# UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF ILLINOIS EASTERN DIVISION

INTERNATIONAL BROTHERHOOD OF TEAMSTERS LOCAL NO. 710 PENSION FUND and SOUTHEASTERN PENNSYLVANIA TRANSPORTATION AUTHORITY, Derivatively on Behalf of Nominal Defendant ABBOTT LABORATORIES,	Case No  Case No  CONFIDENTIAL – FILED UNDER SEAL
Plaintiffs,	) )
v.	) JURY TRIAL DEMANDED
ROBERT B. FORD, HUBERT ALLEN, ROBERT J. ALPERN, ROXANNE S. AUSTIN, CLAIRE BABINEAUX- FONTENOT, SALLY E. BLOUNT, PAOLA GONZALEZ, MICHELLE A. KUMBIER, EDWARD M. LIDDY, DARREN W. MCDEW, NANCY MCKINSTRY, WILLIAM A. OSBORN, MICHAEL F. ROMAN, DANIEL J. STARKS, JOHN G. STRATTON, GLENN F. TILTON, MILES D. WHITE, ERICA BATTAGLIA, CHRISTOPHER J. CALAMARI, ROBERT E. FUNCK, JR., JOSEPH MANNING, LORI J. RANDALL, DANIEL SALVADORI,, and JAMES E. YOUNG,	
Defendants,	) )
- and -	
ABBOTT LABORATORIES	) )
Nominal Defendant	) }

**VERIFIED STOCKHOLDERS' DERIVATIVE COMPLAINT** 

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Plaintiffs International Brotherhood of Teamsters Local No. 710 Pension Fund ("Teamsters Local 710 Pension Fund"), and Southeastern Pennsylvania Transportation Authority ("SEPTA") and (together, "Plaintiffs"), by and through their undersigned counsel, bring this action derivatively on behalf of Nominal Defendant Abbott Laboratories ("Abbott" or the "Company") against certain current and former members of Abbott's Board of Directors (the "Board") and Executive Officers, seeking to remedy violations of the federal securities laws, breaches of fiduciary duties, insider trading, corporate waste, and unjust enrichment from at least January 2019 through the present. Teamsters Local 710 Pension Fund and SEPTA make these allegations upon personal knowledge as to the facts of their ownership of Abbott stock and upon information and belief as to all other matters, based upon counsel's investigation, including a review of: (a) internal books and records obtained pursuant to demands made under 805 Ill. Comp. Stat. §5/7.75 (the "Books and Record Demands" and "Books and Records"); 1 (b) public filings made by Abbott and other related parties and non-parties with the U.S. Securities and Exchange Commission ("SEC"); (c) press releases and other publications disseminated by the Company and other related nonparties; (d) news articles, shareholder communications, and postings on Abbott's website concerning the Company's public statements; (e) the proceedings in an action brought by the U.S. Department of Justice ("DOJ") entering a consent decree with the U.S. Food and Drug Administration ("FDA"), captioned *United States v. Abbott Laboratories*, 1:22-cv-00441 (the "Consent Decree"); (f) a whistleblower report submitted to regulators that was released by a Congressional committee; (g) the proceedings in a related federal securities class action captioned

<sup>&</sup>lt;sup>1</sup> Plaintiffs conducted a books and records investigation under 805 Ill. Comp. Stat. Ann. §5/7.75. On October 11, 2022, Teamsters Local 710 Pension Fund made its demand. On December 14, 2022, SEPTA made its first demand, followed by a second demand on February 28, 2023. In response, the Company made multiple productions to Teamsters Local 710 Pension Fund and SEPTA.

Pembroke Pines Firefighters & Police Officers Pension Fund v. Abbott Laboratories, et al., No. 22-cv-04661 (the "Securities Class Action"); and (h) other publicly available information concerning Abbott and the Individual Defendants.

#### I. NATURE OF THE ACTION

- 1. In this derivative action, Plaintiffs Teamsters Local 710 Pension Fund and SEPTA seek to represent Abbott's interests to hold the Individual Defendants, who are Abbott's current and/or former directors and officers, liable for their misconduct related to the Company's illegal, unsafe, and unethical production and sale of infant formula products in the United States (the "U.S."), which has caused billions of dollars of damage to Abbott since 2019.
- 2. For nearly 50 years, Abbott, an Illinois corporation, has maintained its position as one of the dominant producers and suppliers of infant formula products in the U.S. In recent years,, Abbott's Board and management have allowed the Company to engage in actions to maximize Abbott's profits related to its manufacture and sales of infant formula products in the U.S., regardless of whether those actions were safe, ethical, or complied with federal regulations. Abbott's culture, which focuses on maximizing profits at all costs, has pushed its employees to take risky, unsafe, and illegal actions, which ultimately caused significant harm to Abbott, with the Individual Defendants at the helm.
- 3. Beginning in the early 1970s, the U.S. government established the Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC"), which allowed the states and U.S. territories to secure contracts with infant formula manufacturers, like Abbott, to supply infant formula products to low-income women with babies., In recent years, the Board and the Company's management have allowed Abbott to use potentially anti-competitive actions to secure a majority of the nation's WIC contracts, in order to maximize the Company's profits from infant formula products in the U.S. Indeed, the FTC is currently investigating the Company to

determine whether it engaged in anti-competitive activities in recent years related to its WIC contracts, and in general, when selling infant formula products in the U.S.

- 4. Further, Abbott's Board and management have permitted the Company to engage in deceptive and unethical marketing practices, which include aggressive tactics mimicking those used by tobacco companies that are now banned, and allowing the Company to claim its cow-milk based infant formulas are "safe" for preterm infants. Notably, as many medical studies, cow-milk based formulas increase the risk of preterm infants developing necrotizing enterocolitis ("NEC"), a potentially fatal or debilitating disease. As such, Abbott's touting its cow-milk based formulas as "safe" for preterm infants is deceptive advertising, which violated the Company's corporate governance policies and deceptive advertising or unfair trade practices laws. As a result of its unethical and manipulative marketing tactics, the Company faces a multitude of personal injury and wrongful death actions for pre-term infants who have died and experienced serious injuries, including class actions in Canada, British Columbia and Israel brought by parents who alleged that their infants developed NEC after consuming Abbott's cow-milk based infant formulas.
- 5. Finally, since at least 2019, Abbott's Board and management have allowed the Company to manufacture and sell its infant formula products in the U.S. in violation of federal regulations. In early 2022, the Company's plant located in Sturgis, Michigan (the "Sturgis Plant") produced 20% of the U.S. infant formula products, which equated to nearly 50% of Abbott's production of such products. The Sturgis Plant, however, was a repeat violator of federal laws since 2019, which had resulted in the issuance of "Form 483s" in 2019 and 2021 by the FDA concerning the violations at that plant. Notably, those violations, in part, related to Cronobacter sakazakii ("Cronobacter"), a potentially deadly bacteria for infants that consume it, which often contaminates infant formula products.

- 6. By February 2022, the Sturgis Plant's violations of federal regulations were so severe that they had purportedly caused the deaths of several infants, who consumed Abbott's infant formula products that were produced at the Sturgis Plant and were allegedly contaminated with Cronobacter. As a result of these reports and a related whistleblower's report detailing the egregious conditions at the Sturgis Plant, the FDA repeatedly urged Abbott to conduct a "voluntary" recall of certain products manufactured at the Sturgis Plant. The FDA also forced Abbott to shut down the Sturgis Plant from manufacturing any infant formula products causing a national infant formula shortage in 2022 due to Abbott's dominant position in the U.S. which it had secured by employing predatory and potentially anti-competitive practices. In fact, Abbott now faces consolidated class actions in *re Recalled Abbott Laboratories et al. Infant Formula Products Liability Litigation*, No. 22-cv-02148, MDL No. 3037, related to the wrongful deaths and related damages allegedly caused from Abbott's contaminated infant formula products produced at the Sturgis Plant.
- 7. Moreover, Abbott was not allowed to restart production of infant formula at the Sturgis Plant until months later, and after it agreed to enter into the Consent Decree with the DOJ on May 16, 2022. Among other things, the DOJ required Abbott to hire an expert to oversee its compliance with FDA regulations as part of the Consent Decree. Moreover, the DOJ's related complaint made clear that the Sturgis Plant's illegal conditions has persisted for years: "[The] [o]ngoing inadequacies in manufacturing conditions and practices at Defendants' facilities demonstrates 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.*"

- 8. Due to the severity of Abbott's violations and its large negative impact on the nation's young families, on May 25, 2022, a congressional hearing was held, where Robert Carliff, the FDA Commissioner, testified about the "egregiously unsanitary" conditions at the Sturgis Plant, stating that "the inspection results were shocking." In fact, Commissioner Carliff further testified that the FDA had "lost all confidence that Abbott Nutrition had the appropriate safety and quality culture and commitment to fix these problems quickly."
- 9. At that same Congressional hearing, Defendant Calamari, Abbott's Senior Vice President of Nutrition for North America, tried to downplay Abbott's liability, even though the overwhelming evidence revealed that the Sturgis Plant was non-compliant with federal regulations in multiple ways. In fact, Calamari even lied about when Abbott was purportedly informed by a whistleblower about the rampant violations of federal laws occurring at the Sturgis Plant. Indeed, Abbott and its officers and directors continue to improperly minimize Abbott's actions or inactions, which allowed illegal and unsafe conditions to persist at the Sturgis Plant for years.
- 10. Abbott's Board and management, however, owed fiduciary duties to oversee that the Company's production and sale of infant formula products in the U.S. was conducted in safe and ethical ways that also complied with federal regulations. To fulfill those fiduciary duties, the Individual Defendants were required to implement an information reporting system to alert them when misconduct arose related to the Company's manufacture and sale of infant formula products in the U.S.

11.	Notably,	

As a result, the Individual Defendants missed glaring red flags that the Company's production and sales of infant formula products in the U.S. involved unsafe and noncompliant manufacturing and sales practices, as well as predatory and unethical marketing tactics. The Individual Defendants' oversight failures allowed the Company to operate its infant formula business in the U.S. in numerous illegal, unsafe, and unethical ways, causing billions of dollars of damages to Abbott. And the damage from these failures continues to unfold.

- 12. Further, in violation of Section 10(b) of the Securities and Exchange Act of 1934 ("Exchange Act") and state disclosure laws, the Board authorized the Company to engage in more than \$6.4 billion in stock repurchases while Abbott's stock was artificially inflated due to the failure to disclose material information related to the misconduct concerning Abbott's production and manufacture of infant formula products in the U.S. In fact, insiders relied on that same nonpublic information to sell \$163.7 million of Abbott stock, before the truth started to leak out.
- 13. Certain directors also caused Abbott to file false and misleading proxy statements with the SEC from 2021 through 2023, which were used to re-elect Abbott's directors (i.e., the Director Defendants), approve executive compensation on an advisory basis, and vote on shareholder proposals concerning the requirement of an independent Board chair.
- 14. Accordingly, Teamsters Local 710 Pension Fund and SEPTA bring this derivative action on Abbott's behalf to hold its former and current directors and officers liable for: (1) violating Section 10b and Section 14(a) of the Exchange Act, and the rules promulgated thereunder; (2) their breaches of fiduciary duties, including but not limited to oversight, care, good faith, loyalty and disclosure; (3) insider trading; (4) corporate waste; and (5) unjust enrichment.

## II. JURISDICTION AND VENUE

- This shareholder derivative action is brought pursuant to Rule 23.1 of the Federal Rules of Civil Procedure. This Court has subject matter jurisdiction pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, as well as 28 U.S.C. § 1331 for the claims asserted herein for violations of the Exchange Act. This Court has supplemental jurisdiction over the remaining claims under 28 U.S.C. § 1367.
- 16. In connection with the acts, conduct and other wrongs complained of herein,
  Defendants directly or indirectly used the means and instrumentalities of interstate commerce, the
  United States mails and the facilitates of a national securities market.
- 17. This Court has personal jurisdiction over each of the defendants named herein because Nominal Defendant Abbott is incorporated and maintains and operates its principal executive offices in this District, and the Individual Defendants maintain a place of business in or reside in this District or have sufficient minimum contacts with this District so as to render the exercise of jurisdiction by this Court permissible under traditional notions of fair play and substantial justice.
- 18. Venue in this District is proper because Nominal Defendant Abbott is incorporated in Illinois and is headquartered in this District. Further, a substantial portion of the transactions and wrongs complained of herein occurred in this District.

# III. PARTIES

#### A. Plaintiffs: Teamsters Local 710 Pension Fund and SEPTA

19. Plaintiff Teamsters Local 710 Pension Fund is a pension fund located in Mokena, Illinois. Teamsters Local 710 Pension Fund is a Taft-Hartley defined pension fund with approximately 21,000 active participants and over \$3.5 billion in plan assets. Teamster Local 710 Pension Fund owns Abbott common stock and has been a shareholder at all times relevant to the

claims asserted herein, and will continue to hold Abbott shares throughout the pendency of this action.

20. Plaintiff SEPTA is the sixth largest public transportation agency in the U.S. with 9,500 employees that serve the five million residents of the Greater Philadelphia region, and currently manages \$1.6 billion in its defined benefit plan. SEPTA owns Abbott common stock and has been a shareholder at all times relevant to the claims asserted, and will continue to hold Abbott shares throughout the pendency of this action.

### **B.** Nominal Defendant

21. Nominal Defendant Abbott is an Illinois corporation with its principal executive offices located at 100 Abbott Park Road, Abbott Park, Illinois 60064-6400. Abbott is an international biotechnology and manufacturing firm that makes medical devices and nutritional products, including as one of the main suppliers of infant formula in the U.S.

### C. Director Defendants

- 22. Defendant Robert B. Ford ("Ford") started his career at Abbott more than twenty years ago, and has served as the Company's President and Chief Executive Officer ("CEO") since March 2020. From 2018 to 2020, Ford served as Abbott's President and Chief Operating Officer ("COO"). Defendant Ford has also served on the Abbott Board since 2019. He chairs the Executive Committee, and has served as the executive Chair of the Board since 2021. In 2022 alone, Ford received a compensation package comprising cash payment and stock options worth more than \$21.4 million from Abbott.
- 23. Defendant Robert J. Alpern ("Alpern") has served on the Abbott Board since 2008. He serves on the Nominations and Governance and Public Policy Committees. In 2022 alone, Alpern received a compensation package comprising cash payment and stock options worth more than \$340,000 from Abbott.

- 24. Defendant Roxanne S. Austin ("Austin") served on the Abbott Board from 2000 to April 2022. She chaired the Compensation Committee, and also served on the Executive Committee and the Nominations and Governance Committee. In 2021 alone, Austin received a compensation package comprising cash payment and stock options worth more than \$350,000 from Abbott.
- 25. Defendant Claire Babineaux-Fontenot ("Babineaux-Fontenot") has served on the Abbott Board since 2022. She serves on the Public Policy Committee.
- 26. Defendant Sally E. Blount ("Blount") has served on the Abbott Board since 2011. She serves on the Nominations and Governance and Public Policy Committees. In 2022 alone, Blount received a compensation package comprising cash payment and stock options worth more than \$340,000 from Abbott.
- 27. Defendant Paola Gonzalez ("Gonzalez") has served on the Abbott Board since 2021. She serves on the Audit and Public Policy Committees. In 2022 alone, Gonzalez received a compensation package comprising cash payment and stock options worth more than \$300,000 from Abbott.
- 28. Defendant Michelle A. Kumbier ("Kumbier") has served on the Abbott Board since 2018. She serves on the Audit and Compensation Committees. In 2022 alone, Kumbier received a compensation package comprising cash payment and stock options worth more than \$300,000 from Abbott.
- 29. Defendant Edward M. Liddy ("Liddy") served on the Abbott Board from 2010 to 2021. He chaired the Audit Committee, and also served on the Compensation and Executive Committees. In 2020 alone, Liddy received a compensation package comprising cash payment and stock options worth more than \$340,000 from Abbott.

- 30. Defendant Darren W. McDew ("McDew") has served on the Abbott Board since 2019. He serves on the Nominations and Governance and Public Policy Committees. In 2022 alone, McDew received a compensation package comprising cash payment and stock options worth more than \$300,000 from Abbott.
- 31. Defendant Nancy McKinstry ("McKinstry") has served on the Abbott Board since 2011. She chairs the Audit Committee, and also serves on the Compensation and Executive Committees. In 2022 alone, McKinstry received a compensation package comprising cash payment and stock options worth more than \$300,000 from Abbott.
- 32. Defendant William A. Osborn ("Osborn") served on the Abbott Board from 2008 to April 2023. He chaired the Nominations and Governance Committee, and also served on the Compensation and Executive Committees. In 2022 alone, Osborn received a compensation package comprising cash payment and stock options worth more than \$340,000 from Abbott.
- 33. Defendant Michael F. Roman ("Roman") has served on the Abbott Board since 2021. He serves on the Audit and Compensation Committees. In 2022 alone, Roman received a compensation package comprising cash payment and stock options worth more than \$300,000 from Abbott.
- 34. Defendant Daniel J. Starks ("Starks") has served on the Abbott Board since 2017. He chairs the Compensation Committee, and also serves on the Audit and Executive Committees. In 2022 alone, Starks received a compensation package comprising cash payment and stock options worth more than \$320,000 from Abbott.
- 35. Defendant John G. Stratton ("Stratton") has served on the Abbott Board since 2017. He serves on the Audit and Public Policy Committees. In 2022 alone, Stratton received a

compensation package comprising cash payment and stock options worth more than \$310,000 from Abbott.

- 36. Defendant Glenn F. Tilton ("Tilton") served on the Abbott Board from 2007 to April 2023. He chaired the Public Policy Committee, and also served on the Audit and Executive Committees. In 2022 alone, Tilton received a compensation package comprising cash payment and stock options worth more than \$350,000 from Abbott.
- 37. Defendant Miles D. White ("White") joined Abbott in 1984, served as Abbott's Chairman and Chief Executive Officer from 1999 to 2020 and was Executive Chairman of the Board from 2020 to 2021. In 2020 alone, White received a compensation package comprising cash payment and stock options worth more than \$16.4 million from Abbott.
- 38. Defendants Ford, Alpern, Austin, Babineaux-Fontenot, Blount, Gonzalez, Kumbier, Liddy, McDew, McKinstry, Osborn, Roman, Starks, Stratton, Tilton, and White constitute all of the current members of the Abbott Board and are collectively referred to herein as the "Director Defendants."
- 39. Defendants Gonzalez, Kumbier, McKinstry, Roman, Starks, Stratton, and Tilton also are collectively referred to herein as the "Audit Committee Defendants."
- 40. Defendants Alpern, Babineaux-Fontenot, Blount, McDew, and Stratton are also collectively referred to herein as the "Public Policy Committee Defendants."
- 41. Defendants Ford, Austin, McKinstry, Roman, Starks, and Stratton are also collectively referred to as the "Executive Committee Defendants."
- 42. Defendants Alpern, Blount, Gonzalez, McDew, and Stratton are also collectively referred to as the "Nominations and Governance Committee Defendants."

43. Defendants Kumbier, McKinstry, Roman, and Starks are also collectively referred to as the "Compensation Committee Defendants."

#### **D.** Officer and Executive Defendants

- 44. Defendant Hubert Allen ("Allen") has served as Abbott's Executive Vice President, General Counsel and Secretary since 2013. In 2022 alone, Allen received a compensation package comprising cash payment and stock options worth more than \$6.8 million from Abbott.
- 45. Defendant Erica Battaglia ("Battaglia") serves as Abbott's Chief Ethics and Compliance Officer since June 2021.
- 46. Defendant Christopher J. Calamari ("Calamari") has served as the Senior Vice President of U.S. Nutrition since 2021, and from 2017 to 2021 was Vice President of Pediatric Nutrition.
- 47. Defendant Robert E. Funck ("Funck") has served as Executive Vice President and Chief Financial Officer ("CFO") of Abbott since 2020, and from 2013 to 2020 was the Company's controller. In 2022 alone, Funck received a compensation package comprising cash payment and stock options worth more than \$8.9 million from Abbott.
- 48. Defendant Joseph Manning ("Manning) has served as the Executive Vice President of Nutritional Products since 2021.
- 49. Defendant Lori J. Randall ("Randall") is the Division Vice President of Nutrition Quality Assurance.
- 50. Defendant Daniel Salvadori ("Salvadori") has served as the Executive Vice President and Group President, Established Pharmaceuticals and Nutritional Products from 2021, and from 2017 to 2021 served as the Executive Vice President of Nutritional Products. In 2022 alone, Salvadori received a compensation package comprising cash payment and stock options worth more than \$7.1 million from Abbott.

- 51. Defendant James E. Young ("Young") has served as Abbott's Chief Ethics and Compliance Officer ("CECO") from July 2015 to May 2021.
- 52. Defendants Allen, Battaglia, Calamari, Ford, Funck, Manning, Randall, Salvadori, and Young are collectively referred to herein as the "Officer Defendants."
- 53. The Director and Officer Defendants are collectively referred to herein as the "Individual Defendants."
- IV. THE INDIVIDUAL DEFENDANTS WERE OBLIGATED TO SAFEGUARD THE COMPANY'S INTERESTS AND COMPLY WITH APPLICABLE LAWS WHEN MANUFACTURING AND SELLING ABBOTT'S INFANT FORMULA PRODUCTS IN THE U.S.

# A. Fiduciary Duties Owed By All Individual Defendants Under Illinois Law

- 54. Under Illinois law, as Abbott directors and/or officers, the Individual Defendants owe fiduciary duties of loyalty, good faith and candor to the Company's shareholders. In this regard, the Individual Defendants have the ability to control the Company's business and corporate affairs, and thus, are, required to use their utmost ability to control and manage the Company in a lawful, fair, just, honest, and equitable manner. The Individual Defendants were, and are, required to act in furtherance of the best interests of Abbott and its shareholders, so as to benefit all shareholders equally and not in furtherance of their personal interest or benefit.
- 55. By virtue of their fiduciary duties of loyalty, good faith, and candor, each Individual Defendant was required to, among other things:
  - a. Exercise good faith to ensure that the Company was operated in a diligent, honest, and prudent manner and complied with all applicable federal and state laws, rules, regulations, and requirements;
  - b. When put on notice of problems with the Company's business practices and operations, exercise good faith in taking appropriate action to correct the misconduct and prevent its recurrence; and

- c. Remain informed as to how the Company conducted its operations, and upon receipt of notice or information of imprudent or unsound conditions or practices, make reasonable inquiry in connection therewith.
- 56. In particular, the Individual Defendants owed "oversight" duties (i.e., "Caremark" duties) as part of their fiduciary duties. The Individual Defendants' oversight duties required the directors and/or officers to implement an information reporting system to ensure that they could monitor that Abbott manufactured and sold its infant formula products in the U.S. in a safe and compliant manner. Such a reporting system should alert directors and officers when a company is operating in risky, unsafe, noncompliant and illegal ways.

# B. Obligations of the Individual Defendants to Ensure Abbott's Compliance with FDA Regulations

- 57. Abbott must comply with FDA regulations, among other laws, when manufacturing and selling its infant formula products in the U.S. Indeed, compliance with FDA regulations when manufacturing and selling products, including infant formula, is mission critical for Abbott as its ability to do business in the U.S. rests upon its compliance with those regulations, among other laws. Accordingly, the Individual Defendants as Abbott's directors and/or officers had and have fiduciary duties to oversee and monitor Abbott's compliance with FDA regulations when producing and selling the Company's infant formula products in the U.S.
- 58. Specifically, the Food, Drug, and Cosmetic Act of 1938 ("FDCA") provides the overall statutory framework for regulating food safety, which includes Abbott's infant formula products. The FDCA's purpose is to protect consumers from adulterated food, which is defined as food that "consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food" or if "it had 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).

- 59. With respect to infant formulas, the FDCA prohibits introducing into interstate commerce products that "are adulterated . . . in that they have been processed in a manner that does not comply with current good manufacturing practice requirements for infant formula [i.e., "CGMP"] or "are adulterated . . . in that they have been prepared, packed, or held under unsanitary conditions whereby they may have become contaminated with filth or whereby they may have been rendered injurious to health." 21 U.S.C. §331(a). Furthermore, the FDCA prohibits adulterated items from being "held for sale." 21 U.S.C. §331(k).
- 60. The U.S.'s primary food safety regulator, the FDA promulgates numerous food safety regulations under the FDCA, which apply to Abbott, including those specifically related to infant formula manufacture, for example:
  - "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
  - "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).
- 61. Moreover, manufacturers are required to keep records and have procedures for handling all written and oral complaints, investigate all complaints that indicate a possible health hazard, and failure to comply with these requirements renders infant formulas adulterated. 21 U.S.C. §350(a)(b)(4); 21 C.F.R. §106.100(k).
- 62. General food safety regulations also apply to Abbott's production of its infant formula products, including those related to "Processes and controls" (i.e., 21 C.F.R. §117.80(a)(1)-(5)) and "Manufacturing" operations (i.e., 21 C.F.R. §117.80(c)(1)-(13)).
- 63. Record and reporting requirements for infant formula require specifically, "Every manufacturer of infant formula shall maintain the records specified in this regulation in order to

permit the Food and Drug Administration to determine whether each manufacturer is in compliance with section 412 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350a))." 21 C.F.R. §106.100(a). Moreover, "[t]he failure to comply with the records requirements in this section applicable to the quality factors shall render the formula adulterated[.]" 21 C.F.R. §106.100(r).

- 64. Notably, manufacturers, like Abbott, must "promptly notify" the FDA in at least two circumstances:
  - (1) "When there is a reasonable possibility of a causal relationship between the consumption of an infant formula and an infant's death, the manufacturer shall, within 15 days of receiving such information, conduct an investigation and notify the [FDA]." 21 C.F.R. §106.100(k)(3).
  - (2) "when the manufacturer has knowledge . . . 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).
- 65. The FDA monitors a company's compliance with the FDCA, in part, by conducting periodic usually annual inspections of infant formula manufacturing plants.
- 66. At the conclusion of each FDA inspection, the FDA investigators hold a "close-out meeting" with the company's management and share their observations. If the FDA investigators observe significant deviations from the FDCA, then they are recorded in a "Form 483," which is presented and explained to the company's management. Notably, a Form 483 is intended for use in notifying a company's "senior" or "top" "management" in writing of significant objectionable conditions. Specifically, the FDA Investigations Operations Manual states 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."

- 67. When a Form 483 is issued, it is accompanied by an Establishment Inspection Report ("EIR"). The EIR contains more detail than a Form 483 and may contain additional objectionable conditions in the manufacturing facility than the related Form 483. The company has an obligation to respond to the FDA's observations within fifteen (15) business days with a root cause analysis, impact assessment, and a set of corrective and preventative actions.
- 68. If a company's response is inadequate after issuing a Form 483, the FDA may issue a warning letter to spur a company to voluntarily comply with the FDCA. However, in some instances, a warning letter is bypassed and enforcement action is brought, especially where a violation is intentional or presents a possibility of injury or death. Indeed, a company can face severe sanctions from the FDA, and extensive remedial action, which could require a company to cease operations while implementing costly and time-consuming corrective measures. Accordingly, the failure to adhere to the FDCA can have a very negative effect on a company's ability to market and sell its products.
- 69. Significantly, in 2012, Abbott pled guilty to a criminal misdemeanor violation of the FDCA related to Abbott's pharmaceutical division misbranding a drug called Depakote for use in elderly dementia patients, even though that drug lacked evidence that it was safe for such use. As part of the guilty plea and settlement, Abbott paid a \$1.7 billion fine (the second largest penalty paid for such violation) and agreed to a five-year probationary period. Importantly, the settlement also required Abbott to self-report any violations of the FDCA, along with requiring the Company's CEO to certify compliance with this reporting requirement and the Board to report annually on the effectiveness of the Company's compliance program. Notably, at that time, Director Defendants, Alpern, Austin, Blount, Liddy, McKinstry, Osborn, Tilton, and White, were serving on the Board.

- C. The Board, Its Committees, and Senior Officers Were Expressly Charged with Overseeing Abbott's Compliance with All Laws, and Risk Exposure and Internal and Disclosure Controls Related to its Production and Sales of the Company's Infant Formula Products in the U.S.
- 70. Abbott's bylaws, articles of incorporation, corporate governance guidelines, and Code of Conduct, as well as Board committee charters, specifically set forth the duties and obligations that Abbott Board members and/or officers are required to fulfill on behalf of the Company with respect to overseeing the Company's compliance with all regulations, along with its risk exposure and internal and disclosure controls. The Individual Defendants, who were and are members of the committees of the Board, further assumed the responsibility to carry out the functions of their respective committees.
  - a. Duties of Abbott's Directors and Officers Under the Company's Bylaws
- Abbott's latest operative bylaws, attached as an exhibit to Form 8-K filed with the SEC on February 17, 2023, state, under Article III, Section 1, "The business and affairs of the Corporation shall be managed under the direction of the Board of Directors." Article III, Section 10 further confirms that being present at a meeting where an action was taken means that a director is presumed to have assented to any such action, unless their dissent was formally recorded.
- 72. The Bylaws designate an expansive group of "officers," which is defined by Article V, Section 1, as "the Chief Executive Officer, one or more Presidents, one or more Executive, Group or Senior Vice Presidents, one or more Vice Presidents, a Treasurer, a Secretary, a Controller, a General Counsel and such Assistant Treasurers and Assistant Secretaries as the Board of Directors may elect or the Chair of the Board may appoint." In addition, Article V, Section 5 states that the CEO is responsible for the "overall management of the Corporation subject to the direction of the Board of Directors." Beyond the top C-suite officers, Abbott's Bylaws in Article

V, Sections 7 and 8 also outline the duties of various vice presidents, stating, "Each Executive, Group, or Senior Vice President shall be responsible for supervising and coordinating a major area of the Corporation's activities subject to the direction of the Chief Executive Officer or a President," and "Each of the Vice Presidents shall be responsible for those activities designated by an Executive, Group, or Senior Vice President, a President, the Chief Executive Officer, or the Board of Directors," respectively.

73. The Bylaws also establish the duties of the Executive Committee, and specify that the Board shall have subcommittees, including an Audit Committee, a Compensation Committee, a Nominations and Governance Committee, and a Public Policy Committee, with separate charters to detail their duties.

# **b.** Duties of Public Policy Committee Members

- 74. The Board's Public Policy Committee "assist[s] the board of directors in fulfilling its oversight responsibility with respect to Abbott's public policy, certain areas of legal and regulatory compliance, governmental affairs, and healthcare and other compliance issues that affect Abbott by discharging the responsibilities set forth in its charter." Its charter further details that its "[p]urpose" is to assist the Board's oversight over "public policy, regulatory (including regulation by the Federal Food and Drug Administration (FDA), as well as other domestic, foreign and international regulatory bodies) and government affairs" and "healthcare and other compliance issues (recognizing that other Board committees assist the Board of Directors in reviewing certain areas of legal and regulatory compliance)." Specifically, the Public Policy Committee requires its members to, among other things:
  - "Review and evaluate Abbott's policies and practices with respect to maintaining legal, regulatory and healthcare compliance..., and review them with the Board as appropriate."

- "Review and discuss with management healthcare and regulatory compliance matters, including product cybersecurity and data privacy. In particular, the Chief Ethics and Compliance Officer shall report to the Public Policy Committee at least three (3) times a year regarding healthcare and regulatory compliance matters, and the state of regulatory compliance and issues with respect thereto; any additional reports or discussions may be scheduled as the Public Policy Committee determines are necessary and appropriate."
- "Review annually Abbott's compliance program with respect to legal and regulatory requirements, including FDA regulations, and receive a report from the corporate officer responsible for quality assurance as needed, but at least two (2) times a year, regarding any FDA warning letters and Abbott's responses, as well as any upcoming compliance initiatives."
- "Review and make recommendations to the Board regarding shareholder proposals submitted for inclusion in Abbott's proxy materials that relate to public policy or social responsibility issues."
- 75. To carry out its duties, the Public Policy Committee "may, to the extent it deems necessary or appropriate, conduct or authorize investigations into any matter within the scope of its authority and may retain legal counsel, consultants and others to assist it in the conduct of its responsibilities, including investigations." The Public Policy Committee may also "consult with management and may delegate any of its responsibilities and duties to one or more members of the Public Policy Committee." In addition, the Public Policy Committee "shall meet at least four times a year and report to the Board on a regular basis[.]"<sup>2</sup>

#### c. The Duties of the Audit Committee Members

- 76. According to its publicly available charter, the "[p]urpose" of the Audit Committee is to: "assist the Board in fulfilling its oversight responsibility with respect to, among other things:
  - the quality and integrity of Abbott's financial statements;
  - legal and regulatory compliance as it relates to financial matters, including accounting, auditing, financial reporting, and securities law issues; and

- Abbott's enterprise risk management, including major financial, information security, and enterprise cybersecurity risk exposures.
- 77. To fulfill its purposes, the Audit Committee has a broad range of powers and obligations, including overseeing the work of Abbott's independent auditors, conducting investigations, and consulting with Abbott management. The Audit Committee's specific tasks include, among other things:
  - Review and discuss (with management, the internal auditors and the independent auditors, as appropriate) Abbott's enterprise risk management, including major financial, information security, and enterprise cybersecurity risk exposures, and the steps management has taken to monitor and control those exposures, including Abbott's risk assessment and risk management policies.

#### d. Duties of the Executive Committee Members

78. Article IV, Section 3 of the Bylaws requires that the Executive Committee must have a majority of its membership comprise independent directors, and "may, when the Board of Directors is not in session, exercise the authority of the Board of Directors in the management of the business and affairs of the Corporation," except for a few exceptions that are not relevant here. On its website, Abbott also explains, "The Executive Committee may exercise all the authority of the board in the management of Abbott, except for matters expressly reserved by law for board action."

#### e. Duties of the Nominations and Governance Committee Members

- 79. The Nominations and Governance Committee's overall charge is to, among other things,:
  - assist the Board in identifying individuals qualified to become Board members, and recommend to the Board the nominees for election as directors at the next annual meeting of shareholders;
  - recommend to the Board the persons to be elected as officers of Abbott; and

- develop and recommend to the Board the corporate governance guidelines applicable to Abbott.
- 80. To carry out its charge, the Nominations and Governance Committee has the right to consult management and employees, and to retain counsel, but unlike the Audit and Public Policy Committees, the Nominations and Governance Committee is not given the express authority to conduct its own investigations.

# f. Duties of the Compensation Committee Members

- 81. Abbott's Compensation Committee "assists the board of directors in carrying out the responsibilities of the board relating to the compensation of Abbott's executive officers and directors by discharging the responsibilities set forth in its charter." According to its Charter, the Compensation Committee has the right to consult with management and employees, as well as retain counsel, accountants, and consultants, but unlike the Audit and Public Policy Committees, the Compensation Committee is not given the authority to conduct independent investigations. The Compensation Committee's duties include, but are not limited to:
  - Review corporate goals and objectives relevant to the Chief Executive Officer's compensation and evaluate the Chief Executive Officer's compensation in light of those goals and objectives. Based on that evaluation, the Compensation Committee shall determine and approve the compensation of the Chief Executive Officer, with the exception of the Chief Executive Officer's base compensation, which shall be approved by the independent directors on the full Board following the recommendation of the Compensation Committee.
  - Determine and approve the compensation of Abbott's other Senior Officers.
  - •In establishing compensation for the Senior Officers, consider the recommendations of an independent compensation consultant, performance against the officer's goals and objectives, and Abbott's relative performance.
  - Make recommendations to the Board with respect to incentive compensation plans and equity-based plans of Abbott that are subject to board approval and review, approve, and administer the incentive compensation plans in which any Senior Officer participates and all equity-based plans of Abbott...The Compensation

Committee may approve awards (with or without ratification of the Board) as may be required to comply with applicable tax rules.

- Review, at least annually, the compensation of directors who are not then serving as full-time employees of Abbott or any of its subsidiaries and recommend for approval by the Board any change in the compensation of such directors.
- Review and discuss with management and the Compensation Committee's independent compensation consultant (if any) potential risks associated with Abbott's compensation policies and practices, including its incentive compensation plans, and review these risks with the Board as appropriate.

# **D.** The Board Touted Abbott's Corporate Governance Structures

# a. Abbott's Corporate Governance Guidelines

- 82. Abbott's Governance Guidelines outline, among other things, Board director qualifications and duties. Specifically, Article II, "Director Responsibilities," states, among other things:
  - The board of directors shall review and, where appropriate, approve fundamental operating, financial, risk management and other corporate strategies, as well as major plans and objectives and shall monitor the effectiveness of management policies and decisions, including the execution of strategies.
- 83. Abbott's Governance Guidelines also confirm that its directors must follow Abbott's Code of Business Conduct, which requires that:
  - Directors shall deal honestly and ethically with Abbott and on Abbott's behalf in all matters.
  - Directors shall comply with all laws, rules and regulations applicable to their capacity as directors of Abbott, including, among others, the insider trading laws, rules and regulations.
  - Directors shall protect Abbott's assets, and promote their efficient and legitimate business use.
  - Directors shall report violations of laws, rules, regulations or the Code of Business Conduct to the Chairman of the Board, the Chief Executive Officer, the Vice President and Chief Ethics and Compliance Officer, or any other appropriate Abbott personnel.

- 84. Abbott's Code of Business Conduct further states that it applies to "all officers and employees of Abbott[.]" Accordingly, the Individual Defendants were obligated to follow all provisions of the Company's Code of Business Conduct too.
- 85. Moreover, Abbott maintained Comprehensive Ethics and Compliance Program, which includes relevant provisions as follows:
  - The CECO makes regular reports regarding compliance matters to the Chairman of the Board and the Chief Executive Officer, senior level leadership and Abbott's Board of Directors and committees.
  - The Business Conduct Committee (BCC) consists of senior-level leadership and is chaired by the CECO. The BCC is accountable directly to the Chairman of the Board and the Chief Executive Officer and was established to assist in the implementation of the compliance program.
  - The BCC 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. OEC staff provides dedicated support to each of Abbott's businesses.
  - The OEC utilizes results from internal investigations, internal audits and internal monitoring programs to assess the effectiveness of, and identify areas for improvement in, the compliance program and relevant business practices. In addition, we consider the external environment, including government investigations, settlements, industry codes and government guidance to identify new opportunities to enhance the compliance program.
    - b. Abbott relied on the purported strength of its corporate governance structures to urge shareholders to reject resolutions to adopt an independent Board Chairman
- 86. Abbott's Board consistently boasted the efficacy and approach of Abbott's corporate governance standards, repeatedly claiming "This collaborative approach to risk oversight and emphasis on long term sustainability begins with our leaders and is engrained in the culture of our Company. The Board also regularly monitors leading practices in governance and adopts measures that it determines are in the best interest of Abbott and its shareholders."

- 87. As noted in Section IV, the Board's Nominations and Governance Committee is responsible for reviewing Abbott's Corporate Governance policies.
- 88. Moreover, as described below, the Board emphasized to the Company's shareholders that its purported strong corporate governance was a reason to oppose the adoption of a proposal for an independent Board Chairman, which was included in proxy statements. Specifically, the Board opposed these shareholders proposals to improve corporate governance at Abbott, by highlighting existing corporate governance structures, and contending that they obviate the need for an independent Board Chairman.
- 89. For example, Abbott filed its shareholder meeting notice and proxy statement ahead of the 2018 annual meeting of stockholders (the "2018 Proxy Statement"), on March 16, 2018 with the SEC. In the 2018 Proxy Statement, the Board opposed an Abbott stockholder's proposal for an independent Chairman, claiming:

Abbott has received this shareholder proposal seven times since 2005 (many of which were submitted by this very shareholder). And seven times, Abbott's shareholders have rejected it. Each time this proposal returns, the Board reminds shareholders why they have rejected this cookie-cutter proposal so many times already: (a) there is no proved improvement to governance or performance in separating the CEO role from the chairman role; (b) Abbott's existing governance structure ensures appropriate oversight of management; and (c) the Board is entrusted to act in shareholders' best interests already, and as such should be free to exercise its judgment to select the best person for the chairman role. Last year, the majority of Abbott's shareholders overwhelmingly rejected the proposal again. Given the considerable success Abbott has had with its leadership structure to date, Abbott recommends that shareholders vote AGAINST this proposal for an eighth time. (Emphasis added).

Rather than preclude certain candidates from the chairmanship, Abbott ensures oversight of its management through other means—means the Board believes are more suitable to Abbott. ...

- 90. Based on the Board's recommendation in the 2018 Proxy Statement, Abbott's stockholders voted down the shareholder proposal for an independent Board chair.
- V. FOR DECADES, THE BOARD AND THE COMPANY'S MANAGEMENT ALLOWED ABBOTT TO EMPLOY ILLEGAL, UNSAFE, AND UNETHICAL PRODUCTION AND SALES PRACTICES TO MAINTAIN ITS DOMINANT POSITION IN THE U.S. INFANT FORMULA PRODUCTS MARKET TO MAXIMIZE THE COMPANY'S PROFITS
- 91. In the 1950s, Abbott began producing infant formula products. Currently, Abbott Nutrition is the Company's division that makes nutritional products for adults and children. Abbott Nutrition is one of the largest manufacturers of infant formula in the U.S. Its brands include Similac, Alimentum, and EleCare (the latter two for infants with sensitive or special gastrointestinal or nutritional needs).
- 92. Abbott's primary manufacturing facility for infant formula is located in Sturgis, Michigan, and has six lines of production. The Sturgis plant is responsible for *approximately half* of *Abbott's total infant formula production in the U.S.* In fact, at its peak, the Sturgis facility was responsible for feeding approximately one in five infants in the U.S.
- 93. As further described below, Abbott's Board and management has permitted Abbott to build and maintain its dominant position in the U.S. infant formula market by: (1) using predatory and unethical marketing tactics, while also securing WIC contracts to supply infant formula products to a majority of the low income families in the U.S. through anti-competitive practices, (2) failing to warn its customers about certain potentially fatal risks, like NEC for preterm infants; and (3) manufacturing and selling the Company's infant formal products in unsafe ways that violate the federal regulations.
  - A. The Board and Senior Management Allowed Abbott to Use Potentially Illegal Anti-Competitive Actions to Secure a Majority of the Nation's WIC Contracts, While Also Engaging In Predatory Marketing Tactics To Dominant the U.S. Infant Formula Market to Maximize the Company's Profits

94. Approximately 98% of formula consumed domestically is also manufactured here because U.S. regulatory requirements make it difficult for foreign manufacturers to enter the U.S. market. Moreover, for decades three companies have dominated the majority of the U.S. infant formula market: Abbott, Mead Johnson Nutrition Company ("Mead Johnson"),<sup>3</sup> and Nestle's Gerber.

95. Notably, these three companies are left to fight for a bigger and bigger piece of the cow-milk formula market share as birth rates decline in the United States. In this regard, overall, birth rates have plummeted for Americans over the past five decades. Specifically, between 1976 and 2018, the mean number of children born per woman declined, from three children to two. Moreover, by 2019, the average female aged 15 to 49 had given birth to 1.3 children, and the average male had fathered 0.9 kids. In addition to potentially losing profits due to declining birth rates in the U.S., ironically, cow-milk formula makers, like Abbott, also battle against one other single competitor, breast milk. As such, the Board and Abbott's management authorized Abbott to take potentially illegal anti-competitive actions, along with using predatory and unethical marketing tactics, to secure and maintain a dominant position in the U.S. infant formula products market to maximize the Company's profits. As a result, the Company's culture focuses on maximizing profits, which encourages risky, unsafe, and at times, illegal conduct to achieve the Company's goal of increasing revenues.

96. To maximize profits, the Board and the Company's management have ensured that Abbott has served as one of the biggest suppliers to the government-run WIC, that is Women, Infant, and Children, programs throughout the U.S., which supplies infant formula to low-income

<sup>&</sup>lt;sup>3</sup> Mead Johnson was acquired by Reckitt Benckiser Group plc in June 2017.

women with babies. Established in 1972 and made permanent in 1974, WIC is administered at the federal level by the Food and Nutrition Service of the U.S. Department of Agriculture ("USDA").<sup>4</sup> Significantly, WIC feeds about half of the nation's infants, and therefore, it is the largest buyer of infant formula in the U.S., making up more than half of annual formula sales, according to the USDA. In fact, roughly \$1 billion is typically spent on infant formula by the USDA, according to market research and USDA data.

- 97. Although WIC is federally funded, it is administered by U.S. states and territories. Each state contracts with a single infant formula manufacturer, like Abbott, to supply the program. Moreover, WIC recipients are not able to switch to a different brand if the state-contracted provider's brand is sold out. WIC contracts are also essential to the winning company's sales even to non-WIC consumers in that state. In this regard, under the WIC guidelines, stores are required to stock certain amounts of the winning "brand," which increases brand visibility on store shelves. Many stores, especially smaller ones with more limited shelf space, will exclusively stock that brand, so non-WIC customers will also only have access to the formula sold by the WIC contract holder for that state. These guidelines further put winning brands, like Abbott, in the position to be recommended by doctors or provided by hospitals in that state.
- 98. In its entire 50-year history, WIC contracts for infant formula have gone to *only three companies*: Abbott, Mead Johnson, and Gerber. Moreover, Abbott has the largest share of WIC contracts, with contracts to supply 34 states, and when also including territories and tribes, 49 agreements in total. As a result, 47% of the 1.2 million infants who receive formula through WIC can obtain only Abbott formula through that program.

<sup>&</sup>lt;sup>4</sup> About WIC: WIC's Mission, U.S. DEP'T OF AGRICULTURE (Aug. 2, 2022), https://www.fns.usda.gov/wic/about-wics-mission (last visited June 27, 2023).

- 99. The restrictive pool of infant formula options is a concern not only for new mothers under WIC, but for U.S. regulators, like the FTC. Moreover, the FDA and other qualified academics have continuously voiced their concerns that the U.S. infant-formula market is vulnerable to price and supply shocks in part because the formula market is dominated by a few companies and supply chains are fragile. The Board and Abbott's management, however, do not share those same concerns:those fiduciaries have allowed Abbott to pursue securing as many WIC contracts as possible in order to increase the Company's profits, even if those actions may constitute illegal anti-competitive actions.
- 100. Aside from potentially violating anti-trust regulations related to the Company's WIC contracts, the Board and Abbott's management further allowed the Company to engage in predatory marketing tactics to maximize Abbott's profits, even though those marketing tactics have violated the Company's corporate governance policies, including Abbott's Business Code of Conduct, because those tactics are based on unethical practices, as well as potentially numerous truth in advertising, unfair trade practices, and consumer fraud laws, including Section 5 of the Federal Trade Commission ("FTC") Act, which provides that "provides that "unfair or deceptive acts or practices in or affecting commerce . . . are . . . declared unlawful."
- 101. For example, Abbott's Board permitted Abbott to use predatory marketing techniques that mimic those of tobacco manufacturers who gave out free samples of cigarettes at inner city neighborhoods and playgrounds until such practices were banned in 2009. In this regard, Abbott has repeatedly hooked mothers and their babies to their products by offering free formula, coupons, and other free products in gift baskets given to mothers at hospitals and clinics, or directly to their homes. Parents usually feed their babies one specific formula exclusively, and typically do not switch unless a baby is not responding well. Babies also often resist switching to a different

formula once hooked on an initial brand. Abbott, therefore, has been able to create brand loyalty, so that vulnerable parents will continue to use Abbott's products after the baby's birth.

- 102. Abbott takes additional steps to maximize its profits with its WIC customers by attempting to hook those infants on the Company's most expensive baby formula products to maximize its profits starting at the hospital right after the infant's birth. Specifically, Abbott representatives contact mothers, who will be part of the WIC program, while those mothers are at the hospitals and provide them with free samples of the most expensive infant formula to hook their newborns for a particular "specialized" need. The Abbott representatives further provide the new mothers with a "script" to follow when requesting that their pediatricians approve such specialized formula for purchase under the WIC program, because otherwise the WIC program prohibits the low-income mothers from purchasing Abbott's most expensive brands of infant formula.
- other marketing schemes that also violates the Company's corporate governance policies, as well as potentially violate consumer fraud, unfair trade practices, and truth in advertising laws, to deceive consumers regarding the safety, efficacy, and equivalency of cow-milk formula to breast milk. For instance, since 1989, Abbott has advertised that its infant formula brands, Similac was the "first choice of more physicians." By 1995, Abbott had expanded that claim by using a heavy marketing campaign, which featured "1st choice of Doctors" on *all* its infant formula product labels. A plain interpretation of this claim is that physicians believe Similac is the "1st choice," naturally implying that it is superior even to breastfeeding. In fact, a few years later, in March 1998, Abbott even commissioned a marketing report that highlighted that "1st Choice of Doctors" claim scored highest in terms of consumers' likelihood of purchase. The report concluded: "Doctor

recommendations and the 'science' behind the formula appeared to drive purchase interest for this concept, as well as the other concepts tested," and use of similar pieces emphasizing the claim was "highly recommended."

- 104. Notably, the Board and the Company's management have authorized Abbott to pursue these marketing tactics for decades, and therefore, they are now ingrained as part of the Company's culture,. As such, those tactics, which are unethical and violate the Company's corporate governance policies, while also potentially constitute illegal anti-competitive actions, continue unabated at Abbott while the Individual Defendants served as Abbott's directors and officers.
  - B. Despite Decades of Scientific Proof, Abbott's Board and Management Focused on Maximizing Profits Rather than Warning that Pre-Term Infants Have a Higher Risk of Developing NEC, A Potentially Fatal Disease, From Consuming the Company's Cow-Milk Based Infant Formula Products
- 105. The Board and Abbott's management also allowed the Company to use predatory marketing tactics to maximize its profits by advertising its cow-milk-based infant formulas as "safe" for pre-term infants to consume. Abbott's representations could not be farther from the truth. An overabundance of two decades worth of well-designed clinical studies and medical literature showed that cow-milk-based formulas were unsafe and unreasonably dangerous for administration to premature infants and left babies susceptible to a dangerously high risk of developing NEC, which is potentially fatal. For decades, the Board and the Company's management have allowed Abbott to withhold this information from the public on its infant formula products' labels to maximize its profit.
- 106. NEC is a fatal gastrointestinal disease in premature infants. The Centers for Disease Control and Prevention ("CDC") defines preterm birth as when a baby is born before the 37 weeks

of full-term pregnancy have been completed.<sup>5</sup> Unfortunately, NEC is among the top killers of preterm infants in hospital neonatal intensive care units ("NICU").<sup>6</sup> The mortality rate for NEC patients is astounding, and ranges from 10% to 50%. In fact, NEC is almost 100% fatal for patients with the most severe form of the disease.<sup>7</sup>

107. NEC occurs when tissue in the large intestine, also known as the colon, becomes inflamed.<sup>8</sup> This inflammation damages and kills tissue in the infant's colon leading to bacterial invasion causing cellular damage and cellular death and necrosis of the colon and intestine.<sup>9</sup> Unfortunately, even if an infant survives NEC, they are left with a lifetime of complex health issues that can severely restrict their long term quality of life before they even speak their first words.

108. Abbott mass produces cow-milk-based formulas and fortifiers, which are non-prescription and do not require a physician's recommendation. Critically, a multitude of studies establish that cow-milk formulas and/or fortifiers lead to a significantly higher occurrence of NEC in preterm infants than human milk does. <sup>10</sup> Moreover, studies have also shown that an exclusively

<sup>&</sup>lt;sup>5</sup> Center for Disease Control and Prevention, *Preterm Birth*, https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pretermbirth.htm (last modified Nov. 1, 2021).

<sup>&</sup>lt;sup>6</sup> Sheila M. Gephart, RN, BSN, et al., Necrotizing Enterocolitis Risk: State of Science, 12 Advances in Neonatal Care, 77-89 (2012).

<sup>&</sup>lt;sup>7</sup> Holman RC, et al., Necrotizing Enterocolitis Hospitalizations Among Neonates in the United States, 20 Paediat Perinat Epidemiol, 498–506 (2006).

<sup>&</sup>lt;sup>8</sup> Stanford Children's Health, Necrotizing Enterocolitis in the Newborn, https://www.stanfordchildrens.org/en/topic/default?id=necrotizing-enterocolitis-90-P02388 (last visited Feb. 22, 2022).

<sup>&</sup>lt;sup>9</sup>https://www.ncbi.nlm.nih.gov/books/NBK513357/#:~:text=Necrotizing%20enterocolitis%20(N EC)%20is%20a,of%20the%20colon%20and%20intestine.

human milk-based diet is associated with a lower rate of NEC than a diet of human milk and cowmilk based products.

109. For example, in 1990, a landmark study, the "Cole Study" was published linking cow-milk formula to NEC.<sup>11</sup> In the Cole Study, the authors conducted two parallel dietary studies, involving 926 very low birth weight infants. NEC was determined to be six to ten times more common in those fed cow-milk-based formula, and three times more common than in those who received the formula plus breast milk.

evaluated in another study, the "Schanler Study," which was published in 1999. 12 The Schanler Study found that infants fed with any amount of human milk were discharged earlier than infants fed preterm formula, despite significantly slower rates of weight gain and size. In addition, there was lower incidence of NEC and late onset of sepsis in infants fed fortified human milk as compared to those fed preterm formula. The Schanler Study concluded that the unique properties of human milk promote an improved host defense and gastrointestinal function compared with the feeding of formula.

<sup>&</sup>lt;sup>10</sup> See Chowning R., et al., A Retrospective Analysis of the Effect of Human Milk on Prevention of Necrotizing Enterocolitis and Postnatal Growth, 36 J Perinatol 221-4 (2016); Johnson TJ, et al., Cost Savings of Human Milk as a Strategy to Reduce the Incidence of Necrotizing Enterocolitis in Very Low Birth Weight Infants, 107 Neonatology 271–6 (2015); Sullivan, S., et al., An Exclusively Human Milk-Based Diet is Associated with a Lower Rate of Necrotizing Enterocolitis than a Diet of Human Milk and Bovine Milk-Based Products, 156 J Pediatr 562–7 (2010); Cristofalo EA, et al., Randomized Trial of Exclusive Human Milk versus Preterm Formula Diets in Extremely Premature Infants, 163 J Pediatr1592-5 (2013).

<sup>&</sup>lt;sup>11</sup> Lucas A., Cole TJ, *Breast Milk and Neonatal Necrotizing Enterocolitis*, 336 Lancet 1519-1523 (1990).

<sup>&</sup>lt;sup>12</sup> Schanler RJ, et al., Feeding Strategies for Premature Infants: Beneficial Outcomes of Feeding Fortified Human Milk vs. Preterm Formula, 103 Pediatrics 1150-57 (1999).

111. Then another ten years later, in 2012, the "Sullivan Study" was published, evaluating the benefits of an exclusively human milk-based diet compared with a diet of both human milk and cow-milk based products in extremely premature infants. <sup>13</sup> The groups receiving an exclusively human milk diet had significantly lower rates of NEC and NEC requiring surgical intervention.

112. In addition, a Cochrane Library meta-analysis Study, which was last updated in 2018, analyzed data from eight trials including 1,605 participants who were either preterm or low birth weight infants in a neonatal unit. <sup>14</sup> The combined data showed a higher risk of NEC in the formula-fed group.

113. Notably, the Board and the Company's management allow Abbott to specifically target parents of premature infants in its marketing without providing any warning related to higher NEC risks. In this regard, Abbott markets its cow-milk formulas and/or fortifiers as equally safe alternatives to breast milk and promotes its products as necessary for additional nutrition and growth. Moreover, Abbott specifically marketed its formula and fortifier as necessary to the growth and development of *premature infants*, when its products pose a known and substantial risk to these babies for developing NEC, which can be fatal.

114. For example, a Google search for "feeding preemies formula," results in a "top of the search page" advertisement for Similac NeoSure, with the heading "For Babies Born Prematurely." The web-based advertisement states "Your premature baby didn't get her full 9 months in the womb, so her body is working hard to catch up. During her first full year, feed her

<sup>&</sup>lt;sup>13</sup> Sullivan, supra note 18.

<sup>&</sup>lt;sup>14</sup> Quigley, et al., Formula versus Donor Breast Mild for Feeding Preterm or Low Birth Weight Infants, 6 Cochrane Database of Systematic Reviews (2018), https://pubmed.ncbi.nlm.nih.gov/29926476/.

Similac NeoSure, a nutrient-enriched formula for babies who were born prematurely, and help support her development." The advertisement further claims that it is "pediatrician recommended" and "#1 brand fed in Hospitals" and "backed by science." Abbott's website also assures parents that its cow's-milk-based formula "supports excellent growth in premature babies' gains in weight, length, and head circumference when compared to these gains in preterm babies fed term formulas." Abbott's promotional web page expressly and implicitly represents that its cow-milk products are safe for use with premature infants. This advertising is false, misleading, and unfortunately also potentially deadly for Abbott's youngest customers.

- 115. Despite the plethora of scientific studies confirming that cow-milk based products are unsuitable for premature infants due to increasing their risk for developing NEC for decades, Abbott's Board and management have allowed Abbott to continue marketing its cow-milk based infant formula products without any warnings to alert its consumers of any risks relate to NEC for pre-term infants. Not only did Abbott stay silent on its potentially deadly formula, but the Company, along with its other competitors, invested over \$4 billion in marketing that deceived the consuming public, including parents and healthcare providers of premature infants, into believing that cow milk products were safe and necessary alternatives, supplements, and/or substitutes to human milk.
  - C. In this Past, The Board and the Company's Management Allowed Abbott to Violate FDA Regulations While Manufacturing its Infant Formula Products in the U.S.
- 116. In addition, to taking unethical and anti-competitive actions to dominate the U.S. infant formula market, along with using deceptive and predatory advertising tactics, Abbott has also violated FDA regulations when manufacturing and selling its infant formula products in the U.S. under the Board and the Company's management's purported watch.

117. As highlighted in Section IV, *supra*, the safety of infant formula is a central compliance issue for the Company as its production and sale must comply with federal regulations regardless of what percentage of this business contributes to Abbott's total revenues. In fact, whether Abbott manufactures and sells its infant formula products in safe and compliant ways in the U.S. has an outsized reputational impact on the Company because of how frequently used and widely distributed Abbott's infant formula is in this nation. Even the limited scope of the Company's Books and Records production demonstrates that the Individual Defendants failed to implement a central system of oversight at Abbott concerning this central compliance issue of infant formula safety in the U.S.

118. Moreover, Abbott's Sturgis plant, in particular, has repeatedly been cited for sanitation violations by regulators. For example, in 2010, the FDA found the Sturgis plant to have a flour beetle infestation that dated back to 2007. Abbott recalled 5 million containers of Similac, stopped production, and cleaned the plant. The recall cost Abbott \$100 million. Abbott also replaced Sturgis plant manager, but instead of firing him, Abbott moved him to another position in the Company. Notably, this incident did not cause Abbott to implement systemic changes, including an information reporting system to the Board and its senior executives, *despite having a beetle contamination problem at the Sturgis that went unnoticed by the Company's Board and senior executives for approximately three years*. Director Defendants Alpern, Austin, Blount, Liddy, McKinstry, Osborn, Tilton, Osborn, and White served on the Board, and Officer Defendants Calamari and Randall were Abbott officers.

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- 123. Abbott's Sturgis Plant was especially critical to not only the Company's infant formula business, but to the supply of infant formula for the whole U.S. In this regard, about 20% of *all* infant formula made domestically was manufactured at the Sturgis plant. The Sturgis plant, however, has had a history of sanitation failures, including numerous instances of contamination of formula from *Cronobacter sakazakii* ("Cronobacter").
- 124. While Cronobacter is generally harmless to adults, in young infants with their underdeveloped immune systems, Cronobacter can cause meningitis and sepsis, leading to fatal infections that kill as many as 40% of the babies it sickens and leaving many surviving infants with permanent, crippling disabilities. Unlike many other bacteria, Cronobacter thrives in dry environments, as well as growing in dirt and water, and thus can readily contaminate infant formula powder. As such, there is a heightened risk of Cronobacter contamination in infant formula manufacturing facilities. Because of the heightened risk of contamination, stringent sanitation measures must be taken to prevent contamination.
- 125. From at least 2005 to the present, Abbott has faced civil suits alleging Cronobacter contamination at Sturgis had caused infant injury or death. But Abbott's responses to these lawsuits was not to clean up the Sturgis plant (or any other plant), or implement an information reporting system for the Company's fiduciaries to ensure oversight related to this important safety issue. Instead, Abbott's response for more than a decade has been to consistently wear down plaintiffs through scorched-earth litigation, in such an aggressive manner that Abbott's counsel have drawn

judicial reprimands. For example, one judge presiding over such litigation told Abbott's counsel that their conduct was "the worst by a factor of ten" in the two decades that he had been on the bench. Another judge criticized Abbott's counsel for making "nonsensical" claims that were "a waste of judicial resources." <sup>15</sup>

126. Moreover, if Abbott feared that it would lose a case related to Cronobacter associated with its infant formula product, then it would authorize a secretive settlement, in which the victims and their families are forced to remained silent about such settlement, by signing an NDA as part of its terms. In fact, on October 12, 2022, Senator Warren sent Defendant Ford a letter challenging Abbott's litigation tactics, and requesting that Abbott specifically provide:

Please provide a list of settlements Abbott Nutrition has entered into regarding alleged Cronobacter infections from powdered infant formula since 2003.

- a. For each settlement, please provide the following information:
- i. The amount Abbott Nutrition paid to families impacted by Cronobacter;
- ii. Any non-disclosure agreements included in the settlements;
- iii. Whether these settlements were disclosed to any federal regulators of powdered infant formula;
- iv. Whether these settlements were approved by the Abbott Board of Directors.
- 127. It is currently unknown publicly whether Abbott complied with Senator Warren's requests related to these secret settlements involving claims of injuries to babies due to Cronobacter in Abbott's infant formula products that they consumed. Senator Warren, however,

<sup>&</sup>lt;sup>15</sup> David Enrich, "How Abbott Kept Sick Babies From Becoming a Scandal," N.Y. TIMES (Sep. 6, 2022, *updated* Sep. 8, 2022), https://www.nytimes.com/2022/09/06/business/abbott-baby-formula-lawsuits-jones-day.html.

stated that, "[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."

- i. Two Whistleblowers Confirmed that For Years, Abbott Unsafely Produced and Sold Infant Formula Products In Violation of FDA Regulations To Maximize The Company's Profits
- 128. At least two whistleblowers, who are former Abbott employees that worked at the Sturgis plant have described conditions there, as violating the FDA regulations in multiple ways, while creating fertile grounds for bacterial contamination. Specifically, Whistleblower #1 was a former Quality Assurance Specialist at the Sturgis plant from 2015 to August 2020, while Whistleblower #2 was a former Sturgis plant supervisor. <sup>16</sup>
- 129. Whistleblower #1 described Sturgis' workplace culture as focusing on speed and productivity at the expense of safety. He further described how the Sturgis plant had formerly been owned by Ross Laboratories, before that company was acquired by Abbott, and "[e]ven though the acquisition took place many years ago, the Sturgis site has never been fully integrated into Abbott's system of internal controls."
- over product safety at the Sturgis site. [And he was] aware of multiple situations where [reports] were approved despite the product being out of specification ('OOS'). . . . To make a problematic situation less likely to be tracked and monitored by officials at the division level, management at the Sturgis site often moved OOS batches into a category know as 'quality assessment.'" Furthermore, Whistleblower #1 alleged that "[i]ncreasingly over the last 12 months of [his] time

<sup>&</sup>lt;sup>16</sup> *Politico*, "'A Movie Set': Former Supervisor at baby formula plant says flaws were hidden," Aug. 4, 2022.

at Abbott, management directed him and others to misuse the SQE [Standard Quality Evaluation] procedure in order to meet metrics for the Sturgis site."

- 131. Whistleblower #1 also believed that one reason for the compliance problems at Sturgis was "that management at the Sturgis site is rewarded in terms of bonuses of some sort for meeting metrics vis-à-vis other production sites. . . . It was well known to [Whistleblower #1] and others at the Sturgis site that the information provided to evaluate productivity is frequently and, at times, blatantly false."
- 132. Whistleblower #1 further explained that the Sturgis plant regularly engaged in spot cleaning, rather than the entire area, even when Abbott's policy would require the entire area to be cleaned, because "meeting metrics took precedence."
- 133. Whistleblower #1 "firmly believes that the unrelenting pressure to meet metrics was a factor in overriding product safety concerns. . . . When product safety concerns were raised, employees were told that they would be singled out and held personally responsible for failing to meet and certain metrics in terms of production."
- 134. Whistleblower #2 also described an overall environment where plant management was obsessed with increasing market share and squeezing profits out at low cost, and created an environment where plant workers were discouraged from raising food safety or other concerns for fear of being fired.
- 135. Whistleblower #2 emphasized, "Management 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 with babies completely out to dry[.]" Furthermore, Whistleblower #2 recounted how he "kept hearing

over and over again, 'yeah, you've got to be careful if you start bringing stuff up. You can just disappear around here.'"

- 136. Whistleblower #2 also described how plant management was obsessed with increasing market share: "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.""
- 137. Both Whistleblowers #1 and 2 observed FDA violations and other unsafe conditions at the Sturgis plant. For example, Whistleblower #1 observed, "first-hand[,]" many FDA violations and unsafe, including:
  - "On multiple occasions and in various ways, records have been knowingly falsified. In most but not all of the situations, information of a material nature was not disclosed. This included testing seals on empty cans; signing verifications without adequate knowledge; understanding or inaccurately describing events so as to limit or avoid oversight; issuing certifications of projection pages bereft of pertinent data; shipping packages with fill weights lower than represented on the labels; failing to maintain accurate maintenance records; and prematurely removing holds in the absence of all requisite approvals."
  - "The Sturgis site performed a time code removal after the discovery of microorganisms ('micros') in a batch of infant formula. The remaining portion of the batch outside the time code removal was released without additional testing. On another occasion product was not re-called from the market even after management became aware of a nonconformity ('NC')."
  - "The Sturgis site has continued to permit lax practices associated with clean-in-place ('CIP') procedures. The Sturgis site failed and continues to fail to have staff in place with sufficient training and experience to review CIP charts. Nor are CIP charts regularly reviewed prior to the release of a batch. CIP checklists do not require signatures of those performing the tasks and are not otherwise subject to audit by QS staff."
  - "The Sturgis site has repeatedly failed to undertake reasonable measures to reduce natural or unavoidable defects to the level feasible as mandated by the current Good Manufacturing Practices ('cGMPs'). Deficient testing procedures known to be prone to

causing mistakes have not been corrected. The Sturgis site continues to rely on staff with insufficient training and experience to interact with third-party labs ('TPL')."

- 138. Whistleblower #2 also described how the Company had routine temporary fixes to address longstanding problems. For example, for years, the Sturgis plant suffered from roof leaks. But instead of fixing the roof, its management had a stash of plastic tarp catchers, which were used to deal with water from the roof's leaks on an ad hoc basis.
- 139. In addition, the Sturgis plant had other leaks from using HVAC systems, which were too small to work properly on some packaging lines. Moreover, the HVAC systems were not upgraded to ones of proper size because, according to Whistleblower #1, the Company "didn't want to spend the money to size the HVAC properly." As a result, water would get backed out and present another contamination risk.
- 140. Whistleblower #2 further detailed how the Sturgis plant used decades-old equipment. For example, one line that was responsible for packaging EleCare, one of Abbott's specialized formulas for infants with special medical needs, was designed in 1980 and had not been upgraded. As Whistleblower #2 noted, the line "was very old and it was poorly designed . . . . It was up to code in the 80s. It turns out we've learned some things since then." Whistleblower #2 also described how the line had a defective can seamer, which seals formula cans.
- 141. Whistleblower #1 detailed how Abbott would destroy defective products, which meant they were "deemed to be non-compliant or unsafe for the consumer[,]" yet Abbott kept existing products that was already shipped out on the market rather than issue a recall. This and the fake seam checking were all for the purpose of increasing production and sales, and willfully ignoring or evading regulations or standard practices that would have meant Abbott would have had to take a greater loss.

- 142. Furthermore, Whistleblower #1 described "significant issues regarding the traceability of its products." For example, Sturgis personnel often received notifications from its warehouse regarding pallets that were mislabeled or not labeled at all, due to an improperly working pallet labeler. Sturgis management were aware of the problem but did not fix it; this affected whether the right pallets were inspected when rework was required when production issues arose.
- 143. Whistleblower #1's "remaining and overriding concern is the rather dramatic evidence of inadequate internal controls. The delay in transitioning to electronic records; the absence of adequate procedures to protect employees raising concerns; the pervasive lack of accountability; the questionable incentive structure; and the ongoing failure to address material contingent liability, among others, are endemic to inadequate internal controls were food safety is paramount."
- 144. Whistleblower #1 further described how "Abbott failed to implement and actively enforce adequate internal controls with respect to the Sturgis site." Moreover, unlike many other allegations that Whistleblower #1 raised, he believed, "This failure does not appear to be limited to the Sturgis site. Officials at the division level were aware of many of the problems and failed to take corrective measures. Corporate practices were and are clearly inadequate. Indeed, there is evidence that some officials at the division and corporate levels may also be complicit."
- 145. The first internal control failure that Whistleblower #1 identified was how the Sturgis plant continued to rely on paper records, instead of electronic records. Conversion to electronic records has continually been delayed. In fact, Whistleblower #1 was told by "one member of management" that this delay was because "electronic records would make the Sturgis site more accountable to others at the division and corporate level." This was consistent with other

times "when management at the Sturgis site has repeatedly admitted a desire to keep division and corporate officials from being able to monitor its compliance with regulatory requirements. This need is ever-present with their being multiple episodes where management has consciously misled division officials as to [records] or the seriousness of a situation."

- 146. Furthermore, Whistleblower #1 also complained about a lack of any means to confidentially report concerns. He personally "can attest to a number of instances in which his identity as the source of elevating concern was disclosed by management at the Sturgis site." This led to a workplace environment where employees feared retaliation. In another instance, in discussing a Michigan state regulatory inquiry, "management identified in the presence of other staff the names of the individuals being questioned. Even at the corporate level, no meaningful steps were taken to protect the identity of witnesses or to protect against retaliation." For example, Whistleblower #1 recounted how in another instance, he reported to Abbott's Employee Relations office, which corporate policy indicates was "protected activity" and "disclosures . . . will be treated as confidential." Nevertheless, "his identity was disclosed to others at that Sturgis site and retaliation soon followed."
- 147. Whistleblower #1 "became increasingly concerned as to the absence of accountability in terms of regulatory compliance. He spoke out. He believed the breadth of the lax practices put in jeopardy the safety of the product being produced. . . . [H]e and others reasonably believed that Abbott was under a duty to minimize the likelihood of adulterated product."
- 148. Whistleblower #1 further recounted, that discipline at Abbott was a tool to "chill outspoken employees," but "was almost always overlooked when favored employees were involved." This selective discipline to the Sturgis plant "to have the largest number of certificates

of analysis ('COA') returned for incompleteness or false information. Yet no one was held accountable for this ongoing practice."

- 149. Furthermore, when Whistleblower #1 raised concerns about regulatory compliance to plant and division management, they "summarily dismissed" his concerns as "petty." Furthermore, Whistleblower #1 alleged that rather than address his repeated concerns, the management retaliated against him by intentionally placing inspection reports that contained unaddressed issues in his "batch files after the release of a batch" so that they could trump up a regulatory violation to place in his record, because he had previously insisted on timely submission of those reports even when "[m]anagement looked the other way, including officials at the division level."
- 150. Whistleblower #1 also alleged "that members of management who are intimately involved with circumventing what exist in terms of internal controls are not subject to any discipline other than for failures to meet their metrics. These are individuals who also repeatedly misled officials at the division and corporate level. These are individuals who knowingly direct and approve of actions in direct violation of FDA regulations."
- 151. Whistleblower #1 also noted that Sturgis personnel were filing false certifications of compliance with FDA regulations to secure rebates under the WIC program, which is a huge part of Abbott's infant formula business. Whistleblower #1 believed that the fact that Abbott certifies compliance when it did not also resulted in making false statements in its securities filings.
- 152. Moreover, because FDA inspections would often occur in roughly the same time period every year, they were easy to anticipate and, therefore, prepare for. From 2016 to 2019, every inspection of Abbott's Sturgis plant occurred in September. Whistleblower #2 alleged that the Sturgis' management "would prep heavily before audits" and "basically turned [the plant] into

a movie set where only things the higher ups wanted the FDA to see were seen." Whistleblower #2 alleged that in the weeks leading up to the anticipated FDA inspections, Sturgis personnel would work overtime to clean the facility, as well as conduct internal audits to fix potential problems. Moreover, the inspections were run by only a couple of inspectors. The Sturgis plant, however, covers 787,000 feet, or the equivalent of more than 13 football fields, and sits on 94 acres. Given the sheer size of the plant and the limited number of inspectors meant that an "inspection" consisted largely of reviewing the plant's own records.

- 153. Accordingly, oversight by Abbott's directors and officers to ensure that Abbott's infant formula products were manufactured and sold in compliance with federal laws was critical due to the limited resources of the FDA. The Individual Defendants, however, utterly failed in their oversight duties related to Abbott's manufacture and sale of infant formula products in the U.S., as they focused on maximizing the Company's profits, while those products continued to be made in unsafe and illegal ways and then sold to the U.S. public using unethical and predatory tactics, causing substantial harm to U.S. infants, and the Company itself.
- VI. SINCE AT LEAST 2019, ABBOTT HAS MANUFACTURED AND SOLD INFANT FORMULA PRODUCTS IN THE U.S. BY EMPLOYING UNSAFE, UNETHICAL, AND ILLEGAL PRACTICES WHILE THE INDIVIDUAL DEFENDANTS FAILED TO IMPLEMENT AN INFORMATION REPORTING SYSTEM TO ENABLE THEMSELVES TO OVERSEE SUCH MISCONDUCT AS REQUIRED BY THEIR FIDUCIARY DUTIES

As a result, the Board and/or Abbott's senior management missed numerous significant red flags that would or should

have put them on notice to take action to stop Abbott from violating regulations and its own

corporate policies, when selling the Company's unsafe infant formula products to the U.S.'s youngest consumers. Instead, these fiduciaries, in bad faith, allowed Abbott to continue using deceptive advertising and illegal practices, which were ingrained in the Company's culture for decades, in order to maximize the Company's profits by manufacturing and selling infant formula products in the U.S. in unsafe and unethical ways that also failed to comply with federal laws.

- A. In 2019, Abbott's Board and Executive Officers Missed Red Flags of Misconduct Occurring in the Company's Manufacture and Sale of its Infant Formula Products in the U.S. Because They Failed to Implement an Information Reporting System
- 155. In 2019, the Board and the Company's executive officers acted in bad faith when they failed to fulfill their oversight duties related to Abbott's production and sale of infant formula products in the US, by focusing solely on the Company maximizing profits instead. These failures allowed Abbott's infant formula products to be produced and sold in unsafe and unethical ways that also violated federal regulations.

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result, the Individual Defendants allowed Abbott to continue engaging in potentially anticompetitive behaviors, including in securing a majority of the U.S.'s lucrative WIC contracts. Likewise, those same fiduciaries permitted Abbott to continue its unethically marketing of its cowbased infant formula products as superior to breast milk, including failing to warn its pre-term infant consumers of the higher risk of developing NEC.

157. Similarly, the Individual Defendants' sustained failure to oversee whether Abbott manufactured and sold its U.S. infant formula products in compliance with FDA regulations, allowed Abbott to continue to violate those regulations in 2019. For example, Whistleblower #1

detailed an instance, in 2019, where cans were being filled at weights below that listed on the label. While proper procedure would have required destroying these cans, management at the Sturgis plant instead punted these cans to a "quality assessment," keeping them from being reviewed by division management, and distributed these under-filled cans throughout the batch. Several people complained to Sturgis management, and according to Whistleblower #1, one other member of the Quality Assurance team "went so far as to suggest to [him] the 'criminality' of the decision to proceed in this manner."

158. Whistleblower #1 also described the disrepair of processing equipment: pipes had pinholes that allowed bacteria to enter and were difficult to clean adequately. Bacteria could and did collect in those pipes and were picked up in formula flowing through those pipes. Yet, in 2019, management stopped engineers from reviewing certain cleaning processes, and instead replaced them with inexperienced contract workers, which led to equipment malfunctioning and being covered in moldy formula at the Sturgis plant. In fact, routine testing revealed that batches of finished formula were contaminated, but Abbott's management had only a portion of the potentially contaminated batches destroyed, while the rest was distributed without additional testing.

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On September 17, 2019, the Company announced, "Out of an abundance of caution,
Abbott has voluntarily recalled a single lot of Calcilo XD® powder cans (13.2oz / 375g) with lot
number 79696K80 in the United States and Canada due to an inconsistency in aroma and color in
a small number of cans from this specific batch." Whistleblower #1 discussed this recall because
it was a red flag for an even larger issue. Specifically, Whistleblower #1 alleged that Sturgis
management falsified an appearance of rectifying the problem that caused the recall because they
made it appear that they were checking the seams carefully to prevent powder from getting in.
However, "instead of directly addressing the underlying problem, seam checks were performed on
empty cans." According to Whistleblower #1, this workaround was "the only way to achieve
passing results without finding powder in the seam. [And] Management at the Sturgis site directed
that the checks be performed in this manner."
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- 166. According to Whistleblower #1, Sturgis management was concerned that during its 2019 inspection, the FDA would "find out about the micro batches." One manager was "amazed that the FDA was unable to discover what occurred with the micro batches." Instead of voluntarily disclosing the release of potentially unsafe products into the marketplace, according to the first whistleblower, "staff and department managers congratulated each other on a successful FDA audit." Moreover, during the inspection, "a senior QA official was understood to have . . . avoid[ed[ providing direct answers to questions asked by the FDA." As a result, Whistleblower #1 concluded that there "was a practice of 'sanitizing' files before furnishing them to auditors. It involved records being pulled and reviewed by management officials apart from where the auditors were located." He also concluded "some records were culled before furnishing a file to the auditors."
- 167. Notably, during its September 2019 inspection, the FDA observed from Abbott's own records that it had detected Cronobacter in a batch of formula in August 2019, before distribution. The FDA further noted that a baby who consumed Similac Pro-Advance Optigro formula tested positive for Cronobracter.
- 168. Critically, the FDA also found that Abbott was not abiding by its own protocols for microbiological testing for finished and packaged formula for evidence of Cronobacter and Salmonella. In this regard, the FDA found that Abbott only tested <u>half</u> of the required samples of powered formula for microbiological contamination before distribution. Infant formula producers only test a small sample of their finished products, but Abbott was testing only half of the minimum

required amount. As such, the 2019 Form 483 found that Abbott "did not test a representative sample of a production aggregate of a powered infant formula at the final product stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards."

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174. On November 12, 2019, Defendant Ford replaced Defendant White, who ha
served as Abbott's CEO and Chair of the Board for over two decades, as the Company's CEO an
was appointed to the Board, while Defendant White remained as the "Executive Chairman" of the
Board, continuing to reap millions of dollars in compensation on an annual basis.
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- B. Despite the Critical Need for Oversight in 2020 Due to COVID, the Individual Defendants Continued to Favor Profits Over Safety and Compliance with Federal Laws, Ignoring their Oversight Duties to Monitor the Production and Sale of Abbott's Infant Formula Products in the U.S.
- 177. In 2020, the Individual Defendants again failed to fulfill their oversight duties related to Abbott's production and sale of infant formula products in the US, focusing only on the Company maximizing profits. As in 2019, these failures allowed Abbott's U.S. infant formula products to be produced and sold in unsafe and unethical ways that also violated federal regulations.

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result, the Individual Defendants allowed Abbott to continue engaging in potentially anticompetitive behaviors, including its dominance of securing a majority of the U.S.'s lucrative WIC contracts. Likewise, on their watch, those same fiduciaries permitted Abbott to continue its unethical and potentially illegal marketing of its cow-milk-based infant formula products as superior to breast milk, including failing to warn its pre-term infant consumers of the higher risk of developing NEC, in violation of the Company's corporate governance policies.

179. Similarly, the Individual Defendants' sustained failure to oversee whether Abbott manufactured and sold its U.S. infant formula products in compliance with FDA regulations, allowed Abbott to continue to violate those regulations in 2020. For example,

180. By March 2020, COVID had overtaken the U.S., which caused the FDA to forgo
its annual in-person inspection of Abbott's infant manufacturing plants. Accordingly, it became
even more critical for Abbott's directors and officers to oversee and ensure that Abbott safely
manufactured and sold its infant formulas in compliance with federal laws.
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<sup>&</sup>lt;sup>17</sup> Notably, since 1995, the European Union has banned the sale of all infant formula products containing carrageenan, which is derived from red seaweed, and has no nutritional value. In fact, Abbott adds carrageenan to infant formula products to make it unnecessary to shake the product before a baby consumes it. Because Abbott refuses to remove carrageenan from its infant formula products, they are banned from sale in the European Union, and some other countries.

188. Whistleblower #1 further alleged, "It was not unusual for management to disregard situations involving severe breaches of the most basic regulatory requirements." He detailed a situation in July 2020 when certain pages of test results for some product batches were missing, but the test results were still certified, which "were patently false as the test results were not included." Management was aware of this problem but kept certifying test results "multiple times" that were actually missing. Whistleblower #1 further emphasized, "Despite the blatant nature of what occurred, and its egregiousness in terms of putting consumer safety at risk, management took no corrective action in terms of discipline. Nor were remedial measures put in place to reduce the likelihood of a recurrence."

189. By August 2020, Whistleblower #1 alleged that a sham investigation ensued to justify his termination. For example, the investigation report was "in part, drafted by the supervisor seeking his termination. No follow-up inquiry took place despite an explicit assurance that his side of the allegations made against him would be sought." He reiterated that "the investigator allowed the supervisor to literally draft or re-draft portions of the so-called investigative report." Furthermore, while the investigator did "not fully investigat[e] what occurred, the investigator demonstrated a remarkable lack of knowledge of the relevant issues."

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193. On November 30, 2020, Abbott filed an answer and counterclaims in patent litigation captioned *Evolve Biosystems Inc., et al. v. Abbott Laboratories*, No. 19-CV-05859, ECF #143. Abbott's answer reflects that it understood the scientific literature and studies concerning NEC, including how nutrients in human milk tend to foster a healthy infant gut biome that helps prevent NEC. Therefore, Abbott would or should have understood that ever growing body of medical evidence confirmed that preterm infants who consumer cow-milk based formulas are at a higher risk of developing NEC. For example, in the latest of a long series of similar studies, a 2020

medical journal discussed the "Lucas Study," which found that cow milk derived fortifier was associated with a higher risk of NEC, requiring surgery, reduced head circumference gain, and death. <sup>18</sup> In fact, this study determined that despite the high intake of the mother's own milk, the cow-milk-derived fortifier was still associated with a 4.2-fold increased risk of NEC and a 5.1-fold increased risk of NEC surgery or death. <sup>19</sup>

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Notably, this type of information would have put a Board acting in good
faith to at least consider putting a warning on the label of its infant formula products concerning
the higher risk for preterm babies to develop NEC from consuming cow-based formulas.

C. In 2021, Abbott Continued to Manufacture and Sell its U.S. Infant Formula Products in Unsafe, Illegal, and Unethical Ways as the Individual Defendants Continued to Fail to Exercise their Oversight Duties While Focusing On Maximizing the Company's Profits

<sup>&</sup>lt;sup>18</sup> Lucas, Alan et. al., *Preterm Infants fed Cow's Milk-Derived Fortifier had Adverse Outcomes Despite a Base Diet of Only Mother's Own Milk*, 15 Breastfeeding Medicine 297-303 (2020) .

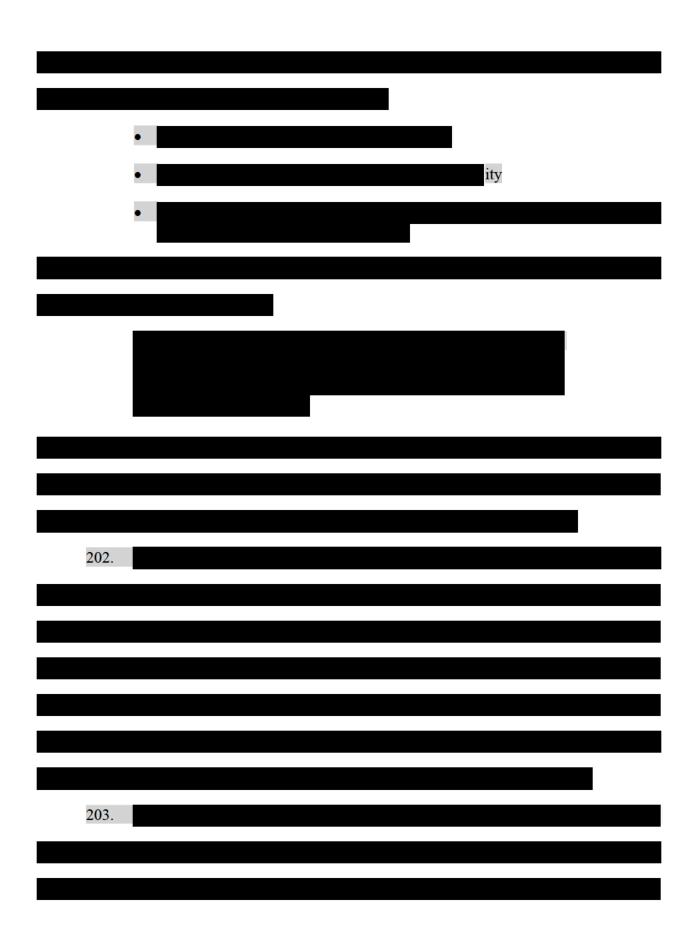
<sup>&</sup>lt;sup>19</sup> *Id*.

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As a result, the Individual Defendants allowed Abbott to continue engaging in potentially anti-competitive behaviors, including its dominance of securing a majority of the U.S.'s lucrative WIC contracts. Likewise, those same fiduciaries permitted Abbott to continue its unethically marketing of its cow-based infant formula products as superior to breast milk in violation of the Company's corporate governance policies.

- 196. Further, the Individual Defendants' constant failure to oversee whether Abbott manufactured and sold its U.S. infant formula products in compliance with FDA regulations, allowed Abbott to continue to violate those regulations in 2021. By this time, however, the Sturgis Plant's longstanding problems caught up with it, and its management could no longer hide them from regulators, after a string of infant fatalities and Whistleblower #1's report, which eventually spurred the FDA to act.
- 197. On February 16, 2021, Whistleblower #1 filed a complaint with OSHA (the "OSHA Complaint"), which detailed how Abbott was engaged in serious illegal activities at the Sturgis Plant. Significantly, Whistleblower #1's OSHA Complaint noted that his legal counsel sent a letter to Defendant Allen, Abbott's Executive Vice President, General Counsel & Secretary, who is Defendant Ford's direct report, to instruct Abbott to preserve records associated with the Whistleblower. In April 2021, Abbott responded to Whistleblower #1's OSHA Complaint, and Defendants Randall and Calamari, who both have direct oversight over the Sturgis Plant, and Defendant Allen would have been involved in such response.

198. As a result, by no later than April 2021, Abbott's senior management became aware
of numerous safety and regulatory issues related to the Company's production and sale of its infant
formula products in the U.S. from Whistleblower #1's OSHA Complaint. However, due to an utter
lack of oversight reporting systems at Abbott, none of Abbott's executive officers, including the
Defendant Allen, the Company's General Counsel, brought this issue to the Board's attention in
199. Despite the dire regulatory, safety, and ethical issues facing Abbott's infant formula
products in the U.S.,
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206. In September 2021, the FDA received a report that an infant in Minnesota had been hospitalized with a Cronobacter infection and had been fed Similac Sensitive formula. While the FDA informed Abbott, it did not inform its own inspectors, who were conducting an inspection of the Sturgis plant from September 20-24, 2021. Nevertheless, the FDA inspectors found widespread quality problems that create risks of contamination: workers reaching into bags of ingredients without cleaning their hands or gloves; crucial drying equipment with pits and cracks where Cronobacter could collect; and pooled water where Cronobacter could multiply. At this time, the FDA cited Abbott for "not test[ing] a representative sample of a production aggregate of a powdered infant formula at the final stage and before distribution to ensure that the production aggregate meets the required microbiological quality standards." But Abbott did not implement changes to correct these problems. Nor did any Abbott executive inform any member of the Board or any of Abbott's senior executives about such issues, much less the resulting Form 483 and EIR.

207. In this regard, on September 24, 2021, the FDA issued another Form 483 to Abbott (the "2021 Form 483") and related EIR after its September 2021 inspection. Notably, the 2021 Form 483 stated, among other things, "You did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition," and "An instrument you used to measure, regulate, or control a processing parameter was not properly maintained." The 2021 Form 483 further – shockingly – stated that "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." (Emphasis added). As such, the Sturgis plant was not even complying with the most basic precautions even though it had a history of microbial contamination.



210. Moreover, this time, Abbott was engaged in another employment litigation case with Whistleblower #1. Specifically, on October 19, 2021, Whistleblower #1 filed a complaint with the FDA (the "FDA Complaint"), which provided a further opportunity for Abbott to learn of and correct its problems at the Sturgis plaint.

- 211. On December 1, 2021, the FDA received a second complaint of a Cronobacter infection in an infant given Abbott formula, who later died. Also in December 2021, the FDA interviewed Whistleblower #1. The FDA further sought to schedule another inspection of the Sturgis plant in January 2022 this one would be a "for cause" inspection, indicating the seriousness of the violations present at the Sturgis plant. But Abbott's management at the Sturgis plant sought to delay this inspection, citing a COVID-19 outbreak at the plant.
- 212. In December 2021, a purported class of Canadian preterm infants filed suit in British Columbia alleging that they had developed NEC because the Company had failed to warn of the higher risk of those babies contracting that disease.

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214. On December 13, 2021, Quality Assurance and Food Safety Magazine published an interview with Defendant Randall, in which she stated that, "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 behaviors," "[i]t is 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 further highlighted how Abbott encouraged employees to speak up to ensure food safety, "[t]he goal is to have everyone advocate for food safety, no matter their role."

- D. In 2022, the Individual Defendants' Oversight Failures Caused an Infant Formula Shortage Crisis in the U.S. When the DOJ Shut Down the Sturgis Plant For Months Due to Severe FDA Violations
- 215. In light of (1) the mounting regulatory issues at the Sturgis Plant; (2) the increasing number of lawsuits concerning preterm infants developing NEC from consuming cow-milk based formulas;; and (3) its continued use of predatory advertising along with potentially anti-competitive actions to secure a majority of the nation's WIC contracts, it was even more critical that the Individual Defendants fulfill their oversight duties to ensure that the Company's infant formula products were manufactured and sold in the U.S. through safe, ethical and compliant means

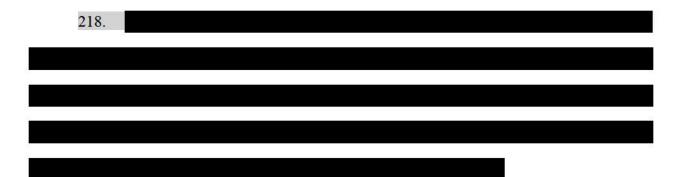
Individual Defendants allowed Abbott to continue to engage in potentially anti-competitive behaviors, in an effort to secure their dominance in securing a majority of the U.S.'s lucrative WIC contracts, while violating FDA regulations. Likewise, those same fiduciaries permitted Abbott to continue its unethical marketing of its cow-milk-based infant formula products as superior to breast milk, including failing to warn its pre-term infant consumers of the higher risk of developing NEC, in violation of the Company's corporate governance policies in 2022.

As a result, the

216. On January 5, 2022, the parents of a preterm infant, who had consumed Abbott's infant formula products, developed NEC and died, and began, what became a floodgate of similar lawsuits against Abbott in the Northern District of Illinois, among other jurisdictions, for failing

to warn of the higher risk of premature infants developing NEC from consuming the Company's cow-milk formula products. These lawsuits were subsequently centralized and transferred to the Northern District of Illinois by the Judicial Panel on Multidistrict Litigation and are currently pending before Chief Judge Pallmeyer.<sup>20</sup>

217. On January 11, 2022, the FDA received a complaint of a third Cronobacter illness in an infant who consumed Abbott's infant formula from the Sturgis Plant.



- 219. Also on January 31, 2022, through February 2, 2022, the FDA finally was able to conduct its "for-cause" inspection at the Sturgis Plant. Consistent with statements made by Whistleblowers #1 and #2, the FDA found systematic problems, such as pits and cracks in dryer towers and standing water, all associated with Cronobacter breeding and contamination risks. In fact, Abbott's own records listed *310 problems* with water in the prior two years.
- 220. Significantly, the FDA's testing detected Cronobracter in multiple environmental sites, including on the "scoop hopper" used to "feed scoops, which are placed directly inside the infant formula containers and contact product." The FDA then instructed Abbott to conduct additional testing between February 6 and February 20, 2022, which found Cronobacter on 20 occasions in "low, medium, and high care areas of powdered infant formula production" at the

<sup>&</sup>lt;sup>20</sup> In re: Abbott Laboratories, et al., Preterm Infant Nutrition Products Liability Litigation, No. 22 ev 3026, MDL No. 00071 (N.D. Ill).

Sturgis Plant. As such, Cronobacter was found in multiple locations in the Sturgis Plant because of the unsafe and illegal practices that had been ongoing for years as workers focused on maximizing profits while violating federal regulations, which was the Company's culture.

- 221. Following this inspection, the FDA repeatedly urged Abbott to recall infant formula products, which were manufactured at the Sturgis Plant, but Abbott resisted doing so until the FDA forced its hand by issuing a consumer advisory regarding those products. Specifically, shortly after the market closed on February 17, 2022, the FDA issued a press release "advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas," which were produced at the Sturgis Plant. The FDA explained that "it is investigating consumer complaints of *Cronobacter sakazakii* and *Salmonella* Newport infections," which were linked to infant formula production at the Sturgis Plant. Notably, the FDA highlighted how its investigation was "on-going."
- 222. On February 17, 2022, Abbott initiated a recall, and its Sturgis Plant shut down *all* production of infant formula products. Abbott, however, misleadingly framed the recall as "voluntary" and "proactive" action by the Company. Abbott's press release further failed to mention that the FDA's investigation was on-going and Whistleblower #1's FDA Complaint to the FDA about similar issues. Nor did Abbott's press release mention that the FDA's investigation was prompted by Cronobacter hospitalizations and an infant's death. In fact, Abbott further misled the market by stating that it conducted "routine testing" and only found Cronobacter in "non-product contact areas" at the Sturgis plaint. Abbott, thus, failed to mention the intensive testing mandated by the FDA when it found Cronobacter in product contact areas.
- 223. As detailed above, in part because of Abbott's success in securing WIC contracts and its successful promotion of its products in hospitals, along with its other predatory marketing and potentially anti-competitive tactics before the 2022 recall, Abbott had acquired a 20% share

of the infant formula market in the U.S. Given its dominant market share and positioning in WIC contracts, Abbott is the sole source of infant formula for millions of babies and their caregivers. As FDA Commissioner Robert Carliff testified in Congress after the 2022 recall, "Abbott's enormous market share left it with the responsibility for producing safe infant formula that wasn't met."

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- 227. On February 18, 2022, Abbott filed a Form 8-K confirming the recall before the start of trading. 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 per share." Abbott explained that it expected to take a "one-time specified item in the first quarter 2022 for recall related expenses," but assured investors that it did "not expect that these expenses will have a material impact on Abbott's consolidated financial statements."
- 228. Also on February 18, 2022, *Politico* reported that the FDA received its first complaint of a Cronobacter-related illness potentially from infant formula produced at the Sturgis

plant in September 2021 – five months prior to the recall – and how the FDA informed Abbott of such complaint shortly thereafter.

- 229. On February 24, 2022, the FDA received a fourth complaint of Cronobacter infection in an infant, who also died, and had consumed infant formula produced at the Sturgis plant.
- 230. On February 26, 2022, *Politico* reported that on February 24, 2022, U.S. Senators Patty Murray and Bob Casey sent a letter to Defendant Ford, stating "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 demand that Abbott turn over internal documents related to the manufacture and sale of infant formula products from the Sturgis plant, including information concerning Cronobacter.
- 231. On February 28, 2022, Abbott expanded its recall. On the same day, the FDA further explained the expanded recall by announcing "one additional illness of *Cronobacter sakazakii* with exposure to powdered infant formula produced at Abbott Nutrition's Sturgis, MI facility." The FDA highlighted how Cronobacter may have contributed to two babies' deaths. The Abbott Board and management, however, did not ensure that Abbott updated its Company recall website to include information on this additional death. Instead, news outlets, like *The Wall Street Journal* reported on this death, and that a spokesperson for Abbott stated that production at the Sturgis plant was "paused" as it continued to work with the FDA.
- 232. On March 22, 2022, in a surprising move, the FDA publicly disclosed the initial results of its January 31, and March 18, 2022, inspections at the Sturgis plant (the "2022 Form 483"), along with redacted versions of the 2019 Form 483 and 2021 Form 483.

- 233. Notably, conditions had deteriorated even more since the violations were reported in 2019 and 2021. The 2022 Form 483 identified several unsanitary conditions, and specifically found violations of FDA regulations because Abbott had 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 further failed to "ensure that all surfaces that contacted infant formula were maintained to protect infant formula from being contaminated by any source."
- 234. Significantly, the 2022 Form 483 directly contradicted Abbott's representation that no Cronobacter had reached its product areas. Instead, the 2022 Form 483 revealed that the FDA observed that Abbott had discovered Cronobacter in its production areas and in the finished formula itself on at least two prior occasions. In addition, the newly released 2019 Form 483 and 2021 Form 483, revealed Abbott's history of failing to correct safety and regulatory issues directly linked to Cronobacter at the Sturgis plant. This news caused Abbott's stock to drop \$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, 2023 an \$8.8 billion single-day-loss of market capitalization.
- 235. The FDA's release of the three Form 483s caused Senator Bob Casey to state, "This is another troubling report establishing a pattern of Abbott Nutrition's inadequate efforts to keep its products safe." Likewise, Senator Patty Murray commented, "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."
- 236. In response, Abbott continued to downplay its role, denying that any Cronobacter found at the Sturgis plant was connected to any of the ill babies. Indeed, during an earnings call related to Abbott's first quarter, on April 20, 2022, Defendant Ford represented that Abbott had a

"very robust manufacturing network and a robust quality system." Ford further continued to push the narrative that Abbott initiated a "voluntary" recall in February 2022, and that none of the Cronobacter found at the Sturgis plant was linked to the infants' illnesses.

- 237. On April 28, 2022, during trading hours, a redacted version of Whistleblower #1's FDA Complaint was made public by Congresswoman Rosa DeLauro, revealing that Abbott's management knew about the unsanitary and illegal conditions that led to the Sturgis plant's shut down and the massive recall, much earlier than the Company had acknowledged in the past, and that no actions were taken to voluntarily correct those conditions by the Company. Congresswoman DeLauro further stated that she was "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." In response to this news, Abbott's stock dropped another \$4.51 per share, 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 a \$7.9 billion single-day-loss of market capitalization.
- 238. In response to the news of the release of Whistleblower #1's FDA Complaint, Abbott attacked Whistleblower #1's credibility, with a spokesperson stating that he was "dismissed due to serious violations of Abbott's food safety policies."
- 239. Also in April 2022, the Chief Judge Rebecca Pallmeyer of the Northern District of Illinois began adjudicating a multi-district litigation concerning numerous lawsuits filed by parents of deceased or injured premature infants, who developed NEC after consuming Abbott's cow's-milk-based formula. This litigation also remains pending.
- 240. Rather than addressing the host of safety and compliance issues facing the manufacture and sale of Abbott's infant formula products in the U.S.,

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249. 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..." This statement further detailed how the FDA, USDA, DOJ, DOT, USTR, DHS, DOC and the White House 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 manufacturers to increase production, expediting the import of infant formula from abroad, and calling on both online and in store retailers to establish purchasing limited to prevent the possibility of hoarding. The White House highlighted how "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."

250. The following day on May 13, 2022, White House Press Secretary Jen Psaki focused on how "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." She also reminded everyone that the February recall "was done because there – in – there was a factory in Michigan that had tainted formula that killed two babies." Abbott rejected these statements in a series of tweets later that day, including that "The formula for this plant did not cause these infants illnesses." In reality, the

FDA could not reach any definitive conclusions due to the significant limitations with available data, which it explained a few days later.

- 251. On May 15, 2022, in a virtual press briefing, FDA Commissioner Carliff stated, "there are so many factors involved in this investigation and we're just not in a position yet to make any definitive statements."
- Consent Decree against Abbott and Defendant Randall, among others. The DOJ Complaint and Consent Decree against Abbott and Defendant Randall, among others. The DOJ Complaint charged Abbott with dangerous and unsafe food practices and business operations in violating numerous regulations of the FDCA. The DOJ Complaint built on the FDA's findings in its Form 483s from 2019 through 2022, 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 sakazaki ("C. sak")* and *Salmonella*." It further alleged that 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 demonstrates that *Defendants have been unwilling or unable to implement sustainable corrective actions to ensure the safety and quality of food manufactured for infants, a consumer group particularly vulnerable to foodborne pathogens.*" The DOJ concluded that Abbott had violated 21 C.F.R. § 117.1(a)(1(ii), along with 21 C.F.R. §§ 106.20(a), 106.55(a), 106.30(b), 106.10(b)(1), and 106.100(k)(2).
- 253. In contrast, on the same day, Abbott issued a press release, in which it again misleadingly stated that Cronobacter was found in "non-product" contact areas and that the Cronobacter "has not been linked to any known infant illness. Abbott, however, agreed to resolve the DOJ Complaint through a Consent Decree, which required Abbott to retain an outside expert

to assist Abbott, with the FDA's supervision, to develop a plan designed to reduce and control the risk of bacterial contamination, and periodically evaluate Abbott's compliance with FDCA regulations, along with the other terms of the Consent Decree. The Consent Decree further requires Abbott to notify the FDA if it finds contamination and to store any samples of Cronobacter it finds for three years. Moreover, violations of the Consent Decree could result in daily fines of \$30,000, which are capped at \$5 million a year.

- 254. On May 21, 2022, *The Washington Post* published a public apology from Defendant Ford, in which he again tried to downplay the blatant violations at the Sturgis plant and any connection between Abbott's infant formula products and the babies' Cronobacter related illnesses.
- 255. On May 25, 2022, in Congressional testimony, FDA Commissioner Robert Carliff testified that the Sturgis plant was "egregiously unsanitary." Carliff further emphasized: "Frankly, the inspection results were shocking . . . . This is so far removed from my previous experience with the company that I am very concerned." Carliff also rebutted Abbott's assertion that the FDA had exonerated it, by testifying that the FDA could not definitely conclude *or* rule out that Cronobacter infections arose from the Sturgis plant, and that, the confluence of events, in particular the instance of four Cronobacter infections arising out of formula produced at the same plant, was "highly unusual."
- 256. Nevertheless, on the same day, Abbott's head of U.S. and Canada Nutrition, Defendant Calamari, continued to push back, in his Congressional testimony, against accountability for Abbott, insisting that there was no "culture problem" at the Sturgis plant. Moreover, Defendant Calamari falsely claimed that Abbott 'became aware of the whistleblower complaint in the end of April [2022] when it was made public by Congress." Calamari further

blamed Whistleblower #1 for not bringing his concerns to Abbott's attention. Yet, as Whistleblower #1 detailed in his FDA Complaint, he did raise his concerns directly with Abbott in 2019 and 2020 before he was terminated, as well as in February 2021 from filing his OSHA Complaint and in October 2021 from filing his FDA Complaint. Moreover, Abbott responded to the Whistleblower #1's OSHA Complaint in April 2021, and it further detailed how his counsel had sent a letter to Abbott's General Counsel to put the Company on notice of Whistleblower #1's contentions about the unsafe and illegal practices that were ongoing at the Sturgis plant when manufacturing and selling the Company's infant formula products.

257. On June 8, 2022, just before the markets closed, news reports confirmed that Abbott had submitted a response to Whistleblower #1's first complaint in April 2021, and therefore, must have been aware of Whistleblower #1's allegations about the unsafe and illegal conditions at the Sturgis Plant since February 2021. Abbott again attacked Whistleblower #1 in response to this news, stating, "We believe this to be a former employee who was dismissed due to serious violations of Abbott's food safety policies," and that his complaints were part of "a pattern of everevolving, ever-escalating allegations." Also this day, *Food Safety News* announced that the FDA had received reports of nine infant deaths between December 1, 2022 and March 3, 2022 of babies that consumed infant formula produced by the Sturgis Plant. This article further reported 25 incidents of "Life Threatening Illness/Injury" and 80 incidents of "Non-Life Threatening Illness/Injury." On this news, Abbott's stock dropped again by \$4.17 per share, from a closing price of \$116.88 per share on June 7, 2022, to a closing price of \$112.71 on June 9, 2022, resulting in a market capitalization loss of \$11.1 billion.

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262. On June 22, 2022, the FDA announced it was investigating another infant's death, which occurred in January 2022, prior to the recall, but was not reported until June 10, 2022. This death brought the total to 10 dead infants from Cronobacter potentially from infant formula produced at the Sturgis plant.

- 263. On October 19, 2022, the Company announced its results for the third quarter of 2022, which included the impact of the Sturgis plant shutdown and related recall of Abbott's infant formula products. Notably, Abbott's total pediatric sales had decreased by 39.1% on an organic basis, or 24.8% on a reported basis for that quarter. Moreover, Abbott's net earnings declined 31.7% from the same quarter in 2021, falling from \$2.1 billion to \$1.44 billion. While Abbott continued to deny its connection to any Cronobacter-related illnesses in babies that consumed the Company's infant formula, during an investor call on the same day, Defendant Ford disclosed that some leadership changes were made at the Sturgis plant and in Abbott's Quality Division, conceding that serious institutional deficiencies that caused the contamination and recall did, in fact, exist. In reaction to this news, Abbott's stock price plummeted, dropping \$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 a \$12 billion single-day-loss of market capitalization.
  - E. Despite Ongoing Investigations by the DOJ, SEC, and FTC, Abbott's Fiduciaries Continue to Deny Wrongdoing Related to the Company's Production and Manufacture of Infant Formula Products in the U.S.
- 264. Though Abbott implicitly acknowledged its sanitation problems by voluntarily recalling multiple lines of products manufactured at the Sturgis plant, Abbott's Board and management have allowed Abbott to continue to deny responsibility. In fact, Abbott also takes every opportunity it can to slant the public record its way. For example, in May 2022, after the FDA stated that it could not conclude definitively that Cronobacter infections were caused by Abbott's formula produced at the Sturgis plant, Abbott spun that finding to claim that the FDA had concluded that Abbott's formula did not cause those illnesses.
- 265. Though Abbott's senior management continued its denials, U.S. regulators continued to scrutinize the Company's failure to manufacture and sell its infant formula products

in safe and compliant manner in the U.S. For example, in January 2023, news reports revealed that the DOJ was conducting a criminal investigation into the safety issues at the Sturgis plant. If prosecutors bring charges, potential penalties could include steep fines for Abbott and its executives under the Food, Drug & Cosmetic Act of 1938, which prohibits the sale of poisonous or unsanitary food and ingredients, or preparing and packing food in unsanitary conditions. Penalties could even include jail time, including sentences from felony charges. Moreover, misdemeanors are relatively easy to prove, under the known facts, because they would only require proof that Abbott produced formula in unsanitary conditions, which the FDA inspection reports already demonstrated. Felony charges require a further showing Abbott or its executives intended to defraud or mislead consumers and regulators, or that Abbot was a repeat offender. Either a misdemeanor that resulted in death or a felony conviction could result in up to three years in prison for an individual.

266. In February 2023, the SEC was also reported to be conducting an investigation into the conduct or statements relating to the Sturgis Plant. This was also confirmed by Abbott in its Form 10-K for 2022 filed on February 17, 2023 (the "2022 Form 10-K"), when the Company revealed that, "In 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."

267. That same month, the FTC was also reported to be conducting an investigation related to Abbott's infant formula products. Similarly, in its 2022 Form 10-K, Abbott disclosed that, "In 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."

- 268. In April 2023, the FTC revealed that it is investigating the possibility of whether infant formula makers colluded on bids for lucrative state WIC contracts. FTC documents explain that it is looking into the possibility that formula makers have "engaged in collusion or coordination with any other market participant regarding the bidding" for state contracts. Also, the FTC is also looking into whether formula makers colluded in the broad market outside of the WIC programs and how that collusion affects sales and supply of infant formula.
- 269. Moreover, in its 2022 Form 10-K, Abbott finally revealed the extent of the numerous lawsuits and class actions that the Company is facing, both in the U.S. and outside of the U.S., in light of its failure to warn about the increased risk of preterm infants developing NEC from consuming Abbott's cow-milk based formula products. Specifically, the 2022 Form 10-K disclosed:

Abbott is a defendant in numerous lawsuits involving certain of its specialty infant formula products administered to preterm infants. The lawsuits allege that preterm infants developed necrotizing enterocolitis as a result of being administered a cow's milk-based preterm infant formula product, which resulted in personal injuries or death. As of January 31, 2023, there were 399 lawsuits pending in federal and state courts in which Abbott is a party. The plaintiffs seek various damages, including punitive damages. In April 2022, the U.S. Judicial Panel on Multidistrict Litigation ordered all federal court cases consolidated for pretrial purposes in the U.S. District Court for the Northern District of Illinois. In addition, in December 2021, a purported class of Canadian preterm infants filed suit in British Columbia and, in October 2022, a purported class of Israeli preterm infants filed suit in Tel Aviv, both of which make similar allegations as those made in the United States against Abbott. These plaintiffs seek various damages, including punitive damages. Many of the lawsuits name another infant formula manufacturer as a codefendant.

270. Despite these ongoing serious regulatory investigations and numerous lawsuits involving multiple aspects of the Company's unsafe and illegal production and sale of infant formula products, Abbott's Board and management have allowed Abbott to take the public

position highlighting how samples have returned no Cronobacter connected to the Company's Sturgis Plant. But, as former FDA official Frank Yiannas ("Yiannas") has explained, in his March 28, 2023, Congressional testimony, testing often involves a mere few grams or few hundred grams out of batches that weigh tens or hundreds of thousands of pounds, so while a positive test is alarming, a negative test is not by itself reassuring.

- 271. In fact, during his March 28, 2023 testimony, Yiannas, responded to earlier statements that Abbott had made that implied that the FDA had exonerated the Company, by explaining that while the FDA could not definitively conclude that the four fatal Cronobacter cases from late 2021 to early 2022 could be traced to the Sturgis factory, it was actually a very high likelihood given the pervasive unsanitary conditions in the plant, the poor processes in place, and the old equipment that no longer conformed to best safety practices.
- 272. In addition, Yiannas further clarified that while Abbott had represented that it had voluntarily recalled formula in an abundance of caution, actually, Abbott was on the verge of being issued a mandatory recall. Yiannas explained that while the FDA had authority to issue a mandatory recall, it was a process that often would take much more time than a voluntary recall. Thus, Yiannas testified, the FDA would usually present its evidence to a company to support a mandatory recall and seek to have the company issue a voluntary recall, which could occur immediately and thus remove unsafe products from the marketplace right away. Yiannas confirmed that was the case for Abbott: that Abbott issued its voluntary recall after it heard a presentation from the FDA. Yiannas's testimony thus confirms that the safety issues at Abbott were more pervasive and serious than Abbott made it appear, as determined by Abbott's primary regulator, rather than what Abbott had misleadingly represented as merely an abundance of caution on Abbott's part.

273. Yiannas's public testimony is consistent with allegations made by Whistleblowers #1 and #2, along with other former employees whose allegations were detailed in the Securities Action, which is further detailed below in Section V, *supra*.

Yianna's public testimony and the allegations made by Whistleblowers #1 and 2 is

274.

corporate governance policies.

- consistent with information gathered from Teamsters Local 710 Pension Fund's and SEPTA's Books and Records investigations.

  As a result, the Individual Defendants utterly failed to oversee whether the Company manufactured and sold infant formula products in the U.S. in safe and ethical ways that complied with federal regulations and Abbott's
- VII. THE INDIVIDUAL DEFENDANTS VIOLATED SECTION 10(b) OF THE EXCHANGE ACT AND SEC RULE 10b-5, AND BREACHED THEIR FIDUCIARY DUTIES, BY KNOWINGLY OR RECKLESSLY ISSUING MATERIALLY FALSE AND MISLEADING STATEMENTS DURING THE RELEVANT PERIOD
- 275. In breach of their fiduciary duties to Abbott and its stockholders, and in violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5, Defendants issued, and caused the Company to issue, statements that, in light of the unsafe and illegal infant formula production and sales scheme detailed above, were materially false or misleading when made. The Individual Defendants' misrepresentations artificially inflated the price of Abbott shares, causing the

Company to purchase shares at artificially inflated prices, through its significant stock repurchase program.

276. The Individual Defendants' conduct had two goals, both of which were realized:

(1) by causing Abbott to make share repurchases, they signaled to investors and stockholders their purported belief that Abbott shares were trading at a discount, which caused investors to purchase shares and thus, drive the price up. Relatedly, the Company's repurchase of shares artificially inflated its financial metrics such as earnings per share ("EPS") as the repurchases resulted in fewer outstanding shares. Together, these actions helped further inflate Abbott's share price. The artificial inflation of Abbott shares was financially beneficial to the Individual Defendants, as numerous of the Officer Defendants' compensation was tied to the Company's financial performance; and (2) as detailed below, as a result of the artificial inflation of Abbott's common stock, the Insider Selling Defendants sold shares at higher prices, and therefore, reaped greater proceeds than they would have absent the artificial inflation.

## A. The Individual Defendants Caused Abbott to Conduct a Massive Stock Repurchase Program

277. Abbott's Board periodically authorizes the Company to repurchase its own shares of common stock. The Board authorized a series of share repurchases from 2019 through 2022, which totaled over \$6.4 billion of over 57 million shares of Abbott common stock.

278. As detailed in the chart below, between 2019 and 2022, Abbott repurchased approximately 57 million shares of its stock, paying over \$6.4 billion for them:

Month/Year of Repurchase	Number of Shares Repurchased	Weighted-Average Price per Share	Total Amount Paid (\$)
July 2019	294	\$88.74	\$26,090
August 2019	28,134	\$85.134	\$2,395,160
September 2019	11,800	\$83.354	\$983,577
October 2019	2,675,000	\$81.95	\$219,216,250

November 2019	1,786,605	\$82.928	\$148,159,579
December 2019	1,844,839	\$82.928	\$152,988,809
Total for 2019	6,346,672	\$84.17	\$523,769,465
January 2020	2,957	\$85.89	\$253,977
April 2020	76,831	\$98.00	\$7,529,438
May 2020	9,188	\$92.10	\$846,215
June 2020	791	\$90.9	\$71,902
September 2020	28,423	\$109.47	\$3,111,466
December 2020	1,600,411	\$107.999	\$172,842,788
Total for 2020	1,718,601	\$97.40	\$184,655,785
January 2021	1,785	\$109.11	\$194,761
February 2021	10,000	\$122.54	\$1,225,430
April 2021	18,202	\$120.90	\$2,200,622
June 2021	4,500,000	\$111.575	\$502,087,500
July 2021	450,000	\$120.849	\$54,382,050
August 2021	2,175,000	\$123.265	\$268,101,375
September 2021	3,002,035	\$120.814	\$362,687,856
October 2021	1,767,000	\$127.811	\$225,842,037
November 2021	4,750,000	\$127.486	\$605,558,500
December 2021	135	\$141.00	\$19,035
Total for 2021	16,674,157	\$125.05	\$2,022,299,167
January 2022	650,000	\$127.262	\$82,720,300
February 2022	8,550,000	\$123.643	\$1,057,147,650
March 2022	8,113,060	\$118.344	\$960,131,973
August 2022	1,050,000	\$102.567	\$107,695,350
September 2022	7,363,597	\$102.895	\$757,677,313
October 2022	2,000,000	\$98.258	\$196,516,000
November 2022	800,000	\$98.103	\$78,482,400
December 2022	3,750,000	\$108.455	\$406,706,250
Total for 2022	32,276,657	\$117.86	\$3,647,077,236
Grand Total	57,016,087		\$6,377,801,652

279. As members of the Board, Director Defendants Alpern, Austin, Blount, Kumbier, Liddy, McDew, McKinstry, Osborn, Scott III, Starks, Stratton, Tilton and White approved a \$3 billion repurchase program announced on October 15, 2019. Likewise, Director Defendants Alpern, Austin, Blount, Ford, Gonzalez, Kumbier, McDew, McKinstry, Osborn, Roman, Starks, Stratton, and White approved the \$5 billion repurchase program announced on December 10, 2021.

- B. The Individual Defendants Issued False and Misleading Statements Regarding Abbott's Production and Sale of Infant Formula Products in the U.S., Including about its Purported Safety and Compliance with Federal Laws and Abbott's Policies, And the Company's Internal and Risk Controls
- 280. From 2019 through 2022, the Individual Defendants issued materially false or misleading statements and omitted material information concerning the Company's purportedly "safe," legally compliant, and ethical production and sale of infant formula products in the U.S. The misleading statements omitted material facts concerning: (1) Abbott's failures to comply with FDA regulations, and potential violations of antitrust regulations; and (2) violations of the Company's corporate governance policies through the use of deceptive and predatory marketing tactics, including a failure to warn about the higher risk for preterm infants to develop NEC from consuming Abbott's cow-milk based formulas. Moreover, in addition to the materially false or misleading misstatements and omissions related to Abbott's U.S. infant formula products, the Individual Defendants knowingly or recklessly made materially false or misleading statements and omissions regarding the Company's purported risk management practices, as the Individual Defendants have known since at least 2019 that Abbott encouraged excessive risk taking by focusing on maximizing profits related to its production and sale of the Company's infant formula products in the U.S., rather than safety and complying with federal regulations and Abbott's ethical obligations, along with rewarding the very executives who had taken undisclosed risks and exposed the Company to severe reputational damage and liability. In addition to violating Section 10(b and Rule 10b-5 of the federal securities laws, the Individual Defendants' misrepresentations also violated their fiduciary duty of disclosure under Illinois law.
- 281. As further detailed in Section VIII below, these materially false or misleading representations failed to disclose the following facts:

- Abbott failed to manufacture and sell its infant formula products in a safe and legally compliant manner in the U.S. because the Company's culture valued maximizing profits over compliance with the law and taking necessary safety precautions.
- The Individual Defendants knew or recklessly disregarded that employees, including those at the Sturgis plant, were engaged in that improper conduct allowing Abbott to produce and sell its infant formula products in the U.S. in unsafe and illegal ways, and they allowed it to continue. In addition, the Company's compensation practices were structured that it encouraged the illicit conduct.
- The Individual Defendants knew or recklessly disregarded that employees were engaged in improper conduct allowing Abbott to manufacture and sell its infant formula products using anticompetitive actions to dominant to the U.S. market, along with predatory and deceptive marketing tactics, which violate the Company's corporate governance policies and, potentially, federal antitrust laws.
- The Company's unsafe and illegal manufacture and sale of its infant formula products in the U.S. was, in material part, the result of oversight failures of the Individual Defendants, who in bad faith failed to implement an information reporting system to alert themselves of such unsafe and illegal activities, while ignoring any red flags that were waved in their face about the urgent need for them to oversee these issues.
- The Individual Defendants failed to implement the requisite risk controls to prevent or detect the Abbott's production and sale of infant formula products in the U.S. that, among other things, were unsafe and violated federal regulations, and were deceptively advertised by among other things failing to warn of the higher risk of preterm infants developing NEC if they consumed Abbott's cowmilk based formulas.
- ii. The Individual Defendants made false or misleading statements about the U.S. production and sale of Abbott's infant formula products by representing that such products complied with federal regulations and were safe for its consumers
- 282. The Individual Defendants also made false or misleading statements in Abbott's press releases, conference calls, investor presentations, and SEC filings concerning how the

Company's U.S. infant formula products were safe for consumption and their production and sale practices complied with federal regulations, which caused the Company to purchase billions of dollars of its stock in order to inflate Abbott's stock price, including for personal gain.

283. For example, on February 20, 2020, the Company filed with the SEC its annual report on Form 10-K, signed by Defendants Alpern, Austin, Blount, Ford, Funck, Kumbier, Liddy, McDew, McKinstry, Novakovic, Osborn, Starks, Stratton, Tilton, and White for the period ended December 31, 2019 (the "2019 Form 10-K"). In the 2019 Form 10-K, Abbott stated that:

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.

- 284. In its 2019 Form 10-K, Abbott further represented that: "Abbott's facilities are deemed suitable and provide adequate productive capacity."
- 285. Abbott then made those same representations from the 2019 Form 10-K in the following SEC filings:
  - The Form 10-K filed with the SEC on February 19, 2021, signed by Defendants Alpern, Austin, Blount, Ford, Funck, Kumbier, Liddy, McDew, McKinstry, Novakovic, Osborn, Starks, Stratton, Tilton, and White, for the period ended December 31, 2020 (the "2020 Form 10-K").
  - The Form 10-K filed with the SEC on February 18, 2022, signed by Defendants Alpern, Austin, Blount, Ford, Funck, Gonzalez, Kumbier, McDew, McKinstry, Novakovic, Osborn, Roman, Starks, Stratton, and Tilton, for the period ended December 31, 2021 (the "2021 Form 10-K").
- 286. The statements above relating to Abbott's production and sales of infant formula were materially false and misleading for the reasons stated in Section VIII concerning Abbott's false and misleading Proxy Statements. In sum:
  - Abbott failed to manufacture and sell its infant formula products in a safe and legally compliant manner in the U.S.
  - The Individual Defendants knew or recklessly disregarded that employees, including those at the Sturgis plant, were engaged in that improper conduct allowing Abbott to produce and sell its infant formula products in the U.S. in unsafe and illegal ways, and they allowed it to continue.
  - The Individual Defendants knew or recklessly disregarded that employees were engaged in improper conduct allowing Abbott to

manufacture and sell its infant formula products using anticompetitive actions to dominant to the U.S. market, along with predatory and deceptive marketing tactics, which violate the Company's corporate governance policies and federal antitrust laws.

- The Company's unsafe and illegal manufacture and sale of its infant formula products in the U.S. was, in material part, the result of oversight failures of the Individual Defendants, who in bad faith focused on generating revenues, and failed to implement an information reporting system to alert themselves of such unsafe and illegal activities, while ignoring any red flags that were waved in their face about the urgent need for them to oversee these issues.
- The Individual Defendants failed to implement the requisite risk controls to prevent or detect the Abbott's production and sale of infant formula products in the U.S. that, among other things, were unsafe and violated federal regulations, and were deceptively advertised by among other things failing to warn of the higher risk of preterm infants developing NEC if they consumed Abbott's cowmilk based formulas.
- This illicit conduct occurred because compensation practices and the Company's business culture was structured such that employees felt pressured to violate federal laws to maximize the Company's profits related to its infant formula sales in the U.S.;
- Despite complaints from employee whistleblowers and customers, including multiple lawsuits and class actions; warnings from the FDA, including multiple Form 483s, media attention, and investigations or litigation by governmental entities (including the FDA, SEC, DOJ and the FTC), the Individual Defendants allowed the illegal activities to continue; and
- Contrary to the Individual Defendants' assertions that the production and sale of Abbott's infant formula is safe and in compliance with all laws, it was immoral, unethical, and unscrupulous in that the Individual Defendants profited by allowing Abbott's infant formula to be produced in violation of federal regulations and using unsafe and unethical practices.
- C. In Repurchasing Stock, Abbott relied on the Individual Defendants' False or Misleading Statements

- 287. In repurchasing shares in connection with the stock repurchase program, Abbott relied on the Individual Defendants' false or misleading statements, directly and/or based on material omissions as articulated in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972).
- 288. Throughout 2019 to 2022, Abbott justifiably expected the Individual Defendants to disclose material information as required by law and SEC regulations in the Company's periodic filings with the SEC. Abbott would not have repurchased its securities at artificially inflated prices had the Individual Defendants disclosed all material information known to them, as detailed in this Complaint.

## D. The Insider Selling Defendants Engaged in Illegal Insider Sales of Abbott Stock

- 289. From 2019 through 2022, the Insider Selling Defendants (i.e., Calamari, Allen, Ford, Funck, Manning, McKinstry, Salvadori, and Starks) took advantage of the artificial inflation of Abbott's shares caused by the Individual Defendants' false or misleading statements. These Defendants collectively sold or otherwise disposed of over \$163 million in Abbott stock, all while in possession of material, nonpublic information. Abbott's stock price was also inflated during that time by the share repurchase program, which was approved despite the Individual Defendants' knowledge or reckless disregard of the unlawful practices detailed in this Complaint.
- 290. The Insider Trading Defendants possessed material inside information regarding the following matters: (i) Abbott's production of infant formula products did not comply with federal regulations or the Company's corporate governance policies; (ii) the illegal conduct occurred because the Company's culture maximized profits over safety; and (iii) the Company lacked the requisite risk controls as wells as internal and disclosure controls to detect and prevent its employees from manufacturing and selling Abbott's U.S. infant formula products in violation

of federal laws and the Company's corporate governance policies. Consequently, the Insider Trading Defendants were in possession of material non-public information and were prohibited from trading Company stock until such information was revealed to the public as further detailed above.

291. The following chart summarizes the dates upon which Defendant Calamari traded, as well as the total proceeds from such trades:

Defendant Calamari, Christopher

Date	Shares	Xcode	Price	Proceeds
2/28/2023	2,827	F	\$99.77	\$282,049.79
7/1/2022	569	F	\$108.65	\$61,821.85
3/1/2022	706	S	\$118.15	\$83,414.11
2/28/2022	2,368	F	\$122.41	\$289,866.88
Total:	6,470			\$717,152.63

292. Defendant Calamari's sales were inconsistent with past trading patterns and suspicious in their timing and amount. Calamari sold his shares, placing them into the open market at fraud-inflated prices, at a time that the Company had failed to disclose material, nonpublic information concerning the unsafe, illegal and unethical production and sale of infant formula products in the U.S.

293. The following chart summarizes the dates upon which Defendant Ford traded, as well as the total proceeds from such trades:

Defendant Ford, Robert B.

Date	Shares	Xcode	Price	Proceeds
2/28/2023	30,742	F	\$99.77	\$3,067,129.34
8/25/2022	102,425	$\mathbf{S}$	\$105.10	\$10,765,154.29
2/28/2022	26,579	$\mathbf{F}$	\$122.41	\$3,253,535.39
2/26/2021	22,865	$\mathbf{F}$	\$121.58	\$2,779,926.70
2/28/2020	16,638	$\mathbf{F}$	\$79.19	\$1,317,563.22
2/28/2019	14,682	F	\$77.23	\$1,133,890.86
Total:	213,931			\$22,317,199.80

294. Defendant Ford's sales were inconsistent with past trading patterns and suspicious in their timing and amount. Ford sold his shares, placing them into the open market at fraudinflated prices, at a time that the Company had failed to disclose material, nonpublic information concerning the unsafe, illegal and unethical production and sale of infant formula products in the U.S.

295. The following chart summarizes the dates upon which Defendant Funck traded, as well as the total proceeds from such trades:

Defendant Funck, Robert E., EVP CFO

Date	Shares	Xcode	Price	Proceeds
3/1/2023	1,264	S	\$100.70	\$127,284.80
2/28/2023	11,500	F	\$99.77	\$1,147,355.00
2/28/2022	10,750	$\mathbf{F}$	\$122.41	\$1,315,907.50
2/26/2021	10,136	F	\$121.58	\$1,232,334.88
2/2/2021	18,241	F	\$122.54	\$2,235,252.14
10/26/2020	83,333	S	\$108.83	\$9,068,955.39
4/21/2020	23,855	F	\$98.00	\$2,337,790.00
3/2/2020	1,356	S	\$77.89	\$105,618.84
2/28/2020	6,710	F	\$79.19	\$531,364.90
8/9/2019	26,818	F	\$85.56	\$2,294,548.08
3/1/2019	1,002	S	\$78.00	\$78,156.00
2/28/2019	4,680	F	\$77.23	\$361,436.40
Total:	199,645			\$20,836,003.93

296. Defendant Funck's sales were inconsistent with past trading patterns and suspicious in their timing and amount. Funck sold his shares, placing them into the open market at fraudinflated prices, at a time that the Company had failed to disclose material, nonpublic information concerning the unsafe, illegal and unethical production and sale of infant formula products in the

U.S. The following chart summarizes the dates upon which Defendant McKinstry traded, as well as the total proceeds from such trades:

Defendant McKinstry, Nancy, Director

Date	Shares	Xcode	Price	Proceeds
2/24/202	22 1,614	S	\$116.42	\$187,901.88
Tot	al			\$187,901.88

297. Defendant McKinstry's sales were inconsistent with past trading patterns and suspicious in their timing and amount. McKinstry sold her shares, placing them into the open market at fraud-inflated prices, at a time that the Company had failed to disclose material, nonpublic information concerning the unsafe, illegal and unethical production and sale of infant formula products in the U.S.

298. The following chart summarizes the dates upon which Defendant Salvadori traded, as well as the total proceeds from such trades:

Defendant Salvadori, Daniel Gesua Sive, EVP

Date	8	Shares	Xcode	Price	Proceeds
3/1/2023	1,085		S	\$100.70	\$109,259.50
2/28/2023	9,002		F	\$99.77	\$898,129.54
3/1/2022	1,550		S	\$118.17	\$183,165.05
2/28/2022	10,551		F	\$122.41	\$1,291,547.91
12/23/2021	58,501		S	\$140.00	\$8,190,140.00
12/13/2021	3,499		S	\$135.00	\$472,365.00
12/13/2021	55,000		S	\$135.00	\$7,425,000.00
3/1/2021	1,664		S	\$120.61	\$200,695.04
2/26/2021	12,596		F	\$121.58	\$1,531,421.68
8/27/2020	42,479		S	\$111.86	\$4,751,700.94
7/21/2020	1,060		F	\$99.08	\$105,024.80
3/2/2020	999		S	\$77.89	\$77,812.11
2/28/2020	12,279		F	\$79.19	\$972,374.01
7/21/2019	1,060		F	\$87.49	\$92,739.40
6/26/2019	71,000		S	\$84.00	\$5,964,007.10
6/13/2019	3,331		S	\$82.00	\$273,142.00

Total:	305,686		10.4.000 2000000000	\$34,121,395.39
2/28/2019	11,097	F	\$77.23	\$857,021.31
3/1/2019	1,664	S	\$78.00	\$129,792.00
6/11/2019	7,269	S	\$82.00	\$596,058.00

299. Defendant Salvadori's sales were inconsistent with past trading patterns and suspicious in their timing and amount. Salvadori sold his shares, placing them into the open market at fraud-inflated prices, at a time that the Company had failed to disclose material, nonpublic information concerning the unsafe, illegal and unethical production and sale of infant formula products in the U.S.

300. The following chart summarizes the dates upon which Defendant Stark traded, as well as the total proceeds from such trades:

Defendant Starks, Daniel, Director

Defendant Starks, Daniel, Director					
Date	Shares	Xcode	Price	\$0.00	
5/2/2023	46,548	S	\$110.97	\$5,165,431.56	
5/2/2023	3,452	S	\$111.75	\$385,761.00	
10/27/2022	40,687	S	\$97.30	\$3,958,991.57	
10/27/2022	9,313	S	\$98.14	\$913,940.57	
7/26/2022	27,749	S	\$108.77	\$3,018,175.48	
7/26/2022	22,251	S	\$109.60	\$2,438,818.63	
5/3/2022	16,822	S	\$112.51	\$1,892,723.97	
5/3/2022	27,055	S	\$113.29	\$3,065,152.94	
5/3/2022	6,123	S	\$114.84	\$703,170.83	
Total:	200,000			\$21,542,166.55	

301. Defendant Starks's sales were inconsistent with past trading patterns and suspicious in their timing and amount. Starks sold his shares, placing them into the open market at fraudinflated prices, at a time that the Company had failed to disclose material, nonpublic information

concerning the unsafe, illegal and unethical production and sale of infant formula products in the U.S.

302. The following chart summarizes the dates upon which Defendant Manning traded, as well as the total proceeds from such trades:

Defendant Manning, Joseph, Sr. VP

Date	Shares	Xcode	Price	Proceeds
3/1/2023	1,339	S	\$100.70	\$134,837.30
2/28/2023	5,438	F	\$99.77	\$542,549.26
9/8/2022	23,008	S	\$107.00	\$2,461,856.00
8/25/2022	23,008	S	\$104.99	\$2,415,704.25
8/25/2022	3,890	S	\$105.24	\$409,383.60
3/1/2022	779	S	\$118.16	\$92,046.80
2/28/2022	5,850	F	\$122.41	\$716,098.50
2/26/2021	5,974	F	\$121.58	\$726,318.92
2/2/2021	3,130	S	\$123.03	\$385,083.90
2/1/2021	18,750	S	\$122.79	\$2,302,263.75
2/28/2020	5,909	F	\$79.19	\$467,933.71
1/27/2020	37,500	S	\$89.58	\$3,359,411.25
8/30/2019	47,226	S	\$85.14	\$4,020,684.68
3/20/2019	113	S	\$79.57	\$8,991.41
3/20/2019	5,500	S	\$79.58	\$437,673.50
3/1/2019	1,223	S	\$78.00	\$95,394.00
2/28/2019	3,959	F	\$77.23	\$305,753.57
Total:	192,596			\$18,881,984.40

- 303. Defendant Manning's sales were inconsistent with past trading patterns and suspicious in their timing and amount. Starks sold his shares, placing them into the open market at fraud-inflated prices, at a time that the Company had failed to disclose material, nonpublic information concerning the unsafe, illegal and unethical production and sale of infant formula products in the U.S.
- 304. The following chart summarizes the dates upon which Defendant Allen traded, as well as the total proceeds from such trades:

Defendant Allen, Hubert L.,

Date	Shares	Xcode	Price	Proceeds
3/1/2023	1,069	S	\$100.70	\$107,648.30
2/28/2023	8,515	F	\$99.77	\$849,541.55
3/1/2022	1,450	S	\$118.17	\$171,347.95
2/28/2022	9,878		\$122.41	\$1,209,165.98
2/26/2021	10,913	F	\$121.58	\$1,326,802.54
2/1/2021	201,343	S	\$123.47	\$24,858,994.70
2/1/2021	2,050	S	\$124.03	\$254,256.99
3/2/2020	1,208	S	\$77.89	\$94,091.12
2/28/2020	14,280	F	\$79.19	\$1,130,833.20
6/20/2019	165,000	S	\$85.00	\$14,025,000.00
3/1/2019	2,246	S	\$78.00	\$175,188.00
2/28/2019	14,843	F	\$77.23	\$1,146,324.89
Total:	432,795			\$45,349,195.22

305. Defendant Starks's sales were inconsistent with past trading patterns and suspicious in their timing and amount. Starks sold his shares, placing them into the open market at fraudinflated prices, at a time that the Company had failed to disclose material, nonpublic information concerning the unsafe, illegal and unethical production and sale of infant formula products in the U.S.

### E. The Individual Defendants' Misstatements and Omissions Caused Damages to Abbott

306. From 2019 through 2022, the price of Abbott's common stock was artificially inflated as a result of the Individual Defendants' materially false and misleading statements and omissions identified above. The Individual Defendants engaged in a scheme to deceive the market and a course of conduct that operated as a fraud or deceit on Abbott, which repurchased shares at artificially inflated prices. When the Individual Defendants' misrepresentations and fraudulent conduct was disclosed and became apparent to the market, the price of Abbott stock fell as the

prior artificial inflation dissipated. As a result of its purchases of Abbott shares during 2019 through 2022, the Company suffered damages.

- 307. On February 10, 2022, barely a week before the scandal began to be revealed, Abbott's common stock closed at \$127.76 per share. On February 16, 2022, the last trading day before the Individual Defendants' fraud was partially revealed, Abbott common stock closed at \$123.68 per share.
- 308. The Individual Defendants' disclosures on February 17, 2022, began to reveal the misleading nature of their false statements and omissions. On that day, the FDA issued a warning about Abbott's infant formula products manufactured at the Company's Sturgis plant, and Abbott announced a "voluntary" recall of such products. The press releases and other communications and media coverage related to the recall and the related shut-down of the Sturgis plant revealed several facts as described above, including that: (i) Abbott's production of baby formula at its Strugis plant did not comply with FDA regulations; and (ii) the Company lacked the requisite risk controls as wells as internal and disclosure controls to detect and prevent its employees from manufacturing and selling Abbott's infant formula in violation of federal laws and the Company's corporate governance policies.
- 309. In response to those disclosures, the price of Abbott common stock declined precipitously. Over a period of several months, as new information about the scandal continued to be revealed, Abbott's share price plummeted by over 25%, falling from its February 10, 2022 price of \$127.76 to close as low as \$95.21 on October 20, 2022, when Abbott revealed more negative news about the financial impact related to the Sturgis plant's recall and shut-down, wiping out over \$56 billion in market capitalization during that time. Moreover, Abbott continues to deny its wrongdoing, so the full extent of this scandal has yet to be revealed.

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

VIII. THE DIRECTOR DEFENDANTS VIOLATED SECTION 14(a) OF THE EXCHANGE ACT AND SEC RULE 14a-9, AND BREACHED THEIR FIDUCIARY DUTIES, BY CAUSING THE COMPANY TO FILE MATERIALLY MISLEADING PROXY STATEMENTS

311. The Director Defendants also violated Section 14(a) of the Exchange Act and SEC Rule 14a-9 by causing Abbott to issue proxy statements that failed to disclose the Company unsafely manufactured and sold its infant formula products in the U.S.: (1) in violation of federal and state health and safety laws; (2) using illegal, unethical and predatory advertising tactics in violation of the Company's corporate policies; or (3) the seriously deficient internal risk management and disclosure controls that allowed those unsafe and illegal conditions to proliferate at Abbott. The Director Defendants' failure to disclose those material facts likewise constitutes a breach of their fiduciary duties.

# A. The 2021 Proxy Defendants Caused Abbott to Issue the Materially False or Misleading 2021 Proxy Statement

312. On March 12, 2021, Director Defendants Alpern, Austin, Blount, Ford, Kumbier, Liddy, McDew, McKinstry, Novakovic, Osborn, Starks, Stratton, Tilton, and White (i.e., the "2021 Proxy Defendants") caused Abbott to file the 2021 Proxy Statement in connection with the 2021 annual shareholders meeting to be held on April 23, 2021. In the 2021 Proxy Statement, the 2021 Proxy Defendants solicited shareholders votes to, among other things, (i) re-elect themselves to the Board; (ii) approve executive compensation, and (iii) decide whether to adopt a policy

requiring an independent Chair. With respect to each of these solicited votes, these Defendants issued materially false or misleading statements.

- 313. With respect to Board re-elections, the 2021 Proxy Statement represented in a section entitled, "CORPORATE GOVERNANCE:
  - "Abbott is committed to strong corporate governance that is aligned with shareholder interests. Our Board spends significant time with the Abbott's senior management to understand the dynamics, issues, and opportunities for Abbott. During these interactions, directors provide insights and ask probing questions which guide management decision-making. This collaborative approach to risk oversight and emphasis on long term sustainability begins with our leaders and is engrained in Abbott's culture. The Board also regularly monitors leading practices in governance and adopts measures that it determines are in the best interest of Abbott and its shareholders."
- 314. The 2021 Proxy Statement represented that "All of Abbott's directors exhibit: Knowledge of corporate governance requirements and practice." The 2021 Proxy Statement further represented that: the "Board receives regular updates and has oversight over Abbott's environmental, social and governance practices."
- 315. The 2021 Proxy Statement specifically directed shareholders to Abbott's website for "additional information... regarding Abbott's business activities." Notably, on its website, Abbott posted a brochure entitled, "Our Global Policy on Marketing of Infant Formula," which is available on the "Policies" section of the Company's website, making the following representations:
  - 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; and

• We maintain compliance with all laws, rules and regulations in every country in which we operate.

In addition, Abbott maintained an "Infographic" presentation on its "Corporate Newsroom" on its website entitled, "The Abbott Quality Promise," in which the Company represented 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." As part of Abbott's Quality Promise, it represented that it had "Clean Facilities," and that "Our facilities are designed and maintained to the highest Good Manufacturing Practice standards, which are globally recognized. All employees follow strict hygiene measures, such as wearing specialized uniforms, facemasks and sanitized gloves." Abbott further represented that its Quality Promise also included "Quality Checks," and "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." Notably, in the "Policy section of Abbott's website in its "Other Disclosures" section, Abbott stated that the Company is "fully committed to delivering products with the highest standards of quality, safety, and performance and also stating that "Our quality culture is embedded in everything that we do."

317. The 2021 Proxy Statement also represented in a section entitled, "Nominations and Governance Committee" that:

The Nominations and Governance Committee assists the Board in fulfilling its oversight responsibility with respect to governance matters. Its primary responsibilities include:

• Assist the Board in identifying individuals qualified to become Board members, and recommend to the Board the nominees for election as directors at the next annual meeting of shareholders,

- Recommend to the Board the people to be elected as executive officers of Abbott,
- Develop and recommend to the Board the corporate governance guidelines applicable to Abbott, and
- Serve in an advisory capacity to the Board and the Chairman of the Board on matters of organization, management succession plans, major changes in the organizational structure of Abbott, and the conduct of Board activities.
- 318. The 2021 Proxy Statement made further specific representations about certain Director Defendants' expertise in corporate governance and risk management. For example, it highlighted how Defendant Blount's corporate governance expertise, noting: "Having served as Dean of the J.L. Kellogg Graduate School of Management at Northwestern University and as the Vice Dean and Dean of the Undergraduate College of New York University's Leonard N. Stern School of Business, Ms. Blount provides Abbott's Board with expertise on business organization, governance and business management matters." Likewise, the 2021 Proxy Statement represented that Defendant Liddy "provides valuable insights on corporate strategy, risk management, corporate governance and many other issues facing large, global enterprises." The 2021 Proxy Statement also represented that "[t]hrough his extensive leadership in the U.S. Air Force, General McDew contributes significant experience managing large, complex global operations, including strategic planning, security and risk management, cybersecurity, and supply chain and infrastructure management. Similarly, the 2021 Proxy Statement highlighted that "[t]hrough his executive leadership at Verizon Communications, Mr. Stratton contributes extensive business and management experience operating a global public company such as Abbott, including valuable insights on corporate strategy and risk management."
- 319. With respect to the Board's role in risk oversight, the 2021 Proxy Statement represented: "The Board has risk oversight responsibility for Abbott and administers this

responsibility both directly and with assistance from its committees," and "[e]ach year, Abbott's directors evaluate the effectiveness of the Board and its Committees in performing its governance and risk oversight responsibilities. Directors assess the performance of their peers, as well as the full Board of Directors and each of the Committees on which they serve."

320. Specifically, with respect to the Audit Committee's oversight responsibilities, the 2021 Proxy Statement represented:

The Audit Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to:...

- Legal and regulatory compliance relating to financial matters, including accounting, auditing, financial reporting, and securities law issues, and
- Enterprise risk management, including major financial and cybersecurity risk exposures.

In performing these functions, the Audit Committee meets regularly with the independent auditor, Abbott's management, and Abbott's internal auditors to review the adequacy, effectiveness and quality of Abbott's accounting and financial reporting principles, policies, procedures and controls, as well as Abbott's enterprise risk management, including Abbott's risk assessment and risk management policies.

321. Specifically, with respect to the Public Policy Committee's oversight responsibilities, the 2021 Proxy Statement represented:

The Public Policy Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to:

- Certain areas of legal and regulatory compliance, including evaluating Abbott's compliance policies and practices and reviewing Abbott's compliance program,
- Governmental affairs and healthcare compliance issues that affect Abbott, and

• Abbott's public policy, including evaluating Abbott's social responsibility policies and practices and reviewing social, political, economic, and environmental trends and public policy issues that affect or could affect Abbott's business activities, performance, and public image.

322. The 2021 Proxy Statement also represented that:

The Executive Committee may exercise all the authority of the Board in the management of Abbott, except for matters expressly reserved by law for Board action.

- 323. In connection with supporting the Board's continued rejection of requiring an independent Board Chair to improve Abbott's corporate governance, the 2021 Proxy Statement represented that "The Board reviews its leadership structure on at least an annual basis. The Board has determined that this leadership structure ensures the appropriate level of oversight, independence and responsibility is applied to all Board decisions, including risk oversight, and is in the best interests of Abbott and its shareholders."
- 324. With respect to executive compensation, the 2021 Proxy Statement represented that:

Our leadership covenant includes commitments to multiple environmental, social and governance efforts. Examples include:

- A sustainable infrastructure to drive quality, environmental, health and safety performance[;]
- Human capital management to ensure an inclusive culture and the fair and balanced treatment of our employees[;]
- Quality products provided at competitive prices to patients and consumers at hospitals and retailers[; and]
- Abbott's Code of Conduct to ensure adequate internal controls for financial reporting and compliance with applicable laws and regulations.

Since this covenant is considered the minimum requirement of being an officer at Abbott, any officer that does not fulfill the covenant can receive a reduction of up to 100% of their annual incentive and/or long-term incentive awards.

- 325. The statements outlined above from the 2021 Proxy Statement convey to its stockholders that Abbott and its Board: (i) maintained sufficient compliance, risk controls, review, and reporting systems to identify and address misconduct; (ii) were unaware of existing material risks that could affect the Company; (iii) had policies to deter unnecessary or excessive risk taking, including compensation and ethics policies; and (iv) maintained risk management practices related to its production and sale of the Company's infant formula products in the U.S.
- 326. The 2021 Proxy Statement omitted any disclosures regarding: (i) Abbott's ineffective internal and disclosure controls; (ii) the existence of the 2019 Form 483 and a related EIR detailing violations of FDA regulations; (iii) operational and reporting failures that did not appropriately address Abbott's manufacture and sale of infant formula products in the U.S. in violation of federal laws and the Company's corporate governance policies; (iv) Abbott's retaliatory practices against employees who report safety and regulatory violations related to the Company's production and sale of infant formula products in the U.S.; and (v) the Board-approved compensation programs that incentivized the concealment of the Company's unlawful and unethical manufacture and sale of infant formula products in the U.S. The 2021 Proxy Statement also failed to disclose that the Individual Defendants took no steps to address the Company's unsafe and illegal manufacture and sale of infant formula products in the U.S., proving fatal to some of the Company's most vulnerable customers.
- 327. The 2021 Proxy Statement harmed Abbott by interfering with the proper governance on its behalf that follows its stockholders' informed voting of directors. As a result of

the false or misleading statements in the 2021 Proxy Statement, Abbott shareholders voted to reelect the 2021 Proxy Defendants to the Board.

328. The 2021 Proxy Statement also urged stockholders to approve an advisory resolution regarding compensation paid to named executives. Notably, the 2021 Proxy Statement explained that certain annual executive compensation would not be paid unless the Company achieved a certain EPS. In support of the requested approval, the 2021 Proxy Statement represented:

During 2020, Abbott conducted its annual risk assessment of its compensation policies and practices for employees and executives. Abbott's risk assessment is reinforced by Abbott's adherence to a number of industry-leading best practices, including:

- Compensation Committee chaired by independent, non-employee director[;]
- Representation from the Audit Committee on the Compensation Committee[;]
- Review of executive compensation programs by the Compensation Committee's independent consultant[;]
- Robust review of compensation program elements and key performance drivers[;]
- Detailed measurement of short- and long-term compensation elements, and related performance metrics and requirements, to ensure balance[;]
- Review of Abbott's historical performance, peer performance and Board-approved strategic plan and related financial goals to determine appropriate incentive plan goals[; and]
- Incorporation of multiple program requirements that mitigate excessive risk-taking (e.g., recoupment policy, stock ownership and share retention guidelines, caps on incentive payouts).

Based on this assessment, Abbott determined its compensation and benefit programs appropriately align employees' compensation and performance without incentivizing risky behaviors. Any risk arising from its compensation policies and practices is not reasonably likely to have a material adverse effect on Abbott or its shareholders.

- 329. Contrary to those statements, Abbott's compensation system actually encouraged and rewarded extreme risk taking and widespread unsafe and illegal practices in its production and sale of the Company's infant formula products in the U.S. The Director Defendants knew or should have known that the Board and management had breached their fiduciary duties to the Company and exposed it to significant and material risks and liability through their conduct.
- 330. Under this false impression, numerous Abbott stockholders voted in support of compensation to Officer Defendants Allen (i.e., approximately \$8.5 million), Ford (i.e., approximately \$20.4 million), Funck (i.e., approximately \$9.8 million), Salvadori (i.e., approximately \$6 million) and White (i.e., approximately \$19.8 million), totaling over \$64.5 million in 2020, without the benefit of material information concerning the Individual Defendants' continued and ongoing failure to address the unsafe and illegal issues concerning the Company's production and sale of its infant formula products in the U.S., along with control and disclosure deficiencies, and their continued failure to reform the Company's compensation structures to ensure they do not promote this misconduct.
- 331. The 2021 Proxy Statement also contained a stockholder proposal to adopt a policy to require an independent Chairman. The Board recommended voting against this proposal for the following reasons:

As stated in Abbott's governance guidelines, "[t]he board of directors believes that it is important to retain the flexibility to allocate the responsibilities of the offices of chairman of the board and chief executive officer in any manner that it determines to be in the best interests of Abbott." The need for that flexibility has never been more apparent than this past year, when Abbott transitioned to a new CEO. The Board's current guidelines provided the Board with the flexibility necessary to adopt the leadership structure in the best interests of Abbott and its shareholders during this transition.

Indeed, every year, the Board reviews its leadership structure to ensure the appropriate level of oversight, independence, and responsibility. The Board continues to believe that flexibility coupled with a strong Lead Independent Director is best for Abbott and its shareholders. Abbott's Lead Independent Director is selected from among the ranks of independent directors. In that role, the Lead Independent Director consults directly with major shareholders on Abbott business. The Lead Independent Director oversees the Board evaluation process. The Lead Independent Director is empowered to call meetings of the independent directors, if necessary. And the Lead Independent Director can review and approve agenda items, the Board's schedule, and, where appropriate, information provided to other Board members.

Not only would the shareholder's proposal handcuff the Board when deciding on the best leadership structure for the Company, it misleadingly suggests there is a trend among S&P 500 companies to do so. The shareholder's proposal confuses the existence of a separate and independent board chair among S&P 500 companies with the adoption of a policy mandating, in all circumstances, the separation and independence of a company's board chair. A number of companies do have separate and independent board chairs, but the actual number of S&P 500 companies that have adopted an inflexible policy mandating the chair and CEO be separate, no matter the situation, is miniscule. The sort of rigidity this proposal calls for does not serve every company. It does not even serve most S&P 500 companies. And it does not serve Abbott's interests or its shareholders, as demonstrated with this recent leadership transition. (Emphasis added and footnote references omitted).

332. These statements conveyed that Abbott's corporate governance structure with "a strong Lead Independent Director is best for Abbott and its shareholders." In reality, Abbott's corporate governance structure allowed senior executives and the Board to sidestep responsibility and instead punish ground-level employees who reported safety violations, in order to continue perpetuating the Individual Defendants' concealment that Abbott was manufacturing and selling infant formula products in the U.S., which violated federal laws and the Company's corporate governance policies, creating unsafe and potentially fatal conditions for its infant consumers.

333. The 2021 Proxy Statement, which contained materially misleading statements and omitted material facts, thus deprived Abbott shareholders of adequate information to make a reasonably informed decision, causing the Company's shareholders to vote down the proposed policy to require an independent Chairman.

# B. The 2022 Proxy Defendants Caused Abbott to Issue the Materially False or Misleading 2022 Proxy Statement

- 334. On March 18, 2022, Director Defendants Alpern, Blount, Ford, Gonzalez, Kumbier, McDew, McKinstry, Novakovic, Osborn, Roman, Starks, Stratton, and Tilton (i.e., the "2022 Proxy Defendants") caused Abbott to file the 2022 Proxy Statement in connection with the 2022 annual shareholders meeting to be held on April 29, 2022. In the 2022 Proxy Statement, the 2022 Proxy Defendants solicited shareholders votes to, among other things, (i) re-elect themselves to the Board; (ii) approve executive compensation, and (iii) decide whether to adopt a policy requiring an independent Chair. With respect to each of these solicited votes, these Defendants issued materially false or misleading statements.
- 335. With respect to Board re-elections, the 2022 Proxy Statement represented in a section entitled, "CORPORATE GOVERNANCE":
  - "Abbott is committed to strong corporate governance that is aligned with shareholder interests. Our Board spends significant time with Abbott's senior management to understand the dynamics, issues, and opportunities for Abbott, and also regularly monitors leading practices in governance and adopts measures that it determines are in the best interest of Abbott and its shareholders."
- 336. The 2022 Proxy Statement represented that "All of Abbott's directors exhibit: Knowledge of corporate governance requirements and practices." The 2022 Proxy Statement further represented that: the "Board receives regular updates and has oversight over Abbott's environmental, social and governance practices."

- 337. The 2022 Proxy Statement specifically directed shareholders to Abbott's website for "additional information... regarding Abbott's business activities." Notably, on its website, Abbott posted a brochure entitled, "Our Global Policy on Marketing of Infant Formula," which is available on the "Policies" section of the Company's website, making the following representations:
  - "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;" and
  - "We maintain compliance with all laws, rules and regulations in every country in which we operate."
- Newsroom" on its website entitled, "The Abbott Quality Promise," in which the Company represented 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." As part of Abbott's Quality Promise, it represented that it had "Clean Facilities," and that "Our facilities are designed and maintained to the highest Good Manufacturing Practice standards, which are globally recognized. All employees follow strict hygiene measures, such as wearing specialized uniforms, facemasks and sanitized gloves." Abbott further represented that its Quality Promise also included "Quality Checks," and "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." Notably, in the "Policy section of Abbott's website in its "Other Disclosures" section, Abbott stated that the Company is "fully committed to delivering products with the highest

standards of quality, safety, and performance and also stating that "Our quality culture is embedded in everything that we do."

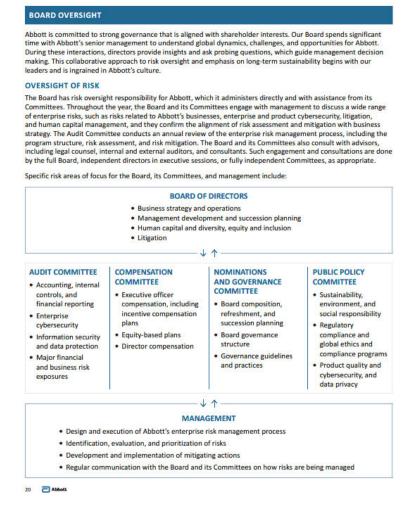
339. The 2022 Proxy Statement also represented in a Section entitled, "Nominations and Governance Committee" that:

The Nominations and Governance Committee assists the Board in fulfilling its oversight responsibility with respect to governance matters. Its primary responsibilities include:

- Assist the Board in identifying individuals qualified to become Board members, and recommend to the Board the nominees for election as directors at the next annual meeting of shareholders,
- Recommend to the Board the people to be elected as executive officers of Abbott,
- Develop and recommend to the Board the corporate governance guidelines applicable to Abbott, and
- Serve in an advisory capacity to the Board and the Chairman of the Board on matters of organization, management succession plans, major changes in the organizational structure of Abbott, and the conduct of Board activities.
- 340. The 2022 Proxy Statement made further specific representations about certain Director Defendants' expertise in corporate governance and risk management. For example, it highlighted Defendant Blount's corporate governance expertise, noting: "Having served as Dean of the J.L. Kellogg Graduate School of Management at Northwestern University and as the Vice Dean and Dean of the Undergraduate College of New York University's Leonard N. Stern School of Business, Ms. Blount provides Abbott's Board with expertise on business organization, governance and business management matters." Likewise, the 2022 Proxy Statement represented that Defendant Osborn "acquired broad experience in successfully overseeing complex global businesses operating in highly regulated industries, including oversight of financial, operational, and governance matters facing large public companies." The 2022 Proxy Statement also

represented that "[t]hrough his extensive leadership in the U.S. Air Force, General McDew contributes significant experience managing large, complex global operations, including strategic planning, security and risk management, cybersecurity, and supply chain and infrastructure management. Similarly, the 2022 Proxy Statement highlighted that "[t]hrough his executive leadership experience, Mr. Stratton contributes extensive business and management experience operating a global public company such as Abbott, including valuable insights on corporate strategy and risk management." The 2022 Proxy Statement also noted that Defendant Roman had "extensive experience leading a multinational public company with multiple businesses, contributing significant manufacturing, supply chain, technology, and finance experience, as well as valuable insights into corporate strategy and risk management."

341. With respect to the Board's role in risk oversight, the 2022 Proxy Statement represented:



342. Specifically, with respect to the Audit Committee's oversight responsibilities, the 2022 Proxy Statement represented:

The Audit Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to:...

- Legal and regulatory compliance relating to financial matters, including accounting, auditing, financial reporting, and securities law issues, and
- Enterprise risk management, including major financial and cybersecurity risk exposures.

In performing these functions, the Audit Committee meets regularly with the independent auditor, Abbott's management, and Abbott's internal auditors to review the adequacy, effectiveness and quality of Abbott's accounting and financial reporting principles, policies, procedures and controls, as well as Abbott's enterprise risk

management, including Abbott's risk assessment and risk management policies.

343. Specifically, with respect to the Public Policy Committee's oversight responsibilities, the 2022 Proxy Statement represented:

The Public Policy Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to:

- Certain areas of legal and regulatory compliance, including evaluating Abbott's compliance policies and practices and reviewing Abbott's compliance program,
- Governmental affairs and healthcare compliance issues that affect Abbott, and
- Abbott's public policy, including evaluating Abbott's social responsibility policies and practices and reviewing social, political, economic, and environmental trends and public policy issues that affect or could affect Abbott's business activities, performance, and public image.
- 344. The 2022 Proxy Statement also represented that:

The Executive Committee may exercise all the authority of the Board in the management of Abbott, except for matters expressly reserved by law for Board action

345. In connection with supporting the Board's continued rejection of requiring an independent Board Chair to improve Abbott's corporate governance, the 2022 Proxy Statement represented that "[t]he Board reviews its leadership structure on at least an annual basis. The Board has determined that this leadership structure ensures the appropriate level of oversight, independence and responsibility is applied to all Board decisions, including risk oversight, and is in the best interests of Abbott and its shareholders."

346. With respect to executive compensation, the 2022 Proxy Statement represented that:

Our leadership covenant includes commitments to multiple environmental, social and governance efforts. Examples include:

- A sustainable infrastructure to drive quality, environmental, health and safety performance
- Human capital management to ensure an inclusive culture and the fair and balanced treatment of our employees
- Quality products provided at competitive prices to patients and consumers at hospitals and retailers
- Abbott's Code of Conduct to ensure adequate internal controls for financial reporting and compliance with applicable laws and regulations.

Since this covenant is considered the minimum requirement of being an officer at Abbott, any officer that does not fulfill the covenant can receive a reduction of up to 100% of their annual incentive and/or long-term incentive awards.

- 347. The statements outlined above from the 2022 Proxy Statement convey to its stockholders that Abbott and its Board: (i) maintained sufficient compliance, risk controls, review, and reporting systems to identify and address misconduct; (ii) were unaware of existing material risks that could affect the Company; (iii) had policies to deter unnecessary or excessive risk taking, including compensation and ethics policies; and (iv) maintained risk management practices related to the production and sale of the Company's infant formula products in the U.S.
- 348. The 2022 Proxy Statement omitted any disclosures regarding: (i) Abbott's ineffective internal and disclosure controls; (ii) the existence of the 2019 Form 483, the 2021 Form 483, the 2022 Form 483, and related EIRs detailing violations of FDA regulations, including but not limited to how the FDA shut down the Sturgis plant from producing infant formula products and a massive related recall of such products, which caused Abbott significant harm; (iii)

operational and reporting failures that did not appropriately address Abbott's manufacture and sale of infant formula products in the U.S. in violation of federal laws and the Company's corporate governance policies; (iv) Abbott's retaliatory practices against its employees reporting safety and regulatory violations related to the Company's production and sale of infant formula products in the U.S.; and (v) the Board-approved compensation programs incentivized the concealment of the Company's unlawful and unethical manufacture and sale of infant formula products in the U.S. The 2022 Proxy Statement also failed to disclose that the Individual Defendants took no steps to address the Company's unsafe and illegal manufacture and sale of infant formula products in the U.S., proving fatal to some of the Company's most vulnerable customers.

- 349. The 2022 Proxy Statement harmed Abbott by interfering with the proper governance on its behalf that follows its stockholders' informed voting of directors. As a result of the false or misleading statements in the 2022 Proxy Statement, Abbott shareholders voted to reelect the 2022 Proxy Defendants to the Board.
- 350. The 2022 Proxy Statement also urged stockholders to approve an advisory resolution regarding compensation paid to named executives. Notably, the 2022 Proxy Statement explained that certain annual executive compensation would not be paid unless the Company achieved a certain EPS. In support of the requested approval, the 2022 Proxy Statement represented:

During 2021, Abbott conducted its annual risk assessment of its compensation policies and plan design practices for employees and executives. Abbott's risk assessment is reinforced by Abbott's adherence to a number of industry-leading best practices, including:

- Compensation Committee chaired by independent, non-employee director[;]
- Representation from the Audit Committee on the Compensation Committee[;]

- Review of executive compensation programs by the Compensation Committee's independent consultant[;]
- Robust review of compensation program elements and key performance drivers[;]
- Detailed measurement of short- and long-term compensation elements, and related performance metrics and requirements, to ensure balance[;]
- Review of Abbott's historical performance, peer performance and Board-approved strategic plan and related financial goals to determine appropriate incentive plan goals[; and]
- Incorporation of multiple program requirements that mitigate excessive risk-taking (e.g., recoupment policy, stock ownership and share retention guidelines, caps on incentive payouts).

Based on this assessment, Abbott determined its compensation and benefit programs appropriately align employees' compensation and performance without incentivizing risky behaviors. Abbott concluded that risks arising from compensation policies and practices are not reasonably likely to have a material adverse effect on Abbott or its shareholders.

- 351. Contrary to those statements compensation system actually encouraged and rewarded extreme risk taking and widespread unsafe and illegal practices in its production and sale of the Company's infant formula products in the U.S., which resulted in the shut-down of the Sturgis plant, along with a massive recall, causing significant harm to the Company in 2022. The Director Defendants knew or should have known that the Board and management had breached their fiduciary duties to the Company and exposed it to significant and material risks and liability through their conduct.
- 352. Under this false impression, numerous Abbott stockholders voted in support of compensation to Officer Defendants Allen (i.e., approximately \$6.8 million), Ford (i.e., approximately \$25 million), Funck (i.e., approximately \$9.5 million), Salvadori (i.e.,

approximately \$6.7 million), and White (i.e., approximately \$15.9 million) totaling over \$63.9 million, in 2021, without the benefit of material information concerning the Individual Defendants' continued and ongoing failure to address the unsafe and illegal issues concerning the Company's production and sale of its infant formula products in the U.S., along with control and disclosure deficiencies, and their continued failure to reform the Company's compensation structures to ensure they do not promote this misconduct.

353. The 2022 Proxy Statement also contained a stockholder proposal to adopt a policy to require an independent Chairman. The Board recommended voting against this proposal for the following reasons:

Abbott's Board believes that the Board is in the best position to determine its structure in light of circumstances at a given moment and mindful of its obligations to shareholders to effectively oversee the management of the company and maximize return to shareholders.

Abbott's Board consists of former and current leaders from business, medicine, academics, and public service who combined have decades of corporate board and other experience and are capable to oversee the management of the company. At present, the Board believes that the current structure is in the best interests of Abbott and its shareholders, as it provides cohesive leadership and direction for the Board and executive management, as well as clear accountability and unified leadership in the execution of strategic initiatives and business plans. Still, the leadership of the Chair is balanced by a fully independent board which is organized in a manner that has and will lead to effective oversight.

Abbott's current board structure and corporate governance practices provide strong independent oversight of a combined Chair and CEO.

As detailed in the 2022 Proxy Statement, apart from the Chair and CEO, Abbott's Board is composed entirely of independent directors who are elected by shareholders annually. These independent directors comprise the Board's principal committees – Audit, Compensation, Nominations and Governance, and Public Policy – and oversee key matters such as the integrity of Abbott's financial

statements, executive compensation, the nomination of directors, the selection of independent auditors, oversight of regulatory compliance, the evaluations of the Board and each of its members, including the Chair and CEO, and the evaluation of the CEO's performance objectives

 $[\ldots]$ 

The Board including the Lead Independent Director have repeatedly demonstrated independence from and oversight of management. In the last several years, the Board has strengthened its recoupment policy, increased targets for vesting of performance shares several times over the last several years, adopted a share-retention policy, and increased share-ownership guidelines for executives and directors. Unquestionably, Abbott's Board exercises independent oversight of the Chair and CEO and Abbott's management.

Abbott shareholders are best served by preserving the Board's flexibility to determine the appropriate leadership structure for the Company.

The Board regularly and carefully considers the merits of separating or combining the Chair and CEO positions, including whether an independent director should be chair. The Board believes that it is important to retain the flexibility to allocate the responsibilities of the offices of the Chair and CEO in the manner that it determines to be in the best interests of Abbott and its shareholders. Adopting a singular approach without the flexibility to adapt to company-specific circumstances would compromise the Board's ability to assess and implement the optimal oversight framework.

Historically, the current structure has greatly benefited Abbott and its shareholders. Under a combined CEO and Chair, Abbott was strategically reshaped into one of the world's leading health technology companies, with the creation of \$220 billion in shareholder value and a total return of 575%.1 Abbott's strong performance has resulted in total shareholder return (TSR) exceeding the peer median and major market indices on a one-, three-, and five-year basis.

The Board believes that it should be able to select the leadership the Company needs to fit the moment.

For these reasons, the Board of Directors recommends that Abbott's shareholders vote AGAINST this proposal. (Emphasis added, footnote references omitted, last emphasis in original).

- 354. These statements conveyed that Abbott's corporate governance structure with "Abbott's current board structure and corporate governance practices provide strong independent oversight of a combined Chair and CEO." In reality, Abbott's corporate governance structure allowed senior executives and the Board to sidestep responsibility and instead punish ground-level employees who reported safety violations, in order to continue perpetuating the Individual Defendants' concealment that Abbott was manufacturing and selling infant formula products in the U.S., which violated federal laws and the Company's corporate governance policies, creating unsafe and potentially fatal conditions for its infant consumers in the U.S.
- 355. The 2022 Proxy Statement, which contained materially misleading statements and omitted material facts, thus deprived Abbott shareholders of adequate information to make a reasonably informed decision, causing the Company's shareholders to vote down the proposed policy to require an independent Chairman.

# C. The 2023 Proxy Defendants Caused Abbott to Issue the Materially False or Misleading 2023 Proxy Statement

356. On March 17, 2023, Director Defendants Alpern, Babineaux-Fontenot, Blount, Ford, Gonzalez, Kumbier, McDew, McKinstry, Novakovic, Osborn, Roman, Starks, and Stratton (i.e., the "2023 Proxy Defendants") caused Abbott to file the 2023 Proxy Statement in connection with the 2023 annual shareholders meeting to be held on April 28, 2023. In the 2023 Proxy Statement, the 2023 Proxy Defendants solicited shareholders votes to, among other things, (i) reelect themselves to the Board; (ii) approve executive compensation, and (iii) decide whether to adopt a policy requiring an independent Chair. With respect to each of these solicited votes, these Defendants issued materially false or misleading statements.

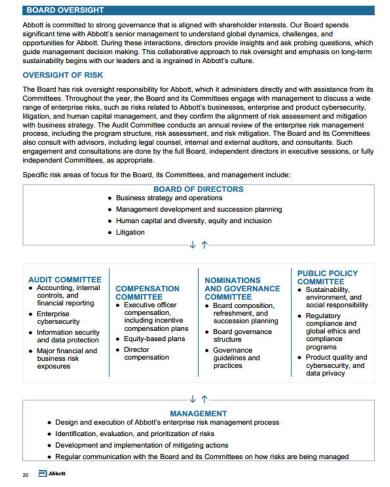
- 357. With respect to Board re-elections, the 2023 Proxy Statement represented in a section entitled, "CORPORATE GOVERNANCE":
  - "Abbott is committed to strong corporate governance that is aligned with shareholder interests. Our Board spends significant time with Abbott's senior management to understand the dynamics, issues, and opportunities for Abbott, and also regularly monitors leading practices in governance and adopts measures that it determines are in the best interest of Abbott and its shareholders."
- 358. The 2023 Proxy Statement represented that "All of Abbott's directors exhibit: Knowledge of corporate governance requirements and practices." The 2023 Proxy Statement further represented that: the "Board monitors management's strategy execution, receiving regular updates to confirm that activities align with such strategies and that progress is made toward strategic objectives. Most years, the Board also visits Abbott facilities and locations around the world to observe business dynamics and strategy execution by the businesses."
- 359. The 2023 Proxy Statement also represented in a Section entitled, "Nominations and Governance Committee" that:

The Nominations and Governance Committee assists the Board in fulfilling its oversight responsibility with respect to governance matters. Its primary responsibilities include:

- Assist the Board in identifying individuals qualified to become Board members, and recommend to the Board the nominees for election as directors at the next annual meeting of shareholders,
- Recommend to the Board the people to be elected as executive officers of Abbott,
- Develop and recommend to the Board the corporate governance guidelines applicable to Abbott, and
- Serve in an advisory capacity to the Board and the Chairman of the Board on matters of organization, management succession plans, major changes in the organizational structure of Abbott, and the conduct of Board activities.

360. The 2023 Proxy Statement made further specific representations about certain Director Defendants' expertise in corporate governance and risk management. For example, it highlighted Defendant Blount's corporate governance expertise: "Having served as Dean of the J.L. Kellogg Graduate School of Management at Northwestern University and as the Vice Dean and Dean of the Undergraduate College of New York University's Leonard N. Stern School of Business, Ms. Blount provides Abbott's Board with expertise on business organization, governance and business management matters." Likewise, the 2023 Proxy Statement represented that Defendant Osborn "acquired broad experience in successfully overseeing complex global businesses operating in highly regulated industries, including oversight of financial, operational, and governance matters facing large public companies." The 2023 Proxy Statement also represented that "[t]hrough his extensive leadership in the U.S. Air Force, General McDew contributes significant experience managing large, complex global operations, including strategic planning, security and risk management, cybersecurity, and supply chain and infrastructure management. Similarly, the 2023 Proxy Statement highlighted that "Through his executive leadership experience, Mr. Stratton contributes extensive business and management experience operating a global public company such as Abbott, including valuable insights on corporate strategy and risk management." The 2023 Proxy Statement also noted that Defendant Roman had "extensive experience leading a multinational public company with multiple businesses, contributing significant manufacturing, supply chain, technology, and finance experience, as well as valuable insights into corporate strategy and risk management."

361. With respect to the Board's role in risk oversight, the 2023 Proxy Statement represented:



362. Specifically, with respect to the Audit Committee's oversight responsibilities, the

#### 2023 Proxy Statement represented:

The Audit Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to: [...]

- Legal and regulatory compliance relating to financial matters, including accounting, auditing, financial reporting, and securities law issues, and
- Enterprise risk management, including major financial and cybersecurity risk exposures.

In performing these functions, the Audit Committee meets regularly with the independent auditor, Abbott's management, and Abbott's internal auditors to review the adequacy, effectiveness and quality of Abbott's accounting and financial reporting principles, policies, procedures and controls, as well as Abbott's enterprise risk

management, including Abbott's risk assessment and risk management policies.

363. Specifically, with respect to the Public Policy Committee's oversight responsibilities, the 2023 Proxy Statement represented:

The Public Policy Committee assists the Board of Directors in fulfilling its oversight responsibility with respect to:

- Certain areas of legal and regulatory compliance, including evaluating Abbott's compliance policies and practices and reviewing Abbott's compliance program,
- Governmental affairs and healthcare compliance issues that affect Abbott, and
- Abbott's public policy, including evaluating Abbott's social responsibility policies and practices and reviewing social, political, economic, and environmental trends and public policy issues that affect or could affect Abbott's business activities, performance, and public image.
- 364. The 2023 Proxy Statement also represented that:

The Executive Committee may exercise all the authority of the Board in the management of Abbott, except for matters expressly reserved by law for Board action

365. In connection with supporting the Board's continued rejection of requiring an independent Board Chair to improve Abbott's corporate governance, the 2023 Proxy Statement represented that "[t]he Board reviews its leadership structure at least annually basis and has determined that this structure is in the best interests of Abbott and its shareholders at this time. This structure balances strong, independent oversight with extensive business knowledge and experience." It further represented that: Defendant "Robert B. Ford currently serves as Chairman of the Board and CEO. *The Board has determined that this is in the best interests of Abbott and* 

its shareholders, as it provides cohesive leadership and direction for the Board and executive management, as well as clear accountability and unified leadership in the oversight and execution of strategic initiatives and business plans. (Emphasis added). Mr. Ford has extensive industry expertise and familiarity with Abbott's diverse, global businesses, such that his strategic and operational insights provide the Board with a comprehensive vision, from long-term strategic direction to day-to-day execution."

366. With respect to executive compensation, the 2023 Proxy Statement represented that:

During 2022, Abbott conducted its annual risk assessment of its compensation policies and plan design practices for employees and executives. Abbott's risk assessment is reinforced by Abbott's adherence to a number of industry-leading best practices, including:

- Compensation Committee chaired by independent, non-employee director[;]
- Representation from the Audit Committee on the Compensation Committee[;]
- Review of executive compensation programs by the Compensation Committee's independent consultant[;]
- Robust review of compensation program elements and key performance drivers[;]
- Detailed measurement of short- and long-term compensation elements, and related performance metrics and requirements, to ensure balance[;]
- Review of Abbott's historical performance, peer performance and Board-approved strategic plan and related financial goals to determine appropriate incentive plan goals[; and]
- Incorporation of multiple program requirements that mitigate excessive risk-taking (e.g., recoupment policy, stock ownership and share retention guidelines, caps on incentive payouts).

Based on this assessment, Abbott determined its compensation and benefit programs appropriately align employees' compensation and performance without incentivizing risky behaviors. Abbott concluded that risks arising from its compensation policies and practices are not reasonably likely to have a material adverse effect on Abbott or its shareholders.

- 367. The statements outlined above from the 2023 Proxy Statement convey to its stockholders that Abbott and its Board: (i) maintained sufficient compliance, risk controls, review, and reporting systems to identify and address misconduct; (ii) were unaware of existing material risks that could affect the Company; (iii) had policies to deter unnecessary or excessive risk taking, including compensation and ethics policies; and (iv) maintained risk management practices related to the production and sale of the Company's infant formula products in the U.S.
- 368. The 2023 Proxy Statement omitted any disclosures regarding: (i) Abbott's ineffective internal and disclosure controls; (ii) the existence of the 2019 Form 483, the 2021 Form 483, the 2022 Form 483, and related EIRs detailing violations of FDA regulations, resulting in the shut-down of the Sturgis plant for many months and a massive related recall of Abbott's infant formula products in the U.S., leading to a national baby food shortage in 2022; (iii) the 2022 DOJ Consent Decree, which was required to restart production of infant formula products at the Sturgis plant; (iv) operational and reporting failures that did not appropriately address Abbott's manufacture and sale of infant formula products in the U.S., in violation of federal laws and the Company's corporate governance policies; (v) Abbott's retaliatory practices against its employees reporting safety and regulatory violations related to the Company's production and sale of infant formula products in the U.S.; and (vi) the Board-approved compensation programs incentivized the concealment of the Company's unlawful and unethical manufacture and sale of infant formula products in the U.S. The 2023 Proxy Statement also failed to disclose that the Individual

Defendants took no steps to address the Company's unsafe and illegal manufacture and sale of infant formula products in the U.S., proving fatal to some of the Company's tiniest customers.

- 369. The 2023 Proxy Statement harmed Abbott by interfering with the proper governance on its behalf that follows its stockholders' informed voting of directors. As a result of the false or misleading statements in the 2023 Proxy Statement, Abbott shareholders voted to reelect the 2023 Proxy Defendants to the Board.
- 370. The 2023 Proxy Statement also urged stockholders to approve an advisory resolution regarding compensation paid to named executives. Notably, the 2023 Proxy Statement explained that certain annual executive compensation would not be paid unless the Company achieved a certain EPS. In support of the requested approval, the 2023 Proxy Statement represented:

During 2022, Abbott conducted its annual risk assessment of its compensation policies and plan design practices for employees and executives. Abbott's risk assessment is reinforced by Abbott's adherence to a number of industry-leading best practices, including:..

• Incorporation of multiple program requirements that mitigate excessive risk-taking (e.g., recoupment policy, stock ownership and share retention guidelines, caps on incentive payouts)

Based on this assessment, Abbott determined its compensation and benefit programs appropriately align employees' compensation and performance without incentivizing risky behaviors. Abbott concluded that risks arising from its compensation policies and practices are not reasonably likely to have a material adverse effect on Abbott or its shareholders.

371. Contrary to those statements Abbott's compensation system actually encouraged and rewarded extreme risk taking and widespread unsafe and illegal practices in its production and sale of the Company's infant formula products in the U.S., which resulted in the shut-down of the Sturgis plant, along with a massive recall, causing significant harm to the Company in 2022. The

Director Defendants knew or should have known that the Board and management had breached their fiduciary duties to the Company and exposed it to significant and material risks and liability through their conduct.

372. Under this false impression, numerous Abbott stockholders voted in support of compensation to Officer Defendants Allen (i.e., approximately \$7 million), Ford (i.e., approximately \$22.7 million), Funck (i.e., approximately \$9.1 million), and Salvadori (i.e., approximately \$7.1 million), totaling over \$45.9 million, in 2021, without the benefit of material information concerning the Individual Defendants' continued and ongoing failure to address the unsafe and illegal issues concerning the Company's production and sale of its infant formula products in the U.S., along with control and disclosure deficiencies, and their continued failure to reform the Company's compensation structures to ensure they do not promote this misconduct.

373. The 2023 Proxy Statement also contained a stockholder proposal to adopt a policy to require an independent Chairman. The Board recommended voting against this proposal for the following reasons:

# The Board of Directors recommends that you vote AGAINST the proposal.

Abbott's Board believes that the Board is in the best position to determine its structure in light of circumstances at a given moment and mindful of its obligations to ensure accountability and provide sufficient oversight of the management of the company while at the same time maximizing return to shareholders.

Abbott has a highly qualified board with broad experience, backgrounds and skills. The Board consists of former and current leaders from business, medicine, academics, and public service who combined have decades of corporate board and other experience and are capable to oversee the management of the company.

At present, the Board believes that the current structure is in the best interests of Abbott and its shareholders, as it provides cohesive leadership and direction for the Board and executive management, as well as clear accountability. The leadership of the Chair is balanced by a fully independent board which is organized in a manner that has and will continue to provide effective oversight.

Abbott's current board structure and corporate governance practices provide strong independent oversight of a combined Chair and CEO.

As detailed in the 2023 Proxy Statement, apart from the Chair and CEO, Abbott's Board is composed entirely of independent directors who are elected by shareholders annually. These independent directors comprise the Board's principal committees – Audit, Compensation, Nominations and Governance, and Public Policy – and oversee key matters such as the integrity of Abbott's financial statements, executive compensation, the nomination of directors, the selection of independent auditors, oversight of regulatory compliance, the evaluations of the Board and each of its members, including the Chair and CEO, and the evaluation of the CEO's performance objectives

[...]

The Board including the Lead Independent Director have repeatedly demonstrated independence from and oversight of management. In the last several years, the Board has strengthened its recoupment policy, increased targets for vesting of performance shares several times, adopted a share-retention policy, and increased share-ownership guidelines for executives and directors. Unquestionably, Abbott's Board exercises independent oversight of the Chair and CEO and Abbott's management.

Abbott shareholders are best served by preserving the Board's flexibility to determine the appropriate leadership structure for the Company.

The Board regularly and carefully considers the merits of separating or combining the Chair and CEO positions, including whether an independent director should be chair.

The Board believes that it should be able to select the leadership the Company needs to fit the moment.

For these reasons, the Board of Directors recommends that Abbott's shareholders vote AGAINST this proposal. (First and last emphasis in original, other emphasis added).

- 374. These statements conveyed that Abbott's corporate governance structure with "Abbott's current board structure and corporate governance practices provide strong independent oversight of a combined Chair and CEO[,]" and "[u]nquestionably, Abbott's Board exercises independent oversight of the Chair and CEO and Abbott's management." In reality, Abbott's corporate governance structure allowed senior executives and the Board to sidestep responsibility and instead punish ground-level employees who reported safety violations, in order to continue perpetuating the Individual Defendants' concealment that Abbott was manufacturing and selling infant formula products in the U.S., which violated federal laws and the Company's corporate governance policies, creating unsafe and potentially fatal conditions for its infant consumers.
- 375. The 2023 Proxy Statement, which contained materially misleading statements and omitted material facts, thus deprived Abbott shareholders of adequate information to make a reasonably informed decision, causing the Company's shareholders to vote down the proposed policy to require an independent Chairman.

## IX. ABBOTT HAS SUFFERED BILLIONS OF DOLLARS IN DAMAGES CAUSED BY THE INDIVIDUAL DEFENDANTS' LACK OF OVERSIGHT

- 376. The fallout from Abbott's infant formula recall and Sturgis plant shutdown has been dramatic, severe, and commercially destructive for Abbott. The Individual Defendants' oversight failures also caused a significant impact on sales of infant formula do to a now eroded consumer trust and confidence in the brands safety and efficacy.
- 377. For example, on October 19, 2022, Abbott reported its third-quarter 2022 results to investors. The results revealed a seismic and unprecedented decline in Nutrition sales due to the Sturgis plant and lack of consumer confidence. Specifically, Abbott reported a 39.1% decrease in total U.S. pediatric sales for 3Q22 on an organic basis (or a 24.8% decrease in total U.S. pediatric

sales for 3Q22 on a reported basis). The Company also reported a 10.3% 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% decline.

378. In addition, Abbott is currently expending an astronomical amount on litigation derived from defendant's lack of oversight pertaining to the Sturgis shutdown, along with other issues related to the failure to warn about the increased risk of preterm infants developing NEC from consuming its cow-milk based formulas. Abbott is not only currently engaged in various types of domestic litigation related to its infant formula in multiple jurisdictions, but in multiple countries as well as disclosed in Abbott's 2022 Form 10-K:

Abbott is a defendant in numerous lawsuits involving certain of its specialty infant formula products administered to preterm infants. The lawsuits allege that preterm infants developed necrotizing enterocolitis as a result of being administered a cow's milk-based preterm infant formula product, which resulted in personal injuries or death. As of January 31, 2023, there were 399 lawsuits pending in federal and state courts in which Abbott is a party. The plaintiffs seek various damages, including punitive damages. In April 2022, the U.S. Judicial Panel on Multidistrict Litigation ordered all federal court cases consolidated for pretrial purposes in the U.S. District Court for the Northern District of Illinois. In addition, in December 2021, a purported class of Canadian preterm infants filed suit in British Columbia and, in October 2022, a purported class of Israeli preterm infants filed suit in Tel Aviv, both of which make similar allegations as those made in the United States against Abbott. These plaintiffs seek various damages, including punitive damages. Many of the lawsuits name another infant formula manufacturer as a codefendant.

379. As a result of the Individual Defendants' knowing misconduct, Abbott engaged in an unlawful and deceptive scheme of violating food safety regulations. Billions of dollars of business have been lost as a result of an in-reality forced recall of infant formula, and continued fallout will occur as a result of massive civil litigation. Furthermore, Abbott faces potential criminal liability.

- 380. Further, as a direct and proximate result of the Individual Defendants' actions, Abbott has expended, and will continue to expend, significant sums of money defending suits and responding to government inquiries.
- 381. Finally, Abbott's business, goodwill, and reputation have been, and will continue to be, severely damaged by the Individual Defendants' decision to allow and/or failure to prevent the Company's systematic violation of food safety regulations that resulted in a shutdown of its major infant formula production facility.

#### X. DEMAND ON THE BOARD IS FUTILE

- 382. Plaintiffs Teamsters Local 710 Pension Fund and SEPTA have not made a pre-suit demand on the Board to assert the claims set forth herein against the Individual Defendants because such a demand would have been futile, and is thereby excused as a matter of law.
- 383. As of the filing of this suit, Abbott's Board consists of twelve directors: Director Defendants Ford, Alpern, Babineuax-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton, and non-defendant Michael O'Grady ("O'Grady"). There is no disinterested and independent majority of the Board (i.e., at least seven current directors) that could impartially consider a demand as to any of the claims alleged in the complaint.
- 384. Moreover, Defendant Ford is Abbott's Board Chair, President and Chief Executive Officer and previously served as Abbott's Chief Operating Officer and as Executive Vice President, Medical Devices. Ford is not considered independent under New York Stock Exchange listing standards. Ford faces personal liability for his breaches of fiduciary duties as both an officer and director. In addition, Ford faces personal liability in a securities class action, which involves some of the same subject matter as this lawsuit. Ford is, thus, interested and cannot impartially consider a demand.

#### A. Count I - Violation of Section 10(b) of the Exchange Act

- 385. Count I of the Complaint asserts claims against the Individual Defendants for violating Section 10(b) of the Exchange Act by disseminating or approving false and misleading statements about Abbott in connection with Abbott's repurchase of Abbott stock. Eleven of these defendants are current members of Abbott's Board.
- 386. Each of the currently serving Individual Defendants served on the Board when they issued, caused to be issued, and participated in the issuance of materially false and misleading statements to stockholders from 2019 through 2022 during their respective Board tenure. While Abbott's stock price was artificially inflated due to Individual Defendants' false and misleading statements, the Individual Defendants caused Abbott to repurchase millions of shares of its own common stock at prices that were artificially inflated due to the Individual Defendants' false or misleading statements and/or omissions. Accordingly, there is not a majority of the Board that can impartially consider a demand to pursue Count I against the Individual Defendants.

### B. Count II – Violation of Section 14(a) of the Exchange Act

- 387. Count II of the Complaint asserts claims against the 2021, 2022, and 2023 Proxy Defendants (defined above) for violating Section 14(a) of the Exchange Act by releasing the false and misleading 2021, 2022, and 2023 Proxy Statements, respectively, in order to solicit Abbott stockholders' votes to elect Abbott directors, approve compensation, and vote on other matters at the respective annual stockholder meetings. Eleven of the Proxy Defendants remain on Abbott's Board today.
- 388. Each of the currently serving Proxy Defendants served on the Board when they issued, caused to be issued, and participated in the issuance of materially false and misleading statements to stockholders which were contained in the 2021, 2022, and/or 2023 Proxy Statements. In seeking the stockholders' votes for Abbott's directors and compensation, among other issues, these Proxy Statements each falsely stated that Abbott: (i) maintained sufficient compliance, risk

controls, review, and reporting programs to identify and address misconduct; (ii) was unaware of existing material risks that could affect the Company; (iii) had policies to deter unnecessary or excessive risk-taking, including compensation and ethics policies, and (iv) maintained risk management practices related to its production and sale of the Company's infant formula products in the U.S. As such, the Proxy Defendants knew that they were violating Section 14(a) of the Exchange Act when they issued the 2021, 2022, and/or 2023 Proxy Statements.

- 389. Accordingly, there is not a majority of the Board that can impartially consider a demand to pursue Count II against the 2021, 2022, or 2023 Proxy Defendants. Specifically:
  - a. eight of the twelve current Board members (Defendants Alpern, Blount, Ford, Kumbier, McDew, McKinstry, Starks, and Stratton) served on the Board when Abbott filed the 2021 Proxy Statement and thus face a substantial likelihood of personal liability for violating Section 14(a) of the Exchange Act;
  - b. ten of the twelve current Board members (Defendants Alpern, Blount, Ford, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton) served on the Board when Abbott filed the 2022 Proxy Statement and thus face a substantial likelihood of personal liability for violating Section 14(a) of the Exchange Act; and c. eleven of the twelve current Board members (Defendants Alpern, Babineaux-Fontenot, Blount, Ford, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton) served on the Board when Abbott filed the 2023 Proxy

Statement and thus face a substantial likelihood of personal liability for violating Section 14(a) of the Exchange Act;

## C. Count III – Breach of Fiduciary Duty

- 390. Count III of the Complaint asserts claims against the Individual Defendants for breaching their fiduciary duties to Abbott and its stockholders by failing to oversee that the Company manufactured and sold its U.S. infant formulas in safe and ethical ways, which also complied with federal regulations.
- 391. Abbott's operative, restated articles of incorporation are attached to a Form 8-K filed with the SEC on April 26, 2021. Restated Article R-IV states that the "purpose or purposes for which the corporation is organized' include conducting "lawful business[.]"
- 392. There is no majority of the Board that could impartially consider a demand to bring a claim of breach of fiduciary duty because eleven of the twelve current directors face a substantial likelihood of liability for failing to monitor that the Company manufactured and sold its U.S. infant formulas in safe and ethical ways, which also complied with federal regulations. Because food safety is a central compliance concern of Abbott, and Abbott was found to have violated multiple federal securities laws related to noncompliance with food safety laws, these directors cannot be expected to impartially investigate and bring claims against themselves.
- 393. Specifically, Defendants Ford, Alpern, Babineuax-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton served during the period when Abbott violated the U.S.'s food safety regulations and otherwise had poor food sanitation at the Sturgis Plant. Despite this, Defendants Ford, Alpern, Babineuax-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton failed to implement a system of food safety oversight related to Abbott's manufacture and sales of its infant formula products in the U.S. at Abbott even though it is a central compliance concern. Moreover, even Defendants Ford, Alpern,

Babineuax-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton were notified of some food safety issues on an ad hoc basis, they did not investigate further or take steps to rectify the problems. These failures of oversight constitute breaches by Defendants Ford, Alpern, Babineuax-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton of their fiduciary duty of loyalty to Abbott. These directors face a substantial likelihood of liability for those breaches. Any investigation or suit brought against themselves, other directors, or Abbott officers would entail putting themselves at legal risk. Defendants Ford, Alpern, Babineaux-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton are thus unable to disinterestedly assess a demand to litigate against themselves, other directors or officers of the Company on this issue.

394. Defendants Ford, Alpern, Babineuax-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton also served during the period when Abbott has marketed cow-milk-based formula as safe, when Abbott knew that such formula presented an unacceptable risk to premature infants of developing NEC. As such, these directors have violated their fiduciary duties to the Company by allowing Abbott to violate Abbott's corporate governance policies by marketing and circulating a product in an unethical way, which has allegedly been fatal for hundreds, if not thousands of preterm infants. As such, Defendants Ford, Alpern, Babineuax-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton each face a substantial likelihood of liability. Therefore, they are unable to disinterestedly assess a demand to litigate against other directors or officers of the Company on this issue.

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399. Furthermore, Whistleblower #1's complaints that were filed in spring and fall of 2021, and were widely reported in 2022, are nowhere referenced in the Board materials produced as part of Abbott's Books and Records production. Thus, the key pieces of evidence that indicate falsification of records, widespread deception of regulators, and further evidence of how poor the sanitation is in the plant were not presented to the Board. This is further evidence of a lack of a monitoring and reporting system, where the Board is blind to even the facts that are widely reported in the media.

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401. Furthermore, in January 2023, Abbott announced that it received a civil investigative demand from the Federal Trade Commission ("FTC") for information in connection with the commission's investigation of companies that bid for infant-formula supply contracts for WIC programs. Prior to the announcement of the FTC's investigation, the FTC made public that it was exploring the bidding process for WIC contracts and if the companies involved in the processes had any impact on the total manufacturing capacity of infant formula and on competition overall.

doz. Defendants Babineaux-Fontenot, Gonzalez, Kumbier, McKinstry, and Stratton currently sit on Abbott's Audit Committee. As described above, the Audit Committee Defendants violated the Audit Committee charter and failed to fulfill their duties because while they designed an enterprise risk management system, they did nothing to ensure that the system was being followed. The Audit Committee Defendants also failed to discharge its duties to ensure accurate securities filings, because they failed to disclose the pervasive and longstanding food safety failures at the Sturgis plant, as well as failed to disclose how Abbott intentionally misled consumers into thinking that cow-milk-based formula was safe even when it knew that there was a high chance that premature infants would develop NEC from consuming that interview. As such, Audit Committee Defendants have violated their fiduciary duties to the Company, and each faces a substantial likelihood of liability. Therefore, they are unable to disinterestedly assess a demand to litigate against other directors or officers of the Company on this count.

403. Defendants Alpern, Babineaux-Fontenot, Blount, McDew, Roman, and Starks currently sit on Abbott's Public Policy Committee (the "PPC"). As described above, the PPC defendants violated the PPC charter and failed to fulfill their charge to oversee regulatory compliance. The PPC defendants did not have a system in place to ensure that food safety measures related to Abbott's manufacture and sale of infant formula products in the U.S. were being reported in a consistent manner. The PPC defendants also failed to conduct any independent investigation, despite their authority and duty to do so, after they were informed of the 2022 FDA inspection that resulted in baby formula recall and the DOJ lawsuit that resulted in required compliance measures to be implemented by Abbott. As such, PPC defendant directors have violated their fiduciary duties to the Company, and each faces a substantial likelihood of liability. Therefore, they are unable to

disinterestedly assess a demand to litigate against other directors or officers of the Company on this count.

404. Defendants Ford, McKinstry, Roman, Starks, and Stratton currently sit on the Executive Committee. The Executive Committee defendants violated their mandate and failed in their charge because they failed to implement an oversight system concerning food safety. As such, Executive Committee defendant directors have violated their fiduciary duties to the Company, and each faces a substantial likelihood of liability. Therefore, they are unable to disinterestedly assess a demand to litigate against other directors or officers of the Company on this count.

405. Defendants Kumbier, McKinstry, Roman, and Starks currently sit on Abbott's Compensation Committee. The Compensation Committee defendants violated the Compensation Committee charter and failed to fulfill their charge when they did not consider the Board and officers' lack of oversight into food safety issues related to the Company's production and sale of infant formula products in the U.S. As such, Compensation Committee defendants have violated their fiduciary duties to the Company, and each faces a substantial likelihood of liability. Therefore, they are unable to disinterestedly assess a demand to litigate against other directors or officers of the Company on this count.

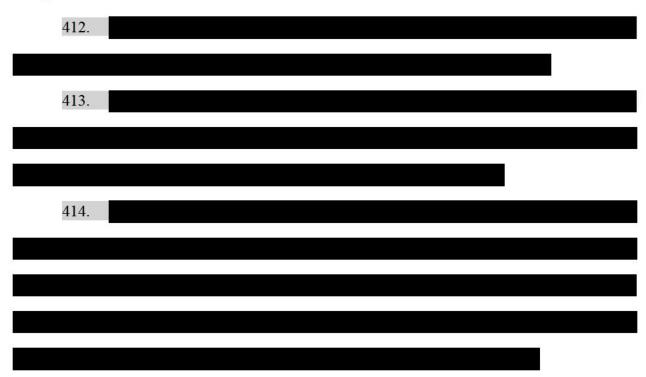
406. Defendants Alpern, Blount, Gonzalez, McDew, and Stratton currently sit on the Nominations and Governance Committee (the "NGC"). The Nominations and Governance Committee defendants violated the NGC charter and failed to fulfill their charge because they failed to conduct a meaningful evaluation of the directors and officers, because they ignored their lack of oversight into food safety issues. As such, NGC Committee defendants have violated their fiduciary duties to the Company, and each faces a substantial likelihood of liability. Therefore,

they are unable to disinterestedly assess a demand to litigate against other directors or officers of the Company on this count.

407. The safety of infant formula is a central compliance issue for the Company because, regardless of the absolute size of the business to Abbott's total revenues, it has an outsized reputational impact on the Company because of how frequently used and widely distributed Abbott's infant formula is. Furthermore, illness and death caused by food contamination led to acute negative publicity and regulatory actions, including, as happened here, the total shutdown of production at the Sturgis Plant. Finally, infant formula production and food safety are heavily regulated areas, again heightening the need to have robust compliance systems in place.

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411. This failure to implement Board-level monitoring of infant formula food safety is particularly egregious in the context of FDA inspection reports that showed serious problems with safety.



- 415. This complete lack of oversight by the Board is particularly egregious given that the Board had a committee that was specifically charged with "health compliance" oversight.
- 416. The Board has a duty to oversee the central compliance concerns of the Company.

  Beyond that general duty, the charter of the Board's Public Policy Committee specifically charges it with more specific oversight regarding regulatory and compliance matters.
- 417. The allegations in Count III overlap with and are substantially similar to the allegations against each current director defendant. For this reason, it would not be in the interest of the current director defendants to pursue a lawsuit alleging breaches of fiduciary duty against any other individual defendant arising from the same factual allegations.

### D. Count IV – Insider Trading

418. Count IV alleges breach of fiduciary duties related to insider trading claims against Defendants Allen, Calamari, Ford, Funck, Manning, McKinstry, Salvadori, and Starks, who knew about the material nonpublic information described in this Complaint regarding Abbott's business operations, and sold or otherwise disposed of Abbott's common stock on the basis of that information. For the same reasons that the current Director Defendants cannot impartially consider a demand to pursue Count III, neither can they consider a demand to pursue Count IV.

### E. Count V – corporate waste

Abbott's corporate assets by approving the stock repurchase program described above. Eleven Director Defendants remain on Abbott's Board today. For the same reasons that the current Director Defendants cannot impartially consider a demand to pursue Count I, neither can they consider a demand to pursue Count V.

### F. Count VI – contribution and indemnification

- 420. Count VI demands contribution and indemnification from Defendants Ford, Funck, Manning, and Calamari arising from liability to Abbott caused by their false and misleading statements to the public should Abbott be found liable for violating federal securities laws.
- 421. Defendant Ford faces a substantial likelihood of personal liability for contribution and indemnification and is thus unable to impartially consider a demand to pursue Count VI against himself or the other Defendants. Many of the factual allegations and legal arguments underlying Count VI also underlie other Counts of the complaint. Proving Count VI would require pursuing allegations that would tend to put the remaining directors at increased risk of personal liability on other counts. The remaining current Board defendants (Alpern, Babineaux-Fontenot, Blount,

Gonzalez, Kumbier, McDew, McKinstry, Roman, Stark, and Stratton) are thus incapable of impartially considering Count VI, and demand is thus excused.

## G. Count VII – unjust enrichment

- 422. Count VII demands disgorgement from Defendants Ford, Funck, Manning, and Calamari arising from liability to Abbott caused by them being unjustly enriched by compensation in light of their misconduct alleged in the Complaint.
- 423. Defendant Ford faces a substantial likelihood of personal liability for unjust enrichment and is thus unable to impartially consider a demand to pursue Count VII against himself or the other Defendants. Many of the factual allegations and legal arguments underlying Count VII also underlie other Counts of the complaint. Proving Count VII would require pursuing allegations that would tend to put the remaining directors at increased risk of personal liability on other counts. The remaining current Board defendants (Alpern, Babineaux-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Stark, and Stratton) are thus incapable of impartially considering Count VII, and demand is thus excused.

#### XI. CLAIMS FOR RELIEF

# A. COUNT I - Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Promulgated Thereunder (Against the Individual Defendants)

- 424. Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth in this paragraph.
- 425. From 2019 through 2022, in connection with Abbott's repurchases of Abbott shares, the Individual Defendants disseminated or caused to be issued false or misleading statements about Abbott, which are specified in Section VII, which they knew or recklessly disregarded were false or misleading and were intended to deceive, manipulate, or defraud. Those

false or misleading statements and the Individual Defendants' course of conduct were designed to artificially inflate the price of the Company's common stock.

- 426. At the same time that the price of the Company's common stock was inflated due to the false or misleading statements made by the Individual Defendants, they also caused Abbott to repurchase millions of shares of its own common stock at prices that were artificially inflated due to the Individual Defendants' false or misleading statements. Defendants engaged in a scheme to defraud Abbott by causing the Company to purchase at least \$6.5 billion in shares of Abbott stock at artificially inflated process.
- 427. The Individual Defendants violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts or omitted to state necessary facts in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit on Abbott in connection with the Company's purchase of Abbott stock during 2019 through 2022.
- 428. The Individual Defendants, individually and in concert, directly and indirectly, by the use of means or instrumentalities of interstate commerce or of the mails, engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon the Company; made various false or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; made the above statements intentionally or with a severely reckless disregard for the truth; and employed devices and artifices to defraud in connection with the purchase and sale of Abbott stock, which were intended to and did, (a) deceive Abbott about its manufacture and sale of its infant formula products in the U.S., the Company's internal controls

and compensation practices, and the Company's financial statements; (b) artificially inflate and maintain the market price of Abbott stock; and (c) cause Abbott to purchase the Company's stock at artificially inflated prices and suffer losses when the true facts became known. From 2019 through 2022, the Individual Defendants were in possession of material, adverse non-public information regarding Abbott's unsafe and illegal production and sale of infant formula products in the U.S.

- 429. The Individual Defendants were among the senior management and the directors of the Company, and were therefore directly responsible for, and are liable for, all materially false or misleading statements made during 2019 through 2022, as alleged above.
- 430. As described above, the Individual Defendants acted with scienter throughout 2019 through 2022, in that they acted either with intent to deceive, manipulate, or defraud, or with severe recklessness. The misstatements and omissions of material facts set forth in this Complaint were either known to the Individual Defendants or were so obvious that the Individual Defendants should have been aware of them. Throughout 2019 to 2022, the Individual Defendants also had a duty to disclose new information that came to their attention and rendered their prior statements to the market materially false or misleading.
- 431. The Individual Defendants' false or misleading statements and omissions were made in connection with the purchase or sale of the Company's stock, both by the Company itself and by the Insider Selling Defendants.
- 432. As a result of the Individual Defendants' misconduct, Abbott has and will suffer damages in that it paid artificially inflated prices for Abbott common stock purchased as part of the repurchase program and suffered losses when the previously undisclosed facts relating to the Company's unsafe and illegal manufacture and sale of infant formula products in the U.S. were

disclosed beginning on February 17, 2022, continuing through at least October 20, 2022. Indeed, the full extent of Abbott's wrongdoing has not been revealed, since Abbott continues to deny and downplay its unsafe and noncompliant conditions related to its production and sale of infant formula products in the U.S. Abbott would not have purchased these securities at the prices it paid, or at all, but for the artificial inflation in the Company's stock price caused by the Individual Defendants' false or misleading statements.

- 433. As a direct and proximate result of the Individual Defendants' wrongful conduct, the Company suffered damages in connection with its purchase of Abbott stock from 2019 through 2022. By reason of such conduct, the Individual Defendants are liable to the Company pursuant to Section 10(b) of the Exchange Act and SEC Rule 10b-5.
- 434. Teamsters Local 710 Pension Fund and SEPTA brought this claim within two years of their discovery of the facts constituting the violation and within five years of the violation.

## B. COUNT II - Violation of §14(a) of the Exchange Act Against All of the Director Defendants

- 435. Teamsters Local 710 Pension Fund and SEPTA incorporate by reference the allegations set forth above as if fully set forth herein.
- 436. SEC Rule 14a-9 (17 C.F.R. § 240.14a-9), promulgated under Section 14(a) of the Exchange Act provides:

No solicitation subject to this regulation shall be made by means of any proxy statement, form of proxy, notice of meeting or other communication, written or oral, containing any statement which, at the time and in the light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false and misleading or necessary to correct any statement in any earlier communication with respect to the solicitation of a proxy statement for the same meeting or subject matter which has become false or misleading.

17 C.F.R. §240.14a-9(a).

437. The Proxy Defendants issued, caused to be issued, and participated in the issuance of materially false and misleading written statements to stockholders that were contained in the 2021 Proxy Statement, the 2022 Proxy Statement, and the 2023 Proxy Statement. The 2021 Proxy Statement, the 2022 Proxy Statement, and the 2023 Proxy Statement contained proposals to Abbott's stockholders urging them to re-elect the members of the Board and approve executive compensation. The 2021 Proxy Statement, the 2022 Proxy Statement, and the 2023 Proxy Statement further urged Abbott's stockholders to vote against stockholder proposals for the Company to adopt a policy to require an independent Chairman. These Proxy Statements, however, misstated or failed to disclose: (i) Abbott's ineffective internal and disclosure controls; (ii) the existence of the 2019 Form 483, the 2021 Form 483, the 2022 Form 483, and related EIRs detailing violations of FDA regulations, resulting in the shut-down of the Sturgis plant for many months and a massive related recall of Abbott's infant formula products in the U.S., leading to a national baby food shortage in 2022; (iii) the 2022 DOJ Consent Decree, which was required to restart production of infant formula products at the Sturgis plant; (iv) operational and reporting failures that did not appropriately address Abbott's manufacture and sale of infant formula products in the U.S. in violation of federal laws and the Company's corporate governance policies; (v) Abbott's retaliatory practices against its employees reporting safety and regulatory violations related to the Company's production and sale of infant formula products in the U.S.; and (vi) the Board-approved compensation programs which incentivized Defendants to conceal the Company's unlawful and unethical manufacture and sale of infant formula products in the U.S.

438. By reasons of the conduct alleged in this Complaint, the Proxy Defendants violated Section 14(a) of the Exchange Act and SEC Rule 14a-9. As a direct and proximate result of the Proxy Defendants' wrongful conduct, Abbott misled or deceived its stockholders by making

misleading statements that were an essential link in stockholders heeding Abbott's recommendation to re-elect those directors, approve certain executive compensation, and vote against stockholder proposals to adopt a policy to require an independent Chairman.

- 439. The misleading information contained in the 2021 Proxy Statement, the 2022 Proxy Statement, and the 2023 Proxy Statement was material to Abbott's stockholders in determining whether or not to elect the Proxy Defendants, approve certain executive compensation, and vote against stockholder proposals to adopt a policy to require an independent Chairman. This information was also material to the integrity of the directors that were proposed for election to the Board. The proxy-solicitation process in connection with the Proxy Statements was an essential link in: (i) the re-election of nominees to the Board, (ii) the approval of executive compensation, and (iii) the decision not to require an independent Chairman.
- 440. Teamsters Local 710 Pension Fund and SEPTA, on behalf of Abbott, thereby seeks relief for damages inflicted on the Company based on the misleading 2021, 2022, and 2023 Proxy Statements in connection with the improper re-election of the members of the Board, approval of executive compensation, and vote against stockholder proposals for the Company to adopt a policy to require an independent Chairman.
- 441. This action was timely commenced within three years of the date of each Proxy Statement and within one year from the time Plaintiffs discovered or reasonably could have discovered the facts on which this claim is based.

#### C. COUNT III - Breach of Fiduciary Duty Against All Individual Defendants

- 442. Teamsters Local 710 Pension Fund and SEPTA incorporate by reference and reallege each and every allegation set forth above as if fully set forth herein.
- 443. At all times relevant hereto, each Individual Defendant was the agent of the Company, and was at all times acting within the course and scope of such agency.

- 444. The Individual Defendants each owe (and owed) Abbott and its shareholders fiduciary duties of loyalty, good faith, candor, trust and due care in managing the Company's affairs.
- 445. The Individual Defendants breached their fiduciary duties by failing to oversee whether Abbott complied with federal regulations while producing and selling the Company's infant formula products in the U.S.
- 446. The Individual Defendants also breached their fiduciary duties by allowing Abbott to falsely market cow-milk-based formula as safe, when knowing of the higher risks that such formula could cause NEC in pre-term infants.
- 447. The Individual Defendants also breached their fiduciary duties by disseminating false and misleading information concerning Abbott's business thereby misleading stockholders.
- 448. The Individual Defendants further breached their oversight duties, allowing Abbott to use predatory advertising tactics along with anti-competitive actions to secure a dominant position in the U.S. infant formula market.
- 449. As a direct and proximate result of the Individual Defendants' breaches of their fiduciary duties, Abbott has been damaged, not only monetarily, but also with regard to its corporate image and goodwill.
- 450. Teamsters Local 710 Pension Fund and SEPTA, on behalf of Abbott, have no adequate remedy at law.
  - D. COUNT IV (Breach of Fiduciary Duty for Insider Selling and Misappropriation of Confidential Information Against Defendants Allen, Calamari, Ford, Funck, Manning, McKinstry, Salvadori, and Starks)
- 451. Teamsters Local 710 Pension Fund and SEPTA incorporate by reference and reallege each and every allegation set forth above as if fully set forth herein.

- 452. As directors and officers of the Company, Allen, Calamari, Ford, Funck, Manning, McKinstry, Salvadori, and Starks owed and owe fiduciary duties to Abbott and its stockholders. By reason of these fiduciary relationships, those defendants specifically owed and owe Abbott the highest obligation of good faith, fair dealing, loyalty, and due care when taking any actions motivated by the Company's material nonpublic information.
- 453. At the time of the stock sales set forth above, Defendants Allen, Calamari, Ford, Funck, Manning, McKinstry, Salvadori, and Starks knew about the material nonpublic information described in this Complaint regarding Abbott's business operations and sold or otherwise disposed of Abbott's common stock on the basis of that information. Specifically, that material non-public information concerns the misconduct related to Abbott's manufacture and sale of infant formula products in the U.S. The information was a proprietary asset belonging to the Company, which Defendants Allen, Calamari, Ford, Funck, Manning, McKinstry, Salvadori, and Starks used improperly for their own benefit and the Company's benefit when they sold over \$147 million of Abbottt common stock.
- 454. Defendants Allen, Calamari, Ford, Funck, Manning, McKinstry, Salvadori, and Starks's sales of Abbott common stock while in possession and control of this material nonpublic information was a breach of their fiduciary duties of loyalty and good faith.
- 455. Because the use of the Company's proprietary information for their own gain and the Company's gain constitutes a breach of the fiduciary duties by Defendants Allen, Calamari, Ford, Funck, Manning, McKinstry, Salvadori, and Starks, the Company is entitled to damages.

### E. COUNT V - Corporate Waste Against the Director Defendants

456. Teamsters Local 710 Pension Fund and SEPTA incorporate by reference and reallege each and every allegation set forth above as if fully set forth herein.

- 457. The Director Defendants have a fiduciary duty to protect Abbott's assets from loss or waste.
- 458. By approving the stock repurchase program, the Director Defendants breached their fiduciary duty and have caused Abbott to waste its corporate assets on the repurchase of stock at artificially inflated prices.
- 459. As a result of the Director Defendants' corporate waste, the Company has suffered damages.

# F. COUNT VI - Contribution and Indemnification Against Defendants Ford, Funck, Manning, & Calamari

- 460. Teamsters Local 710 Pension Fund and SEPTA incorporate by reference and reallege each and every allegation set forth above as if fully set forth herein.
- 461. This claim is brought derivatively on behalf of the Company against Defendants Ford, Funck, Manning, and Calamari for contribution and indemnification.
- 462. Abbott was named as a defendant in a putative shareholder class action filed in this District on August 31, 2022, asserting claims under the federal securities laws for, *inter alia*, false and misleading statements related to Abbott's manufacture and sale of infant formula products in the U.S. and the Company's financial reporting. In the event the Company is found liable for violating federal securities laws, the Company's liability will arise, in whole or in part, from the intentional, knowing, or reckless acts or omissions of some or all of the Defendants as alleged herein. The Company is entitled to receive contribution from those Defendants in connection with the securities fraud class action against the Company currently pending in this district.

## G. COUNT VII - Unjust Enrichment Against Officer Defendants Allen, Battaglia, Calamari, Ford, Funck, Manning, Randall, Salvadori, and Young

463. Accordingly, Abbott is entitled to all appropriate contribution or indemnification for these Defendants.

- 464. Teamsters Local 710 Pension Fund and SEPTA incorporate by reference the allegations set forth above as though fully restated herein.
- 465. Defendants Allen, Battaglia, Calamari, Ford, Funck, Manning, Randall, Salvadori, and Young (collectively, the "Officer Defendants") were unjustly enriched at the expense of Abbott. Despite their misconduct, the Officer Defendants were rewarded with undeserved compensation to the detriment of Abbott. The Officer Defendants were awarded lavish compensation that did not account for their roles in fostering an environment that favored profit over safety, leading to the Company's violations of the FDA's regulations in its production and sale of infant formula products in the U.S., which allegedly caused the deaths of numerous infants, along with a national infant formula shortage when the Sturgis Plant was shut down for months by the U.S. to correct its severe regulatory violations. The Officer Defendants' breaches of fiduciary duties have exposed Abbott to numerous lawsuits, and unrelated damages of billions of dollars.
- 466. The award of this lavish and undeserved compensation was unjust under the circumstances.
- 467. The Officer Defendants should be ordered to disgorge all profits, benefits and other compensation received as a result of their wrongful conduct and breaches of fiduciary duty owed to Boeing.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Teamsters Local 710 Pension Fund and SEPTA demand judgment as follows:

A. Declaring that Plaintiffs Teamsters Local 710 Pension Fund and SEPTA may maintain this derivative action on behalf of Abbott and that Plaintiffs are proper and adequate representatives of the Company;

- B. Declaring that the Individual Defendants have breached their fiduciary duties of loyalty to Abbott;
- C. Determining and awarding to Abbott the damages sustained by it, as a result of the breaches of fiduciary duty and other claims set forth above from each of the Individual Defendants, jointly and severally;
- D. Awarding to Abbott restitution from the Individual Defendants and ordering disgorgement of all profits, benefits, and other compensation obtained by them. Including all profits, special benefits, and unjust enrichment they have obtained as a result of their unlawful conduct, payment of incentive compensation (whether in the form of cash bonuses, stock awards, or stock option grants), and common stock sale proceeds;
- E. Directing Abbott to take all necessary actions to reform and improve its corporate governance and internal procedures, to enable the Company to comply with the Company's existing governance obligations and all applicable laws, and to protect the Company and its stockholders from a recurrence of the damaging events described herein, including but not limited to the following specific relief:
- (i) Requiring the Company to maintain a reporting system to the Board of any food safety concerns;
- (ii) requiring the Company to implement additional audit, compliance, and internal control procedures;
- (iii) requiring independent approval of the terms and timing of insider stock selling and stock option grants rather than allowing insiders to perform trades with the mere approval of the Company's Senior Vice President and Chief Financial Officer or Vice President and Controller; and

- F. Awarding to Plaintiffs Teamsters Local 710 Pension Fund and SEPTA the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses;
- G. Awarding costs and disbursements of this action, including reasonable attorneys', accountants, and experts' fees;
  - H. Awarding pre- and post-judgment interest; and
  - I. Granting such other and further relief as the Court deems just and equitable.

#### JURY DEMAND

Plaintiffs Teamsters Local 710 Pension Fund and SEPTA demand a trial by jury.

Dated: June 27, 2023 Respectfully submitted,

/g/ Can	ffum	11	Johnson	
/s/ Geo	mev	IVI.	Jonnson	

/s/ Carol V. Gilden

Geoffrey M. Johnson SCOTT+SCOTT ATTORNEYS AT LAW LLP

12434 Cedar Road, Suite 12 Cleveland Heights, Ohio 44106

Tel: 216-229-6088

gjohnson@scott-scott.com

Carol V. Gilden

COHEN MILSTEIN SELLERS & TOLL, PLLC

190 South LaSalle Street, Suite 1705

Chicago, Illinois 60603

IL Bar: 6185530 Tel: 312-357-0370

cgilden@cohenmilstein.com

Jing-Li Yu

Tyler C. Yagman SCOTT+SCOTT

ATTORNEYS AT LAW LLP

The Helmsley Building 230 Park Avenue, 17th Floor

New York, NY 10169 Tel: 212-223-6444 iyu@scott-scott.com

tyagman@scott-scott.com

Joseph A. Pettigrew SCOTT+SCOTT

ATTORNEYS AT LAW LLP 600 W. Broadway, Suite 3300 **Richard Speirs** 

Amy Miller

COHEN MILSTEIN SELLERS & TOLL, PLLC

88 Pine Street, 14<sup>th</sup> Floor New York, NY 1005 Tel: 212 828-7791

rspeirs@cohenmilstein.com amiller@cohenmilstein.com

Steven J. Toll Will Wilder

COHEN MILSTEIN SELLERS & TOLL, PLLC

1100 New York Ave., NW

Fifth Floor

Washington, DC 20005

San Diego, CA 92101 Tel: 619-233-4565 jpettigrew@scott-scott.com

Counsel for Plaintiffs

Tel: 202-208-2600 stoll@cohenmilstein.com wwilder@cohenmilstein.com

Counsel for Plaintiffs

John A. Kehoe KEHOE LAW FIRM, P.C. 1500 JFK Boulevard, Suite 1020 Philadelphia, PA 19102 Tel: 215-792-6676 jkehoe@kehoelawfirm.com

Additional Counsel for Plaintiff Southeastern Pennsylvania Transportation Authority