

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

____ 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.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff _____, alleges the following based upon personal knowledge as to itself and its own acts, and upon information and belief as to all other matters, including the investigation of Plaintiff's counsel, which included, among other things, a review of Defendants' (defined below) United States Securities and Exchange Commission ("SEC") filings, wire and press releases published by Abbott Laboratories ("Abbott" or the "Company"), analyst reports and advisories about the Company, media reports concerning the Company, and information obtainable on the internet. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION AND OVERVIEW

1. Plaintiff _____ brings this securities fraud class action on behalf of itself and all other persons or entities who purchased or otherwise acquired shares of Abbott common

stock during the period from February 19, 2021 to June 8, 2022, inclusive (the “Class Period”), and were damaged by the conduct asserted herein (the “Class”). Plaintiff asserts claims against Abbott, Abbott’s Chief Executive Officer Robert B. Ford (“Ford”), Chief Financial Officer Robert E. Funck, Jr. (“Funck”), Executive Vice President, Nutritional Products, Joseph Manning (“Manning”), and President, Nutrition North America & Senior Vice President, U.S. Nutrition, Christopher J. Calamari (“Calamari”) (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.

2. Abbott, an Illinois corporation headquartered in Abbott Park, Illinois, provides a broad line of health care products, with four reporting segments: Nutritional Products, Established Pharmaceutical Products, Diagnostic Products, and Medical Devices. Abbott’s Nutritional Products segment manufactures various forms of infant formula, including formula sold under the brand names Similac, Alimentum and EleCare. Prior to February 2022, Abbott had produced 40 percent of the United States’ infant formula. Of that amount, approximately 40% of Abbott’s formula—nearly half—was produced in its manufacturing facility in Sturgis, Michigan (“Sturgis”), meaning that Abbott’s Sturgis-manufactured infant formula fed roughly one in six formula-fed babies in the United States.

3. This action arises from Defendants’ misrepresentations concerning the safety and salability of Abbott’s infant formula amid the multiple violations of federal and state health and safety regulations at the Company’s Sturgis facility. Throughout the Class Period, Defendants put profitability ahead of children’s safety. During that time, Abbott engaged in a scheme to maximize revenues and inflate the Company’s stock price while disregarding and then concealing lapses in safety protocols that ultimately were linked to serious infant illnesses and even deaths.

4. Throughout the Class Period, Abbott marketed Similac and other popular brands of formula as “nutrition you can trust,” with promises to “help keep your baby fed, happy and healthy.” In annual circulars and Environmental, Social, and Governance (“ESG”) Global Reports, 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 promised investors and the public that any complaints of safety or other concerns 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, while critical to investors, should of course not even have been necessary: Abbott was manufacturing infant formula—food for babies, the most vulnerable constituency possible—and an expectation of food safety was implicit in the very act of offering those products for sale.

5. Based on its representations to investors and the strong market position Abbott had developed based on its reputation for safe, quality products, the Company generated revenues of \$109 billion between 2019 and 2021. Abbott and its leaders, however, knew since at least February 2021 that the Company’s Sturgis facility—Abbott’s primary manufacturing site for infant formula production, suffered from severe, widespread product safety deficiencies and regulatory violations that put infants at serious risk. By at least September 20, 2021, Abbott received complaints of infant deaths linked to Abbott’s infant formula. Also on September 20, 2021, the United States Food and Drug Administration (“FDA”) began a routine four-day inspection of the Sturgis facility,

and reported privately to Abbott that the facility “did not maintain a building used in the manufacturing, processing, packing or holding of infant formula in a clean and sanitary condition.”

6. 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 initiated an onsite inspection at the facility, and to date had found several positive contamination results from environmental samples for a bacteria, *Cronobacter sakazakii* (“*Cronobacter*”), linked to infant illnesses and death. The FDA also 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*.”

7. 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. Abbott made no mention of the open FDA investigation. In the press release, Defendant Manning, characterized Abbott’s “voluntary” recall as “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.”

8. On this news, 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.

9. In the following days, Abbott was forced to close the Sturgis plant due to the 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. This shortage prompted the U.S. government to take the unprecedeted step of

invoking the Defense Production Act to speed production of infant formula and authorize flights to import supply from overseas to keep the country's most vulnerable population fed and healthy.

10. Approximately one month later, on March 22, 2022, after the markets closed, the FDA released 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 stated that these reports "do not constitute final FDA determinations" of specific violations, but highlighted that during its most recent inspection that (a) Abbott failed to establish process controls "designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment" and (b) Abbott failed to "ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source." On the news of these damaging inspection 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.

11. As the FDA investigation continued, a redacted copy of a whistleblower complaint sent to the FDA in October 2021 was made public on April 22, 2022. The whistleblower complaint revealed that the issues disclosed in February and March 2022 were actually known to Abbott's management far earlier. The whistleblower complaint identified numerous serious examples of misconduct by Abbott management at Sturgis, including the falsification of testing records, the release of untested infant formula to the market, efforts to mislead the FDA during its 2019 inspection audit, the continuation of known deficient testing procedures, and an inability to trace products to properly implement recalls of affected pallets of formula. Upon release of the 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.

12. A few weeks later, Abbott entered into a consent decree agreement with the FDA. The consent decree and accompanying complaint largely reiterated the detailed findings released by the FDA in March, and made clear the extent and impact of Abbott's failures, which led the defendants in that action—Abbott and certain principal executives with direct responsibility over the manufacture of infant formula at Sturgis—to “manufacture 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*.”

13. On May 25, 2022, FDA Commissioner Robert Califf provided sworn testimony before a subcommittee of the United States House of Representatives about the baby formula shortage brought about by the Abbott infant formula recall. Mr. Califf described bacteria growing at multiple sites in the facility, cracks in key equipment, leaks from the roof, and standing water. Mr. Califf concluded that there were “egregiously unsanitary” conditions at Abbott’s Sturgis facility, and that “the inspection results were shocking.” As a result, Mr. Califf reported, the FDA “lost confidence that Abbott Nutrition had the appropriate safety and quality culture and commitment to fix these problems quickly” following the 2022 onsite inspection.

14. More recently, investors learned, just before the market closed on June 8, 2022, that Abbott was aware of the whistleblower’s formal allegations in early 2021, when it was reported that the FDA whistleblower had filed a complaint in February 2021 with the United States Labor Department’s Occupational Safety & Health Administration (“OSHA”), and that OSHA delivered that complaint to Abbott and the FDA during the same month. Moreover, Abbott submitted a response to the OSHA complaint two months later, which is not yet public. 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, or 3.5%, from a closing price of \$116.88 per share on June 7, 2022, to a closing price of \$112.71 per share on June 9, 2022.

15. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common stock, Plaintiff and other members of the Class have suffered significant damages.

II. JURISDICTION AND VENUE

16. 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).

17. 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).

18. 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.

19. 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

20. Plaintiff _____. As set forth in the accompanying certification incorporated by reference herein, Plaintiff

purchased Abbott common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

21. Defendant Abbott is an Illinois corporation with its headquarters located in Abbot Park, Illinois. Abbott's common stock trades on the New York Stock Exchange under the ticker "ABT."

22. 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.

23. 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.

24. Defendant Joseph Manning is Abbott's Executive Vice President, Nutritional Products. Manning assumed this role in December 2021.

25. Defendant Christopher J. Calamari is Abbott's President of Nutrition, North America and Senior Vice President for U.S. Nutrition. Calamari joined Abbott in 2005 and has served in a number of roles during his tenure, including Vice President for Pediatric Nutrition.

26. Defendants Ford, Funck, Manning, and Calamari are referred to herein as the "Individual Defendants."

27. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Abbott's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports and

press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and/or were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading.

28. Abbott and the Individual Defendants are collectively referred to herein as “Defendants.”

IV. BACKGROUND

29. Abbott, which does business as Abbott Nutrition with respect to infant formula, manufactures nearly half of its infant formula at a facility located in Sturgis, Michigan. Through the Sturgis facility, Abbott manufactures, processes, packs, labels, holds and distributes infant formulas that are marketed under several brand names throughout the United States.

30. Infant formula is a regulated food product that must be made in compliance with the FDA’s current good manufacturing practice (“CGMP”) requirements established by FDA regulation. These regulations are designed to ensure the safety of infant formula, and they require manufacturers to implement a system of controls to cover all stages of manufacturing, including specific controls to prevent adulteration of infant formula from microorganisms and bacteria.

31. The FDA has also implemented requirements for record-keeping, including a requirement that manufacturers have procedures for handling all written and oral complaints. Under these “Infant Formula Record Requirements,” manufacturers must conduct an investigation when a complaint shows a possible health hazard, and the failure to conduct such an investigation renders infant formula produced under those conditions “adulterated” under the terms of the controlling statute.

32. By no later than February 2021, when the Class Period begins, it was clear to Defendants that Abbott's Sturgis facility was in violation of numerous regulatory requirements relative to the manufacture of infant formula and related products. It was also clear to Defendants that these violations not only posed the threat of regulatory enforcement and fines, but also presented grave risks to the health and safety of the infants who relied on Abbott's infant formula for their most essential nutritional needs. When presented with these dire safety concerns, Defendants did nothing to correct them. To the contrary, Defendants worked to silence concerned employees, and misled the FDA as well as investors regarding the clear and present danger the Sturgis facility posed to vulnerable infants. Only after infant deaths connected to Abbott's baby formula were reported to the FDA, and after the FDA finally acted on the detailed accounts of a former Abbott employee, was Abbott forced to recall its infant formula, cease all production at the Sturgis facility, and enter into an onerous consent decree with the United States Department of Justice and FDA.

V. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS CAUSE SUBSTANTIAL LOSSES TO INVESTORS

33. Throughout the Class Period, Defendants made numerous materially false and misleading statements and omissions concealing the "egregiously unsanitary" conditions at the Sturgis facility, the extent to which those problems had been concealed from the public and regulators, and how those issues would impact Abbott's business.

34. The Class Period begins on February 19, 2021, when Abbott filed the Company's annual report for the year ended December 31, 2020, with the SEC on Form 10-K (the "2020 Annual Report"), signed by Defendants Ford and Funck. Therein, the Company reported that its Total Nutritional Products sales (which includes infant formula manufactured at Sturgis) increased 4.7% in 2020, and its U.S. Pediatric Nutritional business sales (also including the formula

produced at Sturgis) increased 5.8% in 2020. In the 2020 Annual Report, Abbott addressed the need to comply with FDA regulations governing the manufacture of infant formula:

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.

35. On April 20, 2021, the Company held its first-quarter 2021 earnings conference call. Defendants Ford and Funck participated in the call on the Company's behalf. During the call, Ford stated: "In the US and several international markets, we continue to capture share with our leading portfolio of infant formula and toddler brands."

36. On July 16, 2021, Abbott issued its 2020 ESG Global Sustainability Report to shareholders. Defendant Ford wrote an introductory letter to shareholders, where he wrote:

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.

37. Abbott described in the 2020 ESG Global Sustainability Report that “Abbott’s nutrition business ensures food safety through a tightly controlled manufacturing process that encompasses all steps from accepting materials from suppliers through to final product distribution. We monitor and verify microbiology, packaging integrity, and nutrient and lot control. We complete extensive finished product testing before releasing it for commercial distribution.”

38. Abbott’s 2020 ESG Global Sustainability Report also touted the Company’s Code of Business Conduct and strict compliance procedures that enabled employees to “report any concerns” because “Abbott does not tolerate illegal or unethical behavior in any aspect of our business and that employees are required to ask questions and/or report any concerns.” The Company also stressed that it did not tolerate any retaliation against employees who reported concerns:

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.

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

40. On October 20, 2021, the Company held its third-quarter 2021 earnings conference call. Defendants Ford and Funck participated in the call on the Company's behalf. During the call, Ford stated:

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

41. On January 11, 2022, Defendant Ford participated in the J.P. Morgan Healthcare Conference, where he was asked to "highlight a few of the key items in Abbott's pipeline for investors." Ford responded:

I think that our pipeline is second to none. I wouldn't change it for anybody else's, to be honest with you. And I think the team has done an incredible job. I give them kudos to be able to advance the pipeline through COVID. It's challenging with kind of remote work. It's challenging with clinical trials. And I think that the team in 2021 did an excellent job across the board, across all of our businesses to advance our pipeline.

If you look at EPD and Nutrition, we know how that innovation cycle works and what wins in terms of innovation. So, just more iterations, extensions and this kind of continuous drumbeat in this area, whether it's – we did a really good job in Nutrition. Towards the end of the year, we launched our next-generation infant formula, and that will be kind of rolling out globally. And EPD, building regional portfolios in the markets that we're competing in emerging markets, that worked out very well.

42. On January 26, 2022, the Company held its fourth-quarter and year-end 2021 earnings conference call. Defendants Ford and Funck participated in the call on the Company's behalf. During the call, Ford stated:

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

43. The statements set forth above in paragraphs 34 through 42 were materially false and misleading, and omitted information necessary to make the statements not materially false and misleading. Specifically, Defendants touted the strength of Abbott's infant formula brands, and their contribution to the Company's sales and revenue growth, despite knowing that the facility that manufactured those products was in flagrant violations of FDA and other agency health, safety, and manufacturing regulations. Those violations, which Defendants willfully or recklessly concealed from investors, put Abbott's infant formula business in dire jeopardy and left the Company exposed to a risk of severe regulatory action, including the recall of its products and closure of the Sturgis facility. Indeed, by no later than February 2021 and continuing throughout the Class Period, Abbott and Defendants received direct warnings, communications, FDA inspection reports, and consumer complaints identifying in detail the safety and regulatory violations that were rampant at the Sturgis facility. As a result of the foregoing, Defendants' positive statements about Abbott's business, operations, and prospects were materially false and misleading.

44. Abbott's and Defendant Manning's statements on February 17, 2022, in a press release announcing the recall of Abbott's powdered infant formula, continued the Company's pattern of concealing the "egregiously unsanitary" and dangerous conditions at Sturgis. In the

press release, the Company announced that 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.” In addition, in the press release, Manning stated: “We know parents depend on us to provide them with the highest quality nutrition formulas. We’re taking this action so parents know they can trust us to meet our high standards, as well as theirs. We deeply regret the concern and inconvenience this situation will cause parents, caregivers and health care professionals.” Neither Manning nor Abbott disclosed that Abbott had been aware of these dangerous issues at least one year prior, nor did they disclose that the FDA demanded the recall days earlier and that the FDA investigation preceded the “voluntary” and “proactive” recall.

45. Moreover, in the February 17 press release, Abbott reported that: “During testing in our Sturgis, Mich., facility, we found evidence of Cronobacter sakazakii in the plant ***in non-product contact areas***” (emphasis added). However, the FDA inspection report released on March 22, 2022, directly contradicts that assertion, stating that Cronobacter was detected on a “scoop hopper” that was “utilized to feed scoops, ***which are placed directly inside infant formula containers and contact product***” (emphasis added). Likewise, Abbott stated on February 17, 2022, that “While Abbott’s testing of finished product detected no pathogens, we are taking action by recalling the powder formula manufactured in this facility with an expiration of April 1, 2022, or later” (emphasis added). Yet just a little over one month later, the FDA reported that “***both FDA and [Abbott] found evidence of Cronobacter spp. in your powdered infant formula production environment. [Abbott] also identified Cronobacter spp. in finished powdered infant formula products***” (emphasis added).

46. Defendants' February 17, 2022, statements minimized the severity of the danger its infant formula posed, despite the fact that Abbott's infant formula was still for sale on store shelves and being used in the homes of thousands of families at that time.

47. On February 18, 2022, Abbott filed the Company's annual report for the year ended December 31, 2021, with the SEC on Form 10-K (the "2021 Annual Report"), signed by Defendants Ford and Funck. The Company reported that its Total Nutritional Products sales increased 7.7% in 2021, and its U.S. Pediatric Nutritional business sales increased 10.3% in 2021. In the 2021 Annual Report, Abbott addressed the need to comply with FDA regulations governing the manufacture of infant formula:

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.

48. The statements in the 2021 Annual Report were false and misleading for the reasons stated above in paragraph 43.

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

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

50. This and similar statements made by Defendant Calamari during the May 25 congressional hearing were false and misleading when made because, as was revealed just two weeks later, the whistleblower had filed a similar complaint with OSHA in February 2021. That complaint was not only sent to Abbott, but Abbott filed a non-public response to that complaint in April 2021, rendering Calamari's statement that Abbott did not learn of the whistleblower's complaints until April 2022 false and misleading.

VI. THE TRUTH EMERGES

51. On February 17, 2022, as noted above, the FDA publicly announced that it was investigating four consumer complaints of infant illness related to powdered infant formula produced from Sturgis. The FDA stated that the agency had initiated an onsite inspection at the facility, and to date had found several positive contamination results from environmental samples for the Cronobacter that was linked to infant illnesses and death. The FDA also 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." 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.

52. The news of the FDA investigation and the Company’s February 17, 2022, disclosures concerning the safety concerns at Sturgis and resulting infant formula recall 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.

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

54. On April 28, 2022, as the FDA investigation continued, a redacted copy of a 34-page detailed whistleblower complaint sent to the FDA in October 2021 was made public. The whistleblower report revealed that the issues disclosed in February and March 2022 were actually known to Abbott’s management far earlier, and set forth numerous serious examples of misconduct by Abbott management at Sturgis, including the falsification of testing records, the release of untested infant formula to the market, efforts to mislead the FDA during its 2019 inspection audit, the continuation of known deficient testing procedures, and an inability to trace products to

properly implement recalls of affected pallets of formula. Upon release of the whistleblower report, 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.

55. Finally, on June 8, 2022, investors learned, just before the market closed, that Abbott was aware of the whistleblower's formal allegations in early 2021, when a complaint was sent to OSHA and then forwarded to the FDA and Abbott. Investors also learned that Abbott submitted a response to the OSHA complaint two months later.

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

57. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common stock, Plaintiff and other Class members have suffered significant losses and damages.

VII. LOSS CAUSATION

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

59. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions, and engaged in a scheme to deceive the market. This artificially inflated the price of Abbott common stock and operated a fraud or deceit on the Class (as defined below). Later, when Defendants' prior misrepresentations and fraudulent conduct were

disclosed to the market, the price of Abbott common stock fell precipitously as the prior artificial inflation came out of the price. As a result of their acquisition of Abbott common stock during the Class Period, Plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

VIII. ADDITIONAL SCIENTER ALLEGATIONS

60. Plaintiff repeats and realleges each and every paragraph contained above as if set forth herein.

61. The Individual Defendants acted with scienter with respect to the materially false and misleading statements and omissions of material facts set forth above because they knew, or at the very least, recklessly disregarded that those statements were materially false or misleading when made. As senior executives of Abbott, their scienter is imputed to Abbott.

62. As alleged herein:

- a) Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading;
- b) Defendants knew that such statements or documents would be issued or disseminated to the investing public;
- c) Defendants knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws; and
- d) Defendants, by virtue of their receipt of information reflecting the true facts regarding Abbott, their control over, and/or receipt and/or modifications of Abbott's allegedly materially misleading statements and/or their associations with the Company, which made them privy to confidential proprietary information concerning Abbott, participated in the fraudulent scheme alleged herein.

IX. PRESUMPTION OF RELIANCE

63. 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 disseminations 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 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.

64. 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.

65. In addition, Plaintiff is 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.

X. INAPPLICABILITY OF THE STATUTORY SAFE HARBOR AND BE SPEAKS CAUTION DOCTRINE

66. Abbott's "safe harbor" warnings accompanying its forward-looking statements issued during the Class Period were ineffective to shield those statements from liability.

67. 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 speaker knew the statement was false or misleading and the statement was authorized and/or approved by an executive officer at Abbott who knew that the statement was false or misleading when made. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projections or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to, or stated to be dependent on, those historic or present tense statements when made.

XI. CLASS ACTION ALLEGATIONS

68. Plaintiff brings 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 June 8, 2022, inclusive, and who were damaged thereby (the “Class”). 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.

69. 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 May 3, 2022, Abbott had over 1.75 billion shares of common stock outstanding. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes 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.

70. Plaintiff's 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.

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

72. 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.

73. 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. 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.

XII. CLAIMS FOR RELIEF UNDER THE EXCHANGE ACT

COUNT I

**FOR VIOLATIONS OF SECTION 10(b) OF THE EXCHANGE ACT AND SEC RULE
10b-5 PROMULGATED THEREUNDER
(AGAINST ALL DEFENDANTS)**

74. Plaintiff repeats and re-alleges each and every allegation set forth above as if fully set forth herein.

75. During the Class Period, Defendants carried out a plan, scheme, and course of conduct that was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Abbott common stock at artificially inflated prices.

76. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business that operated as a fraud and deceit upon the purchasers of the Company's common stock in an effort to maintain artificially high market prices for Abbott common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5, promulgated thereunder.

77. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about the Company's financial well-being, operations, and prospects.

78. During the Class Period, Defendants made the false statements specified above, which they knew or recklessly disregarded to be false and misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

79. Defendants had actual knowledge of the misrepresentations and omissions of material fact set forth herein, or recklessly disregarded the true facts that were available to them. 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.

80. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Abbott common stock. Plaintiff 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 Defendants' fraudulent course of conduct.

81. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases of the Company's common stock during the Class Period.

82. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5, promulgated thereunder.

COUNT II

FOR VIOLATIONS OF SECTION 20(a) OF THE EXCHANGE ACT (AGAINST THE INDIVIDUAL DEFENDANTS)

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

84. 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).

85. 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.

86. 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 and power to control public statements about Abbott, and the power and ability to control the actions of Abbott and its employees.

87. 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 and misleading statement during the Class Period, and made additional false and 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.

88. 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 Plaintiff and other members of the Class who purchased or otherwise acquired Abbott common stock.

89. As a direct and proximate result of the Individual Defendants' conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchase or acquisition of Abbott common stock.

XIII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays 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 Plaintiff 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 Plaintiff 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.

XIV. JURY DEMAND

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff hereby demands a trial by jury in this action of all issues so triable.