operations, unless all the following conditions are met:

A. Defendants, at their expense, shall retain or continue retention of an independent person or persons ("Expert") who is without any personal or financial ties (other than a retention agreement or agreements to satisfy the requirements of this Decree and/or to perform other consulting or testing work for Abbott Nutrition) to Defendants or their families, and who, by reason of training, education, and experience, is qualified to:

(1) Evaluate the facilities, methods, processes, and controls at the Sturgis Facility to ensure that Defendants' products are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, the CGMP Regulations for Human Food, and the Infant Formula CGMP Regulations; and

(2) Inspect the Sturgis Facility to determine whether Defendants' facilities, methods, processes, and controls are continuously operated and administered in conformity with this Decree, the Act, and its implementing regulations;

B. Defendants shall notify FDA in writing of the identity and qualifications of the Expert within two days after retaining the Expert, and, in coordination with the Expert, Defendants shall:

(1) Verify the dry-out procedures (including time and temperature controls) for production equipment and processing environments, and validate the test method for moisture verification used to assess dryness after the dry-out procedures for production equipment and processing environments. Where applicable, Defendants may rely on completed action described in Defendants' response(s) to the FDA Form-483 issued on March 18, 2022 ("Form-483 Response");

(2) Conduct pre-production cleaning, sanitizing, and dry-out of production equipment and processing environments (using the verified dry-out procedures and the validated test method), followed by environmental testing for pathogens in the processing environment. Where applicable, Defendants may rely on completed actions already conducted in coordination with the Expert or as described in Defendants' Form-483 Response; and

(3) Prior to initiating production pursuant to paragraph 8, provide FDA with the Expert's report documenting completion of the verification and validation activities and pre-production review set out in paragraph 8(B);

C. If Defendants choose to restrict Specialty Operations to specified equipment and processing environments, then Defendants shall ensure that any cleaning, sanitizing, dry-out, and/or environmental testing during the pendency of Specialty Operations of equipment and processing environments that are not part of Specialty Operations is accomplished in a manner that protects against contamination of the specified equipment and processing environments (and utensils therein) that are part of Specialty Operations;

D. Defendants shall, as and when feasible, prioritize production in a manner that minimizes the risk of market disruption;

E. Prior to distribution of each product lot produced during Specialty Operations, Defendants shall ensure that a qualified individual in Defendants' quality unit reviews the batch record, the test results for in-process and finished product, and the environmental monitoring results that pertain to the product lot, and certifies in writing to FDA that such lot meets all specifications;

F. Defendants shall ensure that environmental monitoring during Specialty Operations consists of routine sampling and, when appropriate, investigative sampling, and that a qualified individual in Defendants' quality unit conducts trending analyses of environmental monitoring results from both routine and investigative sampling;

G. Defendants shall collect in-process and finished product samples during Specialty Operations and shall analyze the powdered infant formula samples for *Cronobacter* spp. and *Salmonella* spp., in the manner specified in 21 C.F.R. § 106.55, and shall analyze the powdered non-infant product samples for *Salmonella* spp. If any test of in-process or finished product detects the presence of *Cronobacter* spp. and/or *Salmonella* spp., Defendants shall:

(1) Cease production at the earliest time practicable and, in any event, no later than the completion of any batch then in progress, dispose of the affected in-process and/or finished product batch, conduct a thorough contamination-source determination (i.e., root-cause analysis), and adequately remediate the processing equipment and environment. Defendants shall maintain records of all the steps taken pursuant to this paragraph and shall make the records available to FDA immediately upon request. After a cessation of production pursuant to this paragraph, Defendants shall not resume production unless and until they receive

written notice from FDA that Defendants may resume production. Within fifteen days after receipt of Defendants' written request to resume production, unless FDA determines that, based on the complexity of the issues, a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional fifteen days to complete its review, FDA will review Defendants' request to resume production and provide written notification to Defendants either permitting resumption or explaining the basis for FDA's decision not to permit resumption of production, including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to permit resumption, Defendants may submit a new request to resume production, and the process described in paragraph 8(G)(1) shall be repeated until Defendants receive written notification from FDA that they may resume production. In no circumstance shall FDA's silence be construed as a substitute for written notification;

(2) Forward the test results detecting the presence of *Cronobacter* spp. and/or *Salmonella* spp. in in-process and/or finished product to FDA within twenty-four hours after receipt by Defendants (along with a written statement confirming that Defendants have ceased production in accordance with paragraph 8(G)(1)), speciate each *Cronobacter* spp. isolate to determine whether it is *Cronobacter sakazakii*, and forward each *Cronobacter sakazakii*-positive test result to FDA within twenty-four hours of receipt by Defendants; and

(3) Retain each *Cronobacter sakazakii* and *Salmonella* spp. isolate under appropriate storage conditions for three years from the date of the test result detecting the presence of *Cronobacter sakazakii* and/or *Salmonella* spp. in that isolate, and each isolate is to be provided to FDA within five days of receipt of a written request;

H. Defendants shall maintain a record of all sales and distribution of products, including shipping documents and the following information for the product distributed: the product name; the product size and configuration if variations exist; the batch, lot, and manufacturing codes; and the names of customers to whom the product is shipped, along with quantities shipped to each such customer. Defendants shall make the records described in this paragraph available to FDA immediately upon request; and

I. Defendants shall, in accordance with the procedures in paragraph 10, destroy all Inventory Products defined in paragraph 7(E) that have not been distributed within fifteen days after Defendants initiate production under Specialty Operations. The parties may mutually agree in writing to modify this fifteen-day time frame, which modification may be granted without seeking leave of Court. To the extent that Defendants are under a separate legal obligation to preserve all or a portion of the Inventory Products, Defendants shall be permitted to segregate and retain such Inventory Products for the duration of such preservation obligation.

Other Operations

9. Upon entry of this Decree, Defendants and each and all of their Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a), and the inherent equitable authority of this Court, from conducting Other Operations, unless all the following conditions are met:

A. Defendants shall have continuously complied with paragraph 8 since entry of this Decree;

B. Defendants shall ensure that the Sturgis Facility and equipment therein: (1) are cleaned and sanitized to render them suitable for manufacturing, processing, preparing, packing, labeling, holding, and distributing articles of food in accordance with this Decree, the

Act, and its implementing regulations; and (2) will be continuously maintained in a sanitary condition;

C. Defendants shall ensure that the Expert retained under paragraph 8(A):

(1) Reviews all FDA inspectional observations of deficiencies at the Sturgis Facility identified in the FDA Form-483 issued on March 18, 2022, and all records related to the detection of *Cronobacter* spp. and/or *Salmonella* spp. in the environment or in-process or finished product at the Sturgis Facility from September 2019 to the present;

(2) Reviews, and modifies as necessary, Defendants' written sanitation procedures including, but not limited to, sanitation standard operating procedures for receiving, manufacturing, processing, preparing, packing, holding, and distributing articles of food ("Sanitation Plan") to verify that the Sanitation Plan complies with the CGMP Regulations for Human Food and the Infant Formula CGMP Regulations and adequately: (a) establishes sanitation controls, monitoring procedures, and corrective actions for: *(i)* manufacturing processes; *(ii)* cleaning (including, but not limited to, cleaning in place), sanitizing, and dry-out operations (including, but not limited to, verified dry-out procedures and validated test methods for dry-out of production equipment and processing environments); and *(iii)* facilities (including, but not limited to, building construction and maintenance to ensure, among other things, adequate water management) and equipment and utensils contained therein; (b) addresses the risks of microbiological contamination from contaminants including, but not limited to, pathogens such as *Cronobacter sakazakii* and *Salmonella* spp.; and (c) protects against the contamination of food and food-contact surfaces and prevents insanitary conditions at the Sturgis Facility;

(3) Reviews, and modifies as necessary, Defendants' written environmental monitoring and testing program ("Environmental Monitoring Plan") to verify that the Environmental Monitoring Plan complies with the requirements in paragraph 11(G);

(4) Reviews, and modifies as necessary, Defendants' written product sampling and testing program ("Product Monitoring Plan") to verify that the Product Monitoring Plan complies with the requirements in paragraph 11(H);

(5) Reviews, and modifies as necessary, Defendants' written employee training program ("Employee Training Program") (in English and any other language necessary to effectively convey the substance of the training) that addresses: (a) maintaining sanitation, conducting adequate sampling and analysis, avoiding bacterial contamination, and controlling pathogens; and (b) the CGMP Regulations for Human Food and the Infant Formula CGMP Regulations, and the requirements in the Sanitation Plan, the Environmental Monitoring Plan, and the Product Monitoring Plan. The Employee Training Program shall include training for new employees and ongoing training programs for existing employees;

(6) Conducts a comprehensive inspection at the Sturgis Facility (including, but not limited to, buildings and equipment and utensils contained therein) and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food, and certifies in writing to FDA that:

(a) He or she has evaluated the results of environmental monitoring tests, and inspected the Sturgis Facility (including, but not limited to, buildings and equipment and utensils contained therein) and the methods, processes, and controls used to manufacture, process, prepare, pack, label, hold, and distribute articles of food;

(b) Defendants have corrected all deficiencies at the Sturgis Facility identified in the FDA Form-483 issued on March 18, 2022, and any deficiencies identified during the Expert's record review of the detection of *Cronobacter* spp. and/or *Salmonella* spp. in the environment or in any article of food at the Sturgis Facility (including samples collected during production under Specialty Operations), from September 2019 to the present, specifying each deficiency and Defendants' corrections thereof. Where applicable, the Expert may refer to any completed or ongoing action described in Defendants' Form FDA-483 Response; and

(c) Based on the Expert's review and inspection, Defendants' facilities, methods, processes, and controls (including the Sanitation Plan, the Environmental Monitoring Plan, and the Product Monitoring Plan) are: (*i*) in compliance with this Decree, the Act, and its implementing regulations; and (*ii*) adequate to ensure that Defendants' products are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, the CGMP Regulations for Human Food, and the Infant Formula CGMP Regulations; and

(7) Prepares and submits in writing to FDA a detailed report of all findings, with supporting documentation, and submits the certification, detailed report, and supporting documentation to Defendants and FDA concurrently, within fifteen days after completing the inspection; and

D. Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of paragraphs 9(A) and 9(B). Defendants shall also submit the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and the Employee Training

Program certified by the Expert pursuant to this paragraph to FDA for review and concurrence, and receive written notification of concurrence from FDA. Within twenty days after receipt of the Expert-certified plans (the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and the Employee Training Program), unless FDA determines that a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional twenty days to complete its review, FDA will review the Expert-certified plans and provide written notification to Defendants either concurring with the plans or explaining the basis for FDA's decision not to concur with any plan(s), including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to concur, Defendants shall submit a revised plan to FDA for review and concurrence. Within fifteen days after receipt of a revised plan, unless FDA determines that a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional fifteen days to complete its review, FDA will review the revised plan and provide written notification to Defendants either concurring with the revised plan or explaining the basis for FDA's decision not to concur with the revised plan, including the concerns with Defendants' submission. This process shall be repeated until Defendants receive written notification of concurrence from FDA. In no circumstance shall FDA's silence be construed as a substitute for written notification.

General Provisions

10. Subject to the exception described in this paragraph, within twenty-five days after entry of this Decree, Defendants shall destroy all articles of food that Defendants recalled prior to the date of entry of this Decree ("recalled articles"). Defendants shall give notice to FDA that, under FDA's supervision, Defendants are prepared to destroy the recalled articles and shall

specify the proposed time, place, and method of destruction. Defendants shall not commence, or permit any other person to commence, destruction until they have received written authorization from FDA to commence destruction. In no circumstance shall FDA's silence be construed as a substitute for written notification. Within fifteen days after receiving authorization from FDA to commence destruction, Defendants shall, under FDA supervision, complete destruction in compliance with this provision. Defendants shall not dispose of any recalled article in a manner contrary to the provisions of the Act, any other federal law, any court order, or the laws of any state or Territory, as defined in the Act, in which the recalled articles are disposed. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 17. To the extent that Defendants are under a separate legal obligation to preserve all or a portion of the recalled products, Defendants shall be permitted to segregate and retain such recalled products for the duration of such preservation obligation.

11. After receiving written concurrence from FDA under paragraph 9(D), Defendants shall continuously and effectively comply with the following requirements:

A. Defendants shall immediately implement and follow the Sanitation Plan, the Environmental Monitoring Plan, and the Product Monitoring Plan approved by FDA under paragraph 9(D) and shall ensure that all powdered products at the Sturgis Facility are produced under conditions and practices that comply with these plans and the remaining provisions of this Decree;

B. Prior to distribution of each product lot, Defendants shall ensure that a qualified individual in Defendants' quality unit reviews the batch record, the test results for in-process and finished product, and the environmental monitoring results that pertain to the product lot, and certifies in writing that such lot meets all specifications. Defendants shall

maintain copies of all certifications required by this paragraph at the Sturgis Facility, in a location where the certifications are readily available for reference and inspection by FDA;

C. Within two days after receiving FDA's written notification under paragraph 9(D), Defendants shall assign continuing responsibility for implementing and monitoring the FDA-approved Sanitation, Environmental Monitoring, and Product Monitoring Plans to a person(s) who, by reason of education, training, or experience, is qualified to maintain the Sturgis Facility in a sanitary condition and implement appropriate corrective actions, and Defendants provide such person(s) with the authority and resources to achieve any necessary corrective action. Defendants shall provide to FDA, in writing, the identities, titles, and qualifications of the individual(s) assigned responsibility under this paragraph within ten days after assigning responsibility to such individuals;

D. Within ten days after receiving FDA's written notification under paragraph 9(D), Defendants shall ensure that the FDA-approved Sanitation, Environmental Monitoring, and Product Monitoring Plans are available and accessible (in English and any other language necessary to effectively convey the substance of these documents) to their officers, employees, and all other persons who perform duties at the Sturgis Facility;

E. Within twenty days after receiving FDA's written notification under paragraph 9(D), Defendants shall train their employees, and all other persons who perform duties at the Sturgis Facility, in accordance with the FDA-approved Employee Training Program, to ensure that the individuals who receive, manufacture, process, prepare, pack, label, hold, or distribute articles of food are qualified to perform their assigned duties. Defendants shall submit documentation to FDA demonstrating that they have adequately trained all persons who perform duties at the Sturgis Facility in accordance with the Employee Training Program;

F. Defendants shall provide training to each new employee within five days after the new employee commences duties at the Sturgis Facility, and provide ongoing training programs for existing employees, in accordance with the FDA-approved Employee Training Program;

G. Defendants shall conduct environmental monitoring and testing in accordance with the Environmental Monitoring Plan to demonstrate that the Sanitation Plan is consistently followed to provide systematic control over pathogens, including *Cronobacter* spp. and *Salmonella* spp., to prevent contamination of finished products. Defendants' Environmental Monitoring Plan shall conform to the following requirements:

(1) Environmental monitoring shall include, but not be limited to: (a) collecting samples from equipment and production areas that may pose a high risk of contamination; other environmental sites where food is received, manufactured, processed, prepared, packed, labeled, held, or distributed; and additional areas that may be reservoirs for cross-contamination; (b) analyzing samples in an industry-recognized method that is acceptable to FDA; (c) implementing remedial action, should any pathogen be detected in the environment, including, but not limited to, intensified sanitation measures, intensified sampling and testing measures, comprehensive investigations, and a contamination-source determination (i.e., a root-cause analysis); and (d) conducting trend analyses by a qualified analyst and reviewed by a qualified manager;

(2) A majority of swabs shall be collected from Zone 2 areas (i.e., areas in the vicinity of food contact surfaces) during both routine environmental monitoring and, when appropriate, investigative environmental monitoring. When the Sanitation Plan and/or Environmental Monitoring Plan requires or recommends equipment tear-down, Defendants shall

ensure that swabs are collected from Zone 1 (i.e., food-contact surfaces): (a) after such equipment is disassembled, before being cleaned and sanitized; and (b) after the equipment is cleaned and sanitized. Defendants shall also ensure that, if any *Cronobacter* spp. or *Salmonella* spp. is detected in a Zone 3 environment (i.e., areas surrounding Zone 2 areas), additional swabs are collected from surrounding Zone 2 areas;

(3) If any *Cronobacter* spp. is detected in the environment, Defendants shall speciate each *Cronobacter* spp. isolate to determine whether it is *Cronobacter sakazakii*, and forward each *Cronobacter sakazakii*-positive test result to FDA within twenty-four hours of receipt by Defendants; and

(4) Defendants shall retain each *Cronobacter sakazakii* and *Salmonella* spp. isolate under appropriate storage conditions for three years from the date of the test result detecting the presence of *Cronobacter sakazakii* and/or *Salmonella* spp. in that isolate, and each isolate is to be provided to FDA within five days of receipt of written request;

H. Defendants shall conduct product monitoring and testing in accordance with the Product Monitoring Plan, to ensure that controls are adequate to prevent contamination by pathogens, including *Cronobacter* spp. and *Salmonella* spp. Defendants' Product Monitoring Plan shall conform to the following requirements:

(1) At a minimum, Defendants shall test representative samples from the beginning, middle, and end (i.e., three separate sampling periods) of each lot of each batch of finished product; and

(2) The Product Monitoring Plan shall include remedial action to be implemented should any *Cronobacter* spp. or *Salmonella* spp. be detected in any article of food (including raw ingredients and in-process and finished product batches). As part of the Product

Monitoring Plan's remedial action, if any test of in-process or finished product detects the presence of *Cronobacter* spp. and/or *Salmonella* spp., Defendants shall:

(a) Cease production at the earliest time practicable and, in any event, no later than the completion of any batch then in progress, dispose of the affected in-process and/or finished product batch, conduct a thorough contamination-source determination (i.e., root-cause analysis), adequately remediate the processing equipment and environment, and conduct intensified sanitation measures and intensified sampling and testing measures. Defendants shall maintain records of all these steps and shall make those records available to FDA immediately upon request. After a cessation of production pursuant to this paragraph, Defendants shall not resume production unless and until they receive written notice from FDA that Defendants may resume production. Within fifteen days after receipt of Defendants' written request to resume production, unless FDA determines that, based on the complexity of the issues, a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional fifteen days to complete its review, FDA will review Defendants' request to resume production and provide written notification to Defendants either permitting resumption or explaining the basis for FDA's decision not to permit resumption of production, including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to permit resumption, Defendants may submit a new request to resume production, and the process described in paragraph 11(H)(2)(a) shall be repeated until Defendants receive written notification from FDA that they may resume production. In no circumstance shall FDA's silence be construed as a substitute for written notification;

(b) Forward the test results detecting the presence of *Cronobacter* spp. and/or *Salmonella* spp. in in-process and/or finished product to FDA within

twenty-four hours after receipt by Defendants (along with a written statement confirming that Defendants have ceased production in accordance with paragraph 11(H)(2)(a)), speciate each *Cronobacter* spp. isolate to determine whether it is *Cronobacter sakazakii*, and forward each *Cronobacter sakazakii*-positive test result to FDA within twenty-four hours of receipt by Defendants; and

(c) Retain each *Cronobacter sakazakii* and *Salmonella* spp. isolate under appropriate storage conditions for three years from the date of the test result detecting the presence of *Cronobacter sakazakii* and/or Salmonella spp. in that isolate, and each isolate is to be provided to FDA within five days of receipt of written request;

I. Defendants shall prepare a plan that assesses the need for any repair of buildings (such as roofs) and/or equipment (such as spray dryers), including a determination whether to continue repairing or replace that equipment. Defendants shall submit the plan to FDA within four months after receiving written notification from FDA under paragraph 9(D). If applicable, Defendants may refer to any completed or ongoing action described in Defendants' Form FDA-483 Response;

J. In the event that Defendants decide to transfer any of their equipment that is used for production of powdered products from the Sturgis Facility to any other manufacturing site, Defendants shall notify FDA in writing at least forty-five days prior to the planned transfer. Defendants' notification shall include, but not be limited to, a plan for cleaning and sanitizing, and refurbishing if necessary, the equipment, followed by environmental testing for pathogens, prior to the transfer of equipment to any other manufacturing site. Defendants shall not transfer any such equipment unless and until they: (a) receive written concurrence from FDA on the plan to clean, sanitize, and refurbish the equipment; (b) clean, sanitize, and refurbish the equipment in

accordance with the FDA-concurred plan; (c) submit to FDA a detailed written report, with supporting documentation, describing the actions taken to comply with paragraph 11(J); and (d) receive written notification from FDA that Defendants appear to be in compliance with paragraph 11(J);

K. Defendants shall retain an independent person or persons (the "Auditor") who shall meet the criteria for and may be the same person as the Expert described in paragraph 8(A), to conduct audit inspections at the Sturgis Facility of the facilities, methods, processes, and controls used to receive, prepare, process, pack, label, hold, or distribute articles of food. Defendants shall notify FDA in writing of the identity and qualifications of the Auditor within two days after retaining the Auditor. Defendants shall ensure that the audit inspections are conducted as follows:

(1) Defendants shall ensure that, within six months after Defendants resume operations after receiving FDA's written notification pursuant to paragraph 9(D), the Auditor shall conduct an audit at the Sturgis Facility of the facilities, methods, processes, and controls used to receive, manufacture, process, prepare, pack, label, hold, and distribute articles of food to determine whether Defendants are operating in compliance with this Decree, the Act, and its implementing regulations, and to identify any deviations from such requirements. Defendants shall also ensure that the Auditor submits an Audit Report documenting all findings to Defendants and FDA concurrently, within seven days after completing the audit;

(2) Thereafter, Defendants shall ensure that the Auditor conducts audits no less frequently than once every six months for a period of one year, and then annually for the next three years, unless FDA informs Defendants in writing that more frequent audit

inspections and reporting are required. If any Audit Report identifies any deviation from this Decree, the Act, or its implementing regulations, FDA may require the audit cycle be extended;

(3) Defendants shall ensure that, as part of every Audit Report (except the first one), the Auditor assesses the adequacy of actions taken by Defendants to correct all previous audit observations, if any, indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations. If the Audit Report contains any audit observations indicating that Defendants are not in compliance with this Decree, the Act, or its implementing regulations, Defendants shall make all necessary corrections within ten days after receipt of the Audit Report, unless FDA notifies Defendants in writing that a shorter time period is necessary or, upon written request by Defendants and/or based on the nature of the correction to be made, that a longer time period is permitted; and

(4) Defendants shall ensure that, within twenty days after the required completion date for any corrective action under this paragraph, the Auditor reviews each and all corrective action(s) taken by Defendants and reports in writing to FDA whether each deviation listed in the Audit Report has been corrected;

L. In the event that the Expert or the Auditor determines that the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, or the Employee Training Program needs to be revised, Defendants shall:

(1) Ensure that the Expert or Auditor reviews the proposed changes and certifies in writing that the proposed changes establish methods, processes, and controls at the Sturgis Facility that are adequate to ensure that articles of food are manufactured, processed, prepared, packed, labeled, held, and distributed in compliance with this Decree, the Act, and implementing regulations (“paragraph L certification”);

(2) Ensure that the Expert's or Auditor's paragraph L certification with supporting documentation is submitted to Defendants and FDA concurrently, within five days after completing the review; and

(3) Provide to FDA the revised Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and/or the Employee Training Program, within twenty-four hours of the submission to FDA of the Expert's or Auditor's paragraph L certification. Any change to the Sanitation Plan, the Environmental Monitoring Plan, and/or the Product Monitoring Plan shall ensure that pathogens, including *Cronobacter* spp. and *Salmonella* spp., are systematically controlled to prevent contamination of finished products; and

M. In the event that Defendants terminate their agreement with:

(1) The Expert retained pursuant to paragraph 8(A), Defendants shall notify FDA within five days after such termination and immediately retain another expert who meets the qualifications of the Expert described in paragraph 8(A). Defendants shall notify FDA in writing of the identity and qualifications of the new Expert within five days after retaining the new Expert; and

(2) The Auditor retained pursuant to paragraph 11(K), Defendants shall notify FDA within five days after such termination and immediately retain another expert who meets the qualifications of the Auditor described in paragraph 11(K). Defendants shall notify FDA in writing of the identity and qualifications of the new Auditor within five days after retaining the new Auditor.

12. Defendants and all Associated Persons who have received actual notice of this Decree are permanently restrained and enjoined under 21 U.S.C. § 332(a) from directly or indirectly doing or causing to be done any act at or from the Sturgis Facility that:

A. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4);

B. Violates 21 U.S.C. § 331(a) by introducing or causing to be introduced, or delivering or causing to be delivered for introduction, into interstate commerce articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3);

C. Violates 21 U.S.C. § 331(k) by causing articles of food that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 342(a)(4);

D. Violates 21 U.S.C. § 331(k) by causing articles of food, namely infant formula as defined in 21 U.S.C. § 321(z), that are held for sale after shipment of one or more of their components in interstate commerce to become adulterated within the meaning of 21 U.S.C. § 350a(a)(3); and/or

E. Results in the failure to implement and continuously maintain the requirements of this Decree, the Act, and its implementing regulations.

13. If, at any time after this entry of this Decree, FDA determines, based on the results of an inspection, the analysis of a sample, report or data prepared or submitted by Defendants, the Expert(s), or the Auditor, or any other information, that Defendants have failed to comply with any provision of this Decree, violated the Act or its implementing regulations, or that additional corrective actions are necessary to achieve compliance with this Decree, the Act, or its implementing regulations, FDA may, as and when it deems necessary, notify Defendants in writing of the noncompliance and order Defendants to take appropriate corrective action,

including, but not limited to, ordering Defendants to immediately take one or more of the following actions, which remedies shall be separate and apart from, and in addition to, any other remedy available to the United States under this Decree or under the law:

A. Cease manufacturing, processing, preparing, packing, labeling, holding, and/or distributing any and all powdered products;

B. Recall, at Defendants' expense, any and all articles of food that have been distributed or are under the custody and control of Defendants' agents, distributors, customers, or consumers that, in FDA's judgment, are adulterated or otherwise in violation of this Decree, the Act, or its implementing regulations. Defendants shall initiate the recall(s) within twenty-four hours after receiving notice from FDA that a recall is necessary;

C. Destroy, under FDA supervision, all articles of food (including raw ingredients and in-process and finished products) that are in Defendants' possession, custody, or control. Defendants shall bear the costs of destruction and the costs of FDA's supervision at the rates specified in paragraph 18. Defendants shall be responsible for ensuring that the destruction is carried out in a manner that complies with all applicable federal and state environmental laws, and any other applicable federal or state law. To the extent that Defendants are under a separate legal obligation to preserve all or a portion of such articles of food, Defendants shall be permitted to segregate and retain such articles of food for the duration of such preservation obligation;

D. Revise, modify, expand, or continue to submit any reports or plans prepared pursuant to this Decree;

E. Submit additional reports or information to FDA as requested;

F. Submit samples to a qualified laboratory for analysis;

G. Institute or re-implement any of the requirements set forth in this Decree;

H. Issue a safety alert; and/or

I. Take any other corrective actions as FDA, in its discretion, deems necessary to protect the public health or bring Defendants into compliance with this Decree, the Act, or its implementing regulations.

Any cessation of operations or other action described in this paragraph shall continue until Defendants receive written notification from FDA that Defendants appear to be in compliance with this Decree, the Act, and its implementing regulations. Upon Defendants' written request to resume operations, FDA will determine whether Defendants appear to be in such compliance, and, if so, issue to Defendants a written notification permitting, as appropriate, resumption of operations. Within twenty days after receipt of Defendants' written request to resume production, unless FDA determines that, based on the complexity of the issues, a longer time frame is necessary, in which case FDA can give Defendants notice that FDA needs an additional twenty days to complete its review, FDA will review Defendants' request to resume production and provide written notification to Defendants either permitting resumption or explaining the basis for FDA's decision not to permit resumption of production, including the concerns with Defendants' submission. After addressing all concerns described in FDA's written notification of a decision not to permit resumption, Defendants may submit a new request to resume production, and the process described in paragraph 13(I) shall be repeated until Defendants receive written notification from FDA that they may resume production. In no circumstance shall FDA's silence be construed as a substitute for written notification. The cost of FDA inspections, investigations, supervision, examinations, sampling, testing, travel time, and subsistence expenses to implement and monitor the remedies set forth in this paragraph shall be

borne by Defendants at the rates specified in paragraph 17. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

14. If FDA issues a directive pursuant to paragraph 13, the following process and procedures shall apply:

A. Unless a different time frame is specified by FDA in its directive, within ten days after receiving such directive, Defendants shall notify FDA in writing either that: (1) Defendants are undertaking or have undertaken corrective action, in which event Defendants shall also describe the specific action taken or proposed to be taken and the proposed schedule for completing the action; or (2) Defendants do not agree with FDA's directive. If Defendants notify FDA that they do not agree with FDA's directive, Defendants shall explain in writing the basis for their disagreement and, in doing so, may provide specific alternative actions and time frames for achieving FDA's objectives. After receipt of Defendants' notification and explanation, FDA will review Defendants' notification and explanation and, in writing, affirm, modify, or withdraw its directive, as FDA deems appropriate. If FDA affirms or modifies its directive, it will explain the basis for its decision in writing. The written notice of affirmation or modification shall constitute final agency action. If FDA affirms or modifies its directive, Defendants shall, upon receipt of FDA's affirmed or modified directive, immediately implement it, and may, if Defendants so choose, bring the matter before this Court. While seeking Court review, Defendants shall continue to implement and fully comply with FDA's directive, unless and until the Court stays, reverses, or modifies FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 25; and

B. The process and procedures in paragraph 14(A) shall not apply to any directive issued pursuant to paragraph 13 if such directive states that, in FDA's judgment, the

matter raises a significant public health concern. In such case, Defendants shall, upon receipt of such directive, immediately and fully comply with the terms of that directive, and the directive shall be a final agency decision. Should Defendants seek to challenge any such directive, they may petition the Court for relief while they implement FDA's directive. Any judicial review of FDA's directive under this paragraph shall be made pursuant to paragraph 25.

15. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to inspect the Sturgis Facility, collect samples, and, without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree, the Act, and implementing regulations. During such inspections, FDA representatives shall be permitted to: have immediate access to the Sturgis Facility and/or other place(s) of business including, but not limited to, all buildings or other structures, equipment, raw ingredients, in-process materials, unfinished and finished materials and products, containers, and labeling; take photographs and make video recordings; take samples, without charge to FDA, of raw ingredients, in-process materials, unfinished and finished materials and products, containers, and labeling; and examine and copy all records relating to the receipt, holding, and distribution of any and all articles of food and their components. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate and apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

16. Defendants shall promptly provide any information or records to FDA upon request regarding the receipt, manufacture, processing, preparing, packing, labeling, holding, and/or distributing of articles of food. Defendants shall maintain copies of the Sanitation Plan, the Environmental Monitoring Plan, the Product Monitoring Plan, and the Employee Training

Program, along with copies of all records required by such plans and this Decree, at the Sturgis Facility, in a location where the records are readily available for reference and inspection by FDA. Defendants shall retain all records referred to in this paragraph for at least three years after the date the records are prepared.

17. Defendants shall pay all costs of FDA's supervision, inspections, investigations, analyses, examinations, and reviews that FDA deems necessary to evaluate Defendants' compliance with this Decree, including all transportation and associated costs for FDA investigators and experts, at the standard rates prevailing at the time the costs are incurred. As of the date of entry of this Decree, these rates are: $105.46 per hour or fraction thereof per representative for inspection and investigative work; $126.24 per hour or fraction thereof per representative for analytical or review work; $0.59 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate for subsistence expenses where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

18. Within five days after the entry of this Decree, Defendants shall post a copy of this Decree in a common area at the Sturgis Facility, and publish the Decree on an internal website and a publicly-available website maintained and/or controlled by Defendants. Defendants shall ensure that this Decree remains posted as described herein for as long as this Decree remains in effect. Within ten days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph.

19. Within ten days after the entry of this Decree, Defendants shall provide a copy of this Decree by electronic mail to each and all Associated Persons. Within twenty days after the date of entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of all persons who have received a copy of this Decree pursuant to this paragraph. Within seven days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

20. Within fifteen days after entry of this Decree, Defendants shall hold a general meeting or series of smaller meetings for all Associated Persons, at which they shall describe the terms and obligations of this Decree. Within twenty days after entry of this Decree, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and a copy of the agenda, list of attendees, and meeting minutes from the meeting(s) held pursuant to this paragraph.

21. In the event that any Defendant becomes associated with any additional Associated Person(s) at any time after entry of this Decree, Defendants shall immediately provide a copy of this Decree by electronic mail to such Associated Person(s). On a quarterly basis, Defendants shall provide to FDA an affidavit of compliance, signed by a person with personal knowledge of the facts, stating the fact and manner of compliance with the provisions of this paragraph and identifying the names, addresses, and positions of the additional Associated Person(s) who have received a copy of this Decree pursuant to this paragraph. Within seven

days after receiving a request from FDA for any information or documentation that FDA deems necessary to evaluate Defendants' compliance with this paragraph, Defendants shall provide such information or documentation to FDA.

22. Defendants shall notify FDA in writing at least thirty days before any change in ownership, name, or character of their business at the Sturgis Facility that occurs after entry of this Decree including, but not limited to, any of the following, if they may affect obligations arising out of this Decree: (1) an incorporation, reorganization, relocation, dissolution, bankruptcy, assignment or sale resulting in the emergence of a successor corporation; the creation or dissolution of subsidiaries; the creation of any additional entities that engage in the manufacture and distribution of articles of food; the discontinuation of any line of powdered product; and any other change in the structure or identity of Abbott Nutrition or change in the responsibility of any individual defendant that affects the Sturgis Facility; and (2) the sale or assignment of any business assets, such as buildings, equipment, or inventory. Defendants shall provide a copy of this Decree to any prospective successor or assign at least twenty days before any sale or assignment. Defendants shall furnish FDA with an affidavit of compliance with this paragraph no later than ten days before any such assignment or change in ownership.

23. If any Defendant fails to comply with any provision of this Decree, the Act, or its implementing regulations, including any time frame imposed by this Decree, then Defendants shall pay to the United States of America thirty thousand dollars ($30,000) in liquidated damages for each day such violation continues. The total amount of such liquidated damages shall not exceed five million dollars ($5,000,000) annually. The remedy in this paragraph shall be in addition to any other remedies available to the United States under this Decree or the law.

24. Should the United States bring and prevail in a contempt action to enforce the terms of this Decree, Defendants shall, in addition to other remedies, reimburse the United States for its attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, investigational and analytical expenses, expert witness fees, administrative and court costs, and any other costs or fees incurred by the United States in bringing such an action.

25. Defendants shall abide by the decisions of FDA, and FDA's decisions shall be final. All decisions conferred upon FDA in this Decree shall be vested in FDA's discretion and, to the extent that these decisions are subject to review, shall be reviewed by this Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review by the Court of any FDA decision rendered pursuant to this Decree shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be taken by either party.

26. All notifications, certifications, reports, correspondence, and other communications to FDA required by the terms of this Decree shall be prominently marked "Consent Decree Correspondence," shall reference this civil action by case name and civil action number, and shall be submitted electronically to the Program Division Director, Office of Human and Animal Food Operations, Human and Animal Food Division East 6, at ORAHAFEAST6FIRMRESPONSES@fda.hhs.gov. If electronic submission is not possible, communications shall be addressed to the attention of OHAFO East 6 Program Division Director, FDA, 550 West Jackson Boulevard, Chicago, Illinois 60661.

27. This Decree shall apply only to Defendants and Associated Persons, as defined in paragraph 7(A), involved with the manufacture, processing, preparing, packing, labeling, holding, or distribution of powdered products at or from the Sturgis Facility.

28. No sooner than sixty months after resuming production after receipt of written notification from FDA under paragraph 9(D), Defendants may provide written notice to FDA that they seek relief from this Decree. If, at the time of such notice, in FDA's judgment Defendants have maintained a state of continuous compliance with the terms of this Decree, the Act, and all applicable laws and regulations for at least sixty months after resuming production after receipt of written notification from FDA under paragraph 9(D), the Defendants may petition the Court to grant such relief and the United States will not oppose Defendants' petition.

29. This Court retains jurisdiction over this action and the parties thereto for the purpose of enforcing and modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

IT IS SO ORDERED, this _______ day of ___________, 2022.

____
UNITED STATES DISTRICT JUDGE

The undersigned hereby consent to the entry of the foregoing Decree.

For Defendants

LORI J. RANDALL,
Individually and on behalf of
ABBOTT LABORATORIES DBA
ABBOTT NUTRITION

TJ HATHAWAY,
Individually

KEENAN S. GALE,
Individually

Mark R. Filip, P.C.
Kirkland & Ellis LLP
300 North LaSalle
Chicago, IL 60654
Tel: (312) 862-2192
Email: Mark.Filip@kirkland.com

Attorney for Defendants

For Plaintiff

MARK A. TOTTEN
United States Attorney

By:

ANDREW J. HULL
Assistant United States Attorney
U.S. Attorney's Office for the Western
District of Michigan
P.O. Box 208
Grand Rapids, MI 49503
Tel: (616) 456-2404
Email: Andrew.Hull@usdoj.gov

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney
General
Civil Division

ARUN G. RAO
Deputy Assistant Attorney General

GUSTAV W. EYLER
Director
Consumer Protection Branch

ALLAN GORDUS
Assistant Director

By: s/ Donald Lorenzen
DONALD LORENZEN
CHRISTINA PARASCANDOLA
Senior Litigation Counsels
Consumer Protection Branch
Civil Division
Department of Justice
P.O. Box 386

Washington, D.C. 20044
Tel: (312) 353-5330
Email: Donald.Lorenzen@usdoj.gov
Email: Christina.Parascandola@usdoj.gov

OF COUNSEL:

DANIEL J. BARRY
Acting General Counsel
Department of Health and Human Services

MARK RAZA
Chief Counsel
Food and Drug Administration

PERHAM GORJI
Deputy Chief Counsel for Litigation

CLAUDIA J. ZUCKERMAN
Senior Counsel
Office of the Chief Counsel
Food and Drug Administration
10903 New Hampshire Avenue
Bldg. 31, Rm 4550
Silver Spring, MD 20993-0002