UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS

PEMBROKE PINES FIREFIGHTERS & POLICE OFFICERS PENSION FUND, Individually and on Behalf of All Others Similarly Situated, Plaintiff, v. ABBOTT LABORATORIES, ROBERT B. FORD, ROBERT E. FUNCK, JR., JOSEPH MANNING, and CHRISTOPHER J. CALAMARI, Defendants.	Case No. 1:22-cv-04661 District Judge Steven C. Seeger **JURY TRIAL DEMANDED**

AMENDED CLASS ACTION COMPLAINT

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GLOSSARY OF KEY TERMS

2019 483 Report	Form 483 Report issued to Abbott on September 24, 2019 regarding Sturgis.
2021 483 Report	Form 483 Report issued to Abbott on September 24, 2021 regarding Sturgis.
2022 483 Report	Form 483 Report issued to Abbott on March 18, 2022 regarding Sturgis.
Abbott	Abbott Laboratories, Inc.
AQR	Abbott's Audit Quality and Regulatory Department.
CDC	Centers for Disease Control and Prevention.
CGMP Regulations	Current Good Manufacturing Practice Regulations.
Consent Decree	The consent decree Abbott entered into with the FDA filed by the Civil Division of the DOJ on May 16, 2022, *United States v. Abbott Laboratories d/b/a Abbott Nutrition, et al.*, 22-cv-00441 (W.D. Mich.).
DOJ Complaint	The May 16, 2022, complaint filed by the Civil Division of the U.S. Department of Justice ("DOJ") against Defendants Abbott, Lori C. Randall, Keenan Gale, and TJ Hathaway, captioned *United States v. Abbott Laboratories d/b/a Abbott Nutrition, et al.*, 22-cv-00441 (W.D. Mich.).
EIR	An Establishment Inspection Report drafted by the FDA and issued to a company after the issuance of a Form 483. An EIR may contain more detail than a Form 483, and may address additional objectionable conditions at a facility.
FDA	Food and Drug Administration.
FDCA	Food, Drug, and Cosmetic Act of 1938.
February 2021 Whistleblower Complaint	The complaint filed by the Whistleblower with OSHA on February 16, 2021.
FSMA	Food Safety Modernization Act, 29 C.F.R. § 1987, et seq.
Infant Formula CGMP Regulations	CGMP Regulations for infant formulas promulgated by the FDA at 21 C.F.R. Part 106, Subpart B.
Infant Formula Record Requirements	Record-keeping requirements promulgated by the FDA in conjunction with the Infant Formula CGMP Regulations at 21 U.S.C. § 350a(b)(4); 21 C.F.R. § 106.100(k).

micros	Microbiological organisms, such as *Cronobacter sakazakii* and Salmonella.
MIOSHA	Michigan Occupational Safety and Health Administration.
October 2021 Whistleblower Complaint	The complaint filed by the Whistleblower with the FDA on October 19, 2021.
OSHA	United States Department of Labor Occupational Safety and Health Administration.
Sturgis	Abbott's infant formula manufacturing facility in Sturgis, Michigan.
Trackwise or AbTraq	Internal system at Abbott that tracks internal audits and other documentation of quality issues.
Whistleblower	The former Abbott employee who filed the February 2021 and October 2021 Whistleblower Complaints concerning Abbott's systemic food safety and regulatory violations at Sturgis.
WIC	The United States Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children.

Lead Plaintiffs Quoniam Asset Management GmbH ("Quoniam") and KBC Asset Management NV ("KBC" and together with Quoniam, "Plaintiffs") individually and on behalf of a class of similarly situated persons and entities, by their undersigned attorneys, bring this class action on behalf of themselves and all other persons or entities who purchased or otherwise acquired Abbott Laboratories ("Abbott" or the "Company") common stock during the period from February 19, 2021 to October 19, 2022, inclusive (the "Class Period") and were damaged thereby (the "Class"). Plaintiffs assert claims against Abbott, Abbott's Chief Executive Officer Robert B. Ford ("Ford"); Chief Financial Officer Robert E. Funck, Jr. ("Funck"); Senior Vice President, U.S. Nutrition, Christopher J. Calamari ("Calamari"); and Division Vice President of Nutrition Quality Assurance, Lori J. Randall ("Randall") (collectively, "Defendants"), under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"), 15 U.S.C. §§ 78j(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

Plaintiffs allege the following based upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters, including the investigation of Plaintiffs' counsel, which included, among other things: (i) a review of Defendants' United States Securities and Exchange Commission ("SEC") filings; (ii) transcripts, press releases, news articles, analyst reports, advisories, public testimony, and other public statements issued by or concerning Defendants; (iii) information from former Abbott employees, industry professionals, and other knowledgeable persons; (iv) information obtained through Freedom of Information Act ("FOIA") requests to the Food and Drug Administration ("FDA"), the United States Department of Labor Occupational Safety and Health Administration ("OSHA"), and the Michigan Occupational Safety and Health Administration ("MIOSHA"); and (v) other publicly available information. Counsel's investigation into the factual allegations contained in this Complaint is continuing, and many of

the relevant facts are known only by Defendants or are exclusively within their custody or control. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth in this Complaint after a reasonable opportunity for further investigation or discovery.

I. PRELIMINARY STATEMENT

1. On May 25, 2022, FDA Commissioner Dr. Robert Califf testified before Congress and described the conditions the agency found in Abbott's infant formula manufacturing facility in Sturgis, Michigan ("Sturgis") three months earlier, in February:[1]

> Let's say you had a next door neighbor who had leaks in the roof. They didn't wash their hands. They had bacteria growing all over the kitchen. You walked in and there was standing water on the counters and the floor, and the kids were walking through with mud on their shoes and no one cleaning it up. You probably wouldn't want your infant eating in that kitchen. And that is in essence what the inspection showed. . . . [T]hese are just the facts that we saw.

2. These conditions were not new, nor were they a secret within Abbott. Indeed, Abbott's top management had been made aware of problems at Sturgis since at least late 2019—and no later than the start of the Class Period in February 2021—and failed to correct them. In September 2019, the FDA had cited Abbott for failing to ensure that its powdered infant formula at Sturgis "met the required microbiological quality standards" (the "2019 483 Report"). In September 2019, and again, less than a year later, in June 2020, Abbott destroyed packaged powdered infant formula made in Sturgis due to *Cronobacter sakazakii* ("*Cronobacter*") contamination, yet did not halt production at Sturgis, report the contaminated formula to the FDA or investors, or even take steps to determine and eliminate the root cause of the contamination.

3. Eight months later, and three days before the start of the Class Period, on February 16, 2021, a whistleblower (the "Whistleblower") who had worked in Abbott's Sturgis Quality

[1] All emphasis herein is added unless otherwise indicated.

Assurance unit filed a complaint with OSHA under the Food Safety Modernization Act ("FSMA") that was delivered to Abbott (the "February 2021 Whistleblower Complaint"). The 34-page non-public February 2021 Whistleblower Complaint alleged that Abbott's Sturgis facility management was intentionally falsifying records relating to food safety, releasing infant formula from batches that had tested positive for "micro" contamination, knowingly deceiving FDA investigators during a 2019 site audit, failing to implement and observe clean-in-place procedures necessary to ensure food safety, violating mandatory corrective actions required by FDA regulations, and failing to implement proper procedures necessary to ensure legally required traceability of infant formula manufactured at Sturgis.[2] Several former Abbott Sturgis employees, including the former GMP & Food Safety Specialist for the entire Sturgis facility who witnessed firsthand additional safety violations that were later cited by the FDA as serious violations of food safety laws, corroborate the Whistleblower's allegations. Senior officials at Abbott received the February 2021 Whistleblower Complaint, which notified them of the Whistleblower's allegations at the start of the Class Period. In response to the February 2021 Whistleblower Complaint, Abbott's senior management took no corrective action. They were more concerned with silencing the Whistleblower and other concerned employees than with ensuring the safe production of formula.

4. Throughout 2021, conditions worsened at Abbott's Sturgis facility. On September 20, 2021, the FDA received a report of an infant seriously ill from *Cronobacter* that was linked to Abbott powdered formula manufactured in Sturgis. A few days later, in a September 24, 2021 Form 483 and in an establishment inspection report delivered to Abbott, responded to by Defendant Randall and others, but not disclosed to the public (the "2021 483 Report"), the FDA

[2] Counsel obtained a redacted copy of the February Whistleblower Complaint through a FOIA request to MIOSHA. Its exact contents have not previously been publicly disclosed.

found that Abbott failed to maintain its infant formula production "in a clean and sanitary condition" and that Abbott's staff working directly with infant formula failed to wash their hands thoroughly, a basic step necessary to help prevent *Cronobacter* contamination. Notably, the inspectors who issued the 2021 483 Report were not made aware of the reported illness connected to *Cronobacter*. On October 19, 2021, the Whistleblower, concerned by the continued violations at Abbott and the retaliation reported to him by other employees who remained at Sturgis, filed another non-public complaint (the "October 2021 Whistleblower Complaint"), this time directly with the FDA, repeating and providing additional details to the allegations in the February 2021 Whistleblower Complaint. The October 2021 Whistleblower Complaint described in detail violations of U.S. law and FDA regulations that were "neither inadvertent nor minor in nature," "constitute[d] acts of commission and omission by management," and "hold[] the prospect of putting the ultimate consumer at risk." In December 2021, January 2022, and February 2022, three additional *Cronobacter* infections linked to Sturgis-produced formula were reported, two of which resulted in the death of an infant who consumed Abbott's formula.

5. Despite these direct warnings, Abbott and its top management failed to take the most basic precautions despite the established history of microbial contamination at Sturgis. This conduct was in direct conflict with Defendants' statements to investors. For example, Abbott's Nutrition division made a "Quality Promise" that was published on Abbott's "Corporate Newsroom" section of its website throughout the Class Period, stating that (a) Abbott's "high-tech quality processes ensure safety and quality throughout every stage of the manufacturing process"; (b) Abbott's "facilities are designed and maintained to the highest Good Manufacturing Practice standards"; (c) Abbott's "employees follow strict hygiene measures"; (d) Abbott, "[b]efore releasing products for sale, [] extensively test[s] each batch to ensure it meets our quality

standards"; and (e) Abbott "ensure[s] that our products comply with all global and local regulations."

6. Moreover, in its annual Global Sustainability Reports directed to investors, Abbott emphasized how its "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." Abbott represented that "[w]e monitor and verify microbiology, packaging integrity, and nutrient and lot control. We complete extensive finished product testing before releasing it for commercial distribution." Moreover, Abbott told investors and the public that any complaints regarding food safety would be fully investigated and brought to the attention of the Company's Chief Ethics Compliance Officer, who in turn "monitors all government guidance." Such representations were critical to investors: Abbott was manufacturing infant formula—food for newborn babies, the most vulnerable constituency possible—and food safety was critical to offering those products for sale.

7. Abbott's misrepresentations and omissions posed not only a dire risk to the health of infant consumers, but also threatened to expose Abbott's investors to significant losses once the Company's "egregiously unsanitary" conditions at Sturgis were revealed. Sturgis was the primary manufacturing facility for infant formula in the entire United States. Abbott, through only a few facilities in the U.S., produced 40% of the United States' infant formula. Approximately 40% of that formula was manufactured at Sturgis. In other words, one in every five American babies who were fed formula relied on Sturgis-produced formula for their nutrients. As FDA Commissioner Califf said in the wake of the 2022 recall, "Abbott's enormous market share left it with the responsibility for producing safe infant formula that wasn't met."

8. With the public in the dark, Abbott waited until the FDA, following reports of a rising trend of infant illnesses and deaths related to Sturgis-related *Cronobacter* and *Salmonella* infections and investigation into the Whistleblower Complaints, mandated that Abbott take action. Prompted by these circumstances, the FDA inspected Sturgis for cause, arriving at the facility on January 31, 2022. Within days, the FDA quickly uncovered the extreme public health risks posed by the *Cronobacter* bacteria contamination found throughout the formula production facility at Sturgis, as well as Company records of prior *Cronobacter* contamination.

9. On February 17, 2022, after the markets closed, the FDA publicly announced it was investigating complaints of infant illnesses and deaths related to Sturgis-produced powdered infant formula including *Cronobacter* and *Salmonella* bacteria. The FDA revealed that the agency had initiated an ongoing onsite inspection at the facility where the agency had, to date, found evidence of *Cronobacter*, the microorganism linked to the reported infant illnesses and death. The FDA revealed that its review of Abbott's internal records indicated "environmental contamination with *Cronobacter* and the firm's destruction of product due to the presence of *Cronobacter*." Also on February 17, 2022, in light of the FDA's consumer advisory, Abbott issued a recall of Abbott's infant formula products, including the popular brands Similac, Alimentum and EleCare, all manufactured in Sturgis.

10. In a February 17, 2022 press release, Abbott did not mention the continuing FDA inspection and falsely characterized the recall as "voluntary" and "proactive," stating: "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." Abbott also downplayed the conditions at Sturgis, stating that *Cronobacter* was found only in

"non-product areas" and that "no distributed product has tested positive for the presence of either [*Cronobacter* or *Salmonella*]"—statements that were misleading and inaccurate.

11. On this news after the close of trading, the price of Abbott common stock declined $3.79 per share, from a closing price of $120.58 per share on February 17, 2022, to a closing price of $116.79 per share on February 18, 2022 on heavy trading volume, resulting in a market capitalization single-day-loss of $6.9 billion.

12. In the following days, Abbott was forced to officially shut down production at the Sturgis plant due to its severe safety problems, shuttering one of the major sources of infant formula for the entire United States, as well as certain Canadian and foreign markets. This contributed to a nationwide shortage of infant formula in a market that was already stretched thin due to COVID-related supply chain issues.

13. Approximately one month later, on March 22, 2022, after the markets closed, the FDA publicly disclosed the initial observations of its recent inspection, which occurred between January 31, 2022 and March 18, 2022 (the "2022 483 Report"). The FDA identified several unsanitary conditions at Sturgis, finding that 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 failed to "ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source." Moreover, while Abbott had stated on February 17, 2022 that neither it nor the FDA had found evidence that *Cronobacter* reached "product contact" areas of the Sturgis plant, the FDA directly contradicted that claim in its 2022 483 Report, in which it observed that Abbott had indeed found *Cronobacter* in the production areas and in the finished formula itself on at least two prior occasions, and that the FDA most recently found powder contaminated with *Cronobacter* in

areas that did come into contact with formula scoops that are placed inside containers of packaged formula. Also on March 22, 2022, the FDA, for the first time, released its 2019 483 Report and 2021 483 Report, revealing Abbott's history of uncorrected food safety violations directly linked to *Cronobacter* at Sturgis.

14. On the news of these damaging Form 483 inspection reports after the close of trading, Abbott's stock price dropped $4.97 per share, 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, resulting in a market capitalization single-day-loss of $8.8 billion.

15. While Abbott continued to downplay its culpability and any direct link between the unsanitary conditions in Sturgis and infant formula contamination, news related to the Whistleblower Complaints emerged that painted a different picture—that of a Company placed on direct notice of rampant food safety violations at Sturgis that were not remediated. Rather, the Company chose to conceal the violations and to retaliate against those individuals who sought to address the significant issues present at Sturgis. On April 28, 2022, during trading hours, a redacted copy of the October 2021 Whistleblower Complaint was made public by U.S. Congresswoman Rosa DeLauro, revealing that the conditions leading to the recall and Sturgis shutdown were actually known to Abbott's management far earlier than the Company had acknowledged to investors and the public. In response to its release, Abbott's stock price fell, dropping $4.51 per share, or 3.8%, from a closing price of $118.01 per share on April 28, 2022, to a closing price of $113.50 per share on April 29, 2022, resulting in a market capitalization single-day-loss of $7.9 billion.

16. On May 16, 2022, the United States of America, on behalf of the FDA, filed the DOJ Complaint and Consent Decree against Defendants Abbott and Randall and two senior

managers at Sturgis. The DOJ Complaint charged Abbott with dangerous and unsafe practices and business operations, which constituted numerous violations of the Food, Drug, and Cosmetic Act. The DOJ Complaint and Consent Decree expounded on the detailed findings released by the FDA in March, alleging that Abbott "manufacture[d] infant formulas . . . under conditions and practices that fail to protect the food against the risk of contamination from bacteria including, but not limited to, *Cronobacter sakazakii* (*'C. sak'*) and *Salmonella*." The DOJ Complaint was clear: Abbott and several members of its management had caused "adulterated food" to enter interstate commerce, and that "[o]ngoing 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." Shortly after the DOJ Complaint and Consent Decree, in response to the dire infant formula shortage caused in large part by the Sturgis shutdown, President Joseph Biden authorized "Operation Fly Formula," and on May 22, 2022, a U.S. military plane flew from Germany with the first shipment of infant formula needed to help address the critical shortage precipitated by the contamination at Sturgis.

17. On May 25, 2022, FDA Commissioner Califf provided sworn testimony before Congress. Commissioner Califf described bacteria growing at multiple sites in Sturgis, cracks in key equipment, leaks from the roof, and standing water. Commissioner Califf concluded that there were "***egregiously unsanitary***" conditions at Abbott's Sturgis facility, and that "***the inspection results were shocking***." As a result, Commissioner Califf reported, the FDA "***lost confidence that Abbott Nutrition had the appropriate safety and quality culture and commitment to fix these problems quickly***."

18. At that same May 25, 2022 congressional hearing, Defendant Calamari, Abbott's Senior Vice President of Nutrition for North America, defended Abbott, even in the face of the recall, shutdown, October 2021 Whistleblower Complaint revelations, DOJ Complaint, Consent Decree, and Commissioner Califf's stark testimony just minutes earlier. Calamari specifically denied that anyone at Abbott had any knowledge of the Whistleblower's detailed accounting of the unsanitary conditions at Abbott prior to the April 22, 2022 public release of the October 2021 Whistleblower Complaint. This denial was false. Investors learned, just before the market closed on June 8, 2022, that Abbott was made aware of the February 2021 Whistleblower Complaint allegations at the start of the Class Period. Moreover, news reports confirmed that Abbott even submitted a response to the February 2021 Whistleblower Complaint in April 2021. In response to the news that Abbott had been aware of the Whistleblower's allegations since February 2021, Abbott's stock price dropped yet again, falling $4.17 per share, 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, resulting in a market capitalization loss of $11.1 billion.

19. Finally, at the end of the Class Period on October 19, 2022, the Company disclosed its results for the third quarter ended September 30, 2022, which included significant adverse sales and earnings impacts in pediatric nutrition. Specifically, Abbott's total U.S. pediatric sales had decreased 39.1% on an organic basis, or 24.8% on a reported basis, for the third quarter of 2022. Total nutrition sales fell 10.3% on an organic basis, and Abbott's net earnings declined 31.7% from the same quarter in 2021, falling from $2.1 billion to $1.44 billion. Moreover, during an investor conference call held on October 19, 2022, Defendant Ford announced that the Company had made leadership changes at Sturgis and in its Quality division, acknowledging, finally, that there were serious institutional deficiencies that caused the contamination and recall. In response

to the news, Abbott's stock price dropped precipitously, falling $6.87 per share, from a closing price of $104.98 per share on October 18, 2022, to a closing price of $98.11 per share on October 19, 2022, resulting in a market capitalization single-day-loss of $12 billion.

20. The impact of Defendants' scheme to keep Sturgis running with unsanitary conditions and increase its market share at the expense of its most vulnerable consumers has been severe. In addition to the loss in 2022 of approximately $721 million in revenues and $176 million in charges related to the recall, and the loss of the invaluable trust of parents worldwide and investors who relied on Abbott's "Quality Promise," Abbott is now the focus of a federal criminal investigation by the U.S. Attorney's Office for the Western District of Michigan, as well as an investigation by the SEC into the Company's statements concerning its powdered infant formula business and related public disclosures. Abbott is also a defendant in almost fifty personal injury lawsuits on behalf of infants who consumed Abbott formula and were allegedly infected by *Cronobacter* or *Salmonella*. Those cases are consolidated in a multi-district litigation pending in this district, and document discovery in that proceeding is underway. Moreover, the FDA received a total of 128 consumer complaints linked to Sturgis via the agency's consumer complaint system between December 2021 and March 2022, ten of which tragically resulted in the infant's death after consuming baby formula produced at Sturgis.

21. Defendants' decision to choose profits over necessary investments and improvements in Sturgis had incredibly negative consequences. It led to serious illnesses and deaths in the world's most vulnerable population, and harmed countless families who were fearful that their infants consumed contaminated formula and then struggled to find any safe, uncontaminated formula to meet their basic needs. Defendants' misconduct also severely damaged Abbott's long-standing reputation and caused considerable shareholder losses.All told, through

this unlawful conduct, Abbott fell woefully short of its "promise" to "ensure safety and quality through every stage of the manufacturing process," and, instead, concealed its unlawful scheme to forsake safety and quality in order to increase production and profits. Defendants' representations and omissions, once revealed, caused a massive decline in Abbott's stock price, erasing over $40 billion in market capitalization for investors.

22. Abbott's efforts to distance the Company from the reported infant illnesses and deaths continues. However, just last month, on March 28, 2023, Frank Yiannas, former FDA Deputy Commissioner for Food Policy & Response, who was directly involved in the February 2022 investigation of Sturgis, testified before Congress and refuted the legitimacy of Abbott's "suggest[ion] that their products were not the source of illnesses." Yiannas provided ten facts that contributed to "the weight of the evidence" that had compelled action against Abbott and that rendered Abbott's statements and efforts to avoid blame for infants' illnesses and possibly deaths to be "***misleading.***" Based on the weight of the evidence, Yiannas concluded "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."

23. Through the activities alleged in this Complaint, Defendants directly and indirectly have engaged in conduct that constitutes a scheme to defraud and have made materially false or misleading statements in violation of Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5 promulgated thereunder. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common stock, Plaintiffs and other members of the Class have suffered significant damages. Plaintiffs bring this action to recover the

damages to Abbott investors caused by Defendants' misconduct and to seek accountability for the violations of the securities laws alleged herein.

II. JURISDICTION AND VENUE

24. The claims asserted in this Complaint arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)), and SEC Rule 10b-5 promulgated thereunder (17 C.F.R. § 240.10b-5).

25. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

26. Venue is proper in this Judicial District under 28 U.S.C. § 1391(b), Section 27 of the Exchange Act, 15 U.S.C. § 78aa(c). Many of the acts alleged herein, including the preparation and dissemination of materially false and misleading statements, occurred in substantial part in this District. Additionally, Abbott's principal place of business is located in this District.

27. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the mails, interstate telephone communications, and the facilities of a national securities exchange.

III. PARTIES

A. Lead Plaintiffs

28. Quoniam is an institutional asset management company with its headquarters in Germany. Quoniam is owned and controlled by Union Asset Management Holding AG. As set forth in the attached Appendix A, Quoniam's funds purchased Abbott common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

29. KBC is an asset management company headquartered in Brussels, Belgium. As part of KBC's asset management services, it is responsible for managing mutual funds, private funds, and institutional funds. KBC manages assets in excess of € 200 billion. As set forth in the attached Appendix B, KBC's funds purchased Abbott common stock during the Class Period and suffered damages as a result of the federal securities law violations alleged herein. (A signed PSLRA certification is forthcoming.)

B. Defendants

30. Defendant Abbott is an Illinois corporation with its headquarters located in Abbott Park, Illinois. Abbott's common stock actively traded on the New York Stock Exchange throughout the Class Period under the ticker "ABT." Abbott was founded 135 years ago, and its products are currently distributed and sold in over 160 countries. Abbott Nutrition accounts for roughly 20% of the Company's annual sales. Half of Abbott Nutrition's sales are from the sale of infant formula and other pediatric nutrition products. At the start of the Class Period, Abbott Nutrition manufactured approximately 40% of the Company's infant formula sold in the United States at a facility located in Sturgis, Michigan. At the Sturgis facility, Abbott manufactures, processes, packs, labels, holds, and distributes infant formulas that are marketed under several brand names throughout the United States, including Similac, Alimentum and EleCare.

31. Defendant Robert B. Ford is Abbott's Chairman of the Board and Chief Executive Officer. Ford was appointed Chief Executive Officer in March 2020 and assumed the role of Chairman in December 2021. Prior to his appointment as Chief Executive Officer, Ford served as Abbott's President and Chief Operating Officer and as Executive Vice President, Medical Devices.

32. Defendant Robert E. Funck, Jr. is Abbott's Chief Financial Officer and Vice President, Finance. Funck assumed this role in March 2020. Prior to his appointment as Chief Financial Officer, Funck served as Senior Vice President, Finance and Controller at Abbott. Funck

joined Abbott in 1987 and held multiple positions, including Vice President, Controller; Vice President, Internal Audit; Vice President, Treasurer; and Divisional Vice President and Controller in Abbott's pharmaceutical business.

33. Defendant Christopher J. Calamari is Abbott's Senior Vice President for U.S. Nutrition. Calamari assumed this role in July 2021. Calamari joined Abbott in 2005 and has served in a number of roles during his tenure, including serving as Divisional Vice President and General Manager, Pediatric Nutrition from 2014 to 2017, and Vice President for Pediatric Nutrition from 2017 to July 2021. On May 25, 2022, Calamari testified before Congress on behalf of Abbott.

34. Defendant Lori J. Randall joined Abbott approximately 31 years ago and is Division Vice President of Quality Assurance in Abbott Nutrition. In her position, which she held throughout the Class Period, Randall has overall responsibility for quality operations for global Abbott Nutrition, including oversight of manufacturing locations and food safety, product quality, supplier quality, compliance, complaint management, and corrective and preventive actions. Randall was responsible for approving the decision made during the FDA's 2022 inspection of the Sturgis plant to initiate a recall of certain infant formulas manufactured at Sturgis. Randall performs her duties at the corporate office located in Abbott Park, Illinois. Randall was named as a defendant in the May 16, 2022 DOJ Complaint brought by the FDA against Abbott and certain of its executives and she signed the May 16, 2022 Consent Decree entered into with the FDA on behalf of Abbott.

35. Defendants Ford, Funck, Calamari, and Randall are collectively referred to herein as "the Individual Defendants." The Individual Defendants, because of their high-ranking positions and direct involvement in the everyday business of Abbott—and specifically the production and sale of infant formula—directly participated in the management of Abbott's operations, including its public reporting functions, had the ability to control, and did control, Abbott's conduct, and were

privy to confidential information concerning Abbott and its business, operations, and financial statements, as alleged herein.

36. Abbott and the Individual Defendants are collectively referred to herein as "Defendants."

IV. BACKGROUND AND NATURE OF THE FRAUD

A. Background On Abbott's Infant Formula Business

37. Abbott, an international health care products company that was founded in 1888 and incorporated in 1900, is a conglomerate that recorded sales in 2021 across four reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices.

38. Nutritional Products includes three product lines: infant formula, including primarily products under the Similac, Alimentum, and Elecare brand names; adult and other pediatric nutritional products, such as Ensure and Pedialyte; and enteral (tube-fed) products used in health-care institutions. In 2020, Nutrition accounted for 22% of Abbott's total sales. According to Abbott's Form 10-K for the year-ended December 31, 2021, the Company's pediatric nutritional product sales totaled $4.3 billion in 2021. Abbott's U.S. sales of pediatric nutritional products increased 10% from 2020 ($1.98 billion) to 2021 ($2.19 billion), with total sales of all infant formula totaling more than $12 billion in the United States.

39. Abbott became involved in pediatric nutrition no later than 1925, when it marketed Lactigen, a product created by sterilizing milk and removing the fat content. While this effort failed, the very same year another company, M&R Dietetic Laboratories, created the first version of Similac, the baby formula product that would eventually make Abbott a "leader in nutrition" that would "spearhead Abbott's growing role in nutrition," according to the Company's self-published marketing book *A Promise For Life: The Story Of Abbott*.

40. In public releases, Abbott touts Similac's long history, claiming that "[f]or nearly 90 years, millions of parents in the U.S. and around the world have relied on Similac to provide optimal nutrition to support their infant's healthy growth and development." According to Abbott, "Similac's rich history sets itself apart from others, as it has helped create solutions and championed for moms' choices starting in the early 20th century."

41. With Similac among Abbott Nutrition's crown jewels, Abbott became, and remained, a market leader in infant formula. Class Period earnings statements and calls highlighted market share gains in infant formula as a growth driver for the Company. For example, in January 2022, on the eve of the recall, Abbott President and CEO Robert Ford trumpeted "market share gains for Similac, our market-leading infant formula brand," over the prior quarter. In 2020, Abbott controlled 40% of a U.S. infant formula market that was valued at $3.9 billion and was estimated by market researchers would increase to nearly $7 billion by 2027.

42. The U.S. infant formula market is highly concentrated. Abbott, with its 40% share, and three other manufacturers, Reckitt Benckiser Group (through subsidiary Mead Johnson & Company, LLC) ("Mead Johnson"), Nestlé Group (through subsidiary Gerber Products Company) ("Gerber"), and Perrigo Nutritionals, collectively control 90% of the U.S. infant formula market. Abbott's market dominance stems from a regulatory landscape that disincentivizes international competitors from entering the U.S. infant formula market. As *The Wall Street Journal* reported on May 20, 2022, "[r]egulatory hurdles . . . mean little formula comes into the country from abroad . . . . The U.S. typically produces about 98% of formula consumed domestically." Moreover, strict FDA regulations disincentivize new domestic infant formula producers from entering the market. Abbott manufactures all of its U.S. infant formula in just a handful of plants: the Sturgis plant

produces nearly half of all of Abbott's U.S. formula, and plants in Casa Grande, Arizona, and Ohio produce the remainder.

43. Because of Abbott's outsized share of the entire U.S. infant formula market, infants across the country depended on Abbott's ability to produce safe and salable formula to satisfy their most basic nutritional needs. According to the latest Centers for Disease Control and Prevention (the "CDC") "Breastfeeding Report Card," in 2019, nearly 17% of babies born in the U.S. relied exclusively on infant formula from birth, and up to 75% of babies relied on infant formula together with breastfeeding, by six months of age. In 2021, 3,659,289 babies were born in the United States, meaning that approximately 732,000 babies relied on infant formula exclusively from birth, and over 2.75 million babies relied on infant formula together with breastfeeding after a few months of age. One in every five of those infants consumed formula manufactured in Abbott's Sturgis facility.

44. Hundreds of thousands of families each year rely on infant formula, including Abbott formula, to feed their babies. This is especially true of lower-income families who lack regular access to doctors and lactation consultants and may lack the proper accommodations to pump milk when they return to work—making breastfeeding a challenging option to credibly rely on to nourish their infants. Many of those infants consume only Abbott formula through the Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC"). WIC is a federally-funded, but state administered, federal nutrition program aimed at safeguarding the health of low-income women, infants, and children who are at nutrition risk. Approximately half of the baby formula sold in the United States is purchased through the WIC program. States award exclusive sales contracts to a single formula manufacturer in exchange for discounts for the WIC recipients. Participating stores are required to keep a minimum amount

of the WIC brand in stock, and many choose to exclusively stock that brand. Only three companies have been awarded WIC contracts: Abbott, Mead Johnson, and Gerber. Abbott had the most WIC contracts, with 49 agreements with states, territories, and tribal organizations, according to data from the National WIC Association. This means that about 47 percent of the 1.2 million infants who receive formula benefits through the WIC program are entitled ***only*** to Abbott infant formula.

45. In addition to the WIC program, Abbott, like other formula manufacturers, has taken active steps to promote the use of Abbott's products by working with hospitals to make Abbott formula easily accessible to new parents. In hospitals, babies are sometimes fed formula, whether in a neonatal intensive care unit or an overnight nursery, and hospital staff may send parents home with the ready-made formula, starting the infants off early on a partial-formula diet. To encourage hospitals to promote their products, formula manufacturers provide free samples of powdered infant formula to hospitals, and one-third of U.S. hospitals provide free samples of liquid and powdered formula to new parents.

46. As a result of Abbott's 40% infant formula market share and its role as the only source of formula to half of the 1.2 million WIC consumers, millions of U.S. parents and caregivers have little and sometimes no choice in the formula they are able to provide to their infants. With this control over the supply of U.S. infant formula, Abbott's strict adherence to the FDA's regulations and Abbott's own stated manufacturing guidelines was crucial to the safety and well-being of millions of infants throughout the country. As FDA Commissioner Califf said in the wake of the 2022 recall, "Abbott's enormous market share left it with the responsibility for producing safe infant formula that wasn't met."

B. Abbott Promises Compliance With The FDA's Current Good Manufacturing Practices Standards And Related Regulations

1. Mandatory Federal Regulations Govern The Production Of Powdered Infant Formula And, Specifically, The Detection And Elimination Of *Cronobacter* Contamination

47. On the first day of the Class Period, Abbott filed its Annual Report with the SEC on Form 10-K for the year ended December 31, 2020, and acknowledged that its "products are subject to rigorous regulation by the FDA and numerous international, supranational, federal, and state authorities." In its capacity as an infant formula maker, Abbott is subject to a variety of regulations that require mandatory compliance. As discussed further below, in recognition of the necessity of compliance to the health of its consumers as well as Abbott's ability to be allowed to continue selling its products, Abbott "ensure[d]" its compliance with these regulations in public statements.

48. The Food Drug, and Cosmetic Act of 1938 (the "FDCA") provides protections for consumers against adulterated food. Under the FDCA, food may be adulterated if "it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food," or if "it has been prepared, packed, or held under insanitary conditions . . . whereby it may have been rendered injurious to health." 21 U.S.C. § 342(a)(3)-(4).

49. According to the FDA's own website, the FDA is responsible for enforcing the FDCA and "[p]rotecting the public health by assuring that foods . . . are safe, wholesome, and properly labeled." Beginning in the 1960s, the FDA began working on Good Manufacturing Practices regulations designed "to describe general rules for maintaining sanitary conditions that must be followed by all food processing facilities to ensure the statutory requirements . . . were met." These regulations were promulgated for the first time in 1968. Since then, industry-specific

regulations have been published in certain areas, including infant formula, constituting the agency's Current Good Manufacturing Practices ("CGMPs").

50. Infant formula, which means "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk" (21 U.S.C. § 321(z)), has additional CGMP regulations specific to its production. The FDA promulgated CGMP regulations for infant formulas at 21 C.F.R. Part 106, Subpart B (the "Infant Formula CGMP Regulations"). These regulations are designed to ensure the safety of infant formula and prevent the manufacture of adulterated infant formula, and they require manufacturers to implement a system of controls to cover all stages of manufacturing. Infant Formula CGMP Regulations contain requirements for specific controls including, but not limited to, controls to prevent adulteration of infant formula from microorganisms, specifically *Cronobacter* and *Salmonella*. *See* Interim Final Rule, Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula. 79 Fed. Reg. 7934, 7935 (Feb. 10, 2014); *see also* Final Rule, Current Good Manufacturing Practices, Quality Control Procedures, Quality Factors, Notification Requirements, and Records and Reports, for Infant Formula. 79 Fed. Reg. 33,057 (June 10, 2014).

51. Currently, 21 C.F.R. 106 contains "the minimum current good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula." 21 C.F.R. § 106.5(a).

52. Among the requirements imposed by the CGMP regulations regarding infant formula are that:

a) The manufacturer adopt a "system of production and in-process controls" that "shall be set out in a written plan or set of procedures that is designed to ensure

that an infant formula is manufactured in a manner that will prevent adulteration of the infant formula," 21 C.F.R. § 106.6(a)-(b);

b) "Personnel working directly with infant formula, infant formula raw materials, infant formula packaging, or infant formula equipment or utensil contact surfaces shall practice good personal hygiene to protect the infant formula against contamination. Good personal hygiene includes: . . . Wearing clean outer garments and, as necessary, protective apparel such as head, face, hand, and arm coverings," 21 C.F.R. § 106.10(b)(1);

c) "Buildings used in the manufacture, processing, packing, or holding of infant formula shall be maintained in a clean and sanitary condition . . ." 21 C.F.R. § 106.20(a); and

d) "A manufacturer of infant formula shall establish a system of process controls covering all stages of processing that is designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment," 21 C.F.R. § 106.55(a).

53. In conjunction with Infant Formula CGMP Regulations, the FDA also promulgated requirements for record-keeping, including a requirement that manufacturers have procedures for handling all written and oral complaints (the "Infant Formula Record Requirements"). *See* 21 U.S.C. § 350a(b)(4); 21 C.F.R. § 106.100(k). Under the Infant Formula Record Requirements, manufacturers must conduct an investigation when a complaint shows a possible health hazard. The failure to comply with Infant Formula Record Requirements, including the requirement for complaint-handling procedures, renders infant formulas adulterated.

54. In addition to the Infant Formula CGMP Regulations and Infant Formula Record Requirements, there are overarching food safety CGMPs that Abbott and its Sturgis plant are subject to, including that:

a) All operations in the manufacturing, processing, packing, and holding of food (including operations directed to receiving, inspecting, transporting, and segregating) must be conducted in accordance with adequate sanitation principles. 21 C.F.R. § 117.80(a)(1).

b) Appropriate quality control operations must be employed to ensure that food is suitable for human consumption and that food-packaging materials are safe and suitable. 21 C.F.R. § 117.80(a)(2).

c) Overall sanitation of the plant must be under the supervision of one or more competent individuals assigned responsibility for this function. 21 C.F.R. § 117.80(a)(3).

d) Adequate precautions must be taken to ensure that production procedures do not contribute to allergen cross-contact and to contamination from any source. 21 C.F.R. § 117.80(a)(4).

e) Chemical, microbial, or extraneous-material testing procedures must be used where necessary to identify sanitation failures or possible allergen cross-contact and food contamination. 21 C.F.R. § 117.80(a)(5).

f) All food that has become contaminated to the extent that it is adulterated must be rejected, or if appropriate, treated or processed to eliminate the contamination. 21 C.F.R. § 117.80(a)(6).

g) Equipment and utensils and food containers must be maintained in an adequate condition through appropriate cleaning and sanitizing, as necessary. Insofar as necessary, equipment must be taken apart for thorough cleaning. 21 C.F.R. § 117.80(c)(1).

h) All food manufacturing, processing, packing, and holding must be conducted under such conditions and controls as are necessary to minimize the potential for the growth of microorganisms, allergen cross-contact, contamination of food, and deterioration of food. 21 C.F.R. § 117.80(c)(2).

i) Food that can support the rapid growth of undesirable microorganisms must be held at temperatures that will prevent the food from becoming adulterated during manufacturing, processing, packing, and holding. 21 C.F.R. § 117.80(c)(3).

j) Measures such as sterilizing, irradiating, pasteurizing, cooking, freezing, refrigerating, controlling pH, or controlling a_w that are taken to destroy or prevent the growth of undesirable microorganisms must be adequate under the conditions of manufacture, handling, and distribution to prevent food from being adulterated. 21 C.F.R. § 117.80(c)(4).

k) Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must: . . . Be a qualified individual as that term is defined in § 117.3—*i.e.*, have the education, training, or experience (or a combination thereof) necessary to manufacture, process, pack, or hold clean and safe food as appropriate to the individual's assigned duties. 21 C.F.R. § 117.4(b)(1); and

l) Each individual engaged in manufacturing, processing, packing, or holding food (including temporary and seasonal personnel) or in the supervision thereof must: . . . Receive training in the principles of food hygiene and food safety, including the importance of employee health and personal hygiene, as

> appropriate to the food, the facility and the individual's assigned duties. 21 C.F.R. § 117.4(b)(2).

55. In addition to the above and other manufacturing requirements, the FDA requires infant formula manufacturers to maintain extensive records, including "[d]ocumentation . . . of the monitoring at any point, step or stage in the manufacturer's production process where control is deemed necessary to prevent adulteration." 21 C.F.R. § 106.100(e)(3). Manufacturers are required to "make readily available for authorized inspection all records required under [the record-keeping regulations] or copies of such records." 21 C.F.R. § 106.100(l).

56. Finally, in addition to the requirement that records are maintained and ready for FDA inspection, the Infant Formula CGMP Regulations require that a manufacturer "promptly notify" the FDA "when the manufacturer has knowledge (that is, actual knowledge that the manufacturer had, or the knowledge which a reasonable person would have had under like circumstances or which would have been obtained upon the exercise of due care) that reasonably supports the conclusion that an infant formula that has been processed by the manufacturer and that has left an establishment subject to the control of the manufacturer" has been "adulterated or misbranded." 21 C.F.R. § 106.150(a).

57. The Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21. U.S.C. §331(a), which generally prohibits the introduction of adulterated formula into interstate commerce, is the enforcement mechanism for violations of its provisions as well as for noncompliance with the Infant Formula CGMP Regulations. The FDCA deems infant formulas adulterated if they are not made in compliance with FDA's Infant Formula CGMP Regulations. *See* 21 U.S.C. §§ 350a(a)(3) and 350a(b)(2); 21 C.F.R. §§ 106.1(a) and 106.5(b). Specifically, the FDCA prohibits introducing into interstate commerce:

a) Articles of food, namely infant formulas as defined in 21 U.S.C. § 321(z), that are adulterated within the meaning of 21 U.S.C. § 350a(a)(3) in that they have

been processed in a manner that does not comply with current good manufacturing practice requirements for infant formula set forth at 21 U.S.C. § 350a(b)(2) and 21 C.F.R. Part 106; and

b) Articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health.

58. The FDCA, 21 U.S.C. § 331(k) also prohibits causing:

a) Articles of food, namely infant formulas 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

b) 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).

2. The FDA Highlighted And Addressed The Serious Risks Posed To Babies By *Cronobacter* In Its 2014 Revisions To The Infant Formula CGMP Regulations

59. *Cronobacter* is a naturally-occurring bacteria, which can survive on almost every surface. However, it is especially adept at surviving in dry foods.[3] *Cronobacter* infections are rare and, for most people, the bacteria are harmless. However, for infants, the infections can be deadly, especially for infants who are less than two months old, premature, immunocompromised, or of low birthweight.[4] *Cronobacter* can cause sepsis (a serious blood infection) or meningitis (swelling of the linings surrounding the brain and spinal cord). Infants two months or younger are most at risk of developing meningitis if they become ill from *Cronobacter* infection. Infants born prematurely are also more likely to become ill from *Cronobacter* infection.

[3] *Cronobacter Infection And Infants*, CDC.gov, https://www.cdc.gov/cronobacter/infection-and-infants.html (last visited Dec. 29, 2022)

[4] *Id.*; *see also What To Know About The Risk Of Cronobacter In Powdered Infant Formula*, FDA.gov, https://www.fda.gov/consumers/consumer-updates/what-know-about-risk-cronobacter-powdered-infant-formula (last visited Dec. 29, 2022)

60. *Cronobacter*, which until 2008 was classified as *Enterobacter sakazakii*, emerged as a known contaminant in powdered infant formula in 2001, when it caught the attention of the FDA and the companies it regulates. In April of that year, an 11-day-old premature infant at a university hospital in Knoxville, Tennessee fell ill with a *Cronobacter* infection. He had a fever, an accelerated heart rate, and sepsis. When his brain stopped functioning, his family took him off life support, and he died nine days later. Eight other infants in the unit were also infected. One potential source of the *Cronobacter* was the infants' one common source of nutrition—Portagen, a powdered infant formula made by Mead Johnson. Almost a year after the newborn's death, the company recalled 17,000 cans of the formula.

61. In the wake of the incident, the FDA recommended that U.S. neonatal intensive care units stop using powdered formula altogether and use only liquid ready-made formula, which is pasteurized and therefore sterile, but also more expensive. To more fully assess the risks of powdered infant formula, the FDA collected powdered infant formula samples from different manufacturers. The results were poor. Five of the 22 samples were tainted with low levels of *Cronobacter*. FDA officials briefed doctors and industry representatives about this seemingly new pathogen in 2003. "You can always design something a little better or clean something a little better," an FDA official said. "Things come along, and we're required to raise the bar. I mean, were it not for the Titanic, would we have life preservers on cruise ships?"[5]

62. One reason that powdered formula poses a heightened risk for *Cronobacter* infection is that powdered formulas, unlike liquid baby formulas, do not receive certain processing treatments designed to sterilize them. *Cronobacter* can enter a factory where formula is produced

[5] Susan Berfield and Anna Edney, "How Deadly Bacteria Spread in a Similac Factory—and Caused the US Formula Shortage," *Bloomberg Businessweek* (Aug. 24, 2022).

on people's hands or the soles of shoes, and can survive on surfaces like counters and formula bottles. Contamination at a factory can occur if contaminated ingredients are used to make the formula, or if the formula powder comes into contact with a contaminated surface.

63. When the FDA attempted to add *Cronobacter* testing requirements in 2003, an industry group representing Abbott and other companies pushed back. That group argued that it was unnecessary to test for *Cronobacter* in formula marketed toward healthy, as opposed to premature, babies because they were not as at risk. Ultimately, the FDA held its ground. The 2014 revised Infant Formula CGMP Regulations included, for the first time, testing requirements for the pathogens *Cronobacter* and *Salmonella*. The 2014 revisions required infant formula makers to take at least 30 samples—each the weight of about two nickels—from every lot or batch of formula and test them for *Cronobacter*. These minimum testing requirements do not define the size of a lot or batch. According to a food safety expert quoted by *The New York Times* in a May 23, 2022 article discussing regulations, Abbott's lots can reach 300,000 pounds. These minimum testing requirements for packaged infant formula are not sufficient to ensure a safe product. The true preventative measure is ensuring that the manufacturing facility is sanitary, hygienic, and free of microorganisms in the production environment.

64. In its 2014 interim rule change report, the FDA explained that *Cronobacter* has been described as "a severe hazard for restricted populations, [resulting in] life threatening or substantial chronic sequelae of long duration" by the International Commission for Microbiological Specifications for Foods (ICMSF 2002). The FDA made clear that the risks of infection were severe: "*Cronobacter* spp. have been identified as the etiological agent in neonatal meningitis, septicemia, and necrotizing enterocolitis, and are considered emerging opportunistic pathogens. *Cronobacter* spp. have caused meningitis resulting in brain abscess and ventriculitis

(inflammation of the cerebral ventricles) with a very high associated mortality rate in neonates and infants. Survivors of *Cronobacter*-induced meningitis suffer life-long mental and physical developmental delays." The FDA also made clear that even a small amount of *Cronobacter* could cause illness, noting that "[a]lthough there has been continued study of this pathogen and further characterization, the dose required to cause infection has yet to be determined."

65. The FDA concluded that, "given the absence of a documented infectious dose and the severity of *Cronobacter* spp. infections in infants, even a low risk of such contamination of infant formula from the production environment ***must not be tolerated***." In response to a public comment asserting that "given infant formula's excellent safety record since the passage of the Infant Formula Act, there is no need for additional microbiological requirements," the FDA responded that "*Cronobacter* spp. have been documented as responsible for infant illnesses such as bacteremia, sepsis, and meningitis, with a reported mortality rate as high as 40 to 80 percent." The FDA further emphasized that the known cases of *Cronobacter* infections in infants "have been associated both directly with powdered infant formula," such that any "safety record for infant formula does not obviate the need for the microbiological requirements of this interim final rule."

66. Abbott's former GMP & Food Safety Specialist at Sturgis from 2019 through September 2021 (and Front Line Leader from 2017 through 2019), FE1,[6] explained the steps involved in the manufacture of powdered infant formula at Sturgis, as well as the most sensitive steps where *Cronobacter* could thrive. After the raw materials for the formula arrive at the facility, they are blended together in liquid form for the formula in the processing department. The

[6] The terms "Former Employees" and "FE" refer to the former Abbott employees whose reports are discussed in this Complaint. The Former Employees are listed in Appendix C attached to this Complaint. In order to preserve the Former Employees' anonymity while maintaining readability, the Complaint uses the pronouns "he" and "his" in connection with all the Former Employees, regardless of actual gender.

processing department makes sure the blended formula has all the required nutrients. Once processed, the blended liquid is sent to a dryer. Workers at Sturgis inject the liquid into the dryer, which evaporates the liquid into a powder in an extremely high temperature "tornado." FE1 stated that the biggest area of risk for the spread of microorganisms like *Cronobacter* is inside of the dryer, after the dryer process and until the cans are filled and sealed. The drying process kills everything, but if there is microorganism growth after the drying process, there are no other "kill steps." After the dryer process, the now powdered formula is sent to the powder packaging department, which was also a big area of risk for microorganism growth. FE1 described how there was a "high chance of micro," *i.e.*, *Cronobacter*, contamination at Sturgis because the "Number 1 enemy of powder is water"; especially in an "old facility that wasn't designed to be cleaned in the way we now know it should be." As discussed below, and confirmed by the FDA in the March 22, 2022 release of its 2021 483 Report and 2022 483 Report, standing water, leaking roofs, and broken dryers with cracks and pits that provided a home for standing water, were a constant dangerous condition at Sturgis, and these conditions were formally documented and discussed within the Company.

67. A 2012 study by a longtime official at the CDC, and discussed in a September 6, 2022 article in *The New York Times*, found that it was "extremely unusual" for *Cronobacter* infections to occur in babies who were not fed powdered formula. In another paper, published in 2020, other CDC officials studied cases of infant meningitis since 1961 and found that in the vast majority, 79 percent, the baby had recently consumed powdered formula. Prior to 2021, two to four cases of *Cronobacter* infection in infants were reported to the CDC every year. Therefore, as described below, when four reports of infant illness and death tied to *Cronobacter* were being

reported in a matter of weeks in late 2021 and early 2022, all linked to Abbott and more specifically to formula from the Sturgis facility, the FDA took note and eventually took action.

3. The Consequences Of Noncompliance With Food Safety Regulations Are Severe

68. The FDA's primary way to monitor compliance with the Infant Formula CGMP Regulations and other regulatory requirements is in part through periodic—usually annual—inspections of infant formula manufacturing facilities. These inspections may last a few days, and involve the FDA's review of policies, review of select documents, and observations. At times, these inspections also involve testing at the facility. During a routine inspection, trained FDA investigators tour facilities, accompanied at all times by the inspected company's staff, and cite factual observations of significant deviations from the statutes the FDA enforces.

69. At the conclusion of an FDA inspection, the FDA holds a close-out meeting with company management and shares its observations. Significant deviations from the relevant statutes are then recorded in a "Form 483," which is presented and explained to the company's management. Relevant here, investigators touring a facility such as Sturgis that produces food (and in this case, formula) note in the Form 483 incidents where they "observ[e] any conditions that in their judgment may constitute violations of the [FDCA] and related Acts," and, "in the investigator's 'judgment', conditions or practices observed, would indicate that any food, drug, device or cosmetic have been adulterated or are being prepared, packed or held under conditions whereby they may become adulterated or rendered injurious to health." The FDA's website notes that the Form 483 is not "intended to be an all-inclusive list of every possible deviation from law and regulation" at a facility, and notes that "[c]ompanies are responsible to take corrective action to address the cited objectionable conditions ***and*** any related non-cited objectionable conditions that might exist."

70. A Form 483 is intended for use in notifying the company's "top" or "senior" "management" in writing of significant objectionable conditions, relating to products and/or processes observed during the inspection. According to the FDA Investigations Operations Manual, a Form 483 "should be issued to the most responsible person available at the close of the inspection," and a copy of the Form 483 "***should be sent to the top management of the firm***." The FDA investigators also draft and deliver an Establishment Inspection Report ("EIR"), which contains more detail than a Form 483 and may contain additional objectionable conditions in the manufacturing facility than those listed in the Form 483. Any company that receives a Form 483 is "encouraged to respond . . . in writing with their corrective action plan and then implement that corrective action plan expeditiously."

71. Generally, the FDA does not publish, or announce the issuance of, Forms 483. The company has an obligation to respond to the FDA's observations within fifteen business days with a root cause analysis, impact assessment, and a set of corrective and preventative actions.

72. The FDA may take additional action following a Form 483. If the FDA finds a company's responses to a Form 483 to be inadequate, it may issue a warning letter in order to prompt a company into voluntary compliance with the Act. *See* FDA, Regulatory Procedures Manual 4.1 (2022). However, there are instances where more serious enforcement actions may be taken, and a warning letter bypassed. Examples of situations where the agency will take direct enforcement action without necessarily issuing a warning letter include:

- The violation reflects a history of repeated or continual conduct of a similar or substantially similar nature during which time the individual and/or firm has been notified of a similar or substantially similar violation;
- The violation is intentional or flagrant;
- The violation presents a reasonable possibility of injury or death;

- The violations, under Title 18 U.S.C. § 1001, are intentional and willful acts that once having occurred cannot be retracted. Also, such a felony violation does not require prior notice; and

- A food "product is adulterated under Section 402(a)(3) or 402(a)(4) of the Act" or "[t]here is a violation of current good manufacturing practices (CGMP)."

73. The FDA has emphasized that companies that violate CGMP data integrity requirements, in addition to other violations of the CGMP, face severe sanctions. Indeed, FDA guidance explains that "data integrity-related CGMP violations have led to numerous regulatory actions, including warning letters, import alerts, and consent decrees." In particular, the FDA noted in a 2017 public presentation concerning "Data Integrity Issues and Concerns" that it "rel[ies] on firms to do the right thing when [the] FDA is not present," and data integrity problems "break trust" between an agency and a regulated entity.

74. If the FDA discovers serious, pervasive, and repeat CGMP and other data integrity violations, the FDA may order the Company to take extensive remedial action that could require the company to cease operations, in whole or in part, and implement expensive, time-consuming corrective measures—just like those Abbott was ultimately forced to implement at its Sturgis facility. Regaining the FDA's trust and remediating data integrity violations is invariably a difficult, time-consuming, and expensive process. Thus, a failure to adhere to the FDA's CGMP and data integrity requirements can have serious, and potentially crippling, effects on a company's ability to market and sell its infant formula.

75. Abbott generally acknowledged in filings with the SEC that "possible regulatory actions for non-compliance could include warning letters, fines, damages, injunctions, civil penalties, recalls, seizures of Abbott's products, and criminal prosecution." However, at no time between 2019 and the March 2022 release of the 483 Reports, discussed below, did Abbott ever disclose that the FDA had observed violations of the FDCA and other regulations that posed a

material risk of "warning letters, fines, damages, injunctions, civil penalties, recalls, seizures of Abbott's products, and criminal prosecution." Nor did Abbott ever disclose that the Company was "unwilling or unable" to correct these violations, as the FDA later concluded.

76. The risks posed by Abbott's failed inspection were not hypothetical. Indeed, prior to and during the Class Period, several food manufacturers and their executives experienced serious blows to their reputation and profitability because of their failure to adhere to CGMPs. For example, following a 2015 listeria outbreak that infected ten people and led to the recall of ice cream products distributed by Blue Bell Creameries, the DOJ filed criminal charges against Blue Bell and its CEO for violations of the FDCA. Blue Bell agreed to pay a $19 million fine and plead guilty to two misdemeanor charges. The former CEO, who was charged with a scheme to cover up shipping of contaminated products, entered a plea deal and paid a $100,000 fine.

77. Another criminal conviction in 2015 demonstrated that significant fines and prison time could result for senior executives even if they lacked actual knowledge of contamination. In 2010, Quality Eggs, an Iowa-based egg production company, caused a *Salmonella* outbreak. The company paid a $6.8 million fine after pleading guilty to felony charges of shipping eggs with false processing and expiration dates, and for bribing a U.S. Department of Agriculture Inspector to approve sales of poor-quality eggs. The two co-owners each pled guilty to misdemeanor violations of the FDCA as "responsible corporate officers" under the statute. These executives were each sentenced to three months in prison and a $100,000 fine, sentences that were affirmed by the Eighth Circuit. In another example of the serious ramifications of violations of the food safety laws, in 2015, the owner of Peanut Corporation of America was sentenced to 28 years in prison after being convicted of covering up contaminated peanut products that led to a deadly *Salmonella* outbreak.

78. Abbott also knew firsthand of the severe consequences for violating the FDCA, and the responsibility that senior management, up to the CEO, assumed in preventing these violations. For years, Abbott's pharmaceutical division misbranded a drug called Depakote for use in elderly dementia patients, a branding that lacked evidence that the drug was safe and effective for that use. In 2012, Abbott pleaded guilty to a criminal misdemeanor violation of the FDCA, paid state and federal penalties of ***$1.7 billion*** (the second largest penalty paid for such violation), and agreed to a five-year probationary period as part of the guilty plea and settlement. During that probationary period, Abbott was required to self-report any probable violations of the FDCA. Moreover, Abbott's CEO was required to certify compliance with this reporting requirement, and Abbott's Board of Directors was required to report annually on the effectiveness of the Company's compliance program. The terms of the probation were set forth in a Corporate Integrity Agreement, which "underscores the government's continued focus on what it views as the critical compliance oversight function and responsibility of senior executives and directors," according to a client update posed on the website of law firm Debevoise & Plimpton LLP.

79. Noncompliance with federal regulations also threatened Abbott's dominant share of the country's WIC contracts. Certifications of compliance with FDA regulations, including CGMPs, are required to secure rebates under WIC. WIC 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. As discussed above, Abbott is a major participant in the WIC program, supplying approximately half of all formula to eligible WIC participants. 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), which explicitly

provides that a company may only be eligible to participate in the WIC program if the formula complies with the FDCA, 21 U.S.C. § 321 *et seq*.

80. Moreover, the Sturgis facility was the source of contaminated infant formula before. On September 22, 2010, Abbott issued a voluntary recall of five million containers of Similac formula over concerns regarding contamination by body parts and larvae of *trogoderma variabile*, more commonly known as the "warehouse beetle," in the finished infant formula product at their Sturgis, Michigan plant. The Company put all product manufactured at the Michigan plant on hold and briefly ceased manufacturing at Sturgis. The FDA advised against consumption of the recalled product. In a September 22, 2010 letter to physicians and health care professionals, Abbott's then-Medical Director, Dr. Fabrizis Suarez, directed an "Urgent Product Recall" of various packaging of Similac-brand powdered infant formula, acknowledging that the FDA "determined that while the formula containing these beetles poses no immediate health risk, there is a possibility that infants who consume formula containing the beetles or their larvae, could experience symptoms of gastrointestinal discomfort and refusal to eat as a result of small insect parts irritating the GI tract."

81. The Company then reassured investors and the public that it was committed to product safety. In the press release announcing the recall, Holger Liepmann, an executive vice president at Abbott Nutrition at the time, asserted that "Abbott understands that parents expect to feed their children only the highest quality product," and was "taking this action so that parents know that the infant formula products they provide unquestionably meet the highest quality standards for which they are known."

82. On October 22, 2010, the FDA issued a Form 483, which included the following observations:

a. Failure to manufacture foods under conditions and controls necessary to minimize contamination;

b. Effective measures are not being taken to exclude pests from the processing areas; and

c. There is no assurance that raw materials which are susceptible to contamination with extraneous materials comply with current FDA standards and defect actions levels.

83. The 2010 recall effort caused immediate financial harm to the company, as Abbott estimated the economic impact of recalling the formula at $100 million in the third quarter of 2010.

4. Throughout The Class Period, Abbott Stated That It "Ensured Compliance" With Applicable Regulations And Made A "Quality Promise"

84. Recognizing that the quality, and therefore safety, of its infant formula was of critical importance to Abbott's Nutrition and overall business, Defendants touted the Company's public image as a leader in food quality and safety. In this way, Defendants highlighted Abbott's reputation for food manufacturing quality and compliance as an important differentiator and growth driver.

85. Throughout the Class Period, Abbott prominently trumpeted its food manufacturing processes on the Company's website and in direct statements to investors as meeting and exceeding applicable food quality standards.

86. For instance, throughout the Class Period Abbott featured a slide titled "The Abbott Quality Promise" for its nutrition business that was published on Abbott's "Corporate Newsroom" section of its website. In Annual Reports sent to investors, the Company directed investors to Abbott's website for information about Abbott's "business activities." Highlighting its role as a "trusted global brand," Abbott explained how "from our ingredients to our packaging, our employees are committed to bringing you safe, superior-quality products you can trust." Abbott

specifically highlighted the Company's "Quality Promise" with respect to its manufacturing processes:

- ***Advanced Technology: Typically found in the pharmaceutical industry, our high-tech quality processes ensure safety and quality throughout every stage of the manufacturing process.***

- ***Clean Facilities: Our facilities are designed and maintained to the highest Good Manufacturing Practice standards, which are recognized globally. All employees follow strict hygiene measures, such as wearing specialized uniforms, facemasks and sanitized gloves.***

- ***Quality Checks: Before releasing products for sale, we extensively test each batch to ensure it meets our quality standards, which are among the highest in the world. And, we ensure that our products comply with all global and local regulations.***

87. Throughout the Class Period, Abbott posted a brochure entitled, "Our Global Policy on the Marketing of Infant Formula," available on the "Policies" section of the Company's

website, which similarly claimed that the Company is dedicated to "***improving healthcare by providing high-quality, safe and effective products***" through "***a commitment to quality and continuing effectiveness of our quality management system to meet customer expectations and regulatory requirements***." Abbott explicitly stated that the Company "maintain[s] compliance with all laws, rules and regulations in every country in which we operate."

88. Abbott's Code of Business Conduct (the "Code"), which became effective in January 2015, is available on the "Investor" section of Abbott's website, and Abbott's annual filings, including those filed during the Class Period, direct investors to the Code. Discussing product quality, the Code claims that Abbott "[p]roduce[s] and deliver[s] safe, effective products that people trust." The Code asserts that the Company "endeavor[s] to maintain the ***highest level of quality*** throughout [its] business," an "effort" that "starts with the sourcing of materials and ***the manufacture of [its] products***." Abbott continues by saying that its "commitment to the health and safety of the people who use our product is ***always*** at the forefront of everything we do" and that the Company is "committed to ***timely identifying, evaluating, and addressing product safety issues***."

89. In the Code, Abbott also pledges to "adhere to ***all laws, regulations and Abbott requirements*** that apply to [its] work" and states that "[e]very Abbott employee is expected to adhere to ***all laws and Abbott's policies, procedures, principles and standards***," including standards related to "quality."

90. Elsewhere in its public-facing policies, Abbott asserts that it is "fully committed to delivering products with the ***highest standards of quality, safety, and performance***," insisting that "[o]ur quality culture is embedded in everything we do." This statement was published and available to Abbott investors during the Class Period.

91. Abbott also publishes a description of its "Comprehensive Ethics and Compliance Program," which it describes as an "integrated, company-wide program that is based on ***company values, laws and regulations***." The program description was published and available to investors during the Class Period. Among other things, the program contains the following elements:

a) Abbott has a Chief Ethics and Compliance Officer (the "CECO") responsible for the Office of Ethics and Compliance. The CECO "makes regular reports regarding compliance matters" to Abbotts's officers and directors. The CECO also chairs the Business Conduct Committee, which "consists of senior-level leadership" and "holds periodic meetings to discuss matters including: 1. the legal and regulatory environment, risk areas and best practices; and 2. modifications to the compliance program on the basis of such evaluation."

b) Abbott also asserts that "[c]reating an environment where employees can raise questions and concerns helps us advance our commitment to ethical behavior." Abbott maintains that it has "established systems and process for employees to ask questions and report suspected or actual violations of [the] Code, policies, and procedures."

c) Abbott also notes that its "[t]raining and education programs for employees increase their awareness of our Code's precepts and the legal and ethical implications of their actions and behaviors." It further states that "Abbott ethics and compliance officers work with our local commercial teams throughout the world to help them conduct trainings and education programs that help ensure compliance and strengthen Abbott's reputation as a responsible corporate citizen while enhancing relationships with customers and other stakeholders."

92. Abbott disseminated its 2020 Global Sustainability Report during the Class Period on July 13, 2021 (the "July 13, 2021 Global Sustainability Report"), a report that the Company used to directly engage with its investors. This report set forth the Company's promise of "delivering quality and safety" to its consumers:

> ***Our purpose of enabling fuller lives through the power of health depends on trust, and trust in Abbott depends on our ability to consistently deliver safe, effective and high-quality products.***

93. The report also described Abbott's "Quality Management Systems" in great detail. Among other things, Abbott made the following representations:

a) "We map our critical outputs . . . monitor quality throughout the full product life cycle. When developing new products, ***we conduct rigorous product-safety tests*** that are tailored to the product requirements."

b) "We have developed a multicomponent model and proprietary metrics to track the quality-system performance of our businesses and individual manufacturing sites. We review our model and metrics at least annually to ensure that they ***continue to assess relevant quality and compliance risks***."

c) "When we identify a change in performance at a site or a business, we analyze the causes of the change, ***take action when required***, and capture best practices and key learnings to apply elsewhere in our organization."

d) "Our global internal audit programs assess compliance with both ***regulatory standards and our own internal standards and processes***. . . . 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."

94. Specifically, regarding the nutrition business, Abbott claimed that it "***ensures food safety through a tightly controlled manufacturing process*** that encompasses all steps from accepting materials from suppliers through to final product distribution." Abbott further asserted that it "***monitor[s] and verif[ies] microbiology, packaging integrity, and nutrient and lot control***," and finally that it "***complete[s] extensive finished product testing*** before releasing it for commercial distribution." The July 13, 2021 Global Sustainability Report also represented that "[e]very Abbott nutrition manufacturing operation is ***certified to local and globally recognized GMP and food safety standards***."

95. In addition to its assurances regarding food quality and safety, the July 13, 2021 Global Sustainability Report also portrayed Abbott as committed to obtaining employee feedback in pursuit of meeting the standards it set for itself, claiming it "relies on a variety of formal and informal channels to gather employee feedback." The report noted the emphasis on, and procedures for, reporting concerns in the Code, and insisted that Abbott was committed "to

creating an environment where ***employees raise concerns in good faith without fear of retaliation***."

96. The Individual Defendants also made direct misrepresentations to investors, touting Abbott's food quality and safety, its commitment to reinvesting in its business, its performance and its product distribution process. Defendant Randall made statements trumpeting Abbott's focus on food quality and safety and highlighting the Company's purported culture of encouraging employees to raise any concerns. In an interview published on December 13, 2021 in *Quality Assurance and Food Safety Magazine*, Defendant Randall said she was drawn to Abbott's commitment to providing customers with products that can help them lead fuller, healthier lives. She expounded on this, adding, "[w]e're customer centric. It's about the new mom [] using our products," "[w]e talk a lot about why our work matters and how, at Abbott, ***we protect our product through the actions and the behaviors***," "[i]t's something that we are very focused on within the organization—making certain that ***we're taking best practices and sharing them across the globe.***" Randall also emphasized how Abbott encouraged employees to speak up to ensure food safety: "[t]he ***goal is to have everyone be an advocate for food safety***, no matter their role," and "[y]ou don't have to be the one with the title or, as we say, the one carrying the megaphone. It's the daily actions and ***the confidence in knowing that it's okay to speak up and say something***."

97. While Defendant Ford assured investors that the Company was reinvesting the profits it reaped during the COVID pandemic into the business, in actuality, the Company was starving Sturgis from much-needed investments to ensure the production of safe infant formula. In an interview given to CNBC's Mad Money host Jim Cramer in May 2021, Ford said, "I would say one of the key things that we've done during this pandemic phase [] ***we've taken the profits, the***

cash flows [] taken a portion of that and ***reinvested into the business***, into the pipeline, into the portfolio."

98. On January 11, 2022, Ford touted Abbott's purported "best-in-class performance" during the J.P. Morgan Annual Healthcare Conference, adding that the Company was "in great shape with the businesses we have." A day later, a Company representative stated that Abbott was doing all it can to "ensure ongoing and consistent distribution of our products." A mere month later, the baby formula recall and shortage crisis had begun.

C. Contrary To Defendants' Representations, Sturgis Was "Egregiously Unsanitary" And Defendants Were "Unwilling Or Unable" To Make Sturgis Fit For The Production Of Powdered Infant Formula

1. The Whistleblower Informed Defendants Of Multiple Violations Of The FDCA At Sturgis By The Start Of The Class Period

99. On February 16, 2021, three days prior to the start of the Class Period, the Whistleblower, a former Quality Assurance Specialist at Abbott's Sturgis facility between 2015 and August 2020, filed a complaint with OSHA pursuant to the Food Safety Modernization Act, 21 U.S.C. §399d ("FSMA").

100. FSMA was signed into law in 2011. FSMA was the first major revamp of federal food safety laws since 1938. One noteworthy aspect of FSMA was its parallels to the Sarbanes-Oxley Act with respect to "C-suite" culpability:

> Sarbanes-Oxley Section 906 is a hammer over the heads of corporate chief executives and chief financial officers. It says that any CEO or CFO who falsely certifies the accuracy of company financial statements could be subject to up to $1 million in fines and 10 years in federal prison. Before Sarbanes-Oxley, corporate CEOs were not required to sign off on their financial statements, nor did they have any meaningful responsibility for the accuracy of such statements. ***FSMA is taking a page from Sarbanes-Oxley by making food industry executives largely responsible for FSMA compliance. At the company level, the buck for all the***

> ***monitoring and record-keeping requirements stops with top executives. Playing dumb or shifting the blame to low-level employees is not going to work***.[7]

101. FSMA also ushered in strong whistleblower protections. Before FSMA, no protection from retaliation existed for privately employed food and agriculture workers who took action because of concerns about food safety. FSMA gives those employees protection from being discharged or punished for carrying out their job responsibilities that involve food safety. On April 18, 2016, OSHA published its "Final Rule" for handling whistleblower complaints filed pursuant to FSMA, titled Procedures for Handling Retaliation Complaints Under Section 402 of the U.S. Food and Drug Administration Food Safety Modernization Act. 29 C.F.R. § 1987, et seq. FSMA's whistleblower protections provide that "upon receipt" of a whistleblower complaint, OSHA will "notify the respondent [here, Abbott] of the filing of the complaint, of the allegations contained in the complaint, and of the substance of the evidence supporting the complaint," and send a copy of the complaint to the FDA. Pursuant to the terms of FSMA, Abbott promptly received the February 2021 Whistleblower Complaint and responded to the complaint "within 20 days of receipt of the notice of the filing of the complaint." Subsequent news reports in June 2022 confirmed that Abbott received the February 2021 Whistleblower Complaint within days (*i.e.*, at the start of the Class Period), and that Abbott responded formally to the Complaint by April 2021. An investigation by OSHA followed Abbott's response.

102. The February 2021 Whistleblower Complaint described "product safety issues that [he] had repeatedly raised or objected to in the context of his employment at the Sturgis Site." The Whistleblower explained in the February 2021 Whistleblower Complaint how:

> Increasingly, in the course of his time with Abbott [the Whistleblower] reasonably believed that its practices violated laws, regulations, and other guidance

[7] Dan Flynn, "FSMA Readiness: Accountability Starts at the Top, Just Like Sarbanes-Oxley," *Food Safety News* (May 4, 2015).

> administered and enforced by the FDA. On an increasing basis, [he] raised concerns as to practices that [he] reasonably believed violated applicable regulations. [He] similarly refused to engage in practices that [he] reasonably believed violated applicable regulations.

103. The Whistleblower described in detail a host of regulatory violations, all of which contributed to a manufacturing environment that created unsanitary conditions that allowed the deadly *Cronobacter* bacteria to flourish. Each of these warnings, if addressed, could have avoided the ensuing infant illnesses and deaths, historic recall, six-month facility shutdown, national formula shortage, criminal and SEC investigations, and Abbott's substantial stock price declines when the truth of their misrepresentations about formula safety and quality were revealed. Specifically, the Whistleblower provided credible warnings to the Individual Defendants and to Abbott that the Company was engaged in a scheme that entailed:

- Knowingly and intentionally falsifying records;
- Withholding material information relating to food safety from the FDA;
- Releasing untested infant formula;
- Knowingly deceiving FDA investigators during a 2019 site audit;
- Failing to implement and observe clean-in-place procedures necessary to ensure food safety;
- Failing to take necessary corrective measures as demanded by CGMP;
- Failing to implement proper procedures necessary to ensure legally required traceability of infant formula manufactured at the Sturgis Facility; and
- Lacking internal controls over food safety and data integrity, controls that were certified by Defendant Ford every quarter in Abbott's quarterly and annual SEC filings, and which were especially crucial where food safety for the world's most vulnerable population is at stake.

104. The OSHA investigation into the February 2021 Whistleblower Complaint was ongoing throughout the Class Period while Abbott continued to ignore credible complaints from the Whistleblower and current employees, and conditions worsened at Sturgis. Over the following

eight months after filing the February 2021 Whistleblower Complaint, the Whistleblower became concerned that Abbott was not taking any corrective actions in response to his complaint, but was instead retaliating against and silencing former co-workers who were well-positioned to corroborate his allegations. Therefore, on October 19, 2021, the Whistleblower filed a second Complaint directly with the FDA, copying multiple individuals within the agency, including those in the FDA's criminal division.

105. The October 2021 Whistleblower Complaint repeated and expanded on the violations detailed in the February 2021 Whistleblower Complaint, and the Whistleblower described his "ongoing concerns" that caused him to take this step:

> Most if not all of the concerns raised by the Complainant in his FSMA [February 2021 Whistleblower] 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.
>
> Aside from the compelling need to protect consumers, Complainant believes that other employees at the Sturgis site are currently at risk.

106. The Whistleblower stated that "the common thread" of the reported violations "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.

107. The February 2021 Whistleblower Complaint, and the misconduct described therein, put Abbott and each of the Individual Defendants on direct notice of the unsanitary and illegal practices at Sturgis, and should have prompted immediate corrective action. Moreover, the February 2021 Whistleblower Complaint provides further evidence of Defendants' engagement in

a scheme to defraud and details the practices, and courses of business that operated as a fraud and deceit.

108. Given the nature of the allegations, the statutorily required written response, and ensuing investigation that would involve interviews and documentation, Abbott Nutrition's senior management, including Defendants Randall and Calamari, both of whom had direct oversight over Sturgis, would have been involved in the Company's response to the February 2021 Whistleblower Complaint. Moreover, the Whistleblower noted in the February 2021 Whistleblower Complaint that his legal counsel had written a letter to Hubert L. Allen, Abbott's Executive Vice President, General Counsel & Secretary—a direct report of Defendant Ford—notifying Abbott of the need to preserve records associated with the Whistleblower. That letter was received, as reflected in a response from the General Counsel's office responding to the request. Defendant Ford would also have been informed of the February 2021 and October 2021 Whistleblower Complaints. FE2, a senior level Public Affairs and Media Relations executive who worked directly with Defendant Ford and other Abbott senior executives during his tenure at Abbott from 2016 through November 2021, explained that the February 2021 Whistleblower Complaint, which was filed with OSHA and sent to the FDA, and which reported regulatory quality and safety violations at Sturgis, would have reached the highest levels of Abbott's management, up to and including Defendant Ford.

2. The Whistleblower's Allegations, As Corroborated By Former Abbott Employees, Provided Notice To Defendants That Abbott Was Not Producing Quality Or Safe Formula In Compliance With Federal Regulations

109. The litany of violations and unsafe conditions that constituted a scheme to defraud not only consumers and regulators, but also investors, that was detailed by the Whistleblower, and corroborated by other current and former employees, is set forth in the February 2021 and October 2021 Whistleblower Complaints. Each of these violations created an environment that posed a

significant risk of *Cronobacter* contamination and parallel the violations that ultimately formed the basis of the 2021 and 2022 483 Reports and the ensuing DOJ Complaint and Consent Decree.

a. Abbott Refused To Destroy Potentially Contaminated Infant Formula, Released It To Consumers, And Then Hid That From The FDA

110. The Whistleblower described how, "prior to the [2019] FDA audit, [management] authorized the release of infant formula that tested positive for micros." The term "micros" is short for "microbiological organisms," including *Cronobacter* and *Salmonella*. The Whistleblower had "direct knowledge of this situation as this was a batch for which he was directly involved." The Whistleblower also stated that "members of management, including at the division level . . . were aware of what occurred."

111. The Whistleblower described how, as part of its testing procedures, Abbott would test 10 samples pulled evenly throughout the production of a given batch, not counting the first and last cans produced in the batch. Sometime before the September 2019 FDA audit, several samples in this standard batch tested positive for micros. As a result, Abbott pulled 15 additional cans from the batches, and several more tested positive. At this time, Abbott should have destroyed the batch in its entirety and discovered the root cause of the contamination. However, that is not what occurred:

> At that point, the decision was *not* made to destroy the entire batch. Instead, a time code removal was performed.
>
> 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. The infant formula was released commercially without supporting documentation to suggest it was compliant and safe for consumption.

112. At the time the Whistleblower "told his supervisor that he was not comfortable with the decision to release the product." The Whistleblower later came to understand that "senior

management was under significant pressure to meet its 'numbers' as the Sturgis site had already had to destroy $8 million in product." The Whistleblower provided a roadmap on how to verify his account, noting that "[e]xcluding members of management, including at the division level who were also aware of what occurred, at least five individuals, including the [Whistleblower] 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."

113. The Whistleblower described how, after the Company released the adulterated formula into the market, Abbott prevented the FDA from learning of this incident during the September 2019 inspection:

> 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 [Quality Assurance] leadership kept QS [Quality Systems] 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.

114. The Whistleblower also detailed how "[o]nce the FDA audit was over, staff and department managers congratulated each other on a successful FDA audit. [The Whistleblower] 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 questions asked by the FDA," with that official saying "something along the lines of, 'All I could do was smile. I couldn't answer their questions without incriminating the site.'"

115. The Whistleblower's account of the release of infant formula that was likely contaminated and the subsequent concealment of this release of contaminated formula from the FDA revealed a clear violation of multiple FDA regulations and forms part of Defendants' scheme to defraud. To the extent that the Individual Defendants were not already aware of this incident, the February 2021 Whistleblower Complaint should have prompted an immediate investigation, a

recall of any existing adulterating formula still on the market, and other corrective actions to ensure that the individuals involved in this illegal behavior were appropriately reprimanded.

b. Abbott Falsified Testing, Cleaning, And Maintenance Records In Violation Of CGMP And Other Regulations

116. The Whistleblower described how "[o]n multiple occasions, and in various ways, records have been knowingly falsified" and "information of a material nature was not disclosed." The Whistleblower provided several representative examples of the intentional falsification of records at Sturgis, including (1) falsified data involving the invalid testing of seals on empty cans; (2) the prevalent practice of signing cleaning and testing verifications without adequate knowledge to do so; (3) purposely understating or inaccurately describing events so as to limit or avoid oversight; (4) shipping packages with formula container fill weights lower than represented on the labels; (5) failing to maintain accurate maintenance records; and (6) prematurely removing formula production holds in the absence of all required approvals. The Whistleblower noted that while he had "first-hand knowledge of practices associated with the falsification of records on a regular and ongoing basis," he had "reason to believe that these practices are not limited to what he personally observed." The Whistleblower alleged that "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."

117. One example of falsified testing verifications involved ongoing problems with a contamination risk posed by "seam integrity" in the powdered infant formula packaging. The CGMPs and 21 CFR § 106.40(f)(3), in particular, provides that "[a]ny 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 Act (21 U.S.C. §§ 342(a)(1) through (a)(4)) shall not be approved and released for use." Moreover, the

CGMPs for infant formula and 21 CFR § 106.100, in particular, provides, in pertinent part, that Abbott "shall prepare and maintain records that include ***complete information*** relating to the production and control" of its formula. Moreover, those same regulations mandated that Abbott "maintain quality control records that contain sufficient information to permit a public health evaluation of any production aggregate of infant formula."

118. Compliance with these regulations required that Abbott ensure that its machine used to seal containers—a "seamer"—was actually sealing properly to avoid contaminants, such as *Cronobacter*, from entering the product. The seamer machine was a necessary component of the packaging of powdered infant formula, and federal regulations required that the seamer be regularly tested to ensure an airtight seal was made that prevented bacteria, microorganisms, air, or moisture from entering the formula. This was a vital step in the manufacturing process because if powdered formula becomes caught in the seam of a can, the integrity of the seal, which is needed to keep air and moisture out of the product, is jeopardized and the product poses an unsafe contamination risk and is considered "adulterated" pursuant to the Infant Formula CGMP Regulations and 21 CFR § 106.40(f)(3).

119. By no later than September 2019, Abbott knew that the seamer machine in Sturgis had left powder in the formula can seams, preventing an airtight seal. According to the Whistleblower, this was discovered when Abbott recalled a batch of powdered formula in 2019 because the formula was discolored and smelled rancid. Sturgis management discovered that the recalled formula was rancid because powder was in the seam, and soon discovered that other batches suffered from the same problem. Therefore, problems with the seamer machines at Sturgis were known risks. However, rather than fix the weakness in the seam sealing, Abbott altered the testing process "to test empty cans instead of sealed cans containing the product." According to

the Whistleblower, "[p]erforming seam checks on empty cans was the only way to achieve passing results without finding powder in the seam." Clearly, these sham tests would not find powder in the seam, as no powder ever entered the can.

120. In response to this clearly unsafe and improper practice, a number of Production Operators raised concerns with the Whistleblower and others, reporting that they were being directed to perform seam checks on empty cans and sign verifications that the seamer had been properly tested. The Whistleblower alleged that he "saw the work order associated with the [recalled product] batch(es) and knows that the work order did not disclose that the testing was performed on empty cans." The Whistleblower elevated his concerns about the process to a supervisor, although the identity of the person he elevated the issue to is redacted in the version of the February 2021 Whistleblower Complaint provided to Plaintiffs by MIOSHA.

121. Former employees have confirmed the known (and complained of) issues with the seamers at Sturgis. FE1 was a former Front Line Leader (also functionally known as a Supervisor) at Sturgis from 2017 until 2019, when he was promoted to the newly-created position of GMP & Food Safety Specialist, where he remained until voluntarily stepping down in September 2021. As a Front Line Leader, FE1 was in charge of all six lines on the Sturgis third shift, essentially the night shift. Because the sanitation employees on the third shift lacked any Supervisor, FE1 also supervised sanitation personnel during this time. The GMP Food Safety Specialist role was created for FE1. In that role, he worked on and devised projects that were necessary to meet the requirements of FSMA and other CGMP and regulations. FE1 reported to Susan Elgan, the Site Quality Assurance Director, and Robert Stauffer, Sanitary Manager. FE1 also worked directly with John Murphy, at the time a Divisional Vice President, Manufacturing Operations North America, out of Abbott's Columbus, Ohio Nutrition headquarters. Murphy reported to Daniel Salvadori,

then Executive Vice President, Nutritional Products, who in turn reported to Defendant Ford in Chicago. FE1 explained how the seamer on "Line 5" a newer, poorly built line that processed Alimentum and similar formulas for immunocompromised babies, did a horrible job of sealing the powdered can lids. According to FE1, the blame for this lies with Abbott's corporate officials in the Nutrition division who had acquired a seamer that was designed for a liquid rather than powder line. FE1 stated that the problems with the seamer raised significant food safety concerns. FE1 reported that when the Senior Quality Engineer originally in charge of the line voiced his concerns about the line, Abbott's response was to move the quality engineer to a different line. FE1 also confirmed that there were OSHA incidents relating to the seamer, which broke down all the time. FE1 specifically recalled a 2018 incident in which a maintenance worker almost lost his finger in the seamer.

122. FE3, an Operator at Sturgis from April 2016 through October 2022, similarly confirmed that the seamer on Line 5 was "a piece of junk . . . the cheapest thing," and that management often ignored quality engineers' plans for improvements because they "just wanted to get the line going." As a result, the seamer did not work well, and Abbott even staffed additional people just to visually inspect the line looking for improperly sealed cans. FE3 observed that this acceptance of the poor seamer was troubling: the "writing was on the wall," it was all "to save a buck."

123. FE3 also substantiated the Whistleblower's claim that Abbott falsified its testing of the seamer by performing seam testing on empty cans. FE3 confirmed that Abbott trained FE3 and other Operators to grab cans they knew would be empty from the line when the machine stopped (which happened throughout the day) and test those cans to see if there was any powder in the seam. Clearly, those cans passed with flying colors; no powder had entered the can yet, ensuring

that there would be no powder in the seam. FE3 became aware of the Whistleblower's allegations following the April 2022 release of the October 2021 Whistleblower Complaint, and agreed with the description that the seam testing was performed fraudulently.

124. The Whistleblower also described how falsifying other mandatory verifications was an accepted and prevalent practice at Abbott. The Whistleblower explained that "[i]n 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." A few examples of the falsification of verification records included:

- Multiple incidents where the Whistleblower was asked to falsify verifications attesting that a "line clearance" process—one of the "more critical steps taken in the manufacturing process to ensure that there is no contamination when production on a line changes to a different product"—had been completed when it had not, in violation of 21 CFR § 106.100(f)(4).

- Pressure to sign Plant Information Reports ("PIR") that misrepresented "deviations from the work order that occur[red] during the manufacturing of a batch and, if applicable, the steps taken to correct the deviation," in violation of 21 CFR § 106.40(d).

- Signing off on projection pages that were missing test results associated with nine batches of product in July 2020, as well as "multiple" other times—incidents that were "neither inadvertent nor isolated" in violation of 21 CFR § 117.305.

- The falsification of documents by maintenance staff indicating that certain "tasks have been completed when in reality they have not been completed," in violation of 21 CFR §§ 106.100, 106.35, and 106.100(f)(5).

- Incidents where the Whistleblower or others were directed to sign off on the release of a batch "without having the requisite documentation demonstrating that it was acceptable to remove the hold and release the batch" in violation of 21 CFR § 117.305 and 21 CFR § 106.40(d).

125. Moreover, the Whistleblower described how site management would direct him and others in his department to wrongly code certain adverse events so that production would not be held up and corporate metrics could be met, in violation of 21 CFR § 117.110(a) and 21 CFR § 106.40(d). This practice was "over the objection" of the Whistleblower and others.

126. Several former Abbott employees confirmed that the falsification of verifications and work orders was a common practice that created a dangerous environment for the growth of *Cronobacter* and other microorganisms. These "shortcuts" were taken so that production would not be slowed down and Sturgis could meet operations metrics demanded by senior management in Abbott's corporate offices.

127. FE4, a Packaging Operator at Sturgis from April 2018 through March 2021, recalled several specific incidents where he was asked to falsely verify mandatory documentation for which he had no personal knowledge. FE4 recounted how, in June 2020, Line 5—the line that produced the Alimentum formula for infants with protein and other allergies—was going through a mandatory cleaning process. Each operator would be responsible for specific areas of the line to clean according to regulated standards, and then to sign a verification that the particular area of the line assigned to him was, in fact, clean and ready for production to resume. In June, FE4's supervisor, a Front Line Leader named Coryn Samalik, asked him to sign a verification stating that a particular area of the line had been cleaned. However, FE4 had not cleaned that area, and would only sign the document if he were allowed to go and clean the area. Otherwise, FE4 responded, "I am not signing that shit." FE4's supervisor refused to allow him to clean the area and had a different Operator (who also did not clean the area) sign the document. FE4 reported this incident to Jodee Davis, the Operations Manager of Packaging at Abbott's Sturgis facility. While FE4 was never asked about the incident again, he confirmed that his supervisor continued to ask other Operators at Sturgis "to falsify documents all the time."

128. FE4 described other lapses in the cleaning process caused by the regular practice of verification falsification. FE4 stated that he routinely brought up failures in cleaning protocols he observed to plant management because these alarmed him, knowing that unclean machinery

and leftover powder could make its way into sensitive infant formula. For example, FE4 described another highly concerning incident involving Abbott's acceptance of falsified cleaning verifications. This incident occurred on Line 4, which was used to package powdered Similac into Plastipak containers.

129. FE4 described that there is a scale on Line 4 before the powdered formula travels to the pipes used to fill the container. The scale measures the empty container prior to being filled, the containers are then filled and come out to be weighed once again on a second scale. The two weight measurements confirm how much powder is in each can. The machine flags cans that do not match the correct weight and those cans get kicked off into the "rejecter." The powder from the rejected cans is dumped into a vacuum bin, at which point probes detect how much powder is in there. The powder subsequently gets vacuumed up and put back into the hopper to make sure it is clean enough to be placed back into a container. FE4 remembered reporting for his shift and noticing that the pipe connecting the vacuum bin was "packed full" of powder. That pipe should have been cleaned as the next batch of powder scheduled to be processed was different from the last. The workers on the shift prior to his were supposed to clean inside the pipes and the hoppers with a microfiber cloth in what was called a "dry clean." The previous worker had signed off that the pipe was clean, but it was unmissably and obviously full of powder—the pipe itself was translucent blue; you could see right into it. In that instance, FE4 took the pipe, hopper, and vacuum bin apart and cleaned them as they should have been to ensure no risk of contamination. This was not an isolated incident. FE4 began checking all pipes and machines for cleanliness at the beginning of his shifts. Due to the translucent nature of the pipes, sometimes FE4 could tell just by walking up to the machine that there was powder in the pipe. Other times he was performing

his assigned tasks, perhaps mopping the floor, and happened to glance up and see powder where there should have been none.

130. FE4 reported the cleaning violations he saw. All floor workers had radios, and FE4 would typically call the Front Line Leader on the radio to alert them to any problems, such as the pipe being filled with powder when it was reported to have been cleaned. On the instances when the pipe was dirty, FE4 called the Front Line Leader on duty and told them what he saw, and that the previous worker had falsely verified that the pipe or other component had been cleaned. The Front Line Leaders told FE4 they would report the problem to their managers, but no one was ever held accountable.

131. FE4 also described another, even more concerning, lapse of safety protocols—one that directly implicated the unacceptable risk of *Cronobacter* contamination. This incident occurred in early 2021 in the powder dryer on Line 5, used for Alimentum. The powder dryers at Sturgis were particularly susceptible to *Cronobacter* contamination. FE1, the former GMP and Food Safety Specialist and Front Line Leader before that, explained that the biggest area of risk for microorganisms was inside of the dryer, after the dryer process, because the powder drying process kills everything. But if there is microorganism growth after the drying process—either while the powder sits in the dryer or is being packaged—there are no other "kill steps" to contain contamination. On this day in early 2021, FE4 opened the Line 5 sifter to check to make sure the powder that had been sent to the sifter from the dryer had not burned, which happened from time to time during the drying process. Instead of burnt powder, he found wet powder inside the sifter. FE4 knew, as did everyone involved in the production of powdered formula, it should never be wet inside the sifter because that creates a breeding ground for *Cronobacter*. FE4 immediately reported the situation to the Front Line Leader on duty, a man named Adam Quackenbush.

Quackenbush told FE4 to take a sample of the wet powder so the plant could test it for microorganisms, or "micros," and/or other contagions. FE4 did as he was instructed and obtained a sample, bagged the sample, documented it with the date and time, signed it and turned it in for testing. A few days later, FE4 asked about the results of the sample, and was told that Quackenbush had thrown the sample away. The sample had not been tested. To FE4's knowledge, nothing was done to address the wet powder he discovered.

132. The incidents recalled by FE4 were not isolated events. FE4 found wet powder a few times during his tenure, and he always reported those discoveries. FE4 also stated that he witnessed cleaning violations, such as the falsified verifications or significant breaches in cleaning protocol, "almost every clean," which worked out to several times a week.

133. Abbott also ensured that micro swabs would turn up negative by determining at the start of a cleaning shift what areas would be swabbed such that even apparently dangerous areas not previously targeted for cleaning would be ignored. FE4 reported that often supervisors gave Operators like FE4 a list at the start of a cleaning shift dictating what specific surfaces were going to be swabbed and instructed them to focus on these areas. FE4 noted, for example, that during some cleaning shifts, supervisors observed loose powder on top of filler heads, but ignored the problem because it was not one of the focus areas and the supervisors' attitude was "if the swabs were good, they were good."

134. FE4 also reported other serious cleaning failures at Sturgis. FE4 confirmed that, in order to meet performance metrics and stay on schedule, management did not perform necessary cleaning. FE4 explained that when the plant fell behind schedule, management "pushed the cleaning," forcing employees to complete a planned eight-hour cleaning process in only four hours. Similarly, FE3 confirmed that, in Abbott's zeal to meet a pre-determined production schedule, "a

lot of questionable things went on." FE3 specifically recalled one occasion when, shortly before a product launch, several employees expressed concerns about the cleanliness of the machines that would be used to make the product, and asked management if they should allocate time to properly clean the machines. Plant management responded that because production was already twelve hours behind schedule, the machine's current state of cleanliness would need to be "good enough."

135. FE1 similarly reported that, due to understaffing, plant employees circumvented some of the protocols FE1 personally put in place to ensure proper cleanings were performed in order to prevent the spread of *Cronobacter*. Sturgis electricians were required to, on a regular basis, open the facility's utility boxes, clean the internal components, and replace any faulty parts. Yet FE1 reported that after the Lines tested regularly for bacteria growth, his group traced several swab failures to these utility boxes. On one occasion in spring 2019, FE1 asked an electrician to open a utility box in the area where the cans were filled, which FE1 reported was "unsanitary and nasty" inside. As a result, FE1 conducted an investigation of the utility boxes and learned that the electricians, who were in charge of cleaning the boxes, were not doing so; there were not enough electricians on duty to perform the cleaning, so those who were there would look at the ***outside*** of the box and mark it clean without cleaning the inside. Cleaning the boxes was especially time-consuming because they were located in "high care areas," which are parts of the plant where the cans could be especially vulnerable to contamination and therefore needed to be treated like a "surgical room."

136. FE1 believed that he had addressed the problem by developing a detailed protocol for cleaning the utility boxes, which included pictures and a checklist. He updated the existing Sturgis preventative maintenance program with the new protocol. The protocol dictated that each electrical box be cleaned once a month, and each of the cleaning protocol instructions was tagged

with a number to ensure that electricians completed cleaning each box. However, FE1 learned that this process was "never fully implemented," and the electrical boxes remained dirty because an experienced individual from the maintenance department told FE1 that if the department engaged in the entire cleaning process set forth in the written protocol, they would not "have time to do anything else." FE1 learned the protocol was not being followed when bacterial swabs on one of the Lines continued to test positive for microorganisms. FE1 held meetings with several members of Sturgis management about the electrical box issue, including the Plant Sanitation Pest Control Program Manager, the Electrical Maintenance planner, and Susan Elgan, the Site Quality Assurance Director, who subsequently became Abbott Nutrition's Global Food Safety Director. Despite these meetings, while the protocols may have been "formally" adopted, by the end of FE1's tenure in September 2021, proper implementation still had not occurred. FE3 confirmed that electrical boxes, especially those in the powder filler areas, would fill with powder, describing management's attitude toward the electrical box powder issues as "out of sight out of mind."

137. The recounted pattern of falsification of testing, cleaning and maintenance records constituted a scheme to defraud and also amounted to a course of business practices that operated as a fraud.

c. The Deterioration And Disrepair Of Powdered Infant Formula Dryers And Other Machinery Posed Known Contamination Risks

138. The Whistleblower reported another major issue in 2019 that was caused by outdated equipment. The Whistleblower explained that "[f]or several years, some of the equipment associated with the drying process at the Sturgis [plant] was failing and in need of repair. As a result, a number of product flow pipes were pitting and leaving pin holes." These holes "allowed bacteria to enter the system and, at times, lead to bacteria not being adequately cleaned out in 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," causing contamination. The failure to maintain the dryers at Sturgis violated CGMPs and 21 CFR § 106.30.

139. FE1 corroborated the Whistleblower's account that the powdered infant formula dryers at Sturgis were damaged and posed contamination risks. The dryers were very old; there were cracks that formed, and Abbott needed to hire someone every year to find the cracks and fix them. These risks were known to Abbott's senior management, including Defendant Randall. Issues with these dryers came up during weekly "Protect our Product" ("POP") meetings at Sturgis, and the issues discussed in these meetings were communicated to Nutrition executives, including Defendant Randall, by Susan Elgan, FE1's supervisor. In his positions as a Front Line Leader and then GMP Safety Specialist, FE1 either personally made, or was aware of, documented requests sent to Abbott Nutrition and Abbott Illinois headquarters seeking funding for projects, including for a new dryer to replace the two constantly failing dryers that often tested positive for microorganisms, and for improvements to the facility to stop constant roof and HVAC leaks that introduced water into a dry production environment—the perfect recipe for *Cronobacter*. But adequate funding was not allocated to Sturgis, despite these requests. Worse still, senior management, including specifically Defendant Randall, visited the Sturgis site several times a year, and dangled funding for improvements out like a carrot that employees had to earn by meeting and increasing production metrics. The most prominent carrot was a badly-needed new dryer to replace a decades old dryer that was always breaking down and connected to "water incidents" that threatened the spread of *Cronobacter* contamination.

140. While these improvements were necessary for the production of safe and unadulterated formula, Abbott's corporate senior management demanded better "metrics"—*i.e.*, greater production output—before investing money in Sturgis. FE1 explained that Abbott pushed

to increase production despite the risk that posed to babies: Abbott's "[m]anagement purposefully took the largest market share they could in a plant that they knew had issues, that they weren't funding properly—and then when they finally dropped the ball, they left these families that are on fixed incomes [WIC recipients] with babies completely out to dry." FE1 recalled how "Upper management was bragging about it all the time: 'We're feeding one in five babies and we're going to feed one in four and then one in three from this single plant.'" FE3 confirmed hearing the same claims about the Sturgis plant's purportedly imminent market share increase. But, Abbott's corporate office declined to provide Sturgis with the funding, staff, or equipment necessary to increase market share safely, despite repeated requests for the same.

141. Abbott's counterproductive reasoning that required additional production output before agreeing to make necessary improvements exacerbated the problems at the already inadequately-staffed facility that lacked sufficient machinery and funding necessary to produce safe formula. As FE3 noted, to meet its market share goals, Sturgis had to make more product, but was not provided the additional staffing such additional output required. FE1 explained that in 2019 through his departure in 2021, the Sturgis plant was making a really hard push to get Abbott's corporate headquarters to invest more money into the plant to purchase a new dryer—"Dryer 5"—and processing equipment for the Sturgis plant. Upon information and belief, this project was known as "Project Penta." Dryer 5 was a needed investment in the plant because it would replace "Dryer 3," which was built in the 1970s and had been cracking over the years. However, it is FE1's belief that Dryer 5 would only be approved if Sturgis could meet production metrics dictated by corporate headquarters. FE1 opined that the demand that Sturgis meet metrics in order to be awarded a new dryer was not "always useful for product safety."

142. FE1 described how Abbott's senior management knew that Dryer 5 was needed to replace Sturgis' older and outdated dryers because FE1 saw Defendant Randall, along with John Murphy, Vice President of Operations, and Daniel Salvadori, Abbott's Executive Vice President, Nutritional Products, visit Sturgis often to assess whether the new dryer would be awarded. The amount the three individuals talked about Dryer 5 felt, to FE1, as though the dryer was "being dangled like a carrot." FE1 recalls making statements to Murphy and Salvadori concerning the need for additional staff and less overtime. FE1 stated that there was "no way they didn't know" that Sturgis was in need of staffing and funding. Indeed, overtime reports were distributed regularly within Abbott, and Sturgis was always at top of that list. Moreover, FE1 submitted a request to fill already-approved open headcounts in January 2019, and that request was denied. FE1 stated that the people on the ground at Sturgis, for the most part, tried to comply with FDA regulations, but they "weren't given the resources to succeed." This was despite the fact that Sturgis generated money; it was one of the most profitable plants for Abbott Nutrition—a "golden cow," according to FE1. But Sturgis was still denied funding. Sturgis "generated the money," but Abbott would not "authorize the money" to allow them to comply with FDA regulations. The Defendants' persistent refusal to repair, upkeep and replace essential machinery for the production of infant formula formed part of their scheme to defraud.

d. Constant Water Leaks Were A Known Contamination Risk At Sturgis

143. During his over four years at Sturgis, FE1, the Sturgis GMP & Food Safety Specialist, witnessed regulatory violations and a lax health and safety environment at the facility. FE1 described a contamination risk at Sturgis that was widely known and became a major focus of the FDA inspections in 2021 and 2022. According to FE1, roof and HVAC leaks were a significant problem at Sturgis for years. This was a grave concern at a powdered infant formula production facility because the "Number 1 enemy of powder is water." FE1 described how

"[c]ontrolling moisture is important in any food plant, but it's particularly important in areas that are handling dry material, in this case dry powdered formula destined to be fed to infants without a so-called kill step, which means the formula won't be cooked or boiled before being consumed."[8] FE1 described how the roof "leaked so often and in so many different places throughout the entire plant . . . the plant had a bunch of [special plastic tarp catchers to deal with the water] in the stock room, because these leaks would just pop up all the time," including sometimes when it was sunny out, indicating that these leaks likely stemmed from problems with the HVAC system. FE1 also recounted how additional water leaks came from HVAC systems that were not large enough to work properly on a handful of packaging lines, especially on Line 5. FE1 and other employees believed that the wrongly-sized HVACs were the result of a cost-cutting measure: "[Abbott] didn't want to spend the money to size the HVAC properly." As a consequence, the system would routinely get overloaded and extra water would "overflow back into the line through the wall," which presented another potential contamination point. Indeed, FE1 confirmed that evidence of significant microorganism problems with the HVAC system in Line 5 specifically was documented in weekly "Protect Our Product" ("POP") reports that would show that Line 5 would "light up like a Christmas tree" as far as the number of micro counts discovered on a regular basis.

144. FE1 explained how the funding of Line 5, the newest of the five infant formula production lines, which was dedicated primarily to the manufacturing of specialty formulas

[8] On August 4, 2022, a senior food and agriculture reporter for *Politico* published an article titled, "A movie set: Former supervisor at baby formula plant says flaws were hidden." The article provided the firsthand accounts of "a former supervisor" in Abbott's Sturgis facility who "stepped forward to describe a facility with constant roof leaks, lax food safety and recordkeeping, and a culture of fear, raising new questions about why such problems were allowed to continue and the FDA did not discover them earlier." The former supervisor described in the *Politico* article was FE1, who has independently confirmed to counsel the accuracy of his quoted statements in the *Politico* article.

Alimentum and Elecare, was a prime example of Abbott's decision to cut corners financially at the expense of safety and quality. FE1 explained how a Senior Quality Engineer who helped plan the design of Line 5 described how Abbott cut funding on the line that resulted in the removal of key food safety features including a central vacuum system for cleaning out powder from the Line, and a "Clean-in-Place" system that would have allowed for an automated cleaning process that did not introduce microorganisms into the environment. As a result, Line 5 relied on small handheld vacuums ("shop vacs") to clean the pipes. The food safety issue raised by this is that powder gets left inside the shop vacs because they are hard to clean out, and that powder causes microorganism growth. In addition, the removal of the Clean-in-Place system meant that Line 5 had to be cleaned by hand, which increased the likelihood of errors, and therefore made the likelihood that microorganisms would grow "significantly higher."

145. FE1 opined that Abbott senior management knew that the decisions concerning Line 5 raised the likelihood of contamination from microorganisms. Indeed, Abbott chose to use xanthum gum in Alimentum, a product that is notoriously sticky because it helps the formula stick to an infant's stomach. Because of its stickiness, xanthum gum is very hard to clean. Yet Abbott chose to install Line 5 without mechanisms to adequately clean the xanthum gum from the Line, which was designed for Alimentum and Elecare.

146. The Senior Quality Engineer who helped design the system criticized the decisions to remove the central vac and CIP systems, and "regularly" told management that "this is wrong" and, even after Line 5 was installed and operational, asked management to "spend money to fix it." These complaints were not addressed; instead, the Senior Quality Engineer was moved to a different, liquid line because, according to FE1, he was a "squeaky wheel."

147. As discussed below, the existence of standing water throughout the Sturgis facility was included in both the 2021 and 2022 483 Report observations and was also a cited violation in the DOJ Complaint.

148. FE1 also explained how Sturgis was denied adequate staffing to run all six production lines and cover vacation and sick days. The plant should have had between 55 and 60 employees per shift just for the packaging component of the five lines dedicated to powdered formula and one dedicated to liquid formula. In reality, Sturgis had between 22 and 40 employees per shift. Sturgis should have been running only 2.5 lines each week given the number of staff the facility was permitted to hire, but instead ran four and. more often, five at a time. This understaffing led, inevitably, to errors, with insufficient numbers of people to detect and correct errors or to adequately clean the lines as mandated by law. Senior management rejected requests for additional, necessary staffing by stating that there was not sufficient money budgeted for new staff. FE1 disagreed, opining that, "based on the stock price and buybacks, they [Abbott] were doing just fine." This chronic understaffing posed both employee and food safety concerns because, according to FE1, if you do not have enough staff to run the infant formula lines, quality checks are not performed with the level of scrutiny that is necessary to protect the product. Moreover, the understaffing meant that the insufficient amount of staff working on a line often were regularly required to work overtime in 12-hour shifts (as opposed to standard 8-hour shifts), up to 12 times in a row, without a day off. This led to mistakes and quality errors.

149. Defendants' refusal to address constant water leaks and chronic understaffing, which posed a grave threat of contamination, formed part of Defendants' scheme to defraud.

e. A Culture Of Fear Of Retaliation Silenced Concerned Employees

150. The Whistleblower, in his October 2021 Whistleblower Complaint, also described how Abbott created a culture of fear of retaliation, which silenced individuals from speaking up:

> 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."
>
> 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. As exemplified by the Sturgis site, Abbott's practices fail to meet one of the 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.

151. Indeed, the genesis of the February 2021 Whistleblower Complaint was the Whistleblower's termination after engaging in protected activities concerning identifying and objecting to multiple violations of federal regulations. And in the October 2021 Whistleblower Complaint, the Whistleblower described how "[e]mployees are not free to raise concerns without fear of retaliation." Moreover, both the February and October 2021 Whistleblower Reports describe how current employees feared retaliation for speaking out against Abbott's bad practices.

152. While FE1 corroborated many of the warnings that had been raised directly to the FDA by the Whistleblower, he also described an overarching culture of fear, where employees were discouraged from raising concerns about food safety or other problems to management, as well as a history of cost-saving measures that sometimes conflicted with safety. FE1 said employees often encountered instances where employees felt they could be fired for raising any type of concern. "I kept hearing over and over and over again, 'yeah, you've got to be careful if you start bringing stuff up. You can just disappear around here.'"

153. FE4 also confirmed that most employees did not want to report incidents because it was better to "keep quiet." He explained that while the rule on paper was "if you see something, say something," the true attitude was "we want a perfect image" and "if you tell us otherwise," the response would be dirty looks or being put on the "shit list." FE4 reported once having an issue

with his direct manager after being told that some Operators, having received only a day or two of training, were not comfortable with the machines they were assigned. After being "blown off" by his manager, FE4 contacted the department manager to request a meeting with that manager and the training department; the only response was a lecture from his manager about following the chain of command.

154. Abbott's retaliatory practices demonstrate the falsity of the Company's statements about its policies concerning illegal and unethical behavior. For example, in the 2020 Global Sustainability Report, the Company touted its Code of Business Conduct, under which Abbott "does not tolerate illegal or unethical behavior in any aspect of our business and . . . employees are required to ask questions and/or report any concerns." Abbott also emphasized its purported lack of tolerance for retaliation—a claim that is likewise undermined by the Whistleblower and former employees' accounts: "Our Code of Business Conduct emphasizes our employees' responsibility to report concerns. This requires us to create an environment where they can do so in good faith, without fear of retaliation." A pattern of retaliating against employees who raised concerns formed part of Defendants' scheme to defraud.

f. Former Abbott Employees Have Confirmed The Whistleblower's Credibility

155. Several former employees who worked with the Whistleblower have corroborated pertinent aspects of the Whistleblower Complaints, described above, as well as the credibility of the Whistleblower.[9] In the Whistleblower's position as a Quality Assurance Specialist, the Whistleblower's duties included "review[ing] work orders for product specifications to ensure FDA compliance," "[a]nalyzing data from batches to identify anomalies, initiat[ing] Corrective

[9] Counsel are aware of the identity of the Whistleblower but do not name him in the Complaint out of deference to his apparent desire to maintain anonymity.

Action/Preventative Action. . . and conduct[ing] root cause analysis," and "[m]anag[ing] surveillance programs for infants, adults and foreign substances." FE4 reported that he knew the identity of the Whistleblower, and that he worked with the Whistleblower on quality assurance issues. FE4 believed that the Whistleblower was an "excellent employee" who was one of FE4's "go to" people. FE4 reviewed the redacted October 2021 Whistleblower Complaint and confirmed that he personally experienced many of the situations reported by the Whistleblower. Indeed, after reading a copy of the redacted October 2021 Whistleblower Complaint in 2022, FE4 reached out to the FDA and was later interviewed twice by FDA investigators, including investigators from the FDA's Criminal Investigation Division.

156. FE3, an Operator at Sturgis from April 2016 through October 2022, also verified that the Whistleblower was "a good guy" who cared about his job at Abbott and wanted to do the right thing and "put a safe product out." When the Whistleblower was fired in 2020, FE3 stated that "everyone knew" the Whistleblower was fired because he "called them on [their] bullshit," with "them" being the "higher ups at the plant." FE3 also read the redacted October 2021 Whistleblower Complaint and remarked that he was in a position to confirm most of the Whistleblower's allegations based on his own direct observation and that "nothing" in the complaint surprised him.

157. FE1, Abbott's GMP & Food Safety Specialist at Sturgis, also had a positive opinion of the Whistleblower, and believed that the allegations in the October 2021 Whistleblower Complaint were accurate. In his position, FE1 was particularly well-situated to gauge whether Abbott and the Individual Defendants knew (or were reckless in not knowing) of the multiple food safety violations exposed by the Whistleblower. In his role FE1 was responsible for learning the relevant GMP and CGMP regulations and making sure that Abbott complied with them. While

FE1 was able to implement some improvements in training and processes, no amount of small fixes could sufficiently improve the facility given the fact that Abbott's Nutrition and overarching corporate management refused to provide the funding for necessary improvements in staffing, maintenance and powdered formula manufacturing machinery.

3. Defendants Were On Notice Of Contamination Issues At Sturgis Prior To The February 2021 Whistleblower Complaint

a. Abbott Settles And Avoids Liability In Lawsuits Alleging Cronobacter-Tainted Formula Caused Meningitis In Infants

158. 2021 was not the first time that an infant's *Cronobacter* infection was linked to the consumption of Abbott's powdered infant formula. However, proving a direct link between a specific can of formula—often discarded by unwitting parents—and the infant's infection can be difficult, especially at a time before the true unsanitary conditions at Sturgis were publicly revealed. According to a September 2022 *The New York Times* article, Abbott has settled an unknown number of actions brought on behalf of injured infants, using aggressive legal tactics to silence the families. Abbott also defended itself against two federal court lawsuits in 2014. Those separate lawsuits alleged that two healthy newborn infants, one in North Carolina and one in Iowa, consumed powdered infant formula manufactured by Abbott in their first few days of life and immediately thereafter contracted meningitis caused by *Cronobacter*-contaminated powdered formula made by Abbott. In the North Carolina case, the infant consumed Similac produced in Abbott's Sturgis facility.

159. In *Sisk v. Abbott Laboratories*, Case No.1:11-cv-00159 (W.D.N.C.), an infant named Slade was born a healthy, full term baby on October 19, 2004. Less than one month later, Slade was diagnosed with neonatal *Cronobacter* (then known as *E. sakazakii*) meningitis, from which he experienced severe and permanent brain injury, complicated by cerebral palsy. The only powdered infant formula Slade drank in his first few weeks of life was Abbott's Similac formula,

and the formula was traced back to both Abbott's Sturgis and Casa Grande plants. Slade's parents sued Abbott in state court in 2007. After years of fighting over removal to federal court, and Abbott's successful motion to disqualify Sisk's first attorney, the case was re-filed in 2011 and made its way to trial in early 2014. Time had been on Abbott's side, and the fact that the sickened infant had consumed all of the formula, preventing testing of the formula after he contracted meningitis, did not help the case. A jury concluded that Abbott was not liable. Immediately afterwards, Abbott's attorneys secured a court order sealing trial evidence and testimony concerning Abbott's testing, food safety protocols and "sanitation, housekeeping and hygiene." As a result, details about the Sturgis plant "vanished from public view" according to a September 6, 2022 article in *The New York Times*.

160. The second case was also tied to Abbott's powdered infant formula and met the same fate following a jury trial. In that case, *Security National Bank of Sioux City v. Abbott Laboratories*, No. C 11-4017-MWB (N.D. Iowa), Abbott managed to sow doubt as to the source of the *Cronobacter*, even though the injured infant consumed only Abbott powdered infant formula in her first few days of life and her twin brother, who did not consume any powdered infant formula, was uninfected. In that case, the presiding federal judge later stated to *The New York Times* in September 2022 that the jury reached the wrong outcome: "If it had been a bench trial, I would have ruled for the plaintiffs in all likelihood."

161. In addition to the two jury verdicts, *The New York Times* reported on secret settlements tied to illnesses linked to Abbott's powdered infant formula in the wake of the 2022 recall. Reports of secret, undisclosed settlements related to alleged *Cronobacter* contamination in Abbott's formula caught the attention of senators in Washington. On October 12, 2022, U.S. Senator Elizabeth Warren sent a letter to Abbott and Defendant Ford seeking information about

litigation and settlements since 2003 involving Abbott Nutrition and potentially *Cronobacter*-contaminated baby formula. Senator Warren wrote that "new reports indicate that Abbott Nutrition was aware of these risks for decades, and that the company worked to cover up the consequences by 'deploying scorched earth legal tactics' to 'grind down—and in some cases attack' families seeking compensation for the harm caused and using legal settlements to force impacted families to stay silent." Senator Warren added, "[i]t is deeply troubling that Abbott appears to have been using abusive legal tactics and non-disclosure agreements to avoid accountability for the health and safety risks from its unsafe products, and I write to seek on the information about what Abbott Nutrition kept hidden from the public and the legal tactics the company used against families seeking justice."

b. The FDA Issued A Form 483 In September 2019 Warning Of Potential CGMP Violations While Abbott Concealed Far Worse Contamination From The Agency

162. According to FE1, Abbott hid regulatory violations from the FDA during its routine audits, a practice FE1 witnessed firsthand in 2019. FE1, who also described his experiences and observations at Abbott to a journalist who published some of his accounts in *Politico* on August 24, 2022, described how Sturgis management "would prep heavily before audits," and "[t]he plant basically turned into a movie set where only things the higher ups wanted the FDA to see were seen." FE1 described to *Politico* and confirmed to counsel, how for weeks leading up to the FDA's visits, employees would pull extra overtime cleaning and conducting more frequent internal audits to find and fix any potential issues before the FDA showed up. FE1 also explained how when the FDA did arrive at Sturgis, the agency would usually send only a couple of inspectors, who largely reviewed the plant's own records to check to see if a plant had the right control systems in place. But this type of review limited in-person observation, especially considering that the Sturgis plant

is 787,000 square feet—which is the equivalent of more than 13 football fields—and sits on 94 acres.

163. An Abbott spokesperson responded to FE1's account of the preparation for the FDA audit in the *Politico* article, stating: "this has been taken completely out of context. Our focus 365 days a year is to provide the highest quality formula. Of course, though, you prepare extensively for visitors just as you would if you were having guests over to your home." When presented recently with this Company statement, FE1 responded: "That is terrible – my home isn't a production facility that one-quarter of children in the U.S. rely on." FE1's observations were corroborated by FE3, who worked as an Operator in various powdered formula lines in the Sturgis plant for over six years, from April 2016 through October 2022. FE3 confirmed that the cleaning process prior to FDA or other audits or inspections did not reflect ordinary conditions at the plant. Rather than tidying up before "having guests over to your home," FE3 reported that the pre-FDA inspection cleaning was more akin to living in a "trash truck" and then just "renting a really nice house" when guests came over. As FE3 explained, "it was just not the same house."

164. As discussed above, the Whistleblower described how Abbott management at Sturgis concealed that micros, which include *Cronobacter*, were discovered in the powdered infant formula during batch testing some time prior to the FDA's 2019 inspection. The Whistleblower also reported on Abbott's "practice of 'sanitizing' files before furnishing them to auditors," whereby records were "pulled and reviewed by management officials apart from where the auditors were located," and that "some records were culled before furnishing a file to the auditors."

165. Despite all of the steps taken to conceal the true conditions at Sturgis from the FDA, the FDA made certain non-public observations relating to *Cronobacter* and lax safety practices

following its 2019 inspection that should have raised red flags for senior management, even assuming that management was ignorant of the duplicitous practices described above.

166. The FDA observed that Abbott had detected *Cronobacter* in a batch of formula in August 2019, before distribution: "A review of the firm's finished product testing showed one positive result for *Cronobacter spp*. in Alimentum Infant Formula." Abbott attributed the contamination to a "non-routine intervention," according to the 2019 FDA 483 EIR. The FDA also noted that a baby who consumed Similac Pro-Advance Optigro formula tested positive for *Cronobacter*.

167. Most concerning to the FDA was the agency's discovery that Abbott was not abiding by its own stated microbiological testing procedures that tested finished and packaged powdered formula for evidence of *Cronobacter* and *Salmonella*. In particular, the FDA found that Abbott was testing only half the samples of powdered formula for microbiological contamination that their protocols required before distribution. As noted above, formula manufacturers test only a small representative sample of formula from each lot or batch as a final safeguard to ensure the absence of microorganisms, and Abbott was testing only half of the minimum requirement. This observation was a violation of CGMP, and the FDA issued its 2019 483 Report finding that Abbott "did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards."

168. The FDA's 2019 EIR noted two additional observations: (a) investigators observed a window screen located on floor the floor of a dryer building "with accumulated dust-like debris collected on the exterior of the screen," and (b) investigators observed that Abbott "does not obtain water samples for radiological testing from a point in the system in which water is in the same

condition as when used in infant formula manufacturing." Other observations detailed in this 2019 Establishment Inspection Report include numerous cracks, stains and repairs involving multiple dryers used in Abbott's powdered infant formula manufacturing process at Sturgis. And a review of Abbott's environmental sampling records revealed "the firm had positive EB samples in several non-product contact areas and one product contact area." *Enterobacteriaceae* ("EB") are a broad family of gram negative bacteria that are considered indicators for closely related pathogens like *Salmonella* and *Cronobacter*. In addition to sampling positive for EB, there were "a series of 6 positive results [of Listeria] in the 8oz. filler area over the dates of 4/30/2019 – 6/15/2019."

169. Nevertheless, Abbott kept the nonpublic 2019 483 Report quiet; it was not disclosed to investors. However, the receipt of a 483 Report was material news within the Company given the enormous ramifications such a report could have on the Company's ability to continue production. As noted above, as set forth in the FDA Investigations Operations Manual, a Form 483 "should be issued to the most responsible person available at the close of the inspection," and a copy of the Form 483 "***should be sent to the top management of the firm***."

170. Moreover, Abbott publicly maintained that "delivering high-quality, safe products is always [its] number one priority," and its 2021 Global Sustainability Report detailed a purported policy of product quality oversight that reached the highest levels of the company:

> Global oversight sits with our Senior Vice President, Quality Assurance, Regulatory and Engineering Services, [10] who ***reports directly to our Chief Executive Officer (CEO) and Chairman of the Board***. In each Abbott business, quality and regulatory leaders are responsible for the quality systems specific to their business and ***update each Abbott business president on progress***. The Board's Public Policy Committee ***regularly reviews*** quality metrics, ***inspection findings***, industry progress and emerging issues.

[10] For all relevant times, J. Scott House was Abbott's Senior Vice President, Quality Assurance, Regulatory and Engineering Services. Defendant Randall reported directly to House.

171. In addition, best practices following a Form 483 letter dictate that the response to a Form 483 "include a commitment/statement from senior leadership."[11] Based on available documentation, Abbott Nutrition followed this principle; Defendant Randall was copied on Abbott Nutrition's responses to 483 Reports; she, along with other Abbott Nutrition executives, were at least informed of, if not participants in, Abbott's response in 2019. Moreover, FE2, who worked directly with Defendant Ford and other senior executives in his leadership roles in Public Affairs and Media Relations, stated that any FDA inspection reports that addressed possible contamination involving *Cronobacter* would have been elevated and discussed with Defendant Randall and Abbott's CEO in 2019, along with other senior management in the Nutrition division.

c. Abbott Identified Cronobacter In Packaged Formula In September 2019 And June 2020, And Detected Cronobacter In Infant Formula Production Areas At Least Eight Times Between Fall 2019 And February 2022

172. Internal Company records revealed by the FDA in March 2022 show that, in addition to the infant formula contamination concealed from the FDA during its September 2019 inspection, Abbott positively identified *Cronobacter* in finished formula in September 2019 and June 2020. Moreover, internal Company records show that Abbott's own testing had detected *Cronobacter* in areas of infant formula production ***at least eight times*** between fall 2019 and February 2022. While the Company represented to the FDA that the September 2019 and June 2020 lots were destroyed and never distributed to customers, that does not in any way mean that Abbott addressed the widespread contamination that those positive tests indicated. Finished product testing is a final validation that a Company's process controls are working. While a negative result in a finished can of infant formula does not rule out contamination, a positive result for *Cronobacter* in a finished product should have caused Defendants to take immediate corrective

[11] Michael De La Torre, *The Ultimate Guide To Form FDA 483s*, Redica.com (Feb. 5, 2019).

actions, including but not limited to shutting down production until the root cause of the contamination had been discovered and remedied.

173. As became clear in September 2021, no such action had been taken.

4. The FDA Finds Unsanitary Conditions In Its September 2021 Inspection Of Sturgis

174. Despite the clear warnings of food safety violations in the February 2021 Whistleblower Report, Abbott took no apparent corrective actions. After the FDA conducted a routine inspection at the Sturgis facility from September 20-24, 2021, the agency issued a damning 483 Report that should have further raised alarm bells at Abbott. The 2021 483 Report set forth the following negative observations:

(a) You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition;

(b) You did not install a REDACTED capable of REDACTED when REDACTED is used at a product filling machine;

(c) Personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated; and

(d) An instrument you used to measure, regulate, or control a processing parameter was not properly maintained.

175. In sum, the FDA found that Abbott failed to maintain its infant formula production "in a clean and sanitary condition" and that its staff working directly with infant formula failed to wash their hands thoroughly. Abbott had failed to take even the most basic precautions despite its established history of microbial contamination.

176. Abbott did not disclose receipt of the 2021 483 Report, despite its troubling observations. Abbott responded to the 483 Report and EIR on October 15, 2021, a copy of which was secured by counsel pursuant to a FOIA Request to the FDA. In that response—which was attached to a cover letter signed by the Sturgis Site Director and Quality Assurance Director, with

a copy sent to Defendant Randall and other Nutrition division executives—Lesa Scott, Regional Quality Director, and Oliver McBreaty, Divisional Vice President for Nutrition—Abbott represented that "corrective actions were taken or are planned for completion to help prevent recurrence," and committed to provide "quarterly updates . . . starting in January 2022 until all commitments are met." Yet, the unsanitary and unsafe conditions continued.

5. Reports Of Infant Illnesses And Death Linked To Abbott Formula Are Filed With The FDA And Abbott Between September 2021 And February 2022

177. On September 20, 2021, the FDA learned of a *Cronobacter* infection in an infant who consumed powdered infant formula produced at Sturgis. The FDA immediately reported this case to Abbott and followed up on the complaint. The FDA received a second complaint involving an infant with *Cronobacter* infection on December 1, 2021, and notified Abbott of the case. The FDA received a third report of an infant *Cronobacter* illness on January 11, 2022 and notified Abbott. The FDA learned of a fourth case of *Cronobacter* infection on February 17, 2022.

178. On average, the CDC receives two to four *Cronobacter* case reports annually. These reports are likely not indicative of the extent of infection, however, because *Cronobacter* infection is not reportable in most states. In any event, the receipt of four reported cases within several months all tied to a single manufacturing facility raised significant concerns.

179. On December 6, 2021, given the two case complaints received by the beginning of December 2021 (which were followed by two additional complaints in January and February 2022), the potential severity of *Cronobacter* infections—which included at that time one death—and the FDA's review of the October 2021 Whistleblower Complaint, the FDA initiated a for-cause inspection at the Sturgis facility with an anticipated inspection date in early January 2022. The FDA notified Abbott of the planned inspection on December 30, 2021, with the intent of

arriving the following week. However, Abbott pushed to move the inspection, claiming that the facility had approximately a dozen COVID-19-positive employees.

6. Abbott Management In Sturgis Destroys Evidence Of *Cronobacter* Contamination As The FDA Returns For Its 2022 Inspection

180. The FDA commenced its for-cause inspection at Sturgis on January 31, 2022. After the first day, Sturgis management spent the entire night, until the early hours of the morning, destroying evidence that could test positive for *Cronobacter*. FE3 reported for the third shift, the "late shift," on the first day of the inspection. The FDA inspectors had left for the day. FE3 was ordered to sit tight, and that was the beginning of a "weird time for two months." FE3's supervisor told him that production had stopped, and he reported to a break room where others were. FE3 was told by colleagues and also saw firsthand that the site managers, including Site Director TJ Hathaway, were "throwing everything out that wasn't nailed down" and "pouring bleach on the rest." The Sturgis Operations Manager and Site Director TJ Hathaway were at the facility all night, and management used bleach to clean everything left on the floor that had not been thrown out. FE3 said that this was "not common practice at all"; it was "not like that in any other audits." FE3 confirmed that there were big concerns over *Cronobacter* and listeria at Sturgis because it was a "wet environment . . . any time you have water you can have growth of micro." FE3 believed that this overnight rush to spray the factory with bleach and throw out "everything out that wasn't nailed down" had one purpose: "It was clearly to destroy the evidence that there was *Cronobacter*." Defendants' destruction of evidence prior to the FDA inspection is just one part of their scheme to defraud.

7. The FDA Arrives Back At Sturgis And Immediately Detects *Cronobacter* And Other "Egregiously Unsanitary" Conditions

181. Despite these efforts to destroy evidence linking Sturgis to any *Cronobacter* contamination, the FDA arrived back at Sturgis on February 1, 2022 and found alarming conditions that forced unprecedented action.

182. Testing of samples taken on or about February 1 and February 2, 2022 by the FDA detected *Cronobacter* in the Sturgis facility in multiple environmental sites, including on the "scoop hopper" used to "feed scoops, which are placed directly inside infant formula containers and contact product." Additional testing of samples taken between February 6 and February 20, 2022 by the Company at the FDA's direction identified *Cronobacter* on ***20 occasions*** in "low, medium, and high care areas of powdered infant formula production" in the facility. In other words, both the FDA and Abbott found and confirmed the presence of *Cronobacter* at the Sturgis facility soon after the commencement of the FDA's inspection on January 31, 2022. As FE3 described, the Company effectively shut down production the same day the FDA began its onsite inspection, and Sturgis employees did nothing productive for months.

V. THE TRUTH EMERGES

183. Between February 17, 2022 and October 19, 2022, Abbott investors learned the shocking truth about Abbott's massive violations of CGMP and other mandatory regulations designed to ensure that infant formula was safe for consumption.

A. February 17, 2022: The FDA Issues A Consumer Advisory Warning Against Consumption Of Abbott Formula And Abbott Recalls 70 Million Containers Of Infant Formula

184. On February 17, 2022, shortly after the market closed, the FDA issued a release "advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas" that originated from Abbott Nutrition's Sturgis, Michigan facility. The FDA explained that "it is investigating consumer complaints of *Cronobacter sakazakii* and *Salmonella* Newport infections" that were all linked to powdered infant formula produced at Sturgis. The FDA announced that

there was an "ongoing investigation" by the FDA, "along with the U.S. Centers for Disease Control and Prevention and state and local partners." The FDA revealed additional details of the consumer complaints, explaining that "[a]ll four cases related to these complaints were hospitalized and *Cronobacter* may have contributed to a death in one case." The four cases spanned three different states: Minnesota, Ohio, and Texas. According to an FDA spokesperson, the CDC typically receives reports of two to four *Cronobacter* infections per year. Therefore, concerns were raised when FDA personnel realized all four infants had consumed powdered formula from the same factory.

185. The agency explained the danger posed by *Cronobacter* contamination:

> *Cronobacter* bacteria can cause severe, life-threatening infections (sepsis) or meningitis (an inflammation of the membranes that protect the brain and spine). Symptoms of sepsis and meningitis may include poor feeding, irritability, temperature changes, jaundice (yellow skin and whites of the eyes), grunting breaths and abnormal movements. *Cronobacter* infection may also cause bowel damage and may spread through the blood to other parts of the body.

186. Noting that this was an active and "ongoing investigation," the FDA revealed that it had "initiated an onsite inspection at the facility" and "[f]indings to date include several positive *Cronobacter sakazakii* results from environmental samples taken by the FDA and adverse inspectional observations by the FDA investigators. A review of the firm's internal records also indicate environmental contamination with *Cronobacter sakazakii* and the firm's destruction of product due to the presence of *Cronobacter*." The FDA noted that products made at the Sturgis facility "can be found across the U.S. and were likely exported to other countries." Frank Yiannas, FDA Deputy Commissioner for Food Policy and Response, emphasized the importance of Abbott's powdered infant formula to consumers, stating, "As this is a product used as the sole source of nutrition for many of our nation's newborns and infants, the FDA is deeply concerned about these reports of bacterial infections." The same day, Canadian officials at the Canadian Food

Inspection Agency also issued a separate recall warning, noting that ”[t]here have been reported illnesses in the United States associated with the consumption of these products.”

187. Abbott simultaneously issued a recall of certain infant formula products, including the popular brands Similac, Alimentum, and EleCare, all manufactured in Sturgis. In a press release, Abbott framed the recall as “proactive” and “voluntary” and made no mention of the ongoing FDA investigation.

188. In reality, rather than being “proactive,” Abbott recalled its powdered infant formula only after days of pressure from the FDA that culminated in the FDA consumer advisory. As *Bloomberg* later reported on August 25, 2022, “Despite urging from the FDA on Feb. 15 and again the next day, Abbott didn’t announce a recall. On the 17th, the FDA issued a consumer advisory, and Abbott announced a voluntary recall.” FDA Commissioner Califf later stated in his May 25, 2022 congressional testimony that the FDA initiated discussion of and requested that Abbott recall millions of cans of formula from each of its popular brands: “[D]uring the inspection, we contacted Abbott to ask the company to issue a voluntary recall. The need to make urgent action to protect the most vulnerable of all of our people.”

189. Abbott’s press release made no mention of the on-site investigation that was being conducted by the FDA, which had commenced more than two weeks earlier, and which the FDA had tried unsuccessfully to schedule for early January 2022. Abbott’s recall notice also failed to acknowledge that the FDA investigation was prompted both by reported *Cronobacter* hospitalizations and death and a whistleblower complaint, nor that Abbott’s recall, while touted as “voluntary” and “proactive,” was prompted by the FDA after witnessing the unsanitary conditions at Sturgis.

190. Abbott also downplayed the presence of *Cronobacter* at Sturgis, stating that Abbott conducted "routine testing" and indicated that during that testing (as opposed to the intensive testing mandated by the FDA onsite inspection), *Cronobacter* was only found in "non-product contact areas."

> Abbott is voluntarily recalling these products after four consumer complaints related to *Cronobacter sakazakii* or *Salmonella* Newport in infants who had consumed powder infant formula manufactured in this facility.
>
> Additionally, as part of Abbott's quality processes, we conduct routine testing for *Cronobacter sakazakii* and other pathogens in our manufacturing facilities. During testing in our Sturgis, Mich., facility, we found evidence of *Cronobacter sakazakii* in the plant ***in non-product contact areas***. We found no evidence of *Salmonella* Newport. This investigation is ongoing.

191. As discussed below, the FDA would later reveal that, in fact, evidence of *Cronobacter* was not only found in product contact areas at Sturgis, but had previously been detected by Abbott in samples of powdered infant formula about to be delivered for consumer consumption.

192. Abbott also falsely represented that it "conducts extensive quality checks on each completed batch of infant formula, including microbiological analysis prior to release. ***All finished products*** are tested for *Cronobacter sakazakii*, *Salmonella* Newport and other pathogens and they must test negative before any product is released." As later revealed, Abbott tested only a small sample of finished products manufactured at Sturgis, even after environmental testing at the facility tested positive for *Cronobacter* on multiple occasions.

193. Abbott further falsely represented that "retained samples related to the three complaints for *Cronobacter sakazakii* tested negative for *Cronobacter sakazakii*." In reality, as the FDA later revealed, Abbott failed to test retained samples of the Similac Pro Total Comfort formula that one baby, whose death Abbott was investigating, was drinking when the baby fell ill.

194. Despite the Company's misrepresentations, Joseph Manning, Abbott's Executive Vice President of Nutritional Products, framed the recall as a proactive step to protect its consumers, stating, "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."

195. The next day, on February 18, 2022, before the start of trading, Abbott issued a Form 8-K confirming the recall. In the Form 8-K, Abbott downplayed the recall's likely impact by "confirming its previously issued full-year 2022 guidance for adjusted diluted earnings per share from continuing operations of at least $4.70," noting that "Abbott will incur a one-time specified item in the first quarter 2022 for recall related expenses, including inventory destruction and other recall expenses," and assuring investors that while "[t]hese expenses have not yet been quantified," "Abbott does not expect that these expenses will have a material impact on Abbott's consolidated financial statements." The Company simultaneously announced the issuance of quarterly dividends. In its 2020 Form 10-K issued the same day, Abbott made no mention of the recall or its impact on the Company.

196. However, the consumer advisory and recall shocked consumers and investors, and sparked an immediate concern over available access to infant formula in a market already facing COVID-19-related supply chain shortages of infant formula. As Sturgis produced one-fifth of the entire U.S. infant formula market, a recall of millions of cans and containers of formula raised uncertainty over access to safe, uncontaminated formula. *The Wall Street Journal* reported on February 18, 2022 that, according to the CDC, "*Cronobacter* illnesses, which include sepsis and meningitis, are rare but can be lethal for infants." *The New York Times* reported that *Cronobacter*

"can cause severe, life-threatening infections or inflammation of the membranes that protect the brain and spine. *Cronobacter* infection may also cause bowel damage and may spread through the blood to other parts of the body, according to the F.D.A." Moreover, as *The Wall Street Journal* reported, powdered infant formula cannot be sterilized, such that bacteria can be in the formula powder if "contaminated raw materials were used to make [it]" or "if the formula touched a contaminated surface during the manufacturing process."

197. After the news of the recall came out, many families believed contaminated formula produced at Sturgis sickened their infants, "in some cases almost killing them." As *Politico* reported on March 5, 2022, "a spin through Instagram and TikTok reveals dozens of unconfirmed yet detailed and heartbreaking reports of babies hospitalized for *Salmonella* and other bacterial infections after reportedly consuming recalled formula, using hashtags like #similac #screwyou."

198. Relying on Abbott's reassurances and unaware of the presence of *Cronobacter* in product contact areas and the "egregiously unsanitary" conditions at Sturgis, analysts initially assumed a relatively minor impact on Abbott's operations. In a February 18, 2022 report titled "Nutrition Recall Less Impactful than Feared," J.P. Morgan acknowledged that "[i]t will be hard to fully resupply the shortfall from the other plant," but predicted that "there will continue to be a decent supply of Similac in the market" and that "Abbott is working with the FDA to get the affected plant up and running as fast as possible." Similarly, Evercore ISI estimated that the recall's impact would be "resolved in 3 months," based on the fact that "[t]he FDA has visited the plant and is making its own assessment." RBC Capital likewise predicted that while it "expect[ed] a cash impact," the impact would "likely [] be immaterial at the total company level."

199. Specifically, analysts credited the Company's statements that *Cronobacter* was only found in non-product contact areas. For example, on February 18, 2022, in a report titled

"Reiterate Outperform: Stock Reaction to Powder Recall News Looks Overdone to Us," Cowen reported that "ABT has found evidence of *Cronobacter sakazakii* in the Sturgis plant in non-product contact areas." Analysts from Evercore ISI, J.P. Morgan, and RBC Capital all similarly highlighted the Company's assurance that there was no *Cronobacter* found near the finished infant formula. Analysts also credited the Company's statements that the recall was "voluntary" and "proactive." For example, in a report titled "Reaffirms EPS post Similac recall + Other tidbits (how to think of rev impact –seems minimal)," Evercore reported that the Company had announced that it was initiating a "proactive voluntary recall" of powdered formula.

200. Despite Abbott's false or misleading characterization of the severity of the violations at Sturgis, the February 17, 2022 disclosures concerning the vast product recall and ongoing FDA investigation 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 $3.79 per share, or 3.14%, from a closing price of $120.58 per share on February 17, 2022, to a closing price of $116.79 per share on February 18, 2022.

201. News concerning the extent of the contamination at Sturgis worsened over the coming weeks. On February 18, 2022, *Politico* reported that the FDA received the first newly-cited complaint of illness suspected to be linked to *Cronobacter* potentially originating from Abbott formula produced at Sturgis all the way back in September 2021, five months prior to the recall. On February 26, 2022, *Politico* reported that U.S. Senators Patty Murray and Bob Casey sent a letter to Defendant Ford on February 24, 2022, "demand[ing] Abbott Nutrition hand over information and documents related to the company's sweeping infant formula recall last week," following *Politico's* reporting on February 18, 2022 that the FDA, CDC and Abbott were all informed of the first infant illness in September 2021. The Senators wrote: "It is completely

unacceptable that manufacturing conditions allowed a contaminated product to reach babies, and that it took months for the company to act to warn parents and caregivers about this danger." The Senators requested all internal documents and communications related to (a) "consumer complaints of contamination in powder infant formula manufactured at the Sturgis, Michigan plant from 2017 to present"; (b) monitoring of environmental contamination with *Cronobacter sakazakii, Salmonella* Newport, or any other bacteria harmful to human health at the Sturgis, Michigan plant from 2017 to present; (c) the destruction of product due to the presence of *Cronobacter sakazakii, Salmonella* Newport, or any other bacteria harmful to human health at the Sturgis, Michigan plant from 2017 to present; and (d) "documentation from audits, investigations, and reviews conducted by Abbott or outside consultants or entities related to manufacturing practices and conditions at the Sturgis, Michigan plant from 2017 to present." The lawmakers gave the Company until March 10, 2022 to respond, but no response has been made public to date.

202. On February 28, 2022, before the market opened, Abbott expanded its recall of infant formula products to include Similac PM 60/40 cans following the report of another infant death related to *Cronobacter sakazakii* following consumption of powdered formula produced at the Sturgis facility. That same day, after the market closed, the FDA expanded on the details of the recall in a recall alert update:

> As of February 28, CDC has announced one additional illness of *Cronobacter sakazakii* with exposure to powdered infant formula produced at Abbott Nutrition's Sturgis, MI facility. *Cronobacter* infection may have been a contributing cause of death for this patient. In total, this investigation includes four reports of *Cronobacter sakazakii* infections in infants (three from FDA complaints and one from a CDC case finding) and one complaint of a *Salmonella* Newport infection in an infant. All five (four *Cronobacter* infections and one *Salmonella* Newport infection) illnesses resulted in hospitalization and *Cronobacter* may have contributed to death in two patients.

203. The FDA's recall update revealed that the agency's investigation had now found four reports of *Cronobacter* and one report of *Salmonella* Newport, all of which resulted in

hospitalizations and may have contributed to the deaths of two infants. Abbott had not mentioned the additional report of infant illness in its update on the Company's recall website.

204. News outlets reported on the expanded recall. On February 28, 2022, *Food Safety News* reported that "an additional death in an outbreak linked to powdered infant formula has resulted in an expansion of a recall by Abbott Nutrition." On March 1, 2022, *The Wall Street Journal* reported that Abbott was expanding its recall "after being informed of the death of another infant who consumed the company's product." *The Wall Street Journal* also reported that a spokeswoman for the Company stated that production at the Sturgis plant was paused, though as FE3 explained, production was effectively halted at Sturgis as of January 31, 2022, when the FDA began its onsite inspection.

205. But, even after the two recall announcements, analyst reports continued to credit the Company's misrepresentations about the presence of *Cronobacter* at the Sturgis facility in non-product contact areas. For example, on March 18, 2022, analysts at Cowen reported that "Abt has found evidence of *Cronobacter sakazakii* in the Sturgis plant in non-product contact areas." Cowen also credited the Company's reaffirmance of its 2022 EPS guidance, previously released on February 18, 2022, which the analyst viewed "as a signal that the recall should be manageable."

B. March 22, 2022: FDA Releases Its 2019, 2021 And 2022 Form 483 Inspection Reports Related To Abbott's Sturgis Facility

206. The FDA's onsite inspection of the Sturgis plant concluded on March 18, 2022, after the agency spent six weeks at the facility. In a surprising move, on March 22, 2022, the FDA released the redacted versions of its previously non-public Form 483 Reports from inspections in 2019 and 2021 along with its one from 2022.

207. The 2022 483 Report revealed new information about not only the extent of contamination and unsafe food production conditions at Sturgis, but also a pattern of undisclosed

problems with food safety at the Sturgis facility, the same facility implicated in the outbreak of infant illnesses from *Cronobacter*, including, at that time, one death.

208. As noted above, an FDA Form 483 is used to notify a company's management of potential regulatory violations at the conclusion of an inspection. According to the FDA, "[o]bservations are made when in the investigator's judgment, conditions or practices observed would indicate that any food, drug, device or cosmetic has been adulterated or is being prepared, packed, or held under conditions whereby it may become adulterated or rendered injurious to health." Issued pursuant to Section 704(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §374(b), Forms 483 are issued upon completion of an inspection when the "conditions or practices" observed by the inspectors "indicate that any food . . . in such establishment . . . (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health." The FDA Form 483 thus notifies a company's management of such objectionable conditions, and the company is required to respond in writing within 15 days. There can be no doubt that Abbott's most senior management received and approved responses to these Form 483 observations.

209. The Forms 483 released by the FDA on March 22, 2022 contained a series of shocking observations about the conditions at Sturgis, many of which were repeat observations that had been privately flagged for Abbott during previous inspections by the FDA. While news to the public, these observations were not new to Abbott. Indeed, many of the FDA Form 483 observations are consistent with the detailed complaints lodged by the Whistleblower in his February 2021 and October 2021 Complaints sent to the FDA and Abbott, as well as the accounts of FE1, FE4, and FE3, described above.

210. ***First***, in the 2022 483 Report, the FDA observed the presence of *Cronobacter* contamination within several areas of the Sturgis powdered infant formula production areas, concluding that Abbott "did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment." Specifically, as discussed above, the FDA noted that "FDA environmental samples collected on 2/1/22-2/2/22 during this inspection confirmed the presence of *Cronobacter sakazakii* on zone two and zone three surfaces in ***medium and high care areas of powdered infant formula production***."

211. The 2022 483 Report also directly contradicted one of Abbott's often repeated defenses: that no *Cronobacter* was found in areas that come in contact with the finished powder formula product. The FDA identified that one of the "[p]ositive environmental sites for *Cronobacter sakazakii*" was a "scoop hopper," which was "swabbed and was positive" for *Cronobacter*. The scoop hopper was "utilized to feed scoops, which ***are placed directly inside infant formula containers and contact product***." The FDA noted that Abbott "consider[s] this a high care area." Moreover, the FDA noted that "Similac Pro-Total Comfort with HMO infant formula powder . . . was being packaged" at the same time that the inspectors swabbed for *Cronobacter*. Another positive site for *Cronobacter* was the "foot/base of a structural support piece" of a dryer "and the immediate surrounding floor." The FDA noted that Abbott "consider[s] this a medium care area." "At the time of swabbing, [the dryer] was in a clean-in-place (CIP) cycle." *Cronobacter* was also found on a floor "directly across from [a] door entry," where the floor was covered with "duct tape" and "debris," as well as on a door of a room with a dryer, which was in a CIP cycle at the time.

212. The FDA also observed that Abbott's own microorganism testing between February 6, 2022 and February 20, 2022—performed in response to the positive *Cronobacter* testing performed by the FDA and described above—revealed "the presence of *Cronobacter* spp. in low, medium, and high care areas of powdered infant formula production ***on 20 occasions***," as discussed above. The FDA further noted that Abbott's own internal records showed that "[b]etween 9/25/19 and 2/20/22, [Abbott's] environmental samples and finished product testing confirmed the presence of *Cronobacter* spp., including testing that identified the presence of *Cronobacter* spp. in medium and high care areas of powdered infant formula production through sampling on eight occasions between 10/10/19 - 2/2/22."

213. ***Second***, the 2022 483 Report also revealed that that the FDA's review of Abbott's own internal documentation Non-Conformance Reports ("NCRs") demonstrated that *Cronobacter* similar to that discovered within the facility in February 2022 had made it into finished product at least twice previously. Those NCRs indicated that Abbott's packaged powdered infant formula products tested positive for *Cronobacter* on September 25, 2019 and June 22, 2020.

214. ***Third***, in both the 2022 483 Report and the 2021 483 Report, the FDA identified repeat observations of water in powdered infant formula production areas, a condition that creates a welcoming environment for *Cronobacter*. As noted by FE1 and others, "water is the enemy" in powdered infant formula production environment as it provides a home to *Cronobacter* and other microorganisms. Onsite in 2022, the FDA observed water in a dryer while the dryer was running Similac Comfort infant formula powder, among other instances. Additionally, water was on the floor due to a leak from an "inle[t]," and the water "was dripping from the valves onto the . . . floor." The 2022 483 Report noted that "water events associated with the inlet . . . were also

reported on" February 1, 2021, November 4, 2021, and January 21, 2022, indicating that this was a persistent and recurrent problem.

215. The FDA noted in its 2022 483 Report that "[s]tanding water observed in powdered infant formula production areas is a repeat observation from the FDA inspection dated 9/20/21-9/24/21." Not only was Abbott warned by the FDA of unsanitary conditions due to standing water, but Abbott itself "identified 310 water events including water leaks, moisture and condensation in dry powdered infant formula production areas" between January 1, 2020 and February 1, 2022. As one expert food safety expert testified in a 2014 trial against Abbott concerning allegedly contaminated formula, "water in a dry powder factory is like pouring gasoline on a fire. . . . [A company making powdered infant formula] need[s] to control the water." Abbott did not.

216. ***Fourth***, the FDA observed design and maintenance deficiencies with Abbott's powdered infant formula dryers in its 2022 483 Report, similar to those identified by the Sturgis Whistleblower, FE1 and others. These dryer deficiencies led to the observation that Abbott "did not ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source." Specifically, the FDA noted that "management stated that the dry out steps for . . . dryers were not validated to ensure complete drying is achieved." The FDA also noted that the "dryers . . . have a history of internal deterioration dating back to September 2018," according to Abbott's dryer inspection reports, and the most recent dryer inspections in August 2021 "showed six instances of cracks and pits in the main chamber" for a dryer and "six instances of cracks, pits and damage" for another dryer. "Ten cracked braces were also identified" in a third dryer. The FDA concluded this observation by summarizing that "both FDA and [Abbott] found evidence of *Cronobacter* spp. in [Abbott's] powdered infant formula

production environment. [Abbott] also identified *Cronobacter* spp. in finished powdered infant formula products."

217. ***Fifth***, the FDA observed in the 2022 483 Report that, with respect to the four recent consumer complaints that linked *Cronobacter*-caused illnesses and death with Abbott's powdered infant formula from Sturgis, Abbott failed to "identify the root causes" of the illnesses and improperly "treated infant death and infant illness the same," meaning that Abbott's own practices "did not include the determination as to whether a hazard to health exists and the basis for that determination." The FDA also observed that, on January 31, 2022, Abbott provided a Complaint Detail Report with the status "Closed-Done" for one of the four recent consumer complaints "detailing a *Cronobacter sakazakii* illness and death associated with 7 oz. Similac Pro Total Comfort infant formula powder." However, the FDA noted that the Abbott Nutrition Medical Safety and Surveillance team "***did not request that retain[ed] samples be tested for this lot*** in accordance with" internal policy. Therefore, to the extent that additional samples were positive for *Cronobacter*, the Company did not take any steps to find out.

218. ***Finally***, the FDA observed in the 2022 483 Report that "personnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wear necessary protective apparel." Specifically, the FDA observed, with respect to one dryer, an "employee exit[ed] the elevator and enter the room . . . passing by a shoe spray station and failing to spray the soles of their shoes with sanitizer. At the same time this was observed, the nozzle of the sanitizer bottle was set to steam instead of spray while other individuals were spraying the soles of their shoes, which did not allow a uniform coating of sanitizer on the soles of shoes. This was observed while [the dryer] was running Similac Total Comfort infant formula powder." Moreover, the FDA "found evidence of *Cronobacter sakazakii* in [a] dryer from environmental

samples collected on 2/1/22. [Abbott] found evidence of *Cronobacter* spp. in [a] dryer from [Abbott's] sister swabs collected on 2/1/22 and [Abbott's] vector swabbing conducted during [Abbott's] root cause analysis."

219. The release of the three Form 483 Reports on March 22, 2022 revealed that unsanitary conditions at Sturgis were present and made known to management for years. But management had not corrected the severe problems at the facility, despite the FDA's repeated observations. As noted above, the FDA had warned Abbott of problems with standing water in the production facility back in the 2021 483 Report, sent to Abbott in September 2021. For example, in the 2021 483 Report, the FDA observed that Abbott "***did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition***." Specifically, on September 20, 2021 and September 21, 2021, standing water was observed "under and adjacent to the . . . air handling unit, outside [a] door associated with the Dry Blending Room and in the clean-out-of-place (COP) area." Standing water was also observed on September 23, 2021. The report also described an improperly used forklift, ingredient pallets stored in wrong areas, and a fan with "extensive debris and dust-like build up" "blowing in the direction of the . . . cabinet." The 2021 483 Report also discovered various other safety lapses that, if uncorrected, could create an environment for *Cronobacter*, as it did.

220. News media outlets reportedly widely on the release of the Form 483 Reports. In a March 22, 2022 article titled "Abbott Infant Formula Plant Found Unsanitary Before Recall," *Bloomberg* reported that the FDA inspectors had found "unsanitary conditions" at Sturgis "five months before the company conducted a recall of products associated with the deaths of two babies." The article highlighted the FDA's observations, and specifically noted that in its most recent inspection, the FDA found *Cronobacter* "on machinery that ***comes in direct contact*** with

powdered infant formula, as well as the floor and doors of areas that are supposed to be kept clean," and that "records indicat[ed] that Abbott's own environmental tests had detected [*Cronobacter*] eight times between October 2019 and February of this year [2022]." The article also highlighted that Abbott found *Cronobacter* 20 times "in areas linked to powdered formula production" during the most recent inspection, as well as Abbott's failure to test retained samples when Abbott investigated a complaint of an infant death from *Cronobacter*. *Bloomberg* further noted that during the September 2019 inspection, the FDA "found Abbott workers were testing only half the samples of powdered formula for microbiological contamination that their protocols required before distribution."

221. In response to the release of the FDA Form 483 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.

222. After the release of the Form 483 Reports, Senator Bob Casey underscored the continuing nature of Abbott's failures, stating, "This is another troubling report establishing a pattern of Abbott Nutrition's inadequate efforts to keep its products safe." Senator Patty Murray criticized Abbott's practices: "This FDA report has revealed practices at an Abbott facility that are deeply troubling – and makes it all the more urgent that we get answers from Abbott." Sarah Sorscher of the Center for Science in the Public Interest similarly wanted more answers, stating that "[t]his sheds a little more light on what went wrong, but we still don't have all the answers. Abbott and the FDA really need to do more work to get to the bottom of what happened so we can prevent the next outbreak."

223. Abbott continued issuing misleading statements to investors by misrepresenting the presence of *Cronobacter* in product contact areas at the Sturgis plant. Indeed, the same day that the

FDA reports were released, Abbott stated, "the unique genetic makeup of the *Cronobacter sakazakii* microbes found in ***non-product*** contact areas at the Sturgis facility did not match the *Cronobacter sakazakii* microbes from the reported cases." Abbott also noted that "[w]hile there are actions we need to take to address the FDA observations, it is important to note that no *Cronobacter sakazakii* or *Salmonella* was found in any of our testing of products distributed to consumers." Abbott yet again downplayed the FDA's findings, stating its commitment to upholding the "highest standards for manufacturing of all nutrition products," and that its actions "include . . . [i]ncreasing our finished product testing, which already meets or exceeds regulatory requirements."

224. Relying on Abbott's repeated assurances, analysts continued to view the Company's outlook favorably. On April 12, 2022, Cowen research analysts reported that while the voluntary recall would reduce first quarter Nutrition sales "by $300M by our estimates and was not contemplated in guidance," Cowen still expected "the Company to Deliver Upon Its Full-Year Guidance."

225. Simultaneously, U.S. retailers began rationing baby formula due to the recall's exacerbation of the formula shortage crisis. *USA Today* reported that "[n]early 30% of popular baby formula brands may be sold out at retailers across the U.S.," according to an analysis of supplies at more than 11,000 stores. *The Wall Street Journal* reported: "A Walmart spokeswoman said stores in most states have a five-per-day limit on baby formula at the request of the Food and Drug Administration. CVS said it recently began limiting purchases in stores and online to three per consumer. Walgreens said it implemented limits in stores and online last month."

226. On April 20, 2022, during the Q1 2022 Earnings Call, Defendant Ford continued the trend of the Company's false assurances, misrepresenting Abbott's testing of retained samples related to the recall and downplaying the presence of *Cronobacter* at the Sturgis facility:

> As you know, however, we initiated a voluntary recall in February of certain infant formula products manufactured at one of our U.S. facilities. It's important to highlight, as part of our quality system, we retain in-house samples of products that we ship to customers. ***Testing of retained samples related to this recall action by both Abbott and the FDA have all come back negative*** for the presence of the bacteria that caused the reported illnesses.
>
> Importantly, the FDA and CDC found that there is no genetic match between the strains of the bacteria identified in ***non-product contact areas*** of our facility and available samples obtained from customer complaints, suggesting a different source of contamination.

227. During the earnings call, a Citibank analyst asked Defendant Ford about the impact of the recall on Abbott's reputation: "Let's circle back a little bit to the nutritional business. A lot of the feedback that I get from investors is some level of concern regarding brand name, brand damage if you will. And I'm curious your thoughts on what it would take to sort of revamp this business up." In response, Defendant Ford emphasized Abbott's "very robust manufacturing network and [its] robust quality system":

> Okay. Listen, ***we've got a very robust manufacturing network and a robust quality system***, obviously there's a shortage of product in the market. I highlighted some of the things that we're doing to be able to kind of resupply the market. A key aspect of that is going to be the restart and we're in that process. We've got a strong brand with Similac. We've maintained a lot of our contracts. We've been able to supply those contracts, even with a little bit of this shortage. So I feel confident in our team's ability here to look at once we get restarted to be able to resupply the market and build back our share.

228. Defendant Ford's statements falsely assured investors that the Company had tested all retained samples related to the recall, failed to acknowledge that *Cronobacter* had been found in product contact areas at the Sturgis facility, and focused on the Company's "robust quality system," despite evidence to the contrary. Analysts, trusting Defendants, continued to view

Abbott's outlook optimistically. For example, on April 20, 2022, in a report titled "Impressive Results Despite Tough Macro Environment and Guidance Continues to Look Achievable," BTIG analysts, crediting Abbott's assurances that it was working with the FDA to restart production "***after the agency ruled out linkage of the bacteria to the plant***," stated that the Company's EPS guidance "remains quite achievable, in our view. ABT is one of the best-positioned names in our coverage." Similarly, Evercore ISI analysts reiterated their "Outperform" rating for the Company, crediting Abbott's reassurances that it had "[t]ested in-house products shipped to customers and they have all come back negative for presence of bacteria that caused illnesses" and that the "FDA and CDC found no genetic match for bacteria in ***non-product contact areas*** of ABT facility and samples obtained from customer complaints."

C. April 28, 2022: The Release Of The October 2021 Whistleblower Complaint Reveals That The Unsanitary Conditions At Sturgis Were Reported To Management By The Start Of The Class Period

229. On the morning of April 28, 2022, as the FDA investigation continued, a redacted copy of the 34-page whistleblower complaint sent to the FDA on October 19 was made public by Congresswoman Rosa DeLauro. The existence of the February 2021 Whistleblower Complaint still was unknown at this time. Congresswoman DeLauro submitted the October 2021 Whistleblower Complaint into the public record, stating:

> I want to speak about an extremely disturbing report I recently acquired from a whistleblower who worked at the Abbott facility which produces infant formula recalled by the FDA in February. Chairman Bishop, I appreciate you giving me the opportunity to share this during this hearing.
>
> Mr. Secretary, to my knowledge you have not seen this report. I bring it to your attention because I know your deep commitment to child nutrition and the WIC program's importance to maternal and child health outcomes. Abbott Nutrition is the exclusive supplier for the majority of state WIC agencies, and this has a serious impact on families served by WIC – over 1.2 million infants served by WIC are limited to specific brands of "contract formula," like Similac. I believe you will be as outraged as I am by what this report means for the health of those infants.

> In September 2021, FDA learned of the potential link between a rare and deadly foodborne pathogen and powdered infant formula manufactured by Abbott Laboratories in a facility in Sturgis, Michigan. This week I received a 34-page report from a whistleblower, a former employee at the plant which produced the contaminated formula – which led to at least 4 hospitalizations and the deaths of at least 2 babies. The whistleblower report lays out a damning list of allegations of wrongdoing at this factory, including:
>
> - Falsification of records relating to testing of seals, signing verifications without adequate knowledge, failure to maintain accurate maintenance records, shipping packages with fill weights lower than what was on the label, and more;
> - Releasing untested infant formula;
> - Hiding information during a 2019 FDA audit;
> - Lax practices associated with clean in place procedures;
> - Lack of traceability of the product;
> - Failure to take corrective measures once the company knew their testing procedures were deficient;
> - An atmosphere of retaliation against any employee who raised concerns about company practices.
>
> And these are just a few of the allegations laid out in the report. I want to remind everyone we are talking about infant formula. Parents trust that formula will be safe and healthy for their newborn babies – it should be the most regulated of any product.
>
> I am deeply concerned about the practices at this Abbott facility and their apparent failure to implement and enforce internal controls at this facility. We need to know exactly who in the company was aware of this failure and the alleged attempts to hide this information from the FDA.

230. As discussed more fully above, the Whistleblower outlined numerous regulatory violations undertaken by Abbott at the Sturgis plant in the October 2021 Whistleblower Complaint:

"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."

231. These numerous regulatory violations committed by Abbott at the Sturgis plant included, for example, the Company's refusal to destroy potentially contaminated infant formula and its concealment of the release from the FDA; the Company's falsification of testing, cleaning, and maintenance records; and the Company's failure to maintain the powdered infant formula machinery in a manner sufficient to prevent *Cronobacter* or *Salmonella* contamination.

232. Congresswoman DeLauro renewed her criticism of Abbott for its slow response to the outbreak, calling the allegations "extremely disturbing" on April 28, 2022. She further rebuked Abbott, stating, "I am deeply concerned about the practices at this Abbott facility and their apparent failure to implement and enforce internal controls at this facility. We need to know exactly who in the company was aware of this failure and the alleged attempts to hide this information from the FDA."

233. News outlets echoed Congresswoman DeLauro's "outrage" over the revelations in the October 2021 Whistleblower Complaint, criticizing the newly revealed practices and culture in place at Sturgis. *Politico* reported that the Whistleblower's allegations "raise questions about the overall food safety culture of the plant," citing the example that the Sturgis plant had "ongoing problems" with the seams of its powdered formula cans, as well as "questions about the oversight of this particular formula plant." As *Food Safety News* succinctly described, the Whistleblower's complaint "regarding product safety at a plant that manufactured infant formula linked to a deadly, ongoing outbreak provides damning information against Abbott Nutrition."

234. In response to the release of the October 2021 Whistleblower Complaint, the Company attacked the Whistleblower. An Abbott spokesperson stated that the former employee

had been "dismissed due to serious violations of Abbott's food safety policies." However, contrary to the Company's portrayal of the Whistleblower, the Whistleblower was, as described above, by all accounts (including those of FE1, FE3 and FE4), a credible employee who spoke up and tried to do the right thing.

235. Upon release of the October 2021 Whistleblower Complaint, Abbott's stock price fell again, dropping $4.51 per share, or 3.8%, from a closing price of $118.01 per share on April 28, 2022, to a closing price of $113.50 per share on April 29, 2022.

236. On April 29, 2022, Abbott published a press release, again stating falsely that *Cronobacter* was found in "***non-product*** contact areas" of Sturgis and misleading investors that the bacteria found was "not linked to any known infant illness."

D. May 13, 2022: Abbott Pushes Back Against Accusations From The White House By Misstating The FDA's Investigation Into The Reported Infant Illnesses And Death

237. Despite the evidence that Abbott maintained an unsanitary production facility at Sturgis, Abbott continued to push back and make misleading statements concerning the Company's safety practices and record.

238. On May 16, 2022, Abbott issued yet another press release in which it misled investors about the presence of *Cronobacter* at the Sturgis facility, stating: "The *Cronobacter sakazakii* that was found in environmental testing during the investigation was in ***non-product contact areas*** of the facility." The Company also misled investors by stating that the bacteria "has not been linked to any known infant illness."

239. On May 12, 2022, the White House published a statement on the infant formula shortage:

> President Biden has directed his administration to work urgently to ensure that during the Abbott Nutrition voluntary recall, infant formula is safe and available for families across the country. . . .

> ***On February 17, the largest infant formula manufacturer in the country—Abbott Nutrition—initiated a voluntary recall of several lines of powdered formula. This came after concerns about bacterial contamination at Abbott's Sturgis, Michigan, facility after four infants fell ill and two died.*** The federal government—including the Food and Drug Administration (FDA), Department of Agriculture (USDA), Department of Justice (DOJ), Department of Transportation (DOT), U.S. Trade Representative (USTR), Department of Homeland Security (DHS), Department of Commerce (DOC), and the White House—has worked diligently over the last few months to address the shortfall in infant formula production while the Sturgis plant remains offline, including working with other infant formula manufacturers to increase production, expediting the import of infant formula from abroad, and calling on both online and in store retailers to establish purchasing limits to prevent the possibility of hoarding. As a result, more infant formula has been produced in the last four weeks than in the four weeks preceding the recall — despite one of the largest infant formula production facilities in the U.S. being offline.
>
> Families across the country remain concerned about the availability of infant formula—especially families that depend on specialty formulas for which the Sturgis facility is a key supplier. These 20 specialty formulas are used by about 5,000 infants as well as some older children and adults with rare metabolic diseases, and Abbott Nutrition is the only supplier for some of these formulas.

240. On May 13, 2022, at a White House press conference, when responding to a question about the import of infant formula from abroad, White House Press Secretary Jen Psaki reaffirmed Abbott's role in the shortage crisis and the two infant deaths:

> Well, there have been difficult — there have been limitations on this because, of course, we have a very high level of, you know, FDA approval processes to ensure that we have the best formula that is safe for babies. And, of course, whatever formula would be imported would meet those standards.
>
> But we think the best steps we can take is to work with Abbott, and Abbott has a responsibility here, too, to work closely with the FDA and doing the steps that are necessary to get back and operational online.
>
> We have a great deal of manufacturing capacity here in the United States. That's less the issue. ***The issue is, obviously, this was a recall in February, that, as a reminder, was done because there — in — there was a factory in Michigan that had tainted formula that killed two babies.***
>
> But we have a range of manufacturing capacity here. So this import step would be not forever or necessarily even long term. It's just to address the current need.

241. Abbott rejected the Press Secretary's statements in a series of eleven tweets published on May 13, 2022 before market close. In these tweets, the Company misrepresented the results of the FDA's investigation into the four infant illnesses and death that were linked to formula produced in the Sturgis facility. In rejecting the White House Press Secretary's statement that "our formulas were tainted and killed two infants," Abbott stated that "[a] comprehensive investigation by Abbott, FDA and CDC found ***no evidence*** that our formulas caused infant illnesses. Specifically CDC concluded its investigation with no findings of a link between our formulas and infant illnesses." Abbott also repeated its trope that "[t]he *Cronobacter sakazakii* that was found in environmental testing during the investigation was in ***non-product contact areas*** of the facility and has not been linked to any known infant illness." Abbott ended its series of tweets by stating unequivocally that "[t]he formula from this plant ***did not cause these infant illnesses***."

242. Abbott's blunt assertion that "Abbott, FDA and CDC found ***no evidence*** that our formulas caused infant illnesses" and conclusion that "[t]he formula from this plant did not cause these infant illnesses" was inconsistent with the FDA's investigation. In reality, the FDA and CDC could not reach any definitive conclusions due to significant limitations with available data, as FDA officials explained days later.

243. Importantly, the FDA contradicted Abbott's characterizations of the findings of the FDA and CDC's investigation. During a May 16, 2022 virtual press briefing attended by Dr. Robert Califf, FDA Commissioner; Frank Yiannas, Deputy Commissioner for Food Policy and Response; and Dr. Susan Mayne, Director of the FDA Center for Food Safety and Applied Nutrition, each attendee disputed Abbott's statements in response to a question posed by *Politico* journalist Helena Evich, who asked the FDA officials to comment on Abbott's characterizations of the FDA and CDC's findings: "Abbott did a Twitter thread over the weekend, essentially saying

that FDA and CDC had determined that the plant was not the source of the four reported infections or the hospitalizations here. Can you comment on that sort of messaging from the company?"

244. In response, Commissioner Califf began by stating that the FDA was not in a position to make such "definitive statements" yet: "It's really difficult for us to comment on something that's been an ongoing investigation with a lot of components to it. What is in the public domain is that in the cases so far, the *Cronobacter* genotypes are not necessarily matching what was in the plant. ***But there are many factors involved in this investigation and we're just not in a position yet to make any definitive statements.***" Dr. Mayne then detailed the limitations that prevented the FDA from concluding that there was no link between the formula produced at Sturgis and the four reported illnesses. Specifically, Dr. Mayne described how: (1) *Cronobacter* is only a reportable disease in the state of Minnesota, (2) genetic sequencing was only available for two out of the four cases, and (3) there were multiple strains of *Cronobacter* that were isolated from swabs at the Sturgis plant, and there was a possibility that there were other undetected strains at the plant.

> I think one of the things that the reporter is well aware of is we had four cases, four case complaints here. Because *Cronobacter* is not a reportable disease in the United States, ***it's only reportable in the state of Minnesota***, what that means is that you – they don't go through the normal processes where isolates are collected of the pathogen, whole genome sequencing is done, CDC puts together clinical clusters. And in this case, ***we were only able to get genetic sequences from two out of those four cases.*** So right from the get-go, we were limited in our ability to determine, you know, with a causal link whether or not the consumption of the product from the Abbott Sturgis plant was linked to these four cases because we only had sequence available and on two.
>
> The other thing we will comment on is ***we had multiple strains of Cronobacter that were isolated from the environment in the Sturgis plant. So there certainly is the possibility that other strains that we didn't detect at the time we were in the plant for the inspection certainly could have been in there.*** So we simply don't have the evidence to demonstrate that causality, but again the data are so limited with sequencing available only for two out of the four cases."

245. Deputy Commissioner Yiannas echoed Dr. Mayne's response and emphasized that *Cronobacter* had only 238 genetic sequences in the databases of previous strains that had been

sequenced—a "very small, tiny" amount relative to other diseases. As a result, "***it's hard to read too much into***" the lack of a genetic link or match between identified strains of *Cronobacter*.

246. Deputy Commissioner Yiannas also rebuked Abbott's focus on the fact that unopened samples of the product had not been found to contain *Cronobacter*, explaining that "process control" is the "best way to assure food safety" because the sample testing tests roughly less than one pound of formula—300 grams—out of a 40,000 to 50,000 pound batch:

> ***The other thing we've heard emphasized quite a bit is that these products have been tested and that the product has not been found to contain Cronobacter. It's important to remember that an overreliance on end product testing is not really the best way to assure food safety. It's really about process control.*** Some of these infant formula production runs can be tens of thousands of pounds of product. And the sampling plans typically are 30 samples at 10 grams a piece. That's a total of 300 grams less than a pound for let's say a 40,000 or 50,000 pound production run. So the probability of detecting low levels of contamination through an end product testing plan is almost never going to happen. The probability rates, some statisticians calculate there's a 97% chance that you won't find low levels of contamination using that type of sampling plan. ***And so just caution people to read into the fact, not to read too much into the fact that, uh, there's been negative test results of finished product, or that there hasn't been a genetic clinic established.***"

247. In a May 17, 2022 article titled "FDA obliterates formula maker's defense of contamination linked to baby deaths," *Ars Technica* described how Abbott's May 13, 2022 " blunt assertion [that] '[t]he formula from this plant did not cause these infant illnesses'" was a "***brazen and misleading claim***, according to the Food and Drug Administration." The author noted that FDA "agency officials thoroughly dismantled Abbott's defense" and, in the May 16 Press Briefing, "all but called that reasoning nonsense" because "the lack of a genetic match is not proof that the formula is not the source of the infants' bacterial infections."

E. May 16, 2022: DOJ Files A Civil Injunctive Complaint And Enters A Consent Decree Detailing Abbott's Regulatory Violations And Providing For Strict Oversight As A Condition Of Renewed Formula Production

248. On May 16, 2022, the Civil Division of the U.S. Department of Justice filed the DOJ Complaint and Consent Decree in the Western District of Michigan, *United States v. Abbott*

Laboratories d/b/a Abbott Nutrition, et al., 22-cv-00441 (W.D. Mich.), which would allow Abbott to resume manufacturing powdered infant formula at its Sturgis facility, but also would require the Company to take specific measures designed to increase safety and ensure compliance with the FDCA and the FDA's CGMP regulations. Attorney General Merrick B. Garland stated: "The actions we are announcing today will help to safely increase the supply of baby formula for families. The Justice Department will vigorously enforce the laws ensuring the safety of our food and other essential consumer products, and we will work alongside our partners across government to help make sure those products are available to the American people."

249. In the DOJ Complaint, the United States alleged that Abbott and three officers—Defendant Randall, Division Vice-President of Quality Assurance; Keenan S. Gale, Sturgis Director of Quality; and T.J. Hathaway, Sturgis Site Director—manufactured powdered infant formula under conditions and using practices that failed to comply with regulations designed to ensure the quality and safety of infant formula, including protection against the risk of contamination from bacteria such as *Cronobacter*. Specifically, the DOJ Complaint sought an injunction preventing Abbott and the other defendants from violating 21 U.S.C. § 331(a) and (k) of the FDCA. The Complaint expanded on certain adverse observations made in the 2019, 2021 and 2022 483 Reports.

250. For example, the DOJ Complaint discussed Abbott's prior processing and filling of batches of *Cronobacter* positive product on August 18-19, 2019 and June 12, 2020. The DOJ Complaint alleged that the "presence of *Cronobacter* spp. on different processing equipment at different times indicates the possibility of multiple avenues for spreading bacterial contamination in the manufacturing environment." In the Complaint, the DOJ explained:

> 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***. Defendants' violations of the Act and the likelihood that violations will recur in the absence of court action demonstrate that injunctive relief is necessary.

251. The DOJ concluded in the Complaint that: "Defendants' violations of CGMP Regulations for Human Food render Defendants' products . . . manufactured at AN-Sturgis [] adulterated within the meaning of 21 U.S.C. § 342(a)(4) in that they have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated or been rendered injurious to health. *See* 21 C.F.R. § 117.1(a)(1)(ii)." The DOJ also alleged that Defendants violated the Infant Formula CGMP Regulations set forth at 21 C.F.R. §§ 106.20(a), 106.55(a), 106.30(b), 106.10(b)(1), and 106.100(k)(2)."

252. Notably, the DOJ Complaint detailed how "[t]he 2022 Inspection was not the first time FDA warned Defendants of their failure to comply with FDA requirements to control microbiological growth. The FDA previously conducted an inspection at AN-Sturgis between September 20-24, 2021 ("2021 Inspection"). During the 2021 Inspection, FDA investigators documented several conditions and practices that fail to control microbiological growth within the food-processing areas at AN-Sturgis including, but not limited to, some of the same or similar observations made during the 2022 Inspection." The DOJ alleged that although Abbott and the other defendants "promised corrective actions, they did not implement sustained corrections to achieve ongoing compliance with the Act and its implementing regulations." Moreover, the DOJ warned that "[d]espite the seriousness of having detected *Cronobacter* spp. in their products and processing areas, Defendants have not taken adequate steps to come into compliance, as evidenced by the observations made by FDA investigators during the 2022 Inspection. Accordingly, the United States believes that, unless restrained by the Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and 331(k) in the manner alleged herein."

253. Abbott agreed to resolve the DOJ Complaint through the Consent Decree of permanent injunction. The Consent Decree outlines what Abbott must do to resume safely manufacturing infant formula at the Sturgis facility, and what Abbott must do to continue manufacturing infant formula at Sturgis. Under the terms of the Consent Decree, Abbott must retain outside expert assistance to bring its facility into compliance with the FDCA and GMP 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, GMP regulations, and the terms of the Consent Decree. Moreover, the Consent Decree requires the implementation of a sanitation plan, environmental monitoring plan, and employee training programs. Notably, the Consent Decree requires Abbott to notify the FDA if it finds contamination and to store any samples of *Cronobacter* it finds for three years. Violations of the agreement could result in daily $30,000 fines capped at $5 million per year.

254. Just after market close on May 16, 2022, Abbott published a press release stating that it had agreed to enter into the Consent Decree with the FDA. In its press release, Abbott stated, "Once the FDA confirms the initial requirements for start-up have been met, Abbott could restart the site within two weeks. . . . From the time Abbott restarts the site, it will take six to eight weeks before product is available on shelves." The Company emphasized its cooperation with the FDA:

> Abbott has been working on corrective actions since the FDA inspection and submitted a response and corrective action plan to FDA on April 8. Even before its formal response, Abbott had begun working to implement improvements and take corrective action. Some of these actions included reviewing and updating education, training and safety procedures for both employees and visitors, as well as updating protocols regarding water, cleaning and maintenance procedures at the facility. Abbott immediately implemented corrections to address the items that the FDA raised in its observations provided at the conclusion of the inspection. The company has also been making upgrades to the plant.

255. The press release quoted Defendant Ford, who attempted to reassure investors about Abbott's "safety and quality processes," stating, "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. . . . Our safety and quality processes meet even the toughest scrutiny and we're committed to continuously improving our processes and protocols."

256. The Company again misrepresented the presence of *Cronobacter* at the Sturgis facility and continued to deny any link between its powdered infant formula and the reported illnesses: "The *Cronobacter sakazakii* that was found in environmental testing during the investigation was in ***non-product contact areas*** of the facility and has not been linked to any known infant illness."

257. At the end of the press release, the Company again reiterated its full-year 2022 EPS guidance: "Abbott is confirming its previously issued full-year 2022 guidance for adjusted diluted earnings per share from continuing operations of at least $4.70. Abbott will incur one-time specified charges for expenses related to the consent decree which have not yet been quantified. However, Abbott does not expect that these expenses will have a material impact on Abbott's consolidated financial statements."

258. The DOJ Complaint and Consent Decree confirmed and expanded on the FDA's inspection observations in the Forms 483 released on March 22, 2022. However, the market generally welcomed the Consent Decree because it provided a reliable blueprint for how Abbott could resume production at Sturgis and relieve the infant formula shortage that worried parents throughout the country. For example, Morgan Stanley analysts wrote: "For Abbott, we view the consent decree providing further clarity around the path to facility reopening and manufacturing

resumption, with additional steps required to support facility reopening appearing reasonable. Based on the work completed to date by Abbott in response to the previously issued Form 483, remaining work (across both the Form 483 as well as the consent decree) largely centers around training program documentation and sanitary steps, with Abbott likely needing weeks (as opposed to months) to sufficiently address all outstanding issues and requirements."

259. On May 21, 2022, *The Washington Post* published an apology by Defendant Ford titled: "Abbott CEO: We're sorry about the formula shortage. Here's what we're doing to fix it." As Abbott had been doing for months, Ford tried to soften the egregious regulatory violations at Sturgis and sever the link between Abbott's powdered infant formula and reported illnesses and death. Ford wrote: "We're sorry to every family we've let down since our voluntary recall exacerbated our nation's baby formula shortage. We believe our voluntary recall was the right thing to do. We will not take risks when it comes to the health of children." Ford once again stated the claim debunked by the FDA on March 16, 2022: "The data collected during the investigation, genetic sequencing, retained product samples and available product from the four complaints did not find any connection between our products and the four reported illnesses in children."

260. Ford further stated that "the FDA's investigation did discover a bacteria in our plant that we will not tolerate. I have high expectations of this company, and we fell short of them." Of course, in reality, Abbott itself had discovered *Cronobacter* in its Sturgis facility—and in Sturgis packaged product—for years leading up to the FDA inspection and recall. Moreover, Ford disavowed any link between the Sturgis facility and the four reported illnesses, stating: "The data collected during the investigation, genetic sequencing, retained product samples and available products from the four complaints did not find any connection between our products and the four

reported illnesses in children." Ford concluded: "I want everyone to trust us to do what is right, and I know that must be earned back."

F. May 25, 2022: The FDA Details The "Egregiously Unsanitary" Conditions At Sturgis To Congress While Defendant Calamari Falsely Denies Abbott's Knowledge Of The Whistleblower's Complaints

261. On May 25, 2022, the United States House of Representatives Committee on Energy and Commerce, Subcommittee on Oversight and Investigations held a public hearing during which both FDA Commissioner Califf and Abbott's President of Nutrition North America, Defendant Calamari testified concerning the baby formula shortage.

262. At the hearing, FDA Commissioner Califf emphasized that the FDA and CDC ***could not rule out*** that the "***egregiously unsanitary conditions***" at Sturgis "***caused the illnesses reported***" and described the "***shocking***" results of the FDA inspection:

> ***The FDA and CDC's investigation could not conclude that the egregiously unsanitary conditions in the Abbott facility caused the illnesses reported in our timeline. However, we cannot rule it out either as a confluence of events is highly unusual. There is no dispute that the facility was unacceptably unsanitary as evidenced by the consent decree. Frankly, the inspection results were shocking***: standing water; cracks in the key equipment that present the potential for bacterial contamination to persist; particularly in the presence of moisture; leaks in the roof; a previous citation for inadequate hand washing; and current poor foot sanitation; bacteria growing from multiple sites; ***and many signs of a disappointing lack of attention to the culture of safety in this product that is so essential to the lives of our most precious people.***

263. FDA Commissioner Califf also rebutted Abbott's characterization of the recall as a "voluntary" step the Company had taken, revealing that "During the inspection, we contacted Abbott to ask the company to issue a voluntary recall. The need to take urgent action to protect the most vulnerable of all of our people, infants, presented a dilemma."

264. Commissioner Califf further described how the FDA "had no confidence in the integrity of the 'Abbott Quality Program' at this facility," leading to the initiation of the

proceedings toward a consent decree, which "requires Abbott to undertake steps to assure safe production of formula, including hiring an outside expert with reporting to FDA":

> We concluded early on that getting the Sturgis facility up and running safely was a top priority. ***But we had no confidence in the integrity of the Abbott Quality Program at this facility***. Accordingly, we initiated proceedings toward a consent decree, which requires Abbott to undertake steps to assure safe production of formula, including hiring an outside expert with reporting to FDA. Our oversight is critical. But make no mistake about it, the return to normal will only occur when Abbott takes the steps to resume production in a safe manner.

265. Representative Kim Schrier echoed Commissioner Califf's characterization of Sturgis, and stated, "[I]t feels like there's just corruption from the top down in that plant. . . . [H]ow are you going to oversee this so that we feel confident when this opens that we're getting clean, safe formula?" Commissioner Califf answered that the FDA was doing what it could to ensure the plant reopens safely and could neither confirm nor deny whether there might be criminal proceedings in the future.

266. At the conclusion of his testimony, Commissioner Califf provided a visceral and disturbing explanation of the state in which the FDA found the Sturgis facility in February 2022:

> Let's say you had a next door neighbor who had leaks in the roof. They didn't wash their hands. They had bacteria growing all over the kitchen. You walked in, and there was standing water on the counters and the floor, and the kids were walking through with mud on their shoes and no one cleaning it up. You probably wouldn't want your infant eating in that kitchen. And that is, in essence, what the inspection showed. . . . [T]hese are just the facts that we saw.

267. Commissioner Califf also directly addressed and refuted Abbott's claims that the infants' injuries and death were not caused by Abbott formula: "[T]he absence of being able to prove that there was a connection doesn't mean that there was no connection. We just can't rule it in, nor rule it out."

268. On May 25, 2022, Defendant Christopher Calamari also testified before Congress on behalf of Abbott. Defendant Calamari opened his remarks with an admission that: "We know we let you down."

269. However, in his prepared remarks published on the House of Representatives' website and then during live testimony, Defendant Calamari repeated the same misrepresentations concerning the absence of *Cronobacter* in product-contact areas: "During its inspection, the FDA took 292 environmental swabs throughout the factory and four tested positive for *Cronobacter sakazakii*. ***The four swabs that tested positive were from areas that do not come into direct contact with product. As part of our own investigation, we also found Cronobacter sakazakii in non-product-contact areas of the facility.***" At the hearing, when asked about Defendant Ford's statement in his *Washington Post* editorial that "the FDA's investigation did discover a bacteria in our plant that we will not tolerate," Defendant Calamari similarly misrepresented the presence of *Cronobacter* at the Sturgis plant, stating that it was not found in a product area and downplaying the severity of the contamination by stating the bacteria was "commonly occurring":

> ***So the bacteria in question was found in a part of the facility that's not in contact with product, which is absolutely not acceptable, to be clear.*** And we have taken action to make sure we put processes and training in place so that that does not happen. I will say that the bacteria infection in question is ***commonly occurring***, and part of our process is to test that, to make sure we catch it before it gets distributed to product.

270. Defendant Calamari also made new misrepresentations during his live testimony concerning Abbott's awareness of the Whistleblower's allegations against Abbott. Defendant Calamari falsely stated that Abbott "became aware of the whistleblower complaint in the end of April when it was made public by Congress." During questioning by Representative Kathleen Rice, Defendant Calamari continued to mislead about when Abbott learned about the Whistleblower. When Representative Rice asked Defendant Calamari if it was correct to say that

Abbott was "informed of the [W]histleblower and their report, they went directly to another source, they did not go to you," he responded: "Yes, I would've become aware in the end of . . . the April timeframe." In the same exchange, Representative Rice asked why the Whistleblower did not report his concerns to Abbott before October 2021: "[I]f you have what you're describing as a specific program to allow employees to go directly to someone within the company to register an issue with something that's going on in any one of your facilities, why didn't that happen here?" Defendant Calamari responded that Abbott did not learn of the Whistleblower's complaints until April 2022 and, further, blamed the Whistleblower for not bringing his concerns to Abbott's attention: "Abbott did not find out about it until . . . it was made public [at] the end of April. And it was the--the particular individual who raised the complaint, it was their choice to use that mechanism to raise the complaint." In reality, the Whistleblower not only directly raised his concerns with Abbott in 2019 and 2020, as detailed within both the February 2021 and October 2021 Whistleblower Complaints, the Whistleblower, through his well-qualified legal counsel, filed the February 2021 Whistleblower Complaint with OSHA on February 16, 2021 pursuant to FSMA. As described above, under FSMA, OSHA was statutorily required to promptly deliver the complaint and its allegations to Abbott, and that Abbott was obligated to respond, which it did. Moreover, the Whistleblower described in his Complaints how his attorney also directly contacted Abbott's General Counsel and requested that all documents concerning his employment be preserved while the investigation into his retaliation claims were being investigated, a request to which the General Counsel's office responded. Therefore, Defendant Calamari's claim that Abbott learned of the "the [W]histleblower and their report" for the first time in April 2022 was false or misleading, as was his claim that the Whistleblower chose not to bring his complaints to Abbott's attention any earlier.

271. Defendant Calamari also doubled down on Abbott's stance that the Sturgis plant did not have a culture problem where employees feared retaliation for speaking up to management. Defendant Calamari stated throughout his testimony that the Company's culture "encourages employees to speak up." He emphasized, "We are going to reinforce that we are a culture where we support employees to raise concerns if they see them."

272. News reports highlighted Defendant Calamari's statement that Abbott did not become aware of the whistleblower report filed with the FDA in October 2021 until April 2022 when it was made public by Congress.

G. June 8, 2022: Investors Learn that Abbott Received And Responded To The Whistleblower's Accusations One Year Before The Recall, And The Market Learns That A Total Of Nine Infant Deaths, Five More That Previously Reported, Were Related To Babies Fed Powdered Formula Manufactured at Sturgis

273. On June 8, 2022 just before the market closed, and just two weeks after the May 25, 2022 congressional hearing, investors learned that Abbott had received the Whistleblower's formal allegations in February 2021, when the February 2021 Whistleblower Complaint was sent by the Whistleblower to OSHA and then forwarded to the FDA and Abbott. Specifically, Labor Department officials provided the February 2021 Whistleblower Complaint to Abbott and the FDA that same month. Moreover, Abbott submitted a formal response to the complaint two months later.

274. Up until this point, investors had known only of the October 2021 Whistleblower Complaint sent directly to the FDA. As *The Wall Street Journal* reported, "Abbott Laboratories was alerted to allegations concerning problems at an infant-formula plant ***months earlier than previously publicly known***, according to a government official." Indeed, the February 2021 Whistleblower Complaint "offer[ed] a fuller picture of the timeline leading up to the shutdown in February 2022 of Abbott's plant in Sturgis."

275. In response, an Abbott spokesperson again attacked the Whistleblower: "We believe this to be a former employee who was dismissed due to serious violations of Abbott's food safety policies." The spokesperson claimed that the employee had never raised product safety concerns while at the Company, and that the complaints were part of "a pattern of ever-evolving, ever-escalating allegations."

276. Abbott's attack on the whistleblower could not change the fact that Abbott received the Whistleblower's February 2021 Complaint the same month. Executives at Abbott's highest levels thus were informed of the safety violations one year prior to the formula recall, despite statements denying any knowledge of the Whistleblower and his complaints prior to April 2022.

277. Congresswoman DeLauro expressed her outrage at this revelation, stating, "While these infants suffered from different symptoms, there remains one constant: The sick babies were fed an Abbott powdered formula," and "each new revelation begs more questions." ABC News further pointed out that Abbott failed to mention "being alerted to an OSHA complaint raising product safety concerns in February 2021 during their testimony in late May of this year."

278. On June 8, 2022, at around 3 PM, just before market close, *Food Safety News* also reported that the FDA had received reports of ***nine infant deaths*** between December 1, 2022 and March 3, 2022 among babies who had been fed infant formula manufactured at the Sturgis plant. The nine deaths were included in a list of 128 consumer complaints supplied by the FDA in response to a FOIA request. Two of those deaths were among the four confirmed cases of *Cronobacter* identified by the CDC. The other seven deaths were reported to the FDA via the agency's consumer complaint system, and two of those reports mentioned *Salmonella* in the complaint description. As the report succinctly described, "[e]very one of the sick babies was fed an Abbott powdered formula**.**"

279. In addition to the nine deaths, consumers described 25 incidents of "Life Threatening Illness/Injury" and eighty instances of "Non-Life Threatening Illness/Injury."

280. 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 3.6%, 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.

H. June 22, 2022: The FDA Investigates Another Infant Death Related To Sturgis

281. On June 22, 2022, the FDA announced that the agency was investigating a new report of another child's death. The death occurred in January 2022, prior to the recall, and was reported on June 10, 2022. The infant's death occurred after the infant consumed Abbott's baby formula, bringing the total to ***ten reported infant deaths*** purportedly connected to Abbott infant formula. In a press release titled "FDA Provides Update on Efforts to Increase Supply and Availability of Safe and Nutritious Infant Formula," the FDA reported that to date, the FDA had reviewed and investigated a total of 129 complaints associated with Abbott formula products, 119 of which were reported after the recall**.**

282. On June 22, 2022, *The Wall Street Journal* noted that "disclosure of the investigation is likely to intensify scrutiny of Abbott," adding that Abbott had come under fire in recent months from both sides of the aisle for its slow response to the problems at Sturgis. The following day, June 23, 2022, *The Wall Street Journal* reported that the report of the infant death indicated *Cronobacter* as a cause of death, and noted that disclosure of the investigation "threatens to hurt future sales of the company's widely used formula." The article noted that "Abbott's formula and other pediatric-nutrition product sales, which totaled $4.3 billion globally last year out of the company's $43 billion total sales, have already taken a hit," with Abbott's formula sales dropping from 48% market share right before the recall to 28% the week ending May 21, 2022.

The article quoted a brand consultant, who opined that these reports of infant deaths potentially tied to Abbott would hurt the Company's standing with consumers and that Abbott is "certainly not going to be the first choice you start with as a new parent thinking about which formula you want to try."

I. September 6, 2022: Scrutiny Over Abbott's Use Of Sanctioned Legal Tactics To Quash Prior Accusations of Infants Harmed By *Cronobacter*

283. On September 6, 2022, David Enrich, the business investigations editor for *The New York Times*, published an article titled "How Abbott Kept Sick Babies From Becoming a Scandal." As Enrich noted, the recently reported *Cronobacter*-caused illnesses and deaths linked to Abbott formula were not the first; indeed, over the years, other newborns had fallen sick or died after being fed Abbott's powdered infant formula. Until recently, however, the pattern went largely unnoticed. According to Enrich, a big reason for this was that Abbott and its lawyers deployed "scorched earth" legal tactics that have beaten back attempts to hold the Company liable.

284. Several lawyers who have worked on baby-formula cases said they were not aware of a plaintiff ever beating Abbott or its competitors at trial. According to Enrich, "as the Abbott cases illustrate, when the resources and tactics of Big Law are brought to bear against poor families and their overwhelmed lawyers, the results tend to be lopsided." Enrich described how Abbott's lawyers at a nationally-recognized Big Law firm negotiated secret settlements, used "scorched earth" tactics with families whose infants fell ill after consuming their powdered formula, and successfully beat back claims against Abbott related to alleged *Cronobacter* infections in newborns who consumed Abbott formula, discussed above. Enrich recounted how in one trial, where an infant's meningitis was alleged to have been caused by powdered infant formula produced at the Sturgis facility, Abbott "sought a court order sealing some trial testimony and evidence on the grounds that they contained confidential information about Abbott's testing and

food safety protocols and 'its sanitation, housekeeping and hygiene.'" The judge granted the request, such that "details about Abbott's factory in Sturgis, Mich. — the one that was shut down earlier this year — vanished from public view."

285. The accounts in *The New York Times* article were part of Enrich's research for a then-forthcoming book investigating the legal industry, and the research into Abbott's legal tactics predated the recall. Enrich reported that in January 2022, he asked an Abbott spokesman, Scott Stoffel, for comment. On January 25, 2022, just days before the FDA returned for its "for cause" inspection, and months after the 2021 483 Report and reports of illnesses and death from Abbott-linked *Cronobacter* infections, Stoffel stated: "***Healthy infants and children are at the heart of what we do and ensuring the quality and safety of our products is a top priority***." He continued: "***Our products undergo rigorous quality . . . checks to ensure that they meet both the nutritional and safety needs of infants and children***."

286. The market took notice of Enrich's article. For example, a September 6, 2022 analyst report by Wolfe Research mentioned *The New York Times* article and stated, "[w]e felt compelled to flag what is clearly an unflattering deep dive type of story in a high-profile publication on a recent issue that impacted many families earlier this year."

287. The disturbing information revealed by *The New York Times* also caught the attention of lawmakers in Washington. On October 12, 2022, U.S. Senator Elizabeth Warren sent a letter to Abbott seeking information about litigation and settlements since 2003 involving Abbott Nutrition, as part of an inquiry over concerns that the company attempted to avoid accountability for potentially-contaminated baby formula. The letter, addressed to Defendant Ford, highlighted recent reports, like *The New York Times* article, chronicling "aggressive tactics" that Abbott Nutrition used to escape disclosure. Senator Warren's letter requested that Ford hand over a list

of litigation against Abbott Nutrition alleging the spread of the *Cronobacter* microorganism through powdered infant formula since 2003, including motions to seal documents or evidence and motions Abbott Nutrition filed to recover costs from plaintiffs.

288. Additionally, Senator Warren also asked for a list of settlements regarding alleged *Cronobacter* infections from powdered infant formula that Abbott Nutrition has entered into since 2003, including amounts paid to families impacted by *Cronobacter* and non-disclosure agreements that went with the settlements. As Senator Warren explained, citing *The New York Times* article, "[n]ew reports indicate that Abbott Nutrition was aware of these risks for decades, and that the company worked to cover up the consequences by 'deploying scorched earth legal tactics' to 'grind down—and in some cases attack' families seeking compensation for the harm caused and using legal settlements to force impacted families to stay silent." Senator Warren added, "[i]t is deeply troubling that Abbott appears to have been using abusive legal tactics and non-disclosure agreements to avoid accountability for the health and safety risks from its unsafe products, and I write to seek on the information about what Abbott Nutrition kept hidden from the public and the legal tactics the company used against families seeking justice." Senator Warren also said in her letter that despite an outbreak in 2011 and numerous lawsuits claiming its powdered formula included *Cronobacter*, information on those risks did not reach many new parents, decrying, "[y]our company continued to cut corners and operate under lax safety measures."

J. October 19, 2022: Abbott Announces Significant Declines In Formula Sales And Changes In Leadership Related To The Sturgis Recall And Shutdown

289. On October 19, 2022, before the market opened, Abbott reported its third-quarter 2022 results to investors. The results revealed a significant and greater-than-expected decline in Nutrition sales due to the shutdown of the Sturgis plant. Specifically, Abbott reported a 39.1 percent decrease in total U.S. pediatric sales for 3Q22 on an organic basis (or a 24.8 percent

decrease in total U.S. pediatric sales for 3Q22 on a reported basis). The Company also reported a 10.3 percent decline in total Nutrition sales on an organic basis. Overall, Abbott's net earnings fell to $1.44 billion from $2.1 billion a year earlier, or a 31.7 percent decline.

290. On the earnings conference call that same day, Defendant Funck explained that "organic sales growth was negatively impacted" by the shutdown of the Sturgis plant. Defendant Funck also stated that the Company's "adjusted gross margin ratio was 55.9% of sales, which reflects the impacts of the Nutrition manufacturing disruption and inflation we've experienced on certain manufacturing and distribution costs across our businesses."

291. On the same conference call, Defendant Ford revealed a change in leadership at the Sturgis plant and in its quality organization, stating "we also made leadership changes both at our Sturgis site and in our quality organization." Ford failed to provide any specifics on the leadership changes. In an article titled "Abbott Names New Leadership at Troubled Baby-Formula Plant," *The Wall Street Journal* reported on the leadership overhaul at the Company, citing the shutdown of the Sturgis plant after contamination was found. That article also noted that "U.S. sales of certain Abbott baby-formula products plunged to $102 million in the third quarter from $332 million a year earlier." In a separate article, *The Wall Street Journal* also reported on the significant decline in Abbott's Nutrition sales, specifically noting that the Sturgis shutdown that led to the nationwide formula shortage was "partly to blame for a 25% decrease in pediatric sales to $827 million in the quarter."

292. Analysts reacted negatively to the Company's Nutrition miss and focused on the Company's sales decline, which was higher than prior predictions. In a report titled "Still Struggle with the Math on this One – Underwhelming Read of 3Q22," a Wolfe Research analyst rated the stock "Underperform" and stated that "Pediatric nutrition stepped down sequentially and slowed

in real terms. Pediatric still working off Sturgis impact." Goldman Sachs analysts reported that they were "Sell rated" on the stock, citing "Sales of $1.8B well below (-8%) Street / GS of $1.95B as US peds saw a surprising re-acceleration of financial impact from Infant formula recall over 2Q despite facility resumption in 3Q." The Goldman Sachs analysts noted that the third-quarter results "more closely resembled [the first quarter's] financial headwind" when the recall was first announced, underscoring the underwhelming nature of Abbott's quarterly earnings results. Jefferies analysts similarly highlighted how Abbott's "nutrition miss" caused "softness" and Nutrition was not recovering "as fast as the Street [had] modeled," and consequently, the Company was "still recovering from its nutrition recall, weighing down margins."

293. Following the news of the Company's decline in Nutrition sales and leadership changes, the price of Abbott common stock declined $6.87 per share, or 6.54%, from a closing price of $104.98 per share on October 18, 2022, to a closing price of $98.11 per share on October 19, 2022.

VI. POST-CLASS PERIOD DEVELOPMENTS

A. The Department Of Justice Launches A Criminal Investigation Of Abbott

294. Upon information and belief, a U.S. House Oversight committee reached out to people knowledgeable about the Sturgis facility throughout the Fall of 2022. Former employees have also reported that people, possibly from the government, had shown up at Sturgis in late November 2022, close to Thanksgiving. These attorneys arrived during the overnight shift, *i.e.*, sometime between 11:30 PM and 7:30 AM, and took possession of Sturgis management's computers.

295. On January 20, 2023, *The Wall Street Journal* broke the news that "the Justice Department is investigating conduct at the Abbott Laboratories infant-formula plant in Sturgis, Mich., that led to its shutdown last year and worsened a nationwide formula shortage." The article

noted that attorneys with the DOJ's consumer-protection branch, which was involved in the DOJ Complaint and Consent Decree in May 2022, were conducting a criminal investigation. An Abbott spokesman confirmed the criminal investigation, stating that "The DOJ has informed us of its investigation, and we're cooperating fully." Abbott provided more detail on the criminal investigation in its February 17, 2023 Form 10-K for 2022 for Fiscal Year ended December 31, 2022 (the "2022 Form 10-K"), where the Company disclosed that it first learned about the criminal investigation in November 2022. Notably, in the 2022 Form 10-K, Abbott did not limit the scope of the investigation to Sturgis, but stated that there was "a criminal investigation related to Abbott's manufacturing of infant formula."

296. The January 20, 2023 *The Wall Street Journal* article noted that there has been a push, in the past decade, by the DOJ to investigate numerous food companies that shipped contaminated products that resulted in illnesses or death. For example, several DOJ investigations led to criminal prosecutions, under the FDCA, of companies or executives involved in producing goods from ice cream to peanut butter. As the article stated, the law allows government officials to prosecute entities or individuals who introduce adulterated food into interstate commerce. The article also noted that a Seattle lawyer who represents victims of food-borne illnesses observed that, in many recent cases, the DOJ has been able to successfully prosecute defendants on misdemeanor charges for introducing contaminated food into the market even without proof that officials acted with criminal intent. The article further referenced the prosecution of various companies that paid millions of dollars to resolve investigations involving foodborne illnesses caused by their products.

297. A February 15, 2023 article published in *Crain's Chicago Business* detailed some of the long-term risks posed by the burgeoning criminal investigation, noting that "[s]ince the

formula saga began, Abbott has taken much of the blame for the shortage, had plant safety issues exposed and has seen a steep decline in formula sales. But the DOJ investigation could deepen the damage from an episode that has already hurt the company's bottom line and brand name." *Crain's* explained the potential charges that could be brought against Abbott and its executives for violations of provisions in the FDCA, which prohibits the sale of poisonous or unsanitary food and ingredients, as well as preparing and packing of food in unsanitary conditions. According to the FDA website, misdemeanors of the FDCA that did not cause death could result in a per violation fine of $100,000 and one year in prison for an individual, and a fine of $200,000 per violation for a corporation. Those penalties increase if the violations resulted in a death; if the DOJ finds evidence of felony violations at the Sturgis, Abbott ***could face fines of up to $500,000 per offense*** and up to three years of prison time for individuals involved.

298. The *Crain's* article noted how "[r]ecently, federal prosecutors have shown a willingness to charge executives with crimes," reporting how the DOJ recently filed criminal charges in other food safety cases, such as the charges "against Texas ice cream company Blue Bell Creameries and its former CEO in 2020 following a listeria outbreak tied to deaths and illnesses." In that case, Blue Bell "agreed to pay a $19 million fine and plead guilty to two misdemeanor charges. The former CEO, who was charged with a scheme to cover up shipping of contaminated products, pleaded not guilty. After an initial mistrial, a second trial has been scheduled for later this year." *Crain's* also recounted the 2015 conviction of Peanut Corp. of America owner Stewart Parnell who was sentenced to 28 years in prison after being convicted of covering up contaminated peanut products that led to a deadly *Salmonella* outbreak. The article also discussed analyst concerns over how the recall and its aftermath could trigger changes in the heavily concentrated WIC program previously dominated by Abbott, which would "hurt Abbott's

ability to regain market share," citing an October 2022 analyst report by Mizuho Securities analysts.

B. The SEC Launches An Investigation Into Disclosures Relating To " Abbott's Powder Infant Formula Business "

299. In its 2022 Form 10-K, Abbott revealed an additional probe by the SEC, disclosing that "[i]n December 2022, Abbott received a subpoena from the Enforcement Division of the [SEC] requesting information relating to Abbott's powder infant formula business and related public disclosures."

300. Abbott also revealed in its 2022 Form 10-K that "[i]n January 2023, Abbott received a civil investigative demand from the United States Federal Trade Commission seeking information in connection with its investigation of companies who participate in bids for Women, Infants, and Children infant formula contracts." A *Crain's* article dated February 17, 2023 noted that the investigation could lead to a lawsuit by the FTC if the agency finds the infant formula maker engaged in anticompetitive conduct, such as collusion with other manufacturers on pricing. Separately, the agency, which enforces both consumer protection and antitrust laws, opened an inquiry into the infant formula market last year after lawmakers had urged the FTC to look into whether consolidation in the market helped exacerbate the shortage. FTC Chair Lina Khan had said the agency would look into whether mergers contributed to the current "fragile state" of the market. A report with the findings from that probe, in which the agency sought information from the public, is expected to be released later this spring.

C. Abbott Discloses A 60% Reduction In Infant Formula Sales In 2022

301. After the February 2022 recall, Abbott made financial disclosures through 2022 that highlighted the negative impact the recall had on the Company's finances. Analysts also commented on the same.

302. On February 17, 2023, in its 2022 Form 10-K, the Company reported $1.562 billion in U.S. pediatrics nutritionals revenues for FY 2022, down from $2.192 billion in 2021—***a 28.7% decrease*** that "reflects the impact of the voluntary recall and production stoppage of certain infant powder formula products manufactured at Abbott's facility in Sturgis, Michigan, partially offset by increased demand for Abbott's Pedialyte products." The Company also reported that operating earnings for the Nutritional Products segment decreased 60.0 percent, and operating margins for the worldwide nutritional products business ***decreased from 22.9 percent in 2020 to 9.5 percent in 2022***, and attributed the decreases to "the impact of the voluntary infant product recall and manufacturing stoppage." Overall, for the entire full year, Abbott reported that "U.S. sales of infant powder formula brands associated with the recall were $479 million and $1.2 billion in 2022 and 2021, respectively," reflecting ***a 60% decrease of nearly $721 million*** in 2022. Moreover, the Company recorded ***$176 million*** of charges related to the voluntary recall in 2022, bringing the costs of the recall to ***nearly $900 million in 2022***.

D. Former FDA Deputy Commissioner For Food Policy & Response Testifies That "The Weight Of The Evidence Against Abbott" Rebuts Defendants' "Misleading" Assertion That Abbott's Formula Was Not The Source Of Reported *Cronobacter* Infections

303. Most recently, on March 28, 2023, Frank Yiannas, the former FDA Deputy Commissioner, Food Policy & Response from November 2018 until his resignation in February 2023, testified before the U.S. House of Representatives Oversight Committee's Subcommittee on Health Care and Financial Services concerning the infant formula shortage. Mr. Yiannas provided detailed written testimony where he described, among other things, Abbott's culpability and responsibility for not only the infant formula shortage but also for the reported *Cronobacter* infections that caused infant illnesses and deaths in 2022.

304. Mr. Yiannas' testimony directly challenged and classified as "misleading" Abbott's, Defendant Calamari's, and Defendant Ford's repeated assertions made throughout 2022 that the formula made in Sturgis was not the source of the reported infant illnesses: "Abbott Nutrition and some others have suggested that their products were not the source of illnesses, because the genetic strains of *Cronobacter sakazakii* were never found in product, nor in the Sturgis facility. ***This information is misleading***."

305. Mr. Yiannas provided a summary of "a series of facts, regarding the weight of the evidence of the problem at Sturgis that I was considering as we made the decision to request action by Abbott":

1. *Increased Reports of Cronobacter infections over a Short Period Time* - the FDA received 4 reports of confirmed *C. sakazakii* infections in infants over a short period of time, which is unusual, given that it is NOT a reportable illness in most of the U.S. Again, the CDC reports they have historically received 2 to 4 cases reported per year.

2. *Traceback* - all 4 infants that were infected had ingested PIF [Powdered Infant Formula] products manufactured at a single location (AN's Sturgis facility), which is significant. While AN certainly had a large market share, it was only one of 21 formula plants servicing the US market at that time.

3. *Microbiology* - FDA investigators readily found multiple environmental samples positive for *C. sakazakii* in the Sturgis plant in just a two-day period.

4. *Genetic Diversity* - five (5) different strains of *C. sakazakii* were detected using WGS [Whole Genome Sequencing] of isolates found in the environment at the Sturgis facility, indicating contamination with multiple strains could occur.

5. *Lack of Environmental Control* - FDA's subject matter experts, well versed in infant formula production, described environmental conditions at the Sturgis facility as "out-of-control" and a potential source of recontamination.

6. *Old Spray Dryer with Large Cracks* - FDA investigators observed two sprayer dryers, one purchased in the 1960s, with large, unrepaired cracks, potentially serving as harborage points and sources of recontamination. This

same scenario has been documented in the literature to have caused a PIF outbreak.

7. *Known Product Contamination* - FDA investigators learned that AN previously destroyed 2 batches of PIF contaminated with *Cronobacter* produced at Sturgis, even though it is well documented in the literature that low levels of sporadic contamination is unlikely to be detected by PIF sampling plans. Therefore, it is more likely than not that other batches of PIF produced in this plant were likely to have been contaminated with a variety *C. sakazakii* strains, which evaded end-product testing, and were released into commerce.

8. *Lax Standards* - events were recorded such as

   - contract workers moving from the roof to a production line in dirty boots, highlighting yet further avenues of potential contamination in the plant.

   - numerous water events were documented including water leaks, moisture, and condensation in dry powdered infant formula production areas.

   - spray dryer inspections in August 2021 showed six instances of cracks and pits in the main chamber recorded for spray dryer #3 and six instances of cracks, pits, and damage in dryer #4.

9. *PIF as a Vehicle of C. sakazakii* - contamination of PIF with *C. sakazakii* is well documented and has been the cause of small outbreaks and sporadic infections, sometimes with serious sequelae or death.

10. *Low Significance of Lack of WGS Match* - because *C. sakazakii* infections are not reportable in most states, it makes it more difficult to identify and link infections that may appear as sporadic in nature (*i.e.* Listeria). In this incident, four *C. sakazakii* infections were passively reported to FDA. Isolates were available for only two infants for WGS characterization. Having only two of four clinical cases characterized by WGS, and a scarce library of previous sequences, made it more difficult to compare limited infant infections with the multitude of strains (5) recovered from the firm, as well as previous documented human cases.

306. Mr. Yiannas concluded, based on the above evidence, that "Abbott's Sturgis facility lacked adequate controls to prevent the contamination of powdered infant formula with *C. sakazakii*." Moreover, Mr. Yiannas testified that "***[t]here is also evidence that sporadic contamination of finished product actually did occur, and it is likely that other lots of PIF***

produced in this plant were contaminated with multiple C. sakazakii strains over time, which evaded end-product testing, were released into commerce, and consumed by infants." Ultimately, Mr. Yiannas forcefully pushed back against Defendants' narrative that there was no evidentiary link between Abbott's formula and a risk to infants who consumed that formula prior to the recall: "the factors presented above supported a conclusion that PIF made at Abbott's Sturgis plant was produced under insanitary conditions and a likely source of ongoing, sporadic contamination of PIF with multiple strains *C. sakazakii* over time, notwithstanding a lack of a match by WGS between the plant's environment and/or finished product and two clinical isolates."

307. The Subcommittee also heard testimony from Dr. Peter Lurie, the President and Executive Director of the Center for Science in the Public Interest, a 50-year-old advocacy group that acts as an independent watchdog on food and health issues on behalf of US consumers. Dr. Lurie was also a former Associate Commissioner at the FDA who, in that position, worked on drug shortages. Dr. Lurie was clear that Abbott deserved the lion's share of the blame for the crisis:

> If we are to apportion blame for the now-resolving powdered infant formula crisis, we should start at the Abbott Nutrition plant in Sturgis, MI that produced the formula associated with an outbreak tied to four hospitalizations, including two deaths. ***It was there that infant formula contaminated with Cronobacter sakazakii was destroyed years before the outbreak without FDA being notified. It was there that, according to a whistleblower, there were lax cleaning practices, falsified records, and relevant information hidden from FDA inspectors. And it was there that repeated FDA inspections revealed standing water, decaying dryers, failure to follow sanitary practices and, eventually, multiple environmental samples on medium- and high-care areas positive for Cronobacter sakazakii.*** While many questions remain about the outbreak, including how the *Cronobacter* may have entered the product (the outbreak strain was not one of those captured among the environmental strains FDA detected), these conditions, the increasing numbers of cases, and the deadly nature of *Cronobacter* infections left FDA with little choice but to insist that the company recall affected product.

VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS

308. Throughout the Class Period, Defendants Abbott, Ford, Funck, Calamari, and Randall made materially false and misleading statements and omissions concerning: (i) Abbott's compliance with CGMP and record-keeping requirements in the manufacturing and production of its powdered infant formula; (ii) the quality controls and conditions of Abbott's infant formula production facility in Sturgis, Michigan responsible for nearly half of Abbott's U.S. formula production capacity; (iii) the safety of its infant formula; and (iv) the extent of the contamination at Abbott following the February 17, 2022 recall. The following identifies each of Defendants' materially false and misleading statements and the reasons for their falsity. Plaintiffs allege generally that the statements that are ***bolded and italicized*** are materially false and misleading.

A. Defendants' Materially False Or Misleading Statements Published On The Abbott Website Throughout The Class Period

309. Throughout the Class Period, Defendants made public statements on Abbott's official company website promising that Abbott produced only high-quality, safe nutritional products, ensured adherence to strict CGMP regulations, and maintained rigorous quality standards. Abbott, in its March 1, 2021 and March 1, 2022 Annual Reports specifically directed shareholders to Abbott's website for "additional information . . . regarding Abbott's business activities."

310. Each of these statements published on Abbott's website was materially false or misleading because, as discussed above, Abbott's Sturgis facility suffered from long-standing, pervasive, and serious manufacturing, packaging, maintenance, and quality control deficiencies.

311. In reality, by the start of the Class Period, these representations were in direct conflict with information known to Defendants. For example, Defendants were in receipt of the February 2021 Whistleblower Complaint that detailed a series of CGMP and other regulatory violations directly impacting the safety of Abbott's infant formula and the quality of its

manufacturing, testing and cleaning processes, as well as describing a practice of falsifying records and deceiving FDA inspectors during the agency's September 2019 inspection. Moreover, also by the start of the Class Period, Defendants were in receipt of the FDA's 2019 483 Report that found deficiencies in Abbott's infant formula testing processes. In addition, and also by the start of the Class Period, Abbott had positively confirmed the presence of *Cronobacter* in packaged infant formula in September 2019 and June 2020. While those contaminated batches of formula were destroyed, the detection of *Cronobacter* in finished product indicated a far more widespread contamination at the facility, which went uncorrected. As Frank Yiannas, the former FDA Deputy Commissioner, Food Policy & Response, recently testified, it is "documented in the literature that low levels of sporadic contamination is unlikely to be detected by PIF sampling plans. Therefore, it is more likely than not that other batches of PIF produced in this plant were likely to have been contaminated with a variety of [*Cronobacter*] strains, which evaded end-product testing, and were released into commerce." The FDA once again advised Abbott in the agency's September 2021 483 Report that the Company "did not maintain a building used in the manufacturing, processing, packing or holding of infant formula in a clean and sanitary condition." Abbott's deficient quality controls and manufacturing processes had real world consequences and, starting in September 2021, reports of infant illnesses and deaths from *Cronobacter* infections linked to Sturgis were reported to the FDA, totaling 10 by the end of the Class Period.

312. The subsequent FDA inspection, beginning on January 31, 2022, found evidence of *Cronobacter* and severe safety problems. The inspection determined, among other things, that: (i) 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 (ii) Abbott failed to "ensure that all surfaces that contacted infant formula were

maintained to protect infant formula from being contaminated by any source." Ultimately, the United States sought injunctive relief in the DOJ Complaint after concluding that: "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." As FDA Commissioner Califf testified before Congress, conditions at Sturgis were "egregiously unsanitary" and, in direct conflict with Defendants' affirmative statements to the contrary.

313. Throughout the Class Period, Abbott posted a brochure entitled, "Our Global Policy on the Marketing of Infant Formula," available on the "Policies" section of the Company's website. The brochure stated:

- ***At Abbott, we are dedicated to improving healthcare by providing high-quality, safe and effective products.***
- ***This is achieved through a commitment to quality and the continuing effectiveness of our quality management system to meet customer expectations and regulatory requirements.***
- ***We maintain compliance with all laws, rules and regulations in every country in which we operate.***

314. The above statements were materially false or misleading when made. It was false or misleading for Abbott to proclaim that it was "dedicated to improving healthcare by providing high-quality, safe and effective products" and to boast of a "commitment to quality and the continuing effectiveness of our quality management system to meet customer expectations and regulatory requirements," when: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 Report identified deficiencies in Abbott's infant formula

testing process that violated CGMP; iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility; iv) as multiple Former Employees corroborated, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans; v) the FDA's 483 Reports in 2021 and 2022 confirmed severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing procedures) and additional positive *Cronobacter* tests; and vi) by September 2021, accounts of infants who became ill and even died after consuming Abbott formula had been reported. The FDA and DOJ concluded that Defendants were aware of the food safety issues, but were "unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants."

315. It was also materially false or misleading for Abbott to claim it "maintain[ed] compliance with all laws, rules and regulations" applicable to the Sturgis plant when: i) the February 2021 Whistleblower Complaint, corroborated by other Former Employees detailed a series of CGMP and other regulatory violations directly impacting the safety of Abbott's infant formula and the quality of its manufacturing, cleaning, and testing processes; ii) the same complaint, corroborated by multiple Former Employees, detailed a common practice of falsifying records, whether by improperly performing seam tests on empty cans or by signing records that were inaccurate or misleading; iii) the FDA's inspection reports in 2021 and 2022 confirmed

severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing procedures); and iv) the FDA, in its 2019 483 Report, found that Abbott was not testing a representative sample of its infant formula products in accordance with CGMP. The FDA and DOJ have noted that Defendants were aware of the food safety issues at the plant, but were "unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants." Moreover, having made these affirmative statements, Abbott was obligated to disclose the entire truth about those subjects, but it did not.

316. Throughout the Class Period, Defendants also maintained an "Infographic" presentation posted on the "Corporate Newsroom" page on the Company website titled "The Abbott Quality Promise."

317. In "The Abbott Quality Promise," the Company claimed that:

> Good nutrition is the foundation of a happy and healthy life. So, ***from our ingredients to our packaging, our employees are committed to bringing you safe, superior-quality products you can trust.***

318. The above statements were materially false or misleading when made because, as discussed above, it was misleading for Abbott to claim it was "committed" to producing "superior-quality products [consumers] can trust" because Defendants were aware that: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 report identified deficiencies in Abbott's infant formula testing process; iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility; iv) as multiple Former Employees corroborated, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans and a formula line lacking a central vacuum and CIP system that would have made it easier to clean; v) the FDA's inspection reports in 2021 and 2022 confirmed severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing procedures) and additional positive *Cronobacter* tests; and vi) by September 2021, accounts of infants who became ill and even died after consuming Abbott formula had been reported. The FDA and DOJ have noted that Defendants were aware of the food safety issues, but were "unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants."

319. Defendants also touted Abbott's "Advanced Technology" as part of its Abbott Quality Promise:

> Typically found in the pharmaceutical industry, ***our high-tech quality processes ensure safety and quality throughout every stage of the manufacturing process***.

320. This statement was materially false or misleading when made because, in truth, the Sturgis facility was rife with serious, pervasive, persistent quality control deficiencies and had committed numerous and substantial CGMP violations, including a failure to establish process controls to prevent contamination of its infant formula and processing environment. It was materially false or misleading for Abbott to claim to rely on "high-tech quality processes" when, as Former Employees have noted, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans and a formula line lacking a central vacuum and CIP system that would have made it easier to clean. Defendants were aware of these issues, having received reports from employees on site and, in some cases, having visited the plant, but did not make the necessary changes to ensure actual "high-tech quality processes."

321. It was also materially false or misleading for Abbott to claim that its processes "ensure[d] safety and quality throughout every stage of the manufacturing process" when: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 report

identified deficiencies in Abbott's infant formula testing process; iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility; iv) the FDA's inspection reports in 2021 and 2022 confirmed severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing procedures) and additional positive *Cronobacter* tests; and v) by September 2021, accounts of infants who became ill and even died after consuming Abbott formula had been reported.

322. The Abbott Quality Promise also claimed the following:

> **Clean Facilities**
>
> ***Our facilities are designed and maintained to the highest Good Manufacturing Practice standards, which are recognized globally. All employees follow strict hygiene measures, such as wearing specialized uniforms, facemasks and sanitized gloves.***

323. These statements were materially false or misleading when made because, as detailed above, the Sturgis facility was not "designed and maintained to the highest Good Manufacturing Practice standards," but was in fact rife with serious, pervasive, persistent quality control deficiencies and was in violation of numerous and significant CGMP violations. Defendants were aware that: i) the February 2021 Whistleblower Complaint, corroborated by other Former Employees, detailed a series of CGMP and other regulatory violations directly impacting the safety of Abbott's infant formula and the quality of its manufacturing, cleaning, and testing processes; ii) the same complaint, corroborated by multiple Former Employees, detailed a common practice of falsifying records, whether by improperly performing seam tests on empty cans or by signing records that were inaccurate or misleading; iii) the FDA's inspection reports in 2021 and 2022 confirmed severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing

procedures); and iv) the FDA, in its 2019 483 Report, found that Abbott was not testing a representative sample of its infant formula products in accordance with CGMP.

324. It was also materially false or misleading for Abbott to claim that "[a]ll employees follow strict hygiene measures" when, as the FDA found in its 2021 483 Report, "[p]ersonnel working directly with infant formula, its raw materials, packaging, or equipment or utensil contact surfaces did not wash hands thoroughly in a hand washing facility at a suitable temperature after the hands may have become soiled or contaminated." The FDA and DOJ have concluded that Defendants were aware of the food safety issues at the plant, but were "unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants."

325. The Abbott Quality Promise also made the following claims:

> ***Quality Checks***
>
> ***Before releasing products for sale, we extensively test each batch to ensure it meets our quality standards, which are among the highest in the world. And, we ensure that our products comply with all global and local regulations***.

326. These statements were materially false or misleading when made. It was false or misleading for Abbott to claim that it "extensively test[ed] each batch to ensure it meets our quality standards" and "ensure[ed] that [its] products compl[ied] with all global and local regulations" when i) the February 2021 Whistleblower Complaint, corroborated by other Former Employees, detailed a series of CGMP and other regulatory violations directly impacting the safety of Abbott's infant formula and the quality of its manufacturing, cleaning, and testing processes; ii) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 report identified deficiencies in Abbott's infant formula testing process that violated CGMP; iv) in

September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility v) the Whistleblower Complaints, corroborated by multiple Former Employees, detailed a common practice of falsifying records, whether by improperly performing seam tests on empty cans or by signing records that were inaccurate or misleading; vi) the FDA's inspection reports in 2021 and 2022 confirmed severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing procedures); and vii) the FDA, in its 2019 483 Report, found that Abbott was not testing a representative sample of its infant formula products in accordance with CGMP. The FDA and DOJ have concluded that , Defendants were aware of the food safety issues at the plant but were "unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants."

327. Abbott also publishes on its website a "Policy" section, which claims it is designed to allow visitors to "see the policies that guide [Abbott's] business conduct and decisions." The policy website contains a description of Abbott's "Comprehensive Ethics and Compliance Program," which was available to investors during the Class Period. Abbott describes the program as an "integrated, company-wide program that is based on company values, laws and regulations." Abbott also asserts the following in its program description:

> ***Creating an environment where employees can raise questions and concerns*** helps us advance our commitment to ethical behavior. We have ***established systems and processes for employees to ask questions and report suspected or actual violations of our Code, policies and procedures***. . . .
>
> Training and education programs for employees increase their awareness of our Code's precepts and the legal and ethical implications of their actions and behaviors. Abbott ethics and compliance officers work with our local commercial teams throughout the world to help them conduct trainings and education programs that help ***ensure compliance*** and strengthen Abbott's reputation as a responsible corporate citizen while enhancing relationships with customers and other stakeholders.

328. These statements were materially false or misleading when made. Abbott failed to "[c]reate an environment where employees" could speak up about Company practices, "establish[] systems and processes for employees to ask questions and report suspected or actual violations of our Code, policies and procedures," and to "ensure compliance" at the Company. Indeed, Abbott's culture was one dominated by retaliation against employees who spoke up about the Company's business practices, as described in the accounts of the Whistleblower and former employees.

329. Also in the "Policy" section of its website, in its "Other Disclosures," Abbott asserts that it is "fully committed to delivering products with the ***highest standards of quality, safety, and performance***," insisting that "[o]ur quality culture is embedded in everything that we do." This statement was published and available to investors during the Class Period.

330. This statement was materially false or misleading when made. It was misleading for Abbott to claim it delivered the "highest standards of quality, safety, and performance" when Defendants were aware that: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 report identified deficiencies in Abbott's infant formula testing process that violated CGMP; iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility; iv) as multiple Former Employees corroborated, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer

designed for liquid formula that would frequently fail to properly seal the formula in cans; v) the FDA's 483 Reports in 2021 and 2022 confirmed severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing procedures) and additional positive *Cronobacter* tests; and vi) by September 2021, accounts of infants who became ill and even died after consuming Abbott formula had been reported.

B. Pre-Recall Materially False And Misleading Statements In Defendants' Public Filings, Investor Conference Calls, and Interviews

331. In addition to statements appearing on Abbott's official website, during the Class Period, Defendants made materially false or misleading statements in Abbott's public filings and during interviews prior to the Company's February 17, 2022 recall of millions of containers of powdered infant formula. Those materially false or misleading statements concerned, *inter alia*, Abbott's compliance with federal and state health and safety regulations, the condition of the Company's manufacturing facilities, specifically the Sturgis facility, and the safety of Abbott's powdered infant formula.

332. On the first day of the Class Period, February 19, 2021, the Company filed with the SEC its annual report on Form 10-K, signed by Defendants Ford and Funck, for the period ended December 31, 2020 (the "2020 Form 10-K"). In the 2020 Form 10-K, Abbott stated that "***Abbott's facilities are deemed suitable*** and provide adequate productive capacity."

333. The Company's statement above that its "facilities are deemed suitable" was materially false or misleading when made because the Sturgis facility was not "suitable" for the production of powdered infant formula. As the February 2021 Whistleblower Complaint detailed, Abbott endeavored to mislead the FDA during the agency's 2019 inspection of the Sturgis facility. Despite these efforts, the agency identified serious issues during that inspection in its 2019 483

Report. In particular, the FDA highlighted that Abbott "did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards." Defendants were also aware that: i) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility; ii) as multiple Former Employees corroborated, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans; and (iii) Sturgis experienced the repeated presence of standing water throughout the facility, a clear, known contamination risk that was reported by FE1 and, as later revealed by the FDA in its 2022 483 Report, water events were reported internally in 310 separate incident reports between January 1, 2020 and February 1, 2022.

334. In its 2020 Form 10-K, Abbott reported:

> ***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.

335. Defendants' statements in the immediately preceding paragraph were materially false or misleading when made. While Defendants acknowledged compliance risks associated with the extensive regulations to which the Company was subject, Defendants did not disclose then-known material risks or that the risks had already transpired. For example, Defendants did not disclose that, at the time of this SEC filing, the Sturgis facility suffered from long-standing, pervasive, and serious manufacturing, maintenance, and quality control deficiencies, including, *inter alia*, the use of failing equipment and the release of formula that was potentially contaminated. For example, as Former Employees have noted, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans and a formula line lacking a central vacuum and CIP system that would have made it easier to clean. As the FDA noted following the agency's 2019 inspection of Sturgis, Abbott, among other deficiencies, "did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards." Defendants were also aware that: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch

tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 report identified deficiencies in Abbott's infant formula testing process; and iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility.

336. Attached to the 2020 Form 10-K were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), signed by Defendants Ford and Funck attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting, and the disclosure of all fraud, stating that:

> I, Robert B. Ford [/Robert E. Funck], certify that:
>
> 1. I have reviewed this annual report on Form 10-K of Abbott Laboratories;
>
> 2. ***Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report***;
>
> …
>
> 4. Abbott's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for Abbott and have:
>
> (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to Abbott, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
>
> …
>
> 5. Abbott's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to Abbott's auditors and the audit committee of Abbott's board of directors:
>
> (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely

> affect Abbott's ability to record, process, summarize and report financial information; and
>
> (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in Abbott's internal control over financial reporting.

337. Defendants' statements in the above-referenced SOX certifications were materially false or misleading when made. Contrary to the representations that the Form 10-K did "not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made . . . not misleading," that SEC filing represented, *inter alia*, that the Company's manufacturing facilities were "deemed suitable." In fact, as detailed above, by at least February 2021, the certifying Defendants were aware that the Company's Sturgis facility suffered from long-standing, persistent, serious, and pervasive manufacturing, maintenance, and quality control deficiencies, including, but not limited to, the use of failing equipment, the persistent existence of standing water throughout the facility, and the release of infant formula that was potentially contaminated.

338. The same or substantially similar language appeared in every subsequent Form 10-Q filed by Defendants during the Class Period and prior to the recall, namely the Company's Forms 10-Q filed by Defendants on May 5, 2021, August 4, 2021, and November 3, 2021. For the reasons identified in § IV.C above, each of these Class Period SOX Certifications were materially false or misleading.

339. On July 16, 2021, Abbott issued its 2020 Global Sustainability Report, the Company's annual "ESG" report targeted at Abbott's investors (the "July 16, 2021 Global Sustainability Report").[12] In the report, Defendant Ford addressed a letter to Abbott's shareholders

[12] According to a PwC paper on environmental, social, and governance strategies, published on the auditor's website, "[a]n ESG report or Sustainability report is a report published by a company or organization about environmental, social and governance (ESG) impacts. It enables the

expressing the Company's continued commitment to "helping people live healthier, fuller lives." Defendant Ford stated:

> Sustainability is the fundamental challenge of our time. And it grows continually more pressing, as the last year has demonstrated in so many ways. This is exactly the kind of challenge Abbott is built to address. Because thinking and acting for sustainability is inherent to our culture. ***And it's a natural extension of our purpose—helping people live healthier, fuller lives. We pursue this mission very deliberately through our business strategies and processes. Abbott always takes the long view.*** We've succeeded for more than 130 years because we work at it. And we bring that same orientation—purpose-driven and achievement-focused—to our efforts to sustain not just our company, but our communities and the world around us.

340. Defendant Ford's statements were materially false or misleading because Sturgis was rife with serious, pervasive, persistent quality control deficiencies and was in violation of numerous and significant CGMP violations. Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans and a formula line lacking a central vacuum and CIP system that would have made it easier to clean. As the FDA noted following the agency's 2019 inspection of the Sturgis facility, Abbott, among other deficiencies, "did not test a representative sample of a production aggregate of a powdered infant

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company to be more transparent about the risks and opportunities it faces. It is a communication tool that plays an important role in convincing skeptical observers that the company's actions are sincere." Further, "[t]he growing importance of Sustainability reports is supported by the fact that the investors and other stakeholders are calling on companies to disclose more about their sustainability and environmental, social and governance strategies." *See https://www.pwc.com/sk/en/environmental-social-and-corporate-governance-esg/esg-reporting.html*

formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards." Defendants were also aware that i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 report identified deficiencies in Abbott's infant formula testing process; and iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility.

341. In the July 16, 2021 Global Sustainability Report, Abbott also made affirmative representations about the safety of its manufacturing process for infant formula:

> ***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.***

342. Abbott's statements were materially false or misleading because the Company was ***not*** "ensur[ing] food safety through a tightly controlled manufacturing process" because the Company's Sturgis facility – which manufactured a significant portion of the relevant baby formula – suffered from severe, widespread product safety deficiencies and had violated applicable regulatory requirements. For example, Sturgis experienced the repeated presence of standing water throughout the facility, a clear, known contamination risk that was reported by FE1 and, as later revealed by the FDA in its 2022 483 Report, water events were reported internally in 310 separate incident reports between January 1, 2020 and February 1, 2022. In addition, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on

older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans and a formula line lacking a central vacuum and CIP system that would have made it easier to clean. As the FDA noted following the agency's 2019 inspection of the Sturgis facility, Abbott, among other deficiencies, "did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards." Defendants were also aware that: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 Report identified deficiencies in Abbott's infant formula testing process; and iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility.

343. In the July 16, 2021 Global Sustainability Report, Abbott made further misrepresentations about the safety of its manufacturing process for infant formula, stating in pertinent part:

a) ***Our purpose of enabling fuller lives through the power of health depends on trust, and trust in Abbott depends on our ability to consistently deliver safe, effective and high-quality products.***

b) "We map our critical outputs . . . monitor quality throughout the full product life cycle. When developing new products, we conduct rigorous product-safety tests that are tailored to the product requirements."

c) "We have developed a multicomponent model and proprietary metrics to track the quality-system performance of our businesses and individual manufacturing sites. We review our model and metrics at least annually to ensure that they ***continue to assess relevant quality and compliance risks***."

d) "When we identify a change in performance at a site or a business, we analyze the causes of the change, ***take action when required***, and capture best practices and key learnings to apply elsewhere in our organization."

e) "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."

344. Abbott's statements were materially false or misleading when made. Defendants were aware that: i) the February 2021 Whistleblower Complaint reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the February 2021 Whistleblower Complaint, corroborated by other Former Employees detailed a series of CGMP and other regulatory violations directly impacting the safety of Abbott's infant formula and the quality of its manufacturing, cleaning, and testing processes; iii) the same complaint, corroborated by multiple Former Employees, detailed a common practice of falsifying records, whether by improperly performing seam tests on empty cans or by signing records that were inaccurate or misleading; and iv) the FDA, in its 2019 483 Report, found that Abbott was not testing a representative sample of its infant formula products in accordance with CGMP. Defendants' disregard of, and attempt to conceal, lapses in safety protocols throughout the Class Period refute any claims that the Company "continue[s] to assess relevant quality and compliance risks" and that "[w]hen we identify a change in performance at a site . . . we analyze the causes of the change, take action when required." Having affirmatively touted its internal procedures to address issues that arise during the manufacturing process, including its internal quality audits, Abbott was obligated to tell the entire truth.

345. In its July 16, 2021 Global Sustainability Report, Abbott further asserted that it "***monitor[s] and verif[ies] microbiology, packaging integrity, and nutrient and lot control,***" and that it "***complete[s] extensive finished product testing before releasing it for commercial distribution***." The 2020 Global Sustainability Report also claims that ***"[e]very Abbott nutrition manufacturing operation is certified to local and globally recognized GMP and food safety standards***."

346. These statements were materially false or misleading when made. It was misleading for Abbott to tell investors that it "monitor[ed] and verif[ies] microbiology, product integrity, and nutrient and lot control" or that it "complete[d] extensive finished product testing before releasing it for commercial distribution." Rather, as Defendants were aware: i) the February 2021 Whistleblower Complaint reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the February 2021 Whistleblower Complaint, corroborated by other Former Employees detailed a series of CGMP and other regulatory violations directly impacting the safety of Abbott's infant formula and the quality of its manufacturing, cleaning, and testing processes; iii) the same complaint, corroborated by multiple Former Employees, detailed a common practice of falsifying records, whether by improperly performing seam tests on empty cans or by signing records that were inaccurate or misleading; and iv) the FDA, in its 2019 483 Report, found that Abbott was not testing a representative sample of its infant formula products in accordance with CGMP. The FDA and DOJ have noted that Defendants were aware of the food safety issues at the plant, but were "unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants."

347. The July 16, 2021 Global Sustainability Report directly addressed the Company's "Transparency on Nutrition:"

> Our nutrition business is dedicated to developing science-based nutrition products for people of all ages. ***We are committed to marketing these products ethically and ensuring that our practices comply with all local laws and regulations***. ***We have well-established systems for ensuring that conduct at every level of the business conforms to our Global Infant Formula Marketing Policy, as well as the laws of the countries in which we operate***.

348. These statements were materially false or misleading when made. It was false or misleading for Abbott to claim that it "market[ed]" its formula "ethically" or "ensur[ed] that [Abbott's] practices comply with all local laws and regulations," or that Abbott had "well-established systems for ensuring that conduct at every level of the business conforms to our Global Infant Formula Marketing Policy. In reality, Defendants disregarded and concealed serious lapses in infant formula safety protocols at the Sturgis facility throughout the Class Period, including that: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 Report identified deficiencies in Abbott's infant formula testing process that violated CGMP; iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility; iv) as multiple Former Employees corroborated, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans; and (v) Sturgis experienced the repeated

presence of standing water throughout the facility, a clear, known contamination risk that was reported by FE1 and, as later revealed by the FDA in its 2022 483 Report, water events were reported internally in 310 separate incident reports between January 1, 2020 and February 1, 2022. Moreover, having made these affirmative statements, Abbott was obligated to disclose the entire truth about those subjects, but it did not.

349. The July 16, 2021 Global Sustainability Report also touted the Company's Code of Business Conduct and its strict compliance procedures encouraging employees to "report any concerns" by stating that "***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***." The Company also stressed that it did not tolerate any retaliation:

> ***Process for Reporting Concerns***
>
> ***Our Code of Business Conduct emphasizes our employees' responsibility to report concerns. This requires us to create an environment where they can do so in good faith, without fear of retaliation.*** The code outlines Abbott's responsibilities for handling employee grievances and complaints in an ethical way, and it strictly forbids any retaliation against any person who raises a complaint.
>
> We have clearly defined systems and processes for asking questions and reporting suspected or actual violations of our code, policies or procedures. These include our Speak Up tool, which allows employees and external parties to raise concerns of potential misconduct in a manner that is confidential and (where permitted) anonymous, either by email, by telephone or through a website.
>
> The Ethics and Compliance Officer for Investigations enters every report that is received into the investigations database or delegates somebody else to do so. This person assigns an investigator from the appropriate function to gather evidence so that the OEC can determine if action is required. We aim to conduct investigations as quickly as possible without compromising thoroughness and integrity, and we carry out periodic audits of the investigations process.

350. These statements were materially false or misleading when made. It was false or misleading for Abbott to claim that it "does not tolerate illegal or unethical behavior in any aspect of our business," that "employees are required to ask questions and/or report any concerns," that

Abbott "emphasize[d its] employees' responsibility to report concerns," or that Abbott "create[d] an environment where they can do so in good faith, without fear of retaliation." In reality, the Company consistently ignored employee complaints about the unsafe conditions at its Sturgis facility, and even retaliated against those individuals who tried to report concerns, such as the Whistleblower.

351. The Company's Code of Business Conduct was in effect at the Company throughout the Class Period. Defendant Ford signed the Code, and it was publicly available on the Company's website during the Class Period. The Code contained a subsection addressing "Product Quality," which provided:

> ***We produce and deliver safe, effective products that people trust.***
>
> We endeavor to maintain the highest level of quality throughout our business. This effort starts with the sourcing of materials and the manufacture of our products and moves through how we market, sell, and supply our products, including through our business partners – delivering high quality is imperative every step of the way.
>
> ***Our commitment to the health and safety of the people who use our products is always at the forefront of everything we do.***
>
> ***We are committed to timely identifying, evaluating, and addressing product safety issues.*** We . . . communicate with regulatory or public health agencies in the event of potential safety concerns.
>
> . . . ***We adhere to all laws, regulations and Abbott requirements that apply to our work. Every Abbott employee is expected to adhere to all laws and Abbott's policies, procedures, principles and standards, including this Code.*** This is a fundamental expectation and condition of employment. Abbott's policies and procedures cover topics related to important aspects of our operations, including health care compliance, quality, engineering, customs and trade, finance, security, purchasing, human resources, and information systems, to help ensure that we comply with the many laws and regulations governing our business.

352. The foregoing representations are actionable misstatements. They were not merely aspirational statements about what the Company should do, but rather were concrete statements about what Abbott did do. And these representations were materially false or misleading when

made because Abbott did not "timely" address product safety issues after becoming aware of the Whistleblower Complaint in February 2021, nor did the Company "timely" act following its receipt of the poor inspection report from the FDA in September 2021. In addition, it was materially false or misleading for Abbott to claim that it "produce[d] and deliver[ed] safe, effective products that people trust," that its "commitment to the health and safety of the people who use [Abbott's] products is always at the forefront of everything [Abbott does]," and that Abbott was "committed to timely identifying, evaluating, and addressing product safety issues." In reality, Defendants were aware that: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 Report identified deficiencies in Abbott's infant formula testing process that violated CGMP; iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility; iv) as multiple Former Employees corroborated, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans; v) the FDA's inspection reports in 2021 and 2022 confirmed severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing procedures) and additional positive *Cronobacter* tests; (vi) Sturgis experienced the repeated presence of standing water throughout the facility, a clear, known

contamination risk that was reported by FE1 and, as later revealed by the FDA in its 2022 483 Report, water events were reported internally in 310 separate incident reports between January 1, 2020 and February 1, 2022; and vii) by September 2021, accounts of infants who became ill and even died after consuming Abbott formula had been reported. Moreover, it was misleading for Abbott to claim it "adhere[d] to all laws, regulations and Abbott requirements that apply to our work," when in reality: i) the February 2021 Whistleblower Complaint, corroborated by other Former Employees detailed a series of CGMP and other regulatory violations directly impacting the safety of Abbott's infant formula and the quality of its manufacturing, cleaning, and testing processes; ii) the same complaint, corroborated by multiple Former Employees, detailed a common practice of falsifying records, whether by improperly performing seam tests on empty cans or by signing records that were inaccurate or misleading; iii) the FDA's 483 Reports in 2021 and 2022 confirmed severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing procedures); and iv) the FDA, in its 2019 483 Report, found that Abbott was not testing a representative sample of its infant formula products in accordance with CGMP. The FDA and DOJ have noted that Defendants were aware of the food safety issues at the plant, but were "unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants."

353. On November 15, 2021, Abbott released its "2020 Sustainability Report Summary." In that report, which was available on the Company's official website, Abbott made similar representations about the safety of its manufacturing process for infant formula as it did in its July 16, 2021 Global Sustainability Report, stating in pertinent part:

a) ***Our purpose of enabling fuller lives through the power of health depends on trust, and trust in Abbott depends on our ability to consistently deliver safe, effective and high-quality products.***

b) "We map our critical outputs . . . monitor quality throughout the full product life cycle. When developing new products, we conduct rigorous product-safety tests that are tailored to the product requirements."

c) "We have developed a multicomponent model and proprietary metrics to track the quality-system performance of our businesses and individual manufacturing sites. We review our model and metrics at least annually to ensure that they ***continue to assess relevant quality and compliance risks***."

d) "When we identify a change in performance at a site or a business, we analyze the causes of the change, ***take action when required***, and capture best practices and key learnings to apply elsewhere in our organization."

e) "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."

354. Abbott's statements were materially false or misleading when made. Company employees falsified testing records and released untested infant formula to the market, practices that were known by Defendants as early as February of 2021. Defendants' disregard of, and attempt to conceal, lapses in safety protocols throughout the Class Period refute any claim that "[w]hen we identify a change in performance at a site . . . we analyze the causes of the change, take action when required." Having affirmatively touted its internal procedures to address issues that arise during the manufacturing process, Abbott was obligated to tell the entire truth. But Abbott failed to disclose it had received complaints of infants becoming ill after consuming infant formula manufactured by the Company. Abbott also knew (and failed to disclose) that safety and regulatory violations were rampant at its Sturgis facility and that the FDA was returning to investigate during a special audit.

355. On December 13, 2021, Defendant Randall was featured in a *Quality Assurance and Food Safety Magazine* article titled *Life Lessons with Lori Randall*. In that piece, Randall explained that Abbott's purported commitment to consumers "really drove me to understand what it means to protect the people who use our products," and "I found a sense of quality stewardship that kept me going even as a packaging engineer. I'm thankful for that experience because it really helped me understand — being outside of quality at the time — that ***food safety and quality are everyone's responsibilities***." Defendant Randall further stated:

> ***We're customer centric. It's about the new mom or the caretaker or someone in the hospital using our products.***
>
> We talk a lot about why our work matters and how, at Abbott, ***we protect our product through the actions and the behaviors. It's very easy to put the customer first and see that face of the customer when you're thinking about food safety***.
>
> That makes our supply network and operations more resilient and sustainable. It's something that we are very focused on within the organization — making certain that ***we're taking best practices and sharing them across the globe***.
>
> ***The goal is to have everyone be an advocate for food safety***, no matter their role. We do that through ***recognition of every employee who advocates for food safety or makes improvements that then leads to an improvement in food safety***.
>
> You don't have to be the one with the title or, as we say, the one carrying the megaphone. It's the ***daily actions and the confidence in knowing that it's okay to speak up and say something***.
>
> ***That's been hugely beneficial from a food safety viewpoint.***

356. Defendant Randall's statements were materially false or misleading because they claimed that Abbott was "customer centric," employed "best practices" at its various manufacturing facilities, and "protect[ed] our product through the[actions and the behaviors" and "put the customer first." But, as discussed in § IV.C., Abbott did not employ "best practices," specifically at Sturgis, which Defendant Randall was responsible for overseeing as Abbott Nutrition's Division Vice-President of Quality Assurance. To the contrary, the Sturgis facility

suffered from long-standing, persistent, serious, and pervasive manufacturing, maintenance, and quality control deficiencies, including, but not limited to, the use of failing equipment, the presence of pervasive standing water, the falsification of safety records, and the release of likely contaminated infant formula. Moreover, the Company did not recognize "every employee who advocate[d] for food safety," as Defendant Randall claimed. Rather, Abbott ignored employee complaints about the unsafe conditions at its Sturgis facility, and retaliated against those individuals who tried to report concerns, such as the Whistleblower.

357. On January 11, 2022, Defendant Ford attended J.P. Morgan's 40th Annual Healthcare Conference. At the conference, in response to an analyst's question about Abbott's diversified portfolio and performance of its business lines, Defendant Ford touted Abbott's "best-in-class performance" and that the Company "[is] in great shape" with its current businesses, including nutrition, stating in pertinent part:

> We've always talked about different opportunities for growth and resilience and tough times and never really had a tough time to prove it out, and now we proved it out. I think if you're in the right diversify for just being diversified, I mean you got to be in the right segments. And I think that we've intentionally looked at the segments that we want to be as a healthcare company, whether it's cardiovascular, whether it's nutrition, whether it's emerging markets, diagnostics, these are all kind of high growth areas, important medical needs.
>
> ***And then the question becomes, are you performing at a best-in-class performance? And I would say, if you look at 2021 across every one of our businesses, we either grew markets or we took share, we performed above market. So, I like the businesses that Abbott is involved in***. I like the innovation and the pipeline that exists behind them. ***And I like the performance of the team and the execution that we've been able to do***.
>
> Now we've got to keep added [sic]. new year, 2021 done. So, we'll focus on that. But ***I think we are in a great shape with the businesses that we have.***

358. Defendants Ford's statements were materially false or misleading when made. In particular, Abbott's performance concerning its powdered infant formula lines were "not "best-in class" (as stated by Defendant Ford). Nor was Abbott's powdered infant formula business "in great

shape." In fact, Abbott's Sturgis facility, which played a significant role *vis-à-vis* the Company's infant formula business suffered from long-standing, pervasive, and serious manufacturing, maintenance, and quality control deficiencies. Defendants were aware that: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 Report identified deficiencies in Abbott's infant formula testing process that violated CGMP; iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility; iv) as multiple Former Employees corroborated, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans; v) the FDA's inspection report in 2021 confirmed severe safety violations at the facility (such as the repeated presence of standing water that was also reported by FE1 and workers failing to practice proper handwashing procedures) and additional positive *Cronobacter* tests; and vi) by September 2021, accounts of infants who became ill and even died after consuming Abbott formula had been reported.

C. Post-Recall Materially False And Misleading Statements In Public Filings, Investor Conference Calls, And Interviews

359. Beginning on February 17, 2022, when the recall was first announced, and afterwards, Defendants continued to make numerous materially false or misleading statements in public filings, on calls with investors and securities analysts, and during interviews. These

statements addressed Abbott's compliance with federal and state health and safety regulations, the condition of its manufacturing facilities, specifically the Sturgis facility, the safety of its powdered infant formula lines, and the extent of the contamination at the Sturgis facility identified by the FDA.

360. On February 17, 2022, Abbott issued a press release (the "February 17, 2022 Press Release") announcing the recall of its powdered infant formula. In the press release, Abbott stated:

> ***[Abbott] is initiating a proactive, voluntary recall of powder formulas***, including Similac, Alimentum and EleCare manufactured in Sturgis, Mich., one of the company's manufacturing facilities . . .
>
> ***During testing in our Sturgis, Mich., facility, we found evidence of Cronobacter sakazakii in the plant in non-product contact areas.***
>
> ***Importantly, no distributed product has tested positive for the presence of either of these bacteria, and we continue to test. Abbott conducts extensive quality checks on each completed batch of infant formula, including microbiological analysis prior to release***. All finished products are tested for *Cronobacter* sakazakii, *Salmonella* Newport and other pathogens and they must test negative before any product is released. Additionally, retained samples related to the three complaints for *Cronobacter* sakazakii tested negative for *Cronobacter* sakazakii. . . . ***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.

361. Defendants' statements were materially false or misleading when made. Having disclosed these facts, Abbott was obliged not to omit facts that would make their statements misleading to a reasonable investor. However, the Company failed to disclose that the FDA demanded the recall days earlier and that the FDA investigation preceded the "proactive, voluntary recall of powder formulas." Furthermore, Defendants' statement that *Cronobacter* was found only "***in non-product contact areas***" was materially false or misleading when made because the FDA inspection report dated March 18, 2022, and released publicly on March 22, 2022, revealed that *Cronobacter* was detected on a "scoop hopper" that was "utilized to feed scoops, ***which are placed directly inside infant formula containers that contact product***." Furthermore, Defendants'

statements that "no distributed product has tested positive for the presence of either of these bacteria" and that Abbott "conducts extensive quality checks on each completed batch of infant formula, including microbiological analysis prior to release" were also materially false or misleading because Abbott did not test retained samples when the Company investigated a complaint of an infant death from *Cronobacter*, which the Company failed to disclose in its press release. Finally, the foregoing statements failed to disclose that the Company had been aware of significant, pervasive, and dangerous issues existing at the Sturgis facility for at least one year prior to the recall, that the FDA had demanded the recall days earlier, and that the FDA investigation of Sturgis had preceded the "voluntary" and "proactive" recall. Moreover, as former FDA Deputy Commissioner Yiannas testified on March 28, 2023, Abbott's statements were "misleading" because "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."

362. On February 18, 2022, Abbott filed a Form 10-K with the SEC for the year ending December 21, 2021 (the "2021 Form 10-K"). In the 2021 Form 10-K, Abbott again stated that "***Abbott's facilities are deemed suitable*** and provide adequate productive capacity."

363. The Company's statement above that its "facilities are deemed suitable" was materially false or misleading when made because the Sturgis facility was not "suitable" for the production of powdered infant formula Not only had Abbott endeavored to mislead the FDA during the agency's 2019 inspection of the Sturgis facility, the agency identified pervasive and serious issues during that inspection. In particular, the FDA highlighted that Abbott "did not test a representative sample of a production aggregate of a powdered infant formula at the final product

stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards." Apart from the foregoing, the FDA also issued a five-item Form 483 concerning the Company's Sturgis facility in September 2021. In particular, the agency highlighted that Abbott failed to establish process controls to prevent contamination of its infant formula and processing environment. It was also misleading for Abbott to represent that its facilities were "deemed suitable" when i) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility; ii) as multiple Former Employees corroborated, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans; and iii) Sturgis experienced the repeated presence of standing water throughout the facility, a clear, known contamination risk that was corroborated by FE1 and, as later revealed by the FDA, this and similar water events were reported internally in 310 separate incident reports.

364. In its 2021 Form 10-K, Abbott also addressed the Company's need to comply with FDA regulations governing the manufacturing of infant formula, stating:

> ***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, diagnostic product, or nutritional 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.

365. Defendants' statements set forth above were materially false or misleading when made. While Defendants acknowledged compliance risks associated with the extensive regulations to which the Company was subject, Defendants did not disclose then known material risks or that the risks being warned of had already transpired. By this time, the recall already had been initiated. Yet, Defendants did not address the significance of that action and the underlying causes at all in this disclosure. For example, as Former Employees have noted, Abbott cut costs by not hiring a sufficient number of on-site workers, leading to tasks such as the cleaning of electrical boxes in "high care areas" on Lines 1, 3, 4, and 5 to be neglected or to crucial cleaning and quality checks being performed by overworked and undertrained employees, and by continuing to rely on older, outdated, and otherwise inadequate equipment, such as a powdered formula line with a seamer designed for liquid formula that would frequently fail to properly seal the formula in cans and a formula line lacking a central vacuum and CIP system that would have made it easier to clean. As the FDA noted following the agency's 2019 inspection of the Sturgis facility, Abbott, among other deficiencies, "did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards." Defendants were also aware that: i) as the Whistleblower reported, prior to the FDA's September 2019 audit several samples of an infant

formula batch tested positive for micros, but instead of destroying the entire batch Abbott released portions of the batch to the public and hid this fact from the FDA; ii) the FDA's 2019 483 Report identified deficiencies in Abbott's infant formula testing process; and iii) in September 2019 and June 2020, Abbott confirmed the presence of *Cronobacter* in packaged infant formula, indicating wider contamination at the facility.

366. Attached to the 2021 Form 10-K were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX"), signed by Defendants Ford and Funck attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting, and the disclosure of all fraud, stating that:

> I, Robert B. Ford [/Robert E. Funck], certify that:
>
> 1. I have reviewed this annual report on Form 10-K of Abbott Laboratories;
>
> 2. ***Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report***;
>
> …
>
> 4. Abbott's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for Abbott and have:
>
> (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to Abbott, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
>
> …
>
> 5. Abbott's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to Abbott's auditors and the audit committee of Abbott's board of directors:
>
> (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely

> affect Abbott's ability to record, process, summarize and report financial information; and
>
> (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in Abbott's internal control over financial reporting.

367. Defendants' statements in the above-referenced SOX certifications were materially false or misleading when made. Contrary to the representations that the Form 10-K did "not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made . . . not misleading," that SEC filing represented, *inter alia*, that the Company's manufacturing facilities were "deemed suitable." In fact, by at least February 2021, the certifying Defendants were aware that the Company's Sturgis facility suffered from long-standing, persistent, serious, and pervasive manufacturing, maintenance, and quality control deficiencies, including, but not limited to, the use of failing equipment and the release of infant formula that was potentially contaminated.

368. The same or substantially similar language appeared in every subsequent Form 10-Q filed by Defendants during the Class Period, namely the Company's Forms 10-Q filed on May 3, 2022 and August 2, 2022. For the reasons identified in paragraph 367 above, each of Defendants' Class Period SOX Certifications were materially false or misleading.

369. Also on February 18, 2022, the Company filed a Form 8-K with the SEC, signed by Defendant Funck. In that filing, the Company reported on its purported "proactive, voluntary recall" that was announced the day before, stating:

> ***On February 17, 2022, Abbott initiated a proactive, voluntary recall of Similac-brand powder infant formulas manufactured in Sturgis, Michigan***. The recall primarily involves product distributed in the U.S. and Canada. Abbott is confirming its previously issued full-year 2022 guidance for adjusted diluted earnings per share from continuing operations of at least $4.70. Abbott will incur a one-time specified item in the first quarter 2022 for recall related expenses, including inventory destruction and other recall expenses. These expenses have not yet been quantified.

> However, Abbott does not expect that these expenses will have a material impact on Abbott's consolidated financial statements.

370. The Defendants' statements in this Form 8-K that "Abbott initiated a proactive, voluntary recall" were materially false or misleading when made. Having disclosed the facts described in the 8-K, Abbott was obliged not to omit facts that would make their statements misleading to a reasonable investor. Not only did the Company continue to conceal the "egregiously unsanitary" and dangerous conditions at Sturgis that had existed for several years, the Defendants also failed to disclose that the Company had been aware of these significant, pervasive, and dangerous issues at least one year prior to the recall, that the FDA had demanded the recall days earlier, and that the FDA investigation of Sturgis had preceded the "voluntary" and "proactive" recall. Moreover, the Company's reiteration of its full-year 2022 EPS guidance and its statement that "Abbott does not expect that these expenses will have a material impact on Abbott's consolidated financial statements" were materially misleading when made. Having reaffirmed its EPS guidance and stated that the recall would not have a "material impact" on the Company's financial statements, Defendants had an obligation to disclose the numerous regulatory violations of the Company at the Sturgis facility, of which Defendants were well aware, for at least one year prior to the recall.

371. On March 22, 2022, Abbott issued an update on its official company website regarding its nationwide infant formula recall, stating:

> Abbott is committed to upholding the highest standards for manufacturing of all nutrition products. We have already begun implementing corrective actions and enhancements at the facility, leveraging new technology and strengthening our processes, to give parents and customers renewed confidence in the quality of manufacturing at our Sturgis plant when we restart operations there. Our actions include . . . [i]ncreasing our finished product testing, which already meets or exceeds regulatory requirements.

372. In that same update, the Company stated: "While there are actions we need to take to address the FDA observations, it is important to note that ***no Cronobacter sakazakii or Salmonella was found in any of our testing of products distributed to consumers.*** Additionally, the unique genetic makeup of the *Cronobacter sakazakii* microbes ***found in non-product contact areas at the Sturgis facility did not match the Cronobacter sakazakii microbes from the reported cases***."

373. Defendants' statements in paragraphs 371-72 were materially false or misleading when made. Defendants touted that "no *Cronobacter* . . . was found in any of [their] testing of products distributed to consumers" and how their "finished product testing . . . meets or exceeds regulatory requirements," while failing to disclose the serious shortcomings that existed in the Company's testing protocols. By no later than the end of February 2021, Abbott was aware of the Whistleblower's reports of the plant officials knowingly falsifying testing records, the release of untested infant formula to the market, and deficient testing procedures. Additionally, during its 2019 inspection, the FDA highlighted that Abbott "did not test a representative sample of a production aggregate of a powdered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards." Finally, Abbott's statement that "the unique genetic makeup of the *Cronobacter sakazakii* microbes found in ***non-product*** contact areas at the Sturgis facility did not match the *Cronobacter sakazakii* microbes" was materially false or misleading when made. In fact, the FDA found *Cronobacter* in product contact areas at Sturgis during its 2022 investigation, , and the FDA's former Deputy Commissioner for Food Policy & Response testified before Congress in March 2023 that Abbott's claims were "misleading," concluding that the Sturgis facility was "a

likely source of ongoing, sporadic contamination of PIF with multiple strains [of] *C. sakazakii* over time".

374. On May 25, 2022, Defendant Calamari, Abbott's President of Nutrition North America and Senior Vice President of U.S. Nutrition, testified before the United States Congressional House Oversight and Investigations Subcommittee. In the testimony he offered to Congress, Calamari made multiple materially false or misleading statements regarding the Company's knowledge of the alarming safety concerns expressed by the Whistleblower, stating in relevant part:

- "We [Abbott] became ***aware of the whistleblower complaint in the end of April, when it was made public by Congress. . . . I became aware of it in the April timeframe, when it was made public by Congress."***
- ***"Abbott did not find out about it [the whistleblower complaint] until . . . it was made public in the end of April."***
- ***"We encourage employees to speak up, and we -- and safety and compliance is a top priority."***
- ***"We encourage [employees to speak up] by reinforcing that their voice counts, that we have a zero tolerance policy for retaliation against these types of complaints. And that is our commitment to support those employees to speak up."***
- ***"[T]he Abbott I know prioritizes compliance. It encourages employees to speak up."***
- ***"[T]he whistleblower allegations, we don't know them to be true***. That is an open investigation, and it is ongoing. . . . ***And the whistleblower allegations, again, have not been proven to be true, and that is an ongoing investigation that is very much being done independently.***"
- "***Specific to the whistleblower, though, we do not know those allegations to be true. . . . The Abbott I know encourages compliance, and encourages employees to speak up***."
- "***We're going to reinforce that we are a culture where we support employees to raise concerns if they see them***."

375. During Calamari's questioning, Representative Kathleen Rice asked Defendant Calamari why the Whistleblower did not report his concerns to Abbott before October 2021: "[I]f you have what you're describing as a specific program to allow employees to go directly to someone within the company to register an issue with something that's going on in any one of your facilities, why didn't that happen here?" Defendant Calamari responded that Abbott did not learn of the Whistleblower's complaints until April 2022 and, further, blamed the Whistleblower for not bringing his concerns to Abbott's attention, in part: "Abbott did not find out about it until . . . it [the whistleblower complaint] was made public [at] the end of April. And it was the--the particular individual who raised the complaint, it was their choice to use that mechanism to raise the complaint."

376. The foregoing statements in paragraphs 374-75, made by Defendant Calamari during the May 25, 2022 Congressional hearing were materially false or misleading when made. As was revealed just two weeks later, the Whistleblower had filed a complaint with OSHA under FSMA's whistleblower protections on February 16, 2021. The February 2021 Whistleblower Complaint contained the same complaints as those made in the October 2021 Whistleblower Complaint. As discussed above, the February 2021 Whistleblower Complaint was sent to Abbott by OSHA, was responded to by Abbott by April 2021, and an investigation by Abbott and OSHA followed. Defendant Calamari's attempts to impugn the Whistleblower's credibility and cast doubt as to why the Whistleblower did not bring his concerns directly to Abbott were false or misleading because the Whistleblower had brought those concerns directly to Abbott's attention, both during his employment in 2019 and 2020, and formally thorough the February 2021 Whistleblower Complaint. Additionally, Defendant Calamari's statements that Abbott "encourages compliance," that the Company had "a zero tolerance policy for retaliation against these types of complaints"

and further "encourages employees to speak up" were materially false or misleading because the Company (a) blatantly disregarded, and attempted to conceal, lapses in safety protocols throughout the Class Period that were linked to serious infant illnesses and even deaths, and (b) retaliated against those individuals who tried to report concerns, such as the Whistleblower.

D. Abbott's Class Period SEC Filings Did Not Comply With Mandatory SEC Disclosure Regulations

377. Item 7 of Form 10-K and Item 2 of Form 10-Q requires SEC registrants to furnish the information mandated by Item 303 of Regulation S-K [17 C.F.R. § 229.303], *Management's Discussion and Analysis of Financial Condition and Results of Operations* (MD&A). Among other things, Item 303 of Regulation S-K required that Abbott's Class Period Forms 10-K and 10-Q disclose certain known trends or uncertainties that had, or were reasonably likely to have, a material impact on the Company's revenues or income from continuing operations.

378. In 1989, the SEC issued the following, pertinent interpretative guidance associated with the requirements of Item 303 of Regulation S-K concerning the disclosure of material trends or uncertainties:

> A disclosure duty exists where a trend, demand, commitment, event or uncertainty is both presently known to management and reasonably likely to have material effects on the registrant's financial condition or results of operation.
>
> . . . .
>
> Events that have already occurred or are anticipated often give rise to known uncertainties. . . . In situations such as these, a registrant would have identified a known uncertainty reasonably likely to have material future effects on its financial condition or results of operations, and disclosure would be required.

379. In 2003, the SEC issued additional interpretative guidance relating to the requirements of Item 303:

> We believe that management's most important responsibilities include communicating with investors in a clear and straightforward manner. MD&A is a critical component of that communication. The Commission has long sought

> through its rules, enforcement actions and interpretive processes to elicit MD&A that not only meets technical disclosure requirements but generally is informative and transparent.
>
> . . . .
>
> Financial measures generally are the starting point in ascertaining these key variables and other factors. However, financial measures often tell only part of how a company manages its business. Therefore, when preparing MD&A, companies should consider whether disclosure of all key variables and other factors that management uses to manage the business would be material to investors, and therefore required.
>
> . . . .
>
> Companies should also consider disclosing information that may be peripheral to the accounting function, but is integral to the business or operating activity. Examples of such measures, depending on the circumstances of a particular company, can include those based on units or volume, customer satisfaction, time-to-market, interest rates, product development, service offerings, throughput capacity, affiliations/joint undertakings, market demand, customer/vendor relations, employee retention, business strategy, changes in the managerial approach or structure, regulatory actions or regulatory environment, and any other pertinent macroeconomic measures.

380. The MD&A disclosures in Abbott's Forms 10-K and 10-Q filed with the SEC during the Class Period were materially false or misleading because Defendants failed to disclose material uncertainties and trends associated with Abbott's systemic quality control deficiencies in the production and manufacturing of its powdered infant formula then known to management that were reasonably likely to result in lawsuits and regulatory actions that would have a material effect on the Company's future operating results.

381. As explained in § IV. C., *supra*, at least by February 2021, Defendants were aware that the Company's Sturgis facility suffered from long-standing, persistent, serious, and pervasive manufacturing, maintenance, and quality control deficiencies, including, but not limited to, the use of failing equipment and the release of infant formula that was potentially contaminated. Defendants were also aware that swabs at the facility had led to positive tests in September 2019

and June 2020. These events constituted a "trend" of quality control weaknesses at the Sturgis facility that were likely to result in serious problems for the Company, both financial and otherwise. As such, these events were subject to disclosure under Item 303.

382. In addition, Item 1A of both Form 10-K and Form 10-Q requires SEC registrants to furnish the information called for under Item 503 of Regulation S-K [17 C.F.R. § 229.503], *Risk Factors*. Item 503 of Regulation S-K required that Abbott's Class Period Forms 10-K and 10-Q disclose the most significant matters that made an investment in Abbott risky. During the Class Period, however, Abbott's Forms 10-K and 10-Q instead contained materially false or misleading representations about ***potential*** regulatory and legal risks when, in fact, such risks were ***then existing***.

383. The risk factor disclosure included in the Company's Forms 10-K deceptively referred to ***potential risks*** associated with remaining in compliance with governmental regulations, when, in fact, such risks were ***then existing*** due to Abbott's failure to comply with good manufacturing practices. The Company's disclosures stated, in pertinent part:

> ***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.
>
> These actions could result in, among other things, substantial modifications to Abbott's business practices and operations; refunds, recalls, or seizures of Abbott's products; a total or partial shutdown of production in one or more facilities while Abbott or Abbott's suppliers remedy the alleged violation; the inability to obtain future pre-market approvals or marketing authorizations; and withdrawals or suspensions of current products from the market. Any of these events could disrupt Abbott's business and have a material adverse effect on Abbott's revenues, profitability and financial condition.

384. Abbott's Forms 10-Q during the Class Period incorporated by reference this materially false or misleading risk factor disclosure.

385. Further, Item 9A of Form 10-K and Item 4 of Form 10-Q require SEC registrants to furnish the information called for under Item 307 of Regulation S-K [17 C.F.R. § 229.307], *Disclosure Controls and Procedures.* Item 307 of Regulation S-K required Abbott's Class Period Forms 10-K and 10-Q to disclose Defendants Ford's and Funck's conclusions about the effectiveness of Abbott's disclosure controls, defined by relevant regulations as the controls and procedures designed to ensure that information required to be disclosed in reports filed with the SEC is appropriately recorded, processed, summarized, and reported.

386. During the Class Period, Abbott falsely and misleadingly represented in its Forms 10-K and 10-Q filed with SEC that its disclosure controls were operating effectively when they were not, as detailed herein. These materially false or misleading representations were then fraudulently certified by Defendants Ford and Funck, as set forth herein.

387. Specifically, Abbott's Forms 10-K and 10-Q contained materially false or misleading representations regarding Abbott's disclosure controls being effective, when in reality

they were poorly designed and "ineffective" in assessing the risk of material misstatements. These filings stated, in pertinent part:

> **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.

388. The representations in the Company's Forms 10-K and 10-Q about Abbott's disclosure controls being effective were then falsely and misleadingly certified by Defendants Ford and Funck:

> I, Robert B. Ford [/Robert E. Funck], certify that:
>
> 1. I have reviewed this annual report on Form [10-K or 10-Q] of Abbott Laboratories;
>
> ***2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;***
>
> 3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of Abbott as of, and for, the periods presented in this report;
>
> 4. Abbott's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for Abbott and have:

> (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to Abbott, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
>
> (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
>
> (c) Evaluated the effectiveness of Abbott's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
>
> (d) Disclosed in this report any change in Abbott's internal control over financial reporting that occurred during Abbott's most recent fiscal quarter that has materially affected, or is reasonably likely to materially affect, Abbott's internal control over financial reporting; and
>
> 5. Abbott's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to Abbott's auditors and the audit committee of Abbott's board of directors:
>
> (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect Abbott's ability to record, process, summarize and report financial information; and
>
> (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in Abbott's internal control over financial reporting.

389. The Class Period Forms 10-K and 10-Q filed by the Company failed to disclose material facts required by SEC rules and regulations in connection with Abbott's lack of compliance with good manufacturing practices and the systemic quality control deficiencies in the production and manufacturing of Abbott's infant formula, which affected product safety. These compliance failures and systemic deficiencies were reasonably likely to result in lawsuits and regulatory actions that would have a material effect on the Company's future operating results.

VIII. SUMMARY OF SCIENTER ALLEGATIONS

390. The facts detailed above and summarized below, when viewed holistically and together with the other allegations in this Complaint, establish a strong inference that each of the Defendants knew or were severely reckless in not knowing that each of the misrepresentations and omissions alleged herein would be, and were, false or misleading to investors at the time they were made.

391. At all relevant times, each of the Defendants knew or recklessly disregarded that their statements and omissions concerning Abbott's high-quality, safe infant formula, adherence to strict good manufacturing practices, rigorous quality standards governing the manufacturing of infant formula safety, and knowledge of the Whistleblower's allegations during the Class Period, were false or misleading to investors at the time they were made. In summary of and in addition to the facts more fully discussed above, Defendants' scienter is evidenced by the following facts.

A. The February 2021 Whistleblower Complaint Put Each Defendant On Notice That Sturgis Was In Violation Of Federal Regulations And CGMPs, And Was Manufacturing Powdered Infant Formula In Unsanitary Conditions By The Start Of The Class Period

392. On February 16, 2021, thee days before the start of the Class Period, the Whistleblower filed the February 2021 Whistleblower Complaint with OSHA and, pursuant to federal regulations, Abbott was promptly advised of the February 2021 Whistleblower Complaint, and responded to it by no later than April 2021, as confirmed by news reports in June 2022.

393. As detailed above, the February 2021 Whistleblower Complaint provided, in significant detail, the Whistleblower's firsthand observations of how Abbott's "practices violated laws, regulations, and other guidelines administered and enforced by the [FDA]," and how the Whistleblower "raised concerns as to practices that [he] reasonably believed violated applicable regulations" and "refused to engage in practices that [he] reasonably believed violated applicable

regulations." The Whistleblower filed a second complaint, the October 2021 Whistleblower Complaint, on October 19, 2021. While the second complaint contained a bit more detail, its contents were largely consistent with the February 2021 Whistleblower Complaint. In summary, the Whistleblower alleged multiple violations of the FDCA, Infant Formula CGMP Regulations, Infant Formula Record Requirements, and the Company's own formal policies, including (a) releasing untested infant formula that carried a significant risk of bacterial (*i.e. Cronobacter* or *Salmonella*) contamination; (b) concealing material information from FDA inspectors in 2019 concerning the release of possibly contaminated formula; (c) falsifying testing, cleaning, and maintenance verifications and records; (d) implementing lax and insufficient clean-in-place procedures that introduced water and mold into the formula production environment; and (e) failing to undertake reasonable measures to reduce natural or unavoidable defects to the level feasible as mandated by the regulations, including the perpetuation of deficient testing measures and the refusal to improve or replace damaged or dangerous machinery that "was failing and in need of repair," leading to "product flow pipes [that were] pitting and leaving pin holes," which "allowed bacteria to enter the system and, at times, lead to bacteria not being adequately cleaned out in CIP washes" such that "product flowing through the pipes [] pick[ed] up the bacteria that was trapped in the defective areas of the pipe."

394. While the copy of the February 2021 Whistleblower Complaint in Plaintiffs' Counsel's possession redacts the names of any specific individuals with knowledge, the Whistleblower identifies individuals within Abbott who were personally aware of the violations set forth in the document, individuals or divisions that would have been made aware of the violations, as well as references to employees that the Whistleblower knew would corroborate his account of the violations.

395. Abbott's receipt of the February 2021 Whistleblower Complaint put each Defendant on actual notice of the unsanitary and illegal conditions at Sturgis, conditions that posed a clear and imminent threat to the safety and well-being of Abbott's end consumers who were millions of babies across the United States as well as Canada.

396. The October 2021 Whistleblower Complaint references Abbott's knowledge of and participation in the investigation into the February 2021 Whistleblower Complaint. Indeed, the stated impetus for the Whistleblower's delivery of the October 2021 Whistleblower Complaint was the fact that Abbott knew of the identified violations and was doing nothing to correct them but, rather, was focused on retaliating against or pressuring current employees from speaking truthfully such that the Whistleblower "believe[d] that other employees at the Sturgis site are currently at risk":

> Most if not all of the concerns raised by the Complainant in his FSMA complaint [the February 2021 Whistleblower 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.

397. The October 2021 Whistleblower Complaint specifically notes that Abbott's "senior management"—a group that includes Defendants Ford, Funck, Calamari, and Randall—knew of the alleged violations and that their inaction was in violation of Abbott's internal controls obligations under Sarbanes-Oxley and the DOJ's mandated compliance guidelines, as well as violative of the 2012 Corporate Integrity Agreement entered into when Abbott plead guilty to various criminal violations of the FDCA and agreed to pay $1.7 billion in penalties:

> 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.

398. Defendant Randall was aware of and participated in the response to the February 2021 Whistleblower Complaint. As explained in the DOJ Complaint in which she was named and the Consent Decree that she signed on behalf of Abbott, Randall, Abbott Nutrition's Division Vice-President of Quality Assurance, "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," and conducts "oversight duties" for Sturgis. Defendant Randall reports to J. Scott House, Abbott's Senior Vice President, Quality Assurance, Regulatory and Engineering Services, who reports directly to Defendant Ford, as Abbott reported in its regulatory filings.

399. Others at the senior management and the Abbott Board level also were aware of the Whistleblower Complaint allegations and alleged violations. For example, as stated in Abbott's 2021 Global Sustainability Report, as part of Abbott's promise that "delivering high-quality, safe products is always [its] number one priority," Abbott's Board of Directors' "Public Policy Committee ***regularly reviews*** quality metrics, ***inspection findings***, industry progress and emerging issues." Moreover, the Whistleblower, in the February 2021 Whistleblower Complaint, indicated that Abbott's General Counsel knew of the contents of his complaints because the Whistleblower's counsel had directly contacted Abbott's General Counsel, Hubert L. Allen, requesting that Abbott preserve records associated with the Whistleblower, a request that was acknowledged and rejected.

400. A former senior level executive at Abbott confirms that the Individual Defendants would have been made aware of the February 2021 Whistleblower Complaint. FE2 was a senior level executive in Abbott's Public Affairs and Media Relations departments from 2016 through November 2021, and was based out of Abbott's Illinois headquarters. In FE2's role, FE2 oversaw Abbott's top tier business media relations across all businesses, including Nutrition, and prepped Defendant Ford for media interviews. FE2 explained that a document like the February 2021 Whistleblower Complaint that reported regulatory, quality, and safety violations at Sturgis, and that was filed with federal regulatory agencies with criminal and civil enforcement capabilities, would have reached the highest levels of Abbott's management, up to and including Defendant Ford.

401. FE2 further noted that the February 2021 Whistleblower Complaint would have been sent to Vicky Assardo, who was at the time Senior Director of Global Public Affairs for Abbott Nutrition, as well as to Melissa Brotz, Abbott's Chief Marketing Officer, and Scott Stoffel, head of external communications. Assardo, Brotz and Stoffel would have been involved in crafting the response to OSHA with respect to the February 2021 Whistleblower Complaint, as would have individuals from Abbott's legal department at both the Nutrition level (headed by Stephen Lacey) and overall corporate level (under David Mendelson). Other groups with input on the response, given the nature of the complaint and who received it, would have been Government Affairs, Regulatory Affairs, Quality Control, and Supply Chain. FE2 also confirmed that while the above identified individuals would have been responsible for drafting the response to the February 2021 Whistleblower Complaint, the heads of Nutrition, which includes Defendant Calamari and Defendant Randall, would have been informed of the February 2021 Whistleblower Complaint and Abbott's general strategy for responding. FE2 also reported that Defendant Ford, while likely

not involved in the substantive response, would have been informed about the February 2021 Whistleblower Complaint and the nature of its allegations and Abbott's response.

402. The February 2021 Whistleblower Complaint provided a map and index to the illegal and unsafe conditions at Sturgis that posed a direct and imminent threat to babies who consumed Abbott formula. *See* § IV.C. Defendants knew of these allegations and were, at a minimum, severely reckless in ignoring them. As the Whistleblower made clear in his October 2021 Whistleblower Complaint, Abbott and its senior management were more interested in outing and punishing those who would corroborate the multitude of FDCA violations than identifying and correcting the violations before a baby was injured or died. FE2 confirmed that a culture to protect Abbott's reputation at all costs was endemic, and that from the Public Affairs department, there was a "mantra to protect the reputation of the Company fiercely" such that FE2 wondered if Abbott was taking it "too far."

403. Defendants were "unwilling or unable" to remediate any of the problems identified by the Whistleblower, and this misconduct resulted in massive contamination at Sturgis, dozens of reported serious infant illnesses and deaths from *Cronobacter* and *Salmonella*, a recall and shutdown that cost the Company at least $1 billion in lost revenue and goods, the filing of the DOJ Complaint and entry of the Consent Decree, a nationwide infant shortage, and an ongoing criminal and SEC investigation into Abbott. As the DOJ described: at

> 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. Defendants' violations of the Act and the likelihood that violations will recur in the absence of court action demonstrate that injunctive relief is necessary

404. Defendants' conscious inaction strongly supports a strong inference of scienter. If Defendants were—as they will undoubtedly contend—well-meaning actors caught off guard by

these issues, they would have immediately acted to remediate the Sturgis issues when they learned about them in early 2021. But they did not. Defendants' failure to correct fatal deficiencies in the Company's infant formula manufacturing processes in question, gives rise—at a minimum—to a strong inference of scienter.

B. The 2019 and 2021 483 Reports Put Each Defendant On Notice That Sturgis Was In Violation Of Federal Regulations And CGMPs, And Was Manufacturing Powdered Infant Formula In Unsanitary Conditions

405. Abbott's Sturgis plant received Form 483s—in 2019, 2021 and culminating in 2022, all with worsening identified deficiencies. The 2019 483 Report described how Abbott did not test the minimally required representative sample of powdered infant formula at the final product stage and before distribution. Moreover, the accompanying EIR, which provides additional observations, stated that the investigators had observed dust-like debris accumulation on a window screen, in violation of the Company's own Statement of Procedures. More importantly, the FDA also noted that a review of Abbott's nonconformance reports revealed that Abbott had identified the existence of *Cronobacter* in a ***finished product*** in 2019. As former FDA Deputy Commissioner Yiannas explained in his congressional testimony on March 28, 2023, if a company detects *Cronobacter* in a finished product, that is clearly evidence of a pervasive contamination event: "it is well documented in the literature that low levels of sporadic contamination is unlikely to be detected by PIF sampling plans. Therefore, it is more likely than not that other batches of PIF produced in this plant were likely to have been contaminated with a variety *C. sakazakii*." Yet, there is no indication that Abbott took any additional corrective steps to address that situation. The 2021 483 Report catalogued a total of five objectionable observations. As described in the 2021 483 Report and accompanying EIR in September 2021, Sturgis was not maintained in a clean and sanitary condition, personnel working directly with the baby formula did not wash their hands thoroughly, a necessary instrument for processing was not

properly maintained and the temperature in a thermal processing equipment was not properly controlled. The EIR also noted that a review of Abbott's nonconformance reports revealed that Abbott had identified another instance of *Cronobacter* in a finished product in June 2020.

406. Moreover, as previously described, and as documented in the 2021 483 Report, in 2019, and again, less than a year later, in 2020, Abbott twice destroyed Sturgis powdered infant formula due to *Cronobacter* contamination, yet did not close down Sturgis or determine the root of the contamination. The fact that the Company took no adequate corrective measures only demonstrates the Defendants' reckless indifference to fixing the grave sanitary conditions at Sturgis.

407. The Individual Defendants were directly informed of the 483 Reports and their contents. Defendant Randall was directly involved in the Company's response to the 483 Reports. For example, a copy of the cover letter sent by Abbott to the FDA on October 15, 2021 in response to the 2021 483 Report copied Defendant Randall. FE2 confirmed that Defendant Randall and John Murphy, Vice President, Supply Chain at Abbott Nutrition, together exercised a "dual role" in charge of quality assurance and the supply chain, and took part in formulating Abbott's response to the 483 Reports.

408. Moreover, as discussed above, the FDA directs all companies that receive a Form 483 to send the report "to the top management of the firm." i.e., Defendants Ford, Funck and Calamari. FE2 backed this up, explaining that Abbott's CEO, which was Defendant Ford at the start of the Class Period, and senior management in Nutrition (*i.e.*, Defendants Randall and Calamari, as well as Daniel Salvadori, Senior Vice President of Nutrition) would have been informed of the 483 Reports and Abbott's response. They would have participated in conversations

regarding how to respond, and FE2 believed that all executives at Abbott Nutrition would have a "clear line of sight" into Abbott's regulatory response.

409. Moreover, FE2 confirmed that FDA's findings and observations did not stay "siloed" in Abbott's Nutrition business, but made their way to the corporate level, especially when *Cronobacter* was involved. FE2 explained that, typically, Abbott C-suite executives received briefings where the potential harm to the Company was deemed serious enough that Abbott was at a "reputational risk." C-suite individuals, such as Defendants Ford and Funck, would have received updates regarding the risk posed by the 483 Report as well as Abbott's response. Abbott considered the likelihood of public disclosure to be a factor in determining whether to escalate. FE2 confirmed that, due to the "high risk" associated with *Cronobacter*, its identification during an FDA audit—which occurred in 2019 and 2021 (and of course 2022)—would have been escalated more quickly. FE2 estimated that given that risk, and the fact that the audit results involved dealings with the FDA, any Form 483 Reports showing *Cronobacter* positive results would have been escalated to Defendant Ford during his tenure "in short order," perhaps in "less than a month."

410. Additionally, the multitude, severity, pervasiveness, and duration of the serious CGMPs violations outlined in the three 483 Reports support a strong inference that all Defendants were aware of them. The FDA's consistent scrutiny, over years, of the violations, contributes to a strong inference of the Individual Defendants' scienter. The Company's history of noncompliance, including its 2010 infant formula recall from Sturgis and the 2012 FDCA guilty plea and $1.7 billion penalty, supports an inference that the Individual Defendants kept a close watch on possible violations of FDA regulations. Specifically, the failure to correct a deficiency identified in earlier

Forms 483 is indicative of knowledge or at least of reckless disregard of the falsity of Defendants' misrepresentations.

C. Former Employees Confirm That Abbott's Violations Of Federal Regulations And CGMPs Were Pervasive And Widely Known Inside Of Abbott

411. Abbott senior management's actual knowledge, and access to information, concerning the rampant food safety violations at Sturgis further gives rise to a strong inference of scienter. Senior management had actual knowledge because they visited the plant and saw first-hand the plant's flagrant violations. Moreover, senior management had access to information because of Abbott's company-wide audits and tracking systems.

412. *First*, former employees stated that senior management visited Sturgis. FE1 explained that Daniel Salvadori, Senior VP of Nutrition, visited the plant during his tenure. Moreover, FE1 also said that John Murphy and Defendant Randall**,** both from Abbott Nutrition headquarters, would visit Sturgis frequently and were heavily involved in Project Penta. In fact, corporate employees from Nutrition headquarters in Columbus visited the plant often, approximately once a month. Moreover, as FE1 explained, in connection with assuring that metrics were met in order to sign-off on the project, the pressure was coming from the higher-ups. FE4 also corroborated that corporate employees visited the plant.

413. *Second*, Abbott's own audit and tracking systems provided access to all the information concerning the violations. As described by FE1 and FE5 a Microbiology Supervisor at Abbott's Casa Grande, Arizona infant formula manufacturing facility from 2016 through 2020, there was an internal audit team within Abbott that visited the plant sites approximately once a year, known as the AQR department ("AQR"). These types of internal audits, as well as documentation of quality issues, were tracked in an internal Abbott system known as TrackWise, also known as AbTraq. FE5 stated that all senior management had access to the TrackWise/AbTraq

database. While he worked at Casa Grande, FE5 confirmed that he could see the Sturgis plants' reports in TrackWise/AbTraq, along with every other Abbott facility. FE1 described how AQR who came in once a year had "access to all the documents," including weekly Product Our Product ("POP") reports and the TrackWise/AbTraq database, in which a user could see all food safety problems reported at the facility, as well as corrective actions that should have been taken. FE1 stated that despite their access to this information and to the facility, "AQR did not do a good job at Sturgis," as issues that should have been relevant to them were ignored. AQR, according to FE1, "dropped the ball on protecting the products and the families that rely on us." These allegations further support a strong inference of scienter.

D. Defendants Consented To A Five-Year Injunction In Response To The DOJ Conclusion That Defendants Had, For Years, Been "Unwilling Or Unable" To Correct The "Egregiously Unsanitary" Conditions At Sturgis

414. On May 16, 2022, the DOJ filed an injunctive Complaint alleging that Abbott, Defendant Randall, and two other senior managers at Sturgis violated the FDCA, alleging, based on "inspectional findings from the 2022 Inspection," that "Defendants lack adequate measures to ensure the safety and quality of the Specialty Infant Formulas, the Standard Infant Formulas, and the powdered food for older children that Defendants manufacture at AN-Sturgis. . . . As a result, these products are at risk of contamination from bacteria, such as *C. sak.*" The DOJ Complaint detailed how the FDA detected *Cronobacter* in several surfaces throughout Sturgis, including on the "cover of a scoop hopper, which is used to feed scoops that are placed directly inside infant formula containers and come in contact with product."

415. The FDA also described how "uncontrolled wet environment in processing areas, in conjunction with the presence of *C. sak.* and deteriorating equipment that enables harborage of *C. sak.* (*i.e.*, cracks in food-contact surfaces of equipment, as described below), create an unacceptable risk of bacterial contamination of Defendants' product." Notably, the FDA

determined that this "uncontrolled wet environment" was known to Abbott ***and well-documented since 2018***, yet never corrected:

> FDA investigators observed that ***Defendants' records documented a total of 310 water events, e.g., water leaks and condensation, at AN-Sturgis between January 1, 2020, and February 1, 2022.*** Those water events occurred in dry-production areas for powder infant formulas, e.g., during spray-drying the infant formula and/or filling the infant formula into containers. ***Defendants' records describe several water leaks as necessitating repairs of the AN-Sturgis roof. When C. sak. is present in a manufacturing environment, it can be further spread to other processing areas, particularly where water is poorly controlled***.
>
> FDA investigators observed that Defendants had not validated the "dry-out" step for their spray dryers to ensure that complete drying is achieved after water is introduced into the spray-dryer environment during cleaning.
>
> FDA investigators observed that ***Defendants' records documented a history of internal deterioration of the spray dryers at AN-Sturgis, dating back to September 2018***. Defendants' last spray-dryer inspection, which occurred in August 2021, showed damage including, but not limited to, cracks and pits inside the dryers' main chambers. This type of damage creates the potential for niches and harborage sites for bacterial contamination to persist, particularly in the presence of moisture.

416. The DOJ Complaint also alleged FDCA violations at the Abbott corporate testing level:

> Further, the investigators found that ***Defendants failed to follow their own procedures to determine the root cause of consumer complaints associated with their products***. Specifically, FDA investigators reviewed Defendants' complaint investigations for consumer complaints received by FDA, identified as FDA Consumer Complaint Nos. 171222, 170177, 171771, 171087, that are associated with (but not definitively caused by) powder infant formulas manufactured at AN-Sturgis, including reported *C. sak.* illnesses and a reported illness from *Salmonella newport*. The FDA investigators found that ***Defendants closed their complaint investigations without having identified a root cause for the reported illnesses associated with bacterial infection***.
>
> FDA investigators observed that, although Defendants' standard operating procedure ("Complaint Management and Investigations" v. 26, s. 5.2.2.8 on page 26) states that retained samples are to be evaluated for microbial analysis when "there is a potential for the distributed product not to comply with specifications," ***Defendants closed their complaint investigations without having evaluated any retained samples of the Consumer Complaint-related powder infant formulas for microbiological contamination***.

417. The DOJ Complaint specifically noted that:

> The 2022 Inspection ***was not the first time FDA warned Defendants of their failure to comply with FDA requirements to control microbiological growth***. FDA previously conducted an inspection at AN-Sturgis between September 20-24, 2021 ("2021 Inspection"). ***During the 2021 Inspection, FDA investigators documented several conditions and practices that fail to control microbiological growth within the food-processing areas at AN-Sturgis including, but not limited to, some of the same or similar observations made during the 2022 Inspection***.

418. The DOJ alleged that "***[a]lthough Defendants promised corrective actions, they did not implement sustained corrections to achieve ongoing compliance with the Act and its implementing regulations***." As a result:

> Despite the seriousness of having detected *Cronobacter spp*. in their products and processing areas, ***Defendants have not taken adequate steps to come into compliance, as evidenced by the observations made by FDA investigators during the 2022 Inspection***.
>
> Accordingly, the United States believes that, ***unless restrained by the Court, Defendants will continue to violate 21 U.S.C. §§ 331(a) and 331(k) in the manner alleged herein***.

419. The number of well-documented violations found by the DOJ, Defendants' failure to follow their own procedures, as well as their failure to implement corrective actions—since ***at least 2018***—demonstrates the Defendants' reckless indifference to fixing the grave unsanitary conditions at Sturgis.

420. Abbott consented to the injunctive relief the DOJ petitioned for, and agreed to sign and submit to a Consent Decree signed by Defendant Randall, individually and on behalf of Abbott. As part of the Consent Decree, Abbott is required to hire an independent expert to review the Sturgis facility's operations. The Consent Decree also put in place requirements for testing products and required expert review and implementation of a sanitation plan, environmental monitoring plan and employee training programs. Under the Consent Decree, the

required independent expert must certify that, "Defendants ***have corrected all deficiencies*** at the Sturgis Facility identified in the FDA Form-483 issued on March 18, 2022." Part C. (6) (b)).

421. Defendants, by certifying in the Consent Decree that they are required to correct all deficiencies, admitted to the existence of these rampant deficiencies at the Sturgis facility since at least 2018. These allegations further support a strong inference of scienter.

E. The Sale Of Safe, Uncontaminated Infant Formula Is Critical To Abbott's Operations

422. A strong inference of Defendants' scienter is further evidenced by the critical nature of the sale of safe, uncontaminated infant formula within the U.S. to Abbott.

423. Infant formula is the most heavily regulated food product for a simple reason: babies are defenseless against certain bacteria that are known to thrive in powdered infant formula, the sole or supplemental source of nutrition for millions of babies every year. Without strict adherence to those regulations, babies' lives are at risk. As became all too apparent, when a company like Abbott brazenly violates those regulations, that misconduct can easily cause illness and death, and instill panic and fear in parents and caregivers. Given the critical nature of adherence to those regulations, and how critical infant formula is to Abbott's core operations, the Defendants knew or were reckless in not knowing the truth about the facts Defendants mispresented and failed to disclose to investors, including critical facts about the safety of Abbott's formula and manufacturing processes.

424. The sale of infant formula was highly material to Abbott's financial results. Abbott controlled 40%-50% of the $4 billion per year U.S. infant formula market. The Sturgis facility manufactured 40% of Abbott's formula, which meant that one in five babies relied on Sturgis formula for their nutrition. In 2021, Abbott reported sales of nearly $1.5 billion in pediatric nutrition products, totaling 40% of Abbott Nutrition's total revenues. That number was reduced to

less than $500 million in 2022 as a result of the recall and shutdown, and the Company recorded charges of $176 million to cover the recalled formula and improvements at Sturgis, totaling a loss of over $1billion in 2022.

425. The ability of Abbott to produce safe and salable formula out of Sturgis was critical for the entire U.S. infant formula market. As former FDA Deputy Commissioner Yiannas testified on March 28, 2023, the shutdown of Sturgis—one of only 21 infant formula plants in the U.S.—caused a market shortage and disruption because the U.S. has "an inelastic and fragile infant formula supply chain system." As a result, "[t]he reality is that the FDA has had minimal authorities and levers to affect the system, other than the safety and nutrition standards they create . . ." As FDA Commissioner Robert Califf said in the wake of the 2022 recall, "Abbott's enormous market share left it with the responsibility for producing safe infant formula that wasn't met."

426. The misrepresented and undisclosed facts concern Abbott Nutrition's core operations—the sale of safe infant formula—and, as such, the Company and its key officers knew or were at least reckless in not knowing the multiple identified violations.

F. The Criminal And SEC Investigations Of Abbott Are Strongly Indicative Of Scienter

427. Courts recognize government investigations can support a strong inference of scienter. Here, in addition to the DOJ Complaint and Consent Decree, there are three confirmed open criminal and civil investigations against Abbott and its top executives.

428. As discussed above, on January 20, 2023, *The Wall Street Journal* reported in an article titled "Abbott Under Federal Criminal Investigation Over Baby Formula," broke the news that the DOJ is investigating conduct at the Abbott's Sturgis plant that led to its shutdown last year and worsened a nationwide formula. Abbott confirmed the criminal investigation.

429. Moreover, in its 2022 Form 10-K, Abbott announced that: (1) in December 2022 it received a subpoena from the Enforcement Division of the Securities Exchange Commission requesting information relating to Abbott's powder infant formula business and related public disclosures, and; (2) in January 2023, it received a civil investigative demand from the United States Federal Trade Commission seeking information in connection with its investigation of companies who participate in bids for WIC infant formula contracts.

430. The governmental scrutiny of the improper practices in question further contributes to a strong inference of Defendants' scienter.

G. Leadership Changes At The Sturgis Facility And The Quality Division Further Support A Strong Inference Of Scienter

431. During the Company's quarterly call on October 19, 2022, the last day of the Class Period, Defendant Ford announced: "During the quarter, we also made leadership changes, both at our Sturgis site and in our quality organization[.]" While Ford and the Company declined to identify exactly what "leadership changes" had been made to address the issues that caused the recall, shutdown, and DOJ Complaint and Consent Decree, FE1 reported that those changes included Sturgis Site Director Hathaway. Such remedial measures further support a strong inference of scienter. This type of "house-cleaning" does not typically follow innocent instances of mismanagement.

H. Abbott's Refusal To Make Much Needed Investments And Upgrades Of Sturgis Further Supports A Strong Inference Of Scienter

432. As demonstrated by the facts set forth above, Defendants continuously refused to invest the funds needed to make the Sturgis facility safe.

433. On May 18, 2022, the Senate Finance Committee opened an investigation into Abbott that was focused on investigating why key and necessary investments into Sturgis had not been made. In a pointed letter from Committee Chairman Senator Ron Wyden, to Defendant Ford,

the Senator requested information on Abbott's international tax practices and the astounding $8 billion in stock buy backs that the Company authorized since 2019, as well as increased dividends to shareholders. Senator Wyden also requested information on how much money Abbott had spent to upgrade Sturgis prior to its closure, as well as whether the Company used its billions of dollars in tax cuts to repurchase shares rather than invest in the facility.

434. That Abbott was not dedicating sufficient financial resources to maintain Sturgis is not open to dispute. At the May 22, 2022, Congressional Hearing, FDA Commissioner, Dr. Califf, called the inspection results "shocking." He also expressed that the FDA had "no confidence in the integrity of the Abbott Quality program." The FDA considered the violations so egregious that, as Commissioner Califf testified, they "didn't have confidence that [Abbott] would produce safe formula until [the FDA] got control of the plant through the consent decree," adding that while Abbott had now begun "remediating the plant," ***"it was so bad"*** and ***"beyond the pale."*** He also went on to describe the conditions at the plant in the following way:

> I mean, I have thought about. Let's say you had a next door neighbor who had leaks in the roof. They didn't wash their hands. They had bacteria growing all over the kitchen. You walked in and there was standing water on the counters and the floor, and the kids were walking through with mud on their shoes, and no one cleaning it up. You probably wouldn't want your infant eating in that kitchen. And ***that is, in essence, what the inspection, showed.***

435. Commissioner Califf was not alone in his assessment. For example, Dr. Susan Mayne, Director of the Center for Food and Applied Nutrition at the FDA, who also testified at the May 22, 2022 Congressional Hearing and shared Commissioner Califf's views, stated, "[o]ur experts said this plant had very, very seriously concerning conditions, ***unlike things that they have seen in other plants in the U.S."*** The sanitary violations at Sturgis were so undeniably egregious and pervasive that after providing a high-level summary of the FDA findings at Sturgis during the May 22, 2022 Congressional Hearing, Representative Morgan Griffith categorically said that

Abbott had a ***"culture problem."*** In fact, various Representatives, from both sides of the aisle, noted the same.

436. Despite these fact-based assessments, Defendant Calamari was defiant at the May 25, 2022 Congressional Hearing, and falsely stated that Abbott received no complaint from the Whistleblower until the public release of the October 2021 Whistleblower Complaint in April 2022. Defendant Calamari also falsely stated that "the Abbott I know prioritizes compliance," "encourages employees to speak up," has "a zero tolerance policy for retaliation," and is "committed to those principles." When asked about the resources the Company devotes to ensuring the safety of its products, Defendant Calamari stated that Abbott spends "tens of millions of dollars on quality and on maintenance."

437. Yet nothing could be further from the truth. The rampant lapses in sanitary and safety conditions at Sturgis simply ***do not*** occur when adequate investments are made. The 2019, 2021, and 2022 483 Reports and EIRs exposed serious violations that stemmed in part from Defendants' decision ***not*** to invest in Sturgis. FE1 confirmed the "culture problem," "corporate greed" and "profits over safety" concerns flagged by the Representatives during the May 25, 2022 Congressional Hearing, stating that the plant was "chronically underfunded by corporate.". FE1 also confirmed that Sturgis was chronically and purposefully understaffed—particularly when considering the amount of product Sturgis produced per year, and that this understaffing was designed to keep profits up.

438. As discussed more fully above, the Whistleblower also recounted that the Company failed to upgrade its automatic labeler, failed to repair equipment associated with the drying process and failed to invest in hiring personnel with proper experience or invest in proper training. Former employees corroborate this dereliction. *See* § IV.C.

439. A strong inference of scienter is further reinforced by the fact that Abbott was reaping record-breaking profits and spending billions on buybacks, while failing to make much needed repairs and investments to upgrade Sturgis. In other words, Defendants deliberately placed meeting production metrics over addressing plant safety concerns. As the Whistleblower explained, the Company's incentive structure rewarded cost-cutting, fomenting a culture where safety was sacrificed. The Company rewarded plant management by handing out bonuses tied to meeting certain production metrics. In order to obtain incentive bonuses, Sturgis plant management had to meet certain production metrics. Thus, Sturgis management was incentivized to ignore safety concerns that could threaten production metrics, which is exactly what occurred. FE3 confirmed that management bonuses were based on production, explaining that "the more that goes out the door, the better they do." A lack of reliable, confidential means of reporting, and no independent investigators to look into safety complaints, further exacerbated the problems.

440. FE1's account further corroborates Abbott's metrics over safety culture. As he explained, certain employees at the plant were trying to get Abbott's corporate headquarters to invest more money with an initiative known as Project Penta, which entailed the purchase of a much-needed new dryer for the plaint's powdered infant formula production. However, instead of the drive behind the purchase being the need for product safety, Abbott conditioned the new dryer on Sturgis's ability to meet certain production metrics. The desperately needed new dryer was turned into a reward, instead of a necessity to assure product safety. Similarly, an initiative to automate track cleaning at the plant was abandoned when it was found to impact certain production metrics. As FE1 added, metrics were conflated with product safety—if metrics were met, the product had to be safe. FE3 also attested to production metrics being placed over safety and cleanliness and witnessed retaliatory behavior.

441. These facts were not isolated to Sturgis. *First*, as FE1 recounted, it was Abbott corporate, when the Company acquired Sturgis, that made the executive decision to forgo investments and to carry out cuts to headcount. Moreover, it was Abbott Nutrition that approved (or more likely, not) spending at Sturgis. Furthermore, it is implausible that Abbott's high-level executives were unaware that either none, or an insufficient amount, of the billions of dollars in tax cuts that the Company received were invested in correcting known deficiencies at the plant. Moreover, in a May 2021 interview, Defendant Ford said that the Company had taken a portion of profits and "reinvested into the business," denoting that he was kept appraised of expenditures to upgrade Abbott's business.

442. *Second*, Abbott owns the "culture" at Sturgis. At the May 22, 2022 Congressional hearing, Representative Griffith asked Defendant Calamari point blank if members of Abbott's team at Sturgis were "hiding information from your office" and if that seemed like a "culture problem." Defendant Calamari refused to admit that there was such a thing as a culture problem. Moreover, when he was asked by Representative Vern Buchanan if Sturgis follows Abbott's company-wide systems of internal control or accountability, or if they were on their own, Defendant Calamari responded, "Sturgis is ***very much connected with our quality system, and our accountability measures.*** So, they would be part of that." Accordingly, to the extent there is a culture problem which caused the "egregiously unsanitary conditions at Sturgis, it is "Abbott's culture." These allegations further support a strong inference of scienter.

I. Other Indicia Support A Strong Inference Of Scienter

443. In addition to the averments summarized above, additional facts also support a strong inference that, throughout the Class Period, Defendants knew or recklessly disregarded that their statements and omissions, as set forth above, were materially false or misleading when made.

444. First, as noted in SEC filings during the Class Period, Abbott's "products [were] subject to rigorous regulation by the FDA and numerous international, supranational, federal, and state authorities." Indeed, in its capacity as an infant formula maker, Abbott is subject to a variety of regulations that require mandatory compliance. Given the extensive and "rigorous" nature of the government regulations in question, it can be readily inferred that during the Class Period, the Individual Defendants closely monitored the Company's system of controls connected to product manufacturing, including, but not limited to, the controls that were in place to prevent the adulteration of infant formula from microorganisms. Moreover, given Abbott's express "promise" to "ensure" its compliance with these regulations (made in various public statements), discussed below, it belies common sense that the Company's top-level management, including the Individual Defendants, did not know of the long-standing, pervasive, and serious manufacturing, packaging, maintenance, and quality control deficiencies that plagued the Sturgis facility.

445. Second, it is readily apparent that Abbott's management at the Sturgis facility intentionally falsified records relating to food safety – and also actively engaged in a cover-up to deceive FDA auditors during their onsite inspections. Evidence that a defendant has taken steps to cover-up a misdeed, as occurred here, is strong proof of scienter.

Third, as detailed elsewhere herein, Defendant Ford misleadingly denied any link between the Sturgis facility and the four reported infant illnesses, stating that "[t]he data collected during the investigation, genetic sequencing, retained product samples and available products from the four complaints did not find any connection between our products and the four reported illnesses in children." The specific nature of Ford's denial, including his citation to numerous sources ("the investigation, genetic sequencing, retained product samples and available products from the four complaints") reflect that he was receiving specific information regarding the issue at hand and is

suggestive of actual knowledge. The only other plausible inference that could be drawn from Ford's pronouncement is that he either fabricated the information he provided to the public or he deliberately ignored information he possessed or had access to relating to such matters. In either event, such deliberate recklessness satisfies the scienter requirement.

446. Fourth, on March 21, 2022, more than one month after Abbott recalled its infant formula, Defendant Ford issued a formal apology acknowledging that Abbott caused harm to families in the U.S. and around the world. He stated, "[w]e're sorry to every family we've let down since our voluntary recall exacerbated our nation's baby formula shortage" and acknowledged that "the FDA's investigation did discover a bacteria in our plant that we will not tolerate. I have high expectations of this company, and we fell short of them." Ford concluded this apology stating, "I want everyone to trust us to do what is right, and I know that must be earned back." On May 25, 2022, Defendant Calamari also issued a formal apology on behalf of everyone at Abbott, stating, "I want to express our extraordinary disappointment about the shortage. We are deeply, deeply sorry, and we are committed to ensuring that this never happens again. Safety comes first and the recall and shutdown are necessary steps to ensure that our formula supply was safe." These apologies are indicative of scienter. An apology is a statement offered by a wrongdoer that expresses acknowledgement of the legitimacy of the violated rule, admission of fault and responsibility for its violation, and the expression of genuine regret and remorse for the harm done. Apologies can be distinguished from other forms of accounting in that they acknowledge responsibility for the conduct that caused the harm. With these apologies, Defendants Ford and Calamari were acknowledging Abbott's and their fault and responsibility for the egregious sanitary violations at Sturgis.

IX. LOSS CAUSATION

447. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiffs and the Class.

448. During the Class Period, Plaintiffs and the Class purchased or otherwise acquired shares of Abbott common stock at artificially inflated prices and were damaged thereby when the price of Abbott common stock declined when the truth was gradually revealed through partial disclosures during the Class Period. Throughout the Class Period, the price of Abbott common stock was artificially inflated, as a result of Defendants' materially false or misleading statements and omissions and Defendants' scheme to deceive the market. The price of Abbott common stock significantly declined (causing investors to suffer losses) when Defendants' materially false or misleading statements and omissions, alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, and/or the risks that had been fraudulently concealed by Defendants materialized.

449. Specifically, Defendants' materially false or misleading misstatements and omissions misrepresented Abbott's violation of mandatory CGMP and FDA regulations governing the production of infant formula, the quality of Abbott's manufacturing processes governing the production of infant formula given the "egregiously unsanitary" conditions at the Company's primary infant formula manufacturing facility, the safety of Abbott's powdered formula sold in the U.S. and Canada, and Defendants' receipt of complaints of unsafe conditions and violations of safety conditions at Sturgis from the beginning of the Class Period. When those materially false or misleading misstatements and omissions were corrected and the risk concealed by them materialized, investors suffered losses as the price of Abbott common stock declined net of industry and market movements on the dates set forth in the chart below. As a result of the disclosure of the truth of Defendants' fraud, Abbott common stock declined from a closing price of $120.58 on February 17,

2022 to a closing price of $98.11 on October 19, 2022, a decline of 18.6% with a market capitalization loss of approximately $40 billion.

Date[13]	**Corrective Event Summary**	**Closing Stock Price**	**Common Stock Price Change**
February 17, 2022 (February 18, 2022)	On February 17, 2022, the FDA publicly announced that it was investigating four consumer complaints of infant illness related to powdered infant formula produced by Abbott in Sturgis. The FDA stated that it had found several positive contamination results from environmental samples for *Cronobacter*, linked to infant illnesses and death. On the same day, Abbott issued a recall of certain infant formula products, including the popular brands Similac, Alimentum and EleCare, all manufactured in Sturgis.	$116.79	-3.14%
March 22, 2022 (March 23, 2022)	On March 22, 2022, after the markets closed, the FDA released damaging Form 483 Reports from its three inspections of the Sturgis facility conducted in September 2019, September 2021 and, most recently, between January 31, 2022 and March 18, 2022. The FDA highlighted that Abbott failed to establish process controls to prevent contamination of its infant formula and processing environment.	$116.92	-4.08%
October 19, 2022	On October 18, 2022, Abbott announces changes in leadership at Sturgis and in its Quality division in the wake of the recall and Consent Decree, and reports significant and unanticipated declined in pediatric nutrition sales due to the shutdown of the Sturgis plant.	$98.11	-6.54%

450. It was entirely foreseeable that Defendants' materially false or misleading statements and omissions discussed herein would artificially inflate or maintain the price of Abbott common stock. It was also foreseeable to Defendants that the revelation of the truth about Abbott's violation of regulatory safety protocols, "egregiously unsanitary" conditions in the production of Abbott's infant formula, and threatened and actual retaliation against employees seeking to correct these

[13] Date of stock price drop indicated in parenthesis.

issues, would cause the price of the Company's stock to fall as the artificial inflation caused or maintained by Defendants' misstatements and omissions was removed. Thus, the stock price declines described above were directly and proximately caused by Defendants' materially false or misleading statements and omissions and Defendants' scheme to deceive the market.

X. PRESUMPTION OF RELIANCE

451. At all relevant times, the market for Abbott common stock was efficient for the following reasons, among others:

a) Abbott's stock met the requirements for listing, and was listed and actively traded on the New York Stock Exchange, a highly efficient market, with an average daily trading volume of approximately 5.42 million shares;

b) As a regulated issuer, Abbott filed periodic reports with the SEC;

c) Abbott regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

d) 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, who wrote reports that were distributed to those brokerage firms' sales forces and certain customers. Each of these reports was publicly available and entered the public marketplace.

452. As a result of the foregoing, the market for Abbott common stock promptly digested current information regarding Abbott from all public available sources and reflected such information in Abbott's stock price. Under these circumstances, purchasers of Abbott common stock at artificially inflated prices during the Class Period suffered similar injury through their transactions and a presumption of reliance applies.

453. In addition, Plaintiffs are entitled to a presumption of reliance under *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the claims asserted herein are predicated in part upon material omissions of fact that Defendants had a duty to disclose.

XI. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BESPEAKS CAUTION DOCTRINE

454. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements described in this Complaint. Many of the specific statements described herein were not identified as "forward-looking" when made. To the extent that there were any forward-looking statements, there was no meaningful cautionary language identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements described herein, Defendants are liable for those false forward-looking statements because at the time each was made, the particular speaker knew that the particular forward-looking statement was false or misleading, and/or that the forward-looking statement was authorized and/or approved by an executive officer of Abbott who knew that those statements were false or misleading when made.

XII. CLASS ACTION ALLEGATIONS

455. Plaintiffs bring this action as a class action pursuant to Fed. R. Civ. P. 23(a) and 23(b)(3) on behalf of a Class consisting of all those who purchased or otherwise acquired Abbott common stock between February 19, 2021 and October 19, 2022, inclusive, and who were damaged thereby. Excluded from the Class are Defendants, the officers and directors of Abbott at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest.

456. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Abbott common stock were actively traded on the New York Stock Exchange. As of September 30, 2022, Abbott had 1.74 billion shares of common stock outstanding. While the exact number of Class members is unknown to Plaintiffs at this time and can only be ascertained through appropriate discovery, Plaintiffs believe that there are thousands of members of the proposed Class. Class members who purchased Abbott common stock may be identified from records maintained by Abbott or its transfer agent(s), and may be notified of this class action using a form of notice similar to that customarily used in securities class actions.

457. Plaintiffs' claims are typical of Class members' claims, as all members of the Class were similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

458. Plaintiffs will fairly and adequately protect Class members' interests and have retained competent counsel experienced in class actions and securities litigation.

459. Common questions of law and fact exist as to all Class members and predominate over any questions solely affecting individual Class members. Among the questions of fact and law common to the Class are:

a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

b) whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about Abbott;

c) whether Defendants acted with scienter; and

d) to what extent the members of the Class have suffered damages, as well as the proper measure of damages.

460. A class action is superior to all other available methods for the fair and efficient adjudication of this action because joinder of all Class members is impracticable.

461. Additionally, the damage suffered by some individual Class members may be relatively small so that the burden and expense of individual litigation makes it impossible for such members to individually redress the wrong done to them. There will be no difficulty in the management of this action as a class action.

XIII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

COUNT I

For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5(b) Promulgated Thereunder (Against All Defendants)

462. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

463. This Count is asserted on behalf of all members of the Class against Defendant Abbott and the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(b) promulgated thereunder, 17 C.F.R. § 240.10b-5.

464. During the Class Period, Defendant Abbott and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b) in that they made untrue statements of material fact and/or disseminated and/or approved and/or omitted to state material facts necessary to make the false or misleading statements specified above not misleading. Defendants' actions did: (i) deceive the investing public, including Plaintiffs and other Class members, as alleged herein; and (ii) cause Plaintiffs and other members of the Class to purchase Abbott common stock at artificially inflated prices.

465. Defendant Abbott and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the

mails, made various untrue and/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; which did: (i) deceive the investing public, including Plaintiffs and the Class, regarding, among other things, Abbott's commitment and adherence to regulatory safety protocols in the production of infant formula, its compliance with CGMPs, and the unsanitary conditions at Sturgis; (ii) artificially inflate and maintain the market price of Abbott common stock; and (iii) cause Plaintiffs and other members of the Class to purchase Abbott common stock at artificially inflated prices and suffer losses when the true facts became known.

466. As described above, Defendant Abbott and the Individual Defendants acted with scienter throughout the Class Period, in that they either had actual knowledge of the misrepresentations or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even though such facts were available to them. Defendant Abbott and the Individual Defendants engaged in this misconduct to conceal Abbott's true condition from the investing public and to support the artificially inflated prices of the Company's common stock.

467. Plaintiffs and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Abbott common stock, which artificial inflation was removed from the stock when true facts became known. Plaintiffs and the Class would not have purchased Abbott common stock at the prices they paid, or at all, had they been aware that the market prices for Abbott common stock had been artificially inflated by Defendant Abbott and the Individual Defendants' fraudulent course of conduct.

468. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their respective purchases of the Company's common stock, call options, or put options during the Class Period.

469. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(b), promulgated thereunder.

COUNT II

For Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5(a) and (c) Promulgated Thereunder (Against All Defendants)

470. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

471. This Count is asserted on behalf of all members of the Class against Defendant Abbott and the Individual Defendants for violations of Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5(a) and (c) promulgated thereunder, 17 C.F.R. § 240.10b-5.

472. Defendant Abbott and the Individual Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c) in that they: (1) employed devices, schemes, and artifices to defraud; and (2) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon Plaintiffs and others similarly situated in connection with their purchases of Abbott common stock during the Class Period in an effort to maintain artificially high market prices for Abbott common stock.

473. Defendant Abbott and the Individual Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Plaintiffs and the Class in

connection with the purchase and sale of Abbott common stock; which did: (i) deceive the investing public, including Plaintiffs and the Class, regarding, among other things, Abbott's commitment and adherence to regulatory safety protocols in the production of infant formula, its compliance with CGMPs, and the unsanitary conditions at Sturgis; (ii) artificially inflate and maintain the market price of Abbott common stock; and (iii) cause Plaintiffs and other members of the Class to purchase Abbott common stock at artificially inflated prices and suffer losses when the true facts became known.

474. As part of their scheme to defraud investors in violation of Rule 10b-5(a) and (c), the Defendants engaged in the following course of business conduct, as described by, among things, the FDA's 2019, 2021, and 2022 483 Reports, the Whistleblower's February 2021 and October 2021 Complaints, the DOJ Complaint and Consent Decree, and the accounts of former employees described above. For example, Defendants engaged in the following deceptive activities:

(i) Refusing to destroy potentially contaminated infant formula by releasing to consumers formula derived from batches that had tested positive for micros;

(ii) Knowingly deceiving the FDA investigators during the 2019 audit by failing to disclose the aforementioned incident;

(iii) Knowingly and intentionally falsifying testing, cleaning, and maintenance records in violation of CGMPs and other regulations, which included, among others, falsified data concerning testing of empty cans, the signing of cleaning and testing verifications without knowledge to do so, and failing to maintain accurate maintenance records;

(iv) Failing to repair and upkeep machinery essential for the safe manufacture of infant formula (such as dryers), which posed known contamination risks;

(v) Failing to address pervasive water leaks, which posed known contamination risks;

(vi) Fostering a culture of fear of retaliation against employees who spoke up concerning safety and sanitary violations;

(vii) Failing to properly staff the Sturgis plant despite various requests from plant employees for more staff and resources;

(viii) Failure to devote needed resources to modernize and revamp the Sturgis plant despite various requests from employees calling for the need for investments to upgrade the plant;

(ix) Failing to implement proper procedures necessary to ensure legally required traceability of infant formula manufactured at the Sturgis facility;

(x) Concealment and destruction of evidence of misconduct by staging the Sturgis facility for routine inspections in a way that did not accurately portray the conditions at the facility; and

(xi) Destroying evidence at the Sturgis facility prior to the commencement of the FDA's 2022 inspection.

475. These deceptive acts were part of a course of conduct that operated as a fraud and deceit upon Plaintiffs and others similarly situated in connection with their purchases of Abbott common stock during the Class Period in an effort to maintain artificially high market prices for Abbott common stock.

476. As described above, Defendant Abbott and the Individual Defendants acted with scienter throughout the Class Period, in that they either had actual knowledge of the misrepresentations or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even though such facts were available to them. Defendant Abbott and the Individual Defendants engaged in this misconduct to conceal Abbott's true condition from the investing public and to support the artificially inflated prices of the Company's common stock.

477. Plaintiffs and the Class have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Abbott common stock, which artificial inflation was removed from the stock when true facts became known. Plaintiffs and the Class would not have purchased Abbott common stock at the prices they paid, or at all, had they

been aware that the market prices for Abbott common stock had been artificially inflated by Defendant Abbott and the Individual Defendants' fraudulent course of conduct.

478. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the other members of the Class suffered damages attributable to the fraud alleged herein in connection with their respective purchases of the Company's common stock, call options, or put options during the Class Period.

479. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5(a) and (c), promulgated thereunder.

COUNT III

For Violations of Section 20(a) of the Exchange Act (Against The Individual Defendants)

480. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

481. This Count is asserted on behalf of all members of the Class against the Individual Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

482. Throughout the Class Period, during their tenures as officers and/or directors of Abbott, each of the Individual Defendants was a controlling person of the Company within the meaning of Section 20(a) of the Exchange Act. By reason of their positions of control and authority as officers and/or directors of Abbott, these Defendants had the power and authority to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein.

483. As more fully described above, the Individual Defendants acted as controlling persons of Abbott within the meaning of Section 20(a) of the Exchange Act. In their capacities as senior corporate officers of the Company, the Individual Defendants had direct involvement in the day-to-day operations of the Company, including their power to control or influence the policies

and practices giving rise to Abbott's misleading statements about its commitment and adherence to regulatory safety protocols, compliance with FDA regulations and CGMPs, and the unsanitary conditions at Sturgis alleged herein; the power to control public statements about Abbott; and the power and ability to control the actions of Abbott and its employees.

484. Defendants Ford and Funck signed the Company's SEC filings during the Class Period. The Individual Defendants were directly involved in disseminating Abbott's false or misleading statements during the Class Period, and made additional false or misleading statements in publicly-disseminated conference calls, testimony, and statements on behalf of Abbott. As a result of the foregoing, the Individual Defendants, as a group and individually, were controlling persons of Abbott within the meaning of Section 20(a) of the Exchange Act.

485. Abbott violated Section 10(b) of the Exchange Act by its acts and omissions, as alleged in this Complaint. By virtue of their positions as controlling persons of Abbott, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally to Plaintiffs and other members of the Class who purchased or otherwise acquired Abbott common stock.

486. As a direct and proximate result of the Individual Defendants' conduct, Plaintiffs and the other members of the Class suffered damages in connection with their purchase or acquisition of Abbott common stock.

XIV. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

b) Awarding compensatory damages and equitable relief in favor of Plaintiffs and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongful conduct, in an amount to be proven at trial, including interest thereon;

b) Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

c) Such other and further relief as the Court may deem just and proper.

XV. JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiffs hereby demand a trial by jury in this action of all issues so triable.

Dated: April 21, 2023

Respectfully submitted,

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APPENDIX A

CERTIFICATION PURSUANT TO
THE FEDERAL SECURITIES LAWS

The undersigned, Nigel Cresswell and Silke Weiser-Walther, on behalf of Quoniam Asset Management GmbH ("Quoniam"), on account of the funds listed in the attached Schedule A (the "Funds"), declare the following as to the claims asserted, or to be asserted, under the federal securities laws:

1. As court-appointed Lead Plaintiff, we have reviewed the Amended Complaint in this matter and authorize its filing by counsel.

2. We are duly authorized to institute legal action on behalf of Quoniam and the Funds, including litigation against Abbott Laboratories and any other defendants.

3. The Funds did not purchase the securities that are the subject of this action at the direction of counsel or in order to participate in any action arising under the federal securities laws.

4. Quoniam fully understands the duties and responsibilities of the lead plaintiff under the Private Securities Litigation Reform Act, including the selection and retention of counsel and overseeing the prosecution of the action for the Class.

5. The Funds' transactions in the Abbott Laboratories securities that are the subject of this action are set forth in the attached Schedule A.

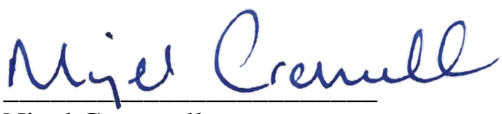
6. Aside from the present action, Quoniam has not sought to serve as a lead plaintiff or representative party on behalf of a class in any action under the federal securities laws filed during the three-year period preceding the date of this Certification.

7. Quoniam will not accept any payment for serving as a representative party on behalf of the Class beyond Quoniam's pro rata share of any recovery, except such reasonable costs and expenses (including lost wages) directly relating to the representation of the Class, as ordered or approved by the Court.

We declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 21st day of April, 2023.

For Quoniam Asset Management GmbH:



Nigel Cresswell
CEO, Managing Partner

Silke Weiser-Walther
CFO & CCO, Managing Partner

Schedule A

Quoniam Asset Management GmbH
Transactions in Abbott Laboratories

Fund	Transaction	Date	Shares	Price
UniMarktführer	Purchase	5/17/2022	43,000	113.9925
UniMarktführer	Purchase	5/23/2022	20,000	115.0613
UniSector: BioPharma	Purchase	7/21/2021	73,039	118.2581
UniSector: BioPharma	Purchase	7/27/2021	84,058	120.5356
UniSector: BioPharma	Purchase	8/6/2021	3,000	121.2520
UniSector: BioPharma	Purchase	8/6/2021	23,424	121.7327
UniSector: BioPharma	Purchase	11/18/2021	15,701	128.8530
UniSector: BioPharma	Purchase	11/24/2021	16,177	124.7551
UniSector: BioPharma	Purchase	5/17/2022	106,158	114.2021
UniSector: BioPharma	Purchase	5/18/2022	16,748	113.3903
UniSector: BioPharma	Purchase	5/20/2022	12,288	113.3805
UniSector: BioPharma	Sale	3/5/2021	(9,140)	116.4573
UniSector: BioPharma	Sale	5/28/2021	(85,509)	116.9442
UniSector: BioPharma	Sale	5/28/2021	(63,155)	117.3227
UniSector: BioPharma	Sale	11/5/2021	(27,654)	125.2831
UniSector: BioPharma	Sale	12/7/2021	(23,607)	133.0945
UniSector: BioPharma	Sale	12/14/2021	(18,440)	134.7801
UniSector: BioPharma	Sale	1/4/2022	(10,010)	136.0105
UniSector: BioPharma	Sale	1/10/2022	(10,237)	134.9389
UniSector: BioPharma	Sale	1/12/2022	(5,427)	133.8961
UniSector: BioPharma	Sale	1/12/2022	(8,033)	133.5128
UniSector: BioPharma	Sale	1/13/2022	(24,906)	131.7287
UniSector: BioPharma	Sale	1/24/2022	(20,188)	121.2285
UniSector: BioPharma	Sale	7/6/2022	(11,533)	108.4503
Global Equities MinRisk	Purchase	3/11/2021	21,477	117.3855
Global Equities MinRisk	Purchase	3/12/2021	2,962	116.6835
Global Equities MinRisk	Purchase	3/12/2021	1,796	116.6880
Global Equities MinRisk	Purchase	4/13/2021	3,063	122.9095
Global Equities MinRisk	Purchase	5/18/2021	3,015	117.6697
Global Equities MinRisk	Purchase	5/19/2021	505	116.2370

Quoniam Asset Management GmbH
Transactions in Abbott Laboratories

Fund	Transaction	Date	Shares	Price
Global Equities MinRisk	Purchase	5/20/2021	796	117.8013
Global Equities MinRisk	Purchase	7/23/2021	4,481	119.8379
Global Equities MinRisk	Purchase	7/26/2021	4,383	119.5200
Global Equities MinRisk	Purchase	12/15/2021	4,150	133.7545
Global Equities MinRisk	Purchase	1/11/2022	4,030	135.7000
Global Equities MinRisk	Sale	5/3/2021	(4,989)	119.5300
Global Equities MinRisk	Sale	9/23/2021	(2,402)	125.2783
Global Equities MinRisk	Sale	11/2/2021	(2,126)	128.5200
Global Equities MinRisk	Sale	11/16/2021	(3,842)	130.8879
Global Equities MinRisk	Sale	11/26/2021	(4,169)	125.8800
Global Equities MinRisk	Sale	4/28/2022	(8,502)	118.2367
Global Equities MinRisk	Sale	6/21/2022	(9,186)	104.3981
Global Equities MinRisk	Sale	7/12/2022	(3,756)	109.3905
UIN-Fonds Nr. 618	Purchase	2/23/2021	637	121.1635
UIN-Fonds Nr. 618	Purchase	3/16/2021	4,024	117.9013
UIN-Fonds Nr. 618	Purchase	3/17/2021	634	117.4873
UIN-Fonds Nr. 618	Purchase	4/22/2021	4,091	123.9549
UIN-Fonds Nr. 618	Sale	11/16/2021	(1,095)	130.8879
UIN-Fonds Nr. 618	Sale	9/20/2022	(1,641)	101.8008
Global Equities	Purchase	3/11/2021	758	117.3855
Global Equities	Purchase	4/13/2021	2,414	122.9095
Global Equities	Purchase	5/18/2021	2,160	117.6697
Global Equities	Purchase	5/19/2021	362	116.2370
Global Equities	Purchase	5/20/2021	570	117.8013
Global Equities	Purchase	12/27/2021	2,094	141.0145
Global Equities	Sale	12/22/2021	(817)	138.9900
Global Equities	Sale	2/11/2022	(1,386)	125.4900
Global Equities	Sale	4/11/2022	(504)	120.2563
Global Equities	Sale	8/26/2022	(1,586)	101.9000

Quoniam Asset Management GmbH
Transactions in Abbott Laboratories

Fund	Transaction	Date	Shares	Price
PrivatFonds: Nachhaltig	Purchase	3/23/2021	25,312	121.8200
PrivatFonds: Nachhaltig	Sale	5/7/2021	(25,312)	119.7443
Global Equities MinRisk All Countries	Purchase	3/16/2021	2,769	117.9013
Global Equities MinRisk All Countries	Purchase	3/17/2021	437	117.4873
Global Equities MinRisk All Countries	Purchase	4/22/2021	659	123.9549
Global Equities MinRisk All Countries	Sale	1/14/2022	(609)	128.1600
Global Equities MinRisk All Countries	Sale	5/9/2022	(2,181)	107.3900
Global Equities MinRisk All Countries	Sale	7/15/2022	(2,383)	108.8200
Global Equities MinRisk All Countries	Sale	9/20/2022	(186)	102.3100
Global Equities MinRisk All Countries	Sale	9/26/2022	(834)	99.8400
UIN-Fonds Nr. 799	Purchase	4/8/2021	750	121.0100
UIN-Fonds Nr. 799	Purchase	3/15/2022	1,185	117.4800
UIN-Fonds Nr. 799	Sale	6/2/2021	(750)	107.0949
UIN-Fonds Nr. 775	Purchase	4/8/2021	1,570	121.0100
UIN-Fonds Nr. 775	Sale	6/2/2021	(1,570)	107.0949
DEVIF-Fonds Nr. 45	Purchase	4/8/2021	1,570	121.0100
DEVIF-Fonds Nr. 45	Sale	6/1/2021	(1,570)	107.2949
UIN-Fonds Nr. 562	Purchase	4/8/2021	660	121.0100
UIN-Fonds Nr. 562	Purchase	2/16/2022	770	121.8978

Quoniam Asset Management GmbH
Transactions in Abbott Laboratories

Fund	Transaction	Date	Shares	Price
UIN-Fonds Nr. 562	Sale	6/2/2021	(660)	107.0949
BIA-Fonds Nr. 5	Purchase	4/8/2021	1,160	121.0100
BIA-Fonds Nr. 5	Sale	6/2/2021	(1,160)	107.1914
UIN-Fonds Nr. 776	Purchase	4/8/2021	960	121.0100
UIN-Fonds Nr. 776	Sale	6/2/2021	(960)	107.0949
DEVIF-Fonds Nr. 35	Purchase	7/8/2021	1,850	118.8911
DEVIF-Fonds Nr. 35	Purchase	4/20/2022	250	119.4800
DEVIF-Fonds Nr. 35	Sale	1/6/2022	(650)	135.1400
UIN-Fonds Nr. 682	Purchase	6/1/2021	1,100	109.8817
UIN-Fonds Nr. 682	Sale	9/23/2022	(553)	100.3900

APPENDIX B

Schedule A

KBC Asset Management NV

Abbott Laboratories (ABT)

Class Period: 02/18/2021 - 10/19/2022

		Date	Shares	Price
KBC Equity Fund				
	Purchases:	2/24/2021	1,881.00	122.38
		2/24/2021	1,739.00	122.38
		2/24/2021	1,937.00	122.38
		2/26/2021	1,564.00	119.78
		3/9/2021	308.00	116.70
		3/11/2021	27,442.00	117.52
		3/11/2021	2,011.00	117.52
		3/11/2021	1,959.00	117.52
		3/16/2021	212.00	118.22
		3/26/2021	286.00	122.07
		4/9/2021	199.00	120.90
		4/13/2021	9,635.00	123.01
		4/16/2021	1,969.00	124.35
		4/16/2021	3,366.00	124.35
		4/16/2021	2,815.00	124.35
		4/16/2021	661.00	124.35
		4/23/2021	654.00	123.31
		4/23/2021	866.00	123.31
		4/23/2021	832.00	123.31
		6/1/2021	972.00	105.79
		6/1/2021	443.00	105.79
		6/2/2021	5,194.00	106.90
		6/2/2021	281.00	106.90
		6/11/2021	1,447.00	109.91
		6/11/2021	995.00	109.91
		6/17/2021	4,073.00	111.63
		6/17/2021	3,794.00	111.63
		6/17/2021	4,041.00	111.63
		6/17/2021	3,348.00	111.63

Date	Shares	Price
6/24/2021	1,542.00	111.70
6/24/2021	2,052.00	111.70
6/24/2021	2,150.00	111.70
6/24/2021	2,119.00	111.70
7/13/2021	314.00	118.65
7/16/2021	203.00	117.51
8/5/2021	1,197.00	122.21
8/5/2021	3,942.00	122.21
8/5/2021	609.00	122.21
8/5/2021	889.00	122.21
8/5/2021	916.00	122.21
8/12/2021	408.00	122.81
8/12/2021	3,405.00	122.81
8/13/2021	1,849.00	123.06
8/13/2021	1,888.00	123.06
8/13/2021	1,793.00	123.06
8/13/2021	1,159.00	123.06
8/19/2021	1,543.00	125.72
8/31/2021	1,969.00	126.37
9/13/2021	279.00	126.62
9/13/2021	1,311.00	126.62
9/27/2021	15,874.00	120.58
10/13/2021	596.00	117.00
10/21/2021	3,056.00	125.05
11/15/2021	41,380.00	129.44
11/15/2021	17,693.00	129.44
11/29/2021	2,415.00	128.03
12/2/2021	11,316.00	128.38
12/2/2021	287.00	128.38
12/2/2021	7,467.00	128.38
12/2/2021	11,956.00	128.38
12/3/2021	92,765.00	130.17
12/3/2021	93,215.00	130.17
12/3/2021	92,890.00	130.17

Date	Shares	Price
12/3/2021	69,251.00	130.17
12/9/2021	2,369.00	132.53
12/13/2021	190.00	135.96
12/13/2021	7,300.00	135.96
12/16/2021	514.00	136.09
12/16/2021	1,582.00	136.09
12/16/2021	519.00	136.09
12/16/2021	5,306.00	136.09
12/20/2021	300.00	134.98
1/4/2022	2,551.00	135.77
1/6/2022	437.00	135.14
1/6/2022	2,981.00	135.14
1/12/2022	363.00	133.72
1/13/2022	616.00	129.65
1/14/2022	4,479.00	128.16
1/14/2022	4,492.00	128.16
1/14/2022	4,481.00	128.16
1/14/2022	3,410.00	128.16
1/20/2022	211.00	124.71
1/20/2022	1,453.00	124.71
1/20/2022	1,101.00	124.71
1/20/2022	1,396.00	124.71
1/21/2022	4,443.00	125.83
1/21/2022	4,803.00	125.83
1/21/2022	4,528.00	125.83
1/21/2022	4,529.00	125.83
1/24/2022	1,480.00	123.82
2/4/2022	335.00	129.71
2/10/2022	3,888.00	127.76
2/10/2022	3,861.00	127.76
2/10/2022	3,820.00	127.76
2/10/2022	4,331.00	127.76
2/14/2022	650.00	122.78
2/14/2022	93,981.00	122.78

Date	Shares	Price
2/17/2022	504.00	120.58
2/17/2022	1,626.00	120.58
2/17/2022	1,302.00	120.58
2/24/2022	36,708.00	118.72
2/24/2022	39,640.00	118.72
2/24/2022	35,523.00	118.72
2/24/2022	35,605.00	118.72
2/25/2022	1,555.00	122.41
2/25/2022	4,953.00	122.41
2/25/2022	5,248.00	122.41
2/25/2022	187.00	122.41
3/3/2022	978.00	120.97
3/3/2022	1,299.00	120.97
3/3/2022	1,252.00	120.97
3/3/2022	1,143.00	120.97
3/3/2022	614.00	120.97
3/3/2022	2,233.00	120.97
3/3/2022	1,119.00	120.97
3/11/2022	348.00	114.02
3/14/2022	76,151.00	115.52
3/17/2022	345.00	121.20
3/30/2022	445.00	120.38
3/30/2022	462.00	120.38
3/30/2022	480.00	120.38
3/31/2022	832.00	118.36
3/31/2022	3,835.00	118.36
4/12/2022	2,667.00	118.39
4/12/2022	2,497.00	118.39
4/13/2022	2,608.00	119.48
4/13/2022	2,608.00	119.48
4/21/2022	560.00	123.37
4/29/2022	24,419.00	113.44
4/29/2022	30,252.00	113.44
4/29/2022	30,495.00	113.44

Date	Shares	Price
4/29/2022	30,192.00	113.44
4/29/2022	1,557.00	113.43
4/29/2022	23,441.00	113.44
4/29/2022	28,411.00	113.44
4/29/2022	25,414.00	113.44
4/29/2022	21,392.00	113.44
5/12/2022	3,565.00	107.97
5/20/2022	320.00	113.24
5/31/2022	133,264.00	117.46
5/31/2022	37,000.00	115.53
6/10/2022	3,089.00	109.63
6/22/2022	1,249.00	105.44
6/22/2022	1,387.00	105.44
6/22/2022	1,282.00	105.44
6/22/2022	1,045.00	105.44
6/22/2022	2,513.00	105.44
6/23/2022	2,410.00	106.21
6/24/2022	3,621.00	109.45
7/6/2022	226.00	108.69
7/12/2022	221.00	108.30
7/13/2022	1,647.00	106.21
7/13/2022	1,416.00	106.21
7/28/2022	2,876.00	110.36
7/29/2022	3,861.00	108.84
8/9/2022	2,805.00	107.91
8/11/2022	444.00	110.49
8/16/2022	4,913.00	112.03
8/18/2022	2,468.00	109.96
9/2/2022	3,236.00	102.50
9/8/2022	2,205.00	106.99
9/8/2022	5,274.00	106.99
9/8/2022	5,490.00	106.99
9/8/2022	5,237.00	106.99
9/8/2022	3,491.00	106.99

	Date	Shares	Price
	9/8/2022	2,374.00	106.99
	9/8/2022	2,131.00	106.99
	9/8/2022	1,424.00	106.99
	9/13/2022	395.00	105.84
	9/15/2022	822.00	105.06
	9/15/2022	1,472.00	105.06
	9/15/2022	1,358.00	105.06
	9/15/2022	1,680.00	105.06
	9/15/2022	3,294.00	105.06
	9/15/2022	223.00	105.06
	9/15/2022	450.00	105.06
	9/15/2022	959.00	105.06
	9/29/2022	522.00	98.29
	9/29/2022	846.00	98.29
	9/29/2022	862.00	98.29
	9/29/2022	998.00	98.29
	9/29/2022	1,005.00	98.29
	9/29/2022	970.00	98.29
	9/29/2022	506.00	98.29
	9/29/2022	3,210.00	98.29
	10/5/2022	549.00	103.38
	10/14/2022	2,298.00	100.91
	10/14/2022	2,298.00	100.91
	10/14/2022	2,298.00	100.91
Sales:	3/5/2021	-1,682.00	117.25
	3/5/2021	-1,691.00	117.25
	3/5/2021	-1,705.00	117.25
	3/5/2021	-1,371.00	117.25
	3/11/2021	-10,287.00	117.52
	3/19/2021	-2,389.00	120.25
	3/19/2021	-6,024.00	120.25
	3/19/2021	-6,327.00	120.25
	3/19/2021	-1,954.00	120.25
	3/25/2021	-11,777.00	119.05

Date	Shares	Price
4/13/2021	-728.00	123.01
4/30/2021	-3,043.00	120.08
4/30/2021	-3,166.00	120.08
4/30/2021	-3,153.00	120.08
4/30/2021	-2,309.00	120.08
5/7/2021	-37,317.00	118.95
5/12/2021	-3,566.00	116.35
5/12/2021	-935.00	116.35
5/17/2021	-2,226.00	116.74
5/17/2021	-1,982.00	116.74
5/17/2021	-2,095.00	116.74
5/17/2021	-1,544.00	116.74
6/3/2021	-604.00	109.20
6/24/2021	-72,253.00	111.70
6/24/2021	-18,443.00	112.04
7/8/2021	-1,237.00	119.26
7/8/2021	-765.00	119.26
7/8/2021	-1,184.00	119.26
7/8/2021	-394.00	119.26
7/13/2021	-173,645.00	118.65
7/30/2021	-2,200.00	120.98
7/30/2021	-1,186.00	120.98
7/30/2021	-2,001.00	120.98
7/30/2021	-1,320.00	120.98
9/20/2021	-5,033.00	124.87
9/20/2021	-4,459.00	124.87
9/20/2021	-4,896.00	124.87
9/20/2021	-7,336.00	124.87
9/22/2021	-385.00	124.65
9/30/2021	-1,755.00	118.13
9/30/2021	-1,391.00	118.13
9/30/2021	-1,612.00	118.13
9/30/2021	-4,962.00	118.13
10/6/2021	-482.00	116.49

Date	Shares	Price
10/13/2021	-21,619.00	117.00
10/29/2021	-3,190.00	128.89
10/29/2021	-2,427.00	128.89
10/29/2021	-3,145.00	128.89
10/29/2021	-2,715.00	128.89
11/9/2021	-677.00	126.43
11/9/2021	-1,025.00	126.43
11/9/2021	-990.00	126.43
11/9/2021	-1,077.00	126.43
11/16/2021	-3,570.00	130.89
11/16/2021	-1,772.00	130.89
11/16/2021	-3,570.00	130.89
11/16/2021	-742.00	130.89
12/16/2021	-488.00	136.09
12/16/2021	-1,717.00	136.09
12/16/2021	-261.00	136.09
12/22/2021	-167.00	138.99
12/22/2021	-333.00	138.99
1/6/2022	-53,974.00	135.15
1/6/2022	-58,736.00	135.15
1/6/2022	-54,801.00	135.15
1/6/2022	-47,484.00	135.15
1/13/2022	-171.00	129.65
1/13/2022	-68,898.00	129.65
1/20/2022	-715.00	124.71
1/20/2022	-1,025.00	124.71
1/20/2022	-1,361.00	124.71
1/21/2022	-3,705.00	125.83
1/21/2022	-1,510.00	125.83
1/21/2022	-1,514.00	125.83
1/21/2022	-1,063.00	125.83
1/25/2022	-361.00	123.27
1/27/2022	-57,817.00	120.43
1/27/2022	-35,997.00	120.43

Date	Shares	Price
1/27/2022	-40,871.00	120.43
1/27/2022	-40,333.00	120.43
1/27/2022	-1,483.00	120.43
1/27/2022	-29,838.00	120.43
1/27/2022	-66,308.00	120.43
1/27/2022	-60,381.00	120.43
1/27/2022	-55,578.00	120.43
2/17/2022	-1,237.00	120.58
2/25/2022	-423.00	122.41
3/3/2022	-1,783.00	120.97
3/4/2022	-367.00	121.41
3/8/2022	-5,848.00	116.11
3/8/2022	-5,629.00	116.11
3/8/2022	-5,580.00	116.11
3/8/2022	-5,611.00	116.11
3/8/2022	-1,649.00	116.11
3/8/2022	-4,347.00	116.11
3/8/2022	-5,724.00	116.11
3/8/2022	-4,125.00	116.11
3/8/2022	-6,856.00	116.11
3/14/2022	-47,051.00	115.52
3/16/2022	-1,887.00	119.48
3/16/2022	-4,862.00	119.48
3/16/2022	-4,984.00	119.48
3/16/2022	-4,804.00	119.48
3/16/2022	-3,543.00	119.48
3/16/2022	-1,644.00	119.48
3/16/2022	-1,998.00	119.48
3/16/2022	-1,266.00	119.48
4/7/2022	-570.00	123.37
4/25/2022	-2,349.00	120.01
4/25/2022	-1,951.00	120.01
4/25/2022	-1,949.00	120.01
4/25/2022	-1,032.00	120.01

		Date	Shares	Price
		4/28/2022	-465.00	118.01
		5/11/2022	-339.00	105.84
		5/12/2022	-1,720.00	107.97
		5/12/2022	-1,842.00	107.97
		5/20/2022	-15,602.00	113.24
		6/14/2022	-849.00	102.94
		6/30/2022	-3,578.00	108.65
		6/30/2022	-3,621.00	108.65
		6/30/2022	-3,538.00	108.65
		6/30/2022	-3,525.00	108.65
		6/30/2022	-3,373.00	108.65
		6/30/2022	-4,342.00	108.65
		6/30/2022	-4,609.00	108.65
		6/30/2022	-5,346.00	108.65
		7/20/2022	-1,658.00	108.23
		7/29/2022	-3,770.00	108.84
		7/29/2022	-3,313.00	108.84
		7/29/2022	-3,507.00	108.84
		7/29/2022	-3,563.00	108.84
		7/29/2022	-1,796.00	108.84
		7/29/2022	-3,221.00	108.84
		7/29/2022	-3,870.00	108.84
		7/29/2022	-1,349.00	108.84
		8/22/2022	-496.00	107.45
		9/1/2022	-1,350.00	104.84
		9/1/2022	-1,372.00	104.84
		9/1/2022	-1,360.00	104.84
		9/1/2022	-1,090.00	104.84
		9/22/2022	-445.00	101.07
		9/27/2022	-400.00	98.33
		9/29/2022	-27,100.00	98.29
KBC Institutional Fund				
	Purchases:	12/7/2021	47,115.00	132.42

	Date	Shares	Price
	12/8/2021	11,957.00	132.37
	12/9/2021	3,321.00	132.53
	12/13/2021	276.00	135.96
	12/16/2021	544.00	136.09
	1/6/2022	1,426.00	135.14
	1/6/2022	524.00	135.14
	1/7/2022	1,030.00	135.56
	1/10/2022	7,604.00	135.26
	1/14/2022	275.00	128.16
	1/25/2022	1,296.00	123.27
	1/27/2022	2,750.00	120.44
	4/8/2022	553.00	123.25
	5/25/2022	224.00	113.19
	7/8/2022	1,795.00	109.26
	7/14/2022	10,830.00	105.71
	7/29/2022	13,346.00	108.84
	9/1/2022	158.00	104.84
Sales:	3/8/2022	-1,527.00	116.11
	4/29/2022	-166.00	113.50
	7/20/2022	-530.00	108.23
	7/28/2022	-372.00	110.36
	9/1/2022	-8,228.00	104.84
	9/29/2022	-7,376.00	98.29

APPENDIX C

Former Employee Key

FE	Tenure	Relevant Position(s) or Role(s)	Description
1	Pre-Class Period – September 2021	Sturgis Front Line Leader (2017-2019), Sturgis GMP & Food Safety Specialist (2019-September 2021)	As Front Line Leader: FE1 supervised all six lines at Sturgis during the a shift. As GMP & Food Safety Specialist, FE1 worked on and devised projects that were necessary to meet the requirements of FSMA and other CGMP and regulations.
2	Pre-Class Period – November 2021	Senior Executive in Abbott's Media Relations and Public Affairs Department	FE2 participated in Abbott's corporate media relations across all businesses, including Nutrition.
3	Pre-Class Period – October 2022	Sturgis Operator	FE3 ran equipment on various powdered formula lines at Sturgis.
4	Pre-Class Period – March 2021	Sturgis Packaging Operator	FE4 ran packaging equipment on various powdered formula production lines at Sturgis.
5	Pre-Class Period – End of 2020	Casa Grande, Arizona Microbiology Supervisor	FE5 oversaw microorganism testing and the environmental monitoring program for manufacturing areas.