**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF ILLINOIS**
**EASTERN DIVISION**

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| | ) | Civil Action No.: 22 CV 5513 |
| *In re Abbott Laboratories Infant Formula* | ) | |
| *Shareholder Derivative Litigation* | ) | Judge Manish S. Shah |
| | ) | |

**CONSOLIDATED AMENDED VERIFIED STOCKHOLDERS'**
**DERIVATIVE COMPLAINT**

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Plaintiffs International Brotherhood of Teamsters Local No. 710 Pension Fund ("Teamsters Pension Fund"), and Southeastern Pennsylvania Transportation Authority ("SEPTA," together with Teamsters Pension Fund, "Lead 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 certain Executive Officers (together the Board and Executive Officers are "Defendants"), seeking to remedy violations of the federal securities laws, breaches of fiduciary duties, and for insider trading, corporate waste, and unjust enrichment. Lead Plaintiffs 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 among other things, a review of: (a) internal books and records obtained pursuant to demands made under 805 Ill. Comp. Stat. §5/7.75 (2023) (the "Books and Record Demands" and "Books and Records");[1] (b) public filings by Abbott with the U.S. Securities and Exchange Commission ("SEC") including on Form 10-K and Schedule 14A; (c) press releases and other publications disseminated by the Company and certain non-parties; (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"), *United States v. Abbott Labs.* (W.D. Mich. 2022) (No. 1:22-cv-00441), which resulted in Abbott entering into a consent decree with the U.S. Food and Drug Administration ("FDA"), ECF no. 2-1, *Abbott Labs.* (No. 1:22-cv-00441) (the "Consent Decree"); (f) a whistleblower report submitted to regulators

[1] Lead Plaintiffs conducted books and records investigations under 805 Ill. Comp. Stat. Ann. §5/7.75. On October 11, 2022, the Teamsters Pension Fund made its demand for books and records. On December 14, 2022, SEPTA made its first demand for books and records, followed by a second demand on February 28, 2023. In response to Lead Plaintiffs' Books and Records Demands, the Company made multiple productions to the Teamsters Pension Fund and SEPTA.

that was released by a Congressional committee; (g) information obtained from an expert concerning federal food safety regulations; (h) information obtained from a Freedom of Information Act request; (i) proceedings in other lawsuits and government proceedings involving Abbott's manufacture and sale of infant formula; and (j) other publicly available information concerning Abbott and Defendants.

## I. NATURE OF THE ACTION

1. On February 15, 2022, Abbott closed its Sturgis, Michigan infant formula manufacturing facility (the "Sturgis Plant") due to the contamination and sale of tainted baby formula. Two day later, on February 17, 2022, Abbott announced a "voluntary" recall of contaminated infant formula products that were produced at the Sturgis Plant. The shutdown and the recall occurred as a result of FDA inspections that had found multiple regulatory violations, and the deaths of several infants who had consumed tainted baby formula produced at the Sturgis Plant. The shutdown of the Sturgis Plant and the related recall were the culmination of years of Abbott's directors' and senior officers' failures to oversee food safety systems and monitor for compliance with federal regulations designed to protect the most vulnerable population – infants.

2. The consequences were devastating. A nationwide shortage of baby formula ensued as the facility remained shut down for several months until June 4, 2022. Abbott's business suffered hundreds of millions in lost sales and profits and costs to remediate the facility and upgrade food safety compliance, risk management systems, and internal controls. The Company's business and reputation were badly tarnished as it came under regulatory, criminal, and Congressional scrutiny. The Company is now exposed to lawsuits from consumers, investors, whistleblowers, and infants harmed by the formula. Unfortunately, these catastrophic events could have been avoided had Defendants complied with their mandatory fiduciary duties and instituted an information reporting system designed to monitor the food safety and manufacturing processes

related to its U.S. infant formula business and had Defendants responded to red flags of non-compliance – something they failed to do for years.

3. Abbott's production and sale of infant formula products in the U.S. is highly regulated, and must comply with federal food safety laws, under the FDA's watch. Abbott's infant formula business line presents significant legal, safety, and reputational risks should compliance failures occur. Compliance is, therefore, a mission critical business risk, which Abbott's directors and officers owe fiduciary duties to the Company and its shareholders to oversee and manage.

4. Compliance failures were a well-known risk to Abbott's leadership due to past violations, which had led to significant fines along with reputational damage.

5. Despite these known risks, Abbotts' directors and officers failed to fulfill their oversight duties related to monitoring infant formula manufacturing and sale. First, they failed to make a good faith effort to implement an information reporting system to gather critical information, and second, they ignored red flags warning of unsanitary and unsafe conditions that violated federal food safety laws at the Sturgis Plant. As a result, Abbott repeatedly violated federal food safety laws in connection with the manufacture of infant formula at the Sturgis Plant, ultimately resulting in a shutdown and a massive recall, which caused a nationwide shortage of baby formula.

6. Abbott has a dominant role in the American infant formula market, producing 40% of all infant formula products consumed in the U.S. before the recall of infant formula products produced at the Sturgis Plant. Abbott's infant formula business line is at the locus of significant private and governmental scrutiny. For example, the Federal Trade Commission ("FTC") is currently investigating whether Abbott's dominance in the market resulted from anti-competitive conduct. Additionally, numerous lawsuits are pending concerning the risk of pre-term infants who

consume Abbott's cow-milk based infant formula products developing necrotizing enterocolitis ("NEC"), a potentially fatal gastrointestinal disease. The NEC lawsuits allege that Abbott's design of the products was defective, that the Company failed to warn of the risks, and that the Company was negligent.

7. Abbott's Sturgis Plant has also been the subject of scrutiny. The Sturgis Plant is particularly significant to the Company's infant formula business line in the U.S.; in early 2022, the Sturgis Plant produced between half and two-thirds of Abbott's supply of those products.

8. The Sturgis Plant, however, was a repeat violator of federal food safety regulations going back decades, resulting in the issuance of "Form 483s" by the FDA. A Form 483 is the FDA's vehicle to provide notice to a company of serious violations of federal food safety laws found during an inspection.

9. In September 2019, FDA inspectors found violations of federal food safety laws at the Sturgis Plant. Those violations were not fully corrected and other more serious violations were uncovered in September 2021. Certain of the Sturgis Plant's violations related to Cronobacter sakazakii ("Cronobacter"), a bacteria that can contaminate infant formula products and be potentially deadly. Accordingly, at the end of 2021, the FDA demanded that Abbott allow it to conduct a "for-cause" inspection at the Sturgis Plant.

10. By February 2022, according to the FDA's Form 483s and its findings during its for-cause inspection in early 2022, conditions at the Sturgis Plant were "unsanitary." The deaths of several infants were purportedly linked to the Sturgis Plant, as the infants had consumed Abbott's infant formula products that were produced there and allegedly contaminated with Cronobacter. As a result of these reports, a related whistleblower's complaint filed in 2021 with the FDA detailing dangerous conditions at the Sturgis Plant, and the FDA's for-cause inspection

that revealed additional violations of federal food safety laws, the FDA urged Abbott to conduct a "voluntary" recall of certain infant formula products manufactured at the Sturgis Plant.

11. [redacted] Such information would have put any director acting in good faith on notice to take a deep dive into the Company's compliance, or lack thereof, with respect to its manufacture and sale of infant formula in the U.S. at the Sturgis Plant. [redacted]

12. [redacted]

13. [redacted]

[redacted]

14. [redacted]

15. Abbott's directors' and officers' dereliction of their oversight duties has caused significant harm to the Company, including a 31.75% decline in net earnings as reflected in Abbott's third quarter 2022 financial results disclosed in the Form 8-K filed by Abbott on October 19, 2022, attributed in part to to the Sturgis Plant shutdown; entry into a DOJ Consent Decree requiring significant remediation efforts; and numerous lawsuits, including personal injury lawsuits *In re Recalled Abbott Infant Formula Prods. Liability Litig.*, No. 22-cv-02148, MDL No. 3037, related to the wrongful deaths and related damages allegedly caused by Abbott's contaminated infant formula products produced at the Sturgis Plant.

16. Abbott has also suffered significant reputational harm, with its regulators publicly criticizing the Company. In his prepared testimony, FDA Commissioner Robert Califf testified at a Congressional hearing about the "egregiously unsanitary" conditions at the Sturgis Plant, that Abbott's "inspection results were shocking," and that the FDA had "lost confidence that Abbott

Nutrition had the appropriate safety and quality culture and commitment to fix these problems quickly." And as the DOJ later stated, "[the] [o]ngoing inadequacies in manufacturing conditions and practices at Defendants' [Abbott's] 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."** (Emphasis added.)

17. In addition to their oversight failures, certain directors also caused Abbott to file false and misleading proxy statements with the SEC from 2021 through 2023, failing to disclose that, among other things: (1) the Company manufactured and sold its infant formula products in the U.S. in violation of federal health and safety laws and regulations; and (2) the seriously deficient internal risk management controls that allowed those unsafe and illegal conditions to proliferate at Abbott, exposing Abbott to significant regulatory, reputational, and legal risks. These misrepresentations caused the Director Defendants to be re-elected, executive compensation to be approved on an advisory basis, and shareholder proposals concerning the requirement of an independent Board chair to be voted on (Defendant Ford was acting as both the Chair and Chief Executive Officer of the Company) and rejected. Those false and misleading proxies caused significant harm to Abbott, and therefore, those claims are properly brought as derivative claims.

18. In addition, the Board violated Section 10(b) of the Securities and Exchange Act of 1934 ("Exchange Act"), by authorizing the Company to engage in billions of dollars in stock repurchases while Abbott's stock was artificially inflated due to false and misleading statements regarding Abbott's production and manufacture of infant formula products in the US. Certain insiders benefited from the artificially inflated stock prices to their own personal benefit, selling over $117 million worth of Abbott common stock before the truth started to leak out.

19. Accordingly, Lead Plaintiffs Teamsters Pension Fund and SEPTA bring this derivative action on Abbott's behalf to hold its former and current directors and officers liable for: (1) violations of Section 14(a) and Section 10(b) of the Exchange Act, and the rules promulgated thereunder; (2) breaches of fiduciary duties, including but not limited to oversight, good faith, and loyalty; (3) insider trading; (4) corporate waste; and (5) unjust enrichment.

## II. JURISDICTION AND VENUE

20. This shareholder derivative action is brought pursuant to Fed. R. Civ. P. 23.1. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1331, as well as Section 27 of the Exchange Act, 15 U.S.C. § 78aa, over the claims asserted herein for, *inter alia*, violations of Sections 14(a) and 10(b) of the Exchange Act, 15 U.S.C.§§ 78(n)(a), 78(j), and the rules promulgated thereunder. This Court has supplemental jurisdiction over the state law claims asserted herein under 28 U.S.C.§ 1367.

21. 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.

22. This Court has personal jurisdiction over each of the defendants named herein because Nominal Defendant Abbott is incorporated in Illinois and maintains and operates its principal executive offices in this District, and 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.

23. 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. Lead Plaintiffs

24. Lead Plaintiff Teamsters Pension Fund is a pension fund located in Mokena, Illinois. Teamsters Pension Fund is a Taft-Hartley defined pension fund with approximately 21,000 active participants and over $3.5 billion in plan assets. Teamsters 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.

25. Lead 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

26. 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. In 2022, the Company reported $43.7 billion in revenue.

### C. Director Defendants

27. 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 also has served on the Abbott Board since 2019. He chairs the Executive Committee and has served as the executive Chair of the Board since 2021. From 2020 when Ford

became CEO through 2022, Ford received a total compensation package worth more than $67 million from Abbott.

28. Defendant Robert J. Alpern ("Alpern") has served on the Abbott Board since 2008. He serves on the Nominations and Governance and Public Policy Committees. Alpern is the Ensign Professor of Medicine and Physiology and Professor of Internal Medicine and Cellular and Molecular Physiology at Yale School of Medicine. He also serves on the boards of AbbVie Inc. ("AbbVie"), which was spun off from Abbott in 2012, and Tricida, Inc., both pharmaceutical companies. From 2019 through 2022, Alpern received a total compensation package worth more than $1.5 million from Abbott.

29. 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 Audit Committee, Executive Committee and the Nominations and Governance Committee. She is the President and CEO of Austin Investment Advisors, a private investment and consulting firm. Like Alpern, she also serves on AbbVie's board. From 2019 through 2022, Austin received a total compensation package worth more than $1.1 million from Abbott.

30. Defendant Claire Babineaux-Fontenot ("Babineaux-Fontenot") has served on the Abbott Board since September 2022, and earned over $31,000 in compensation for her limited service in 2022. She serves on the Public Policy Committee. She is also the CEO of Feeding America, an anti-hunger charity.

31. Defendant Sally E. Blount ("Blount") has served on the Abbott Board since 2011. She serves on the Nominations and Governance and Public Policy Committees. She is the President and CEO of Catholic Charities of the Archdiocese of Chicago. From 2019 to 2022, Blount received a total compensation package worth more than $1.3 million from Abbott.

32. Defendant Paola Gonzalez ("Gonzalez") has served on the Abbott Board since April 2021. She serves on the Audit and Public Policy Committees. She is the Vice President and Treasurer of The Clorox Company. In 2021 and 2022, Gonzalez received a total compensation package worth more than $360,000 from Abbott.

33. Defendant Michelle A. Kumbier ("Kumbier") has served on the Abbott Board since 2018. She serves on the Audit and Compensation Committees. Kumbier is the President of Turf & Consumer Products at engine manufacturer Brigg & Strattons. From 2019 through 2022, Kumbier received a total compensation package worth more than $1.2 million from Abbott.

34. 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. Liddy was most recently a partner at Clayton, Dubilier & Rice, LLC, a private equity firm. He also previously served on the board of Abbvie, 3M Company, and the Boeing Company (and was a defendant in a derivative action against Boeing, a 2020 lawsuit alleging Boeing's officers and directors failed to monitor for aircraft safety that resulted in a historic settlement). In 2019 through 2020, Liddy received a total compensation package worth more than $700,000 from Abbott.

35. Defendant Darren W. McDew ("McDew") has served on the Abbott Board since 2019. He serves on the Nominations and Governance and Public Policy Committees. McDew is a retired United States Air Force general; he is also on the boards of General Electric and Parsons Corporation. From 2019 through 2022, McDew received a total compensation package worth more than $960,000 from Abbott.

36. 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. McKinstry is the CEO and Chairman of the Executive Board of Wolters Kluwer N.V., an information, software, and service provider; she also is on the board of Accenture PLC and the Board of Overseers of Columbia Business School. From 2019 through 2022, McKinstry received a total compensation package worth more than $1.3 million from Abbott.

37. Defendant Phebe N. Novakovic ("Novakovic") was an Abbott director from 2010 to April 2021. Novakovic served as the Chair of the Public Policy Committee in 2019 and 2020, and also served as a member of the Compensation and Executive Committees. She is the Chair and CEO of General Dynamics, a defense contractor, and also serve on the board of JP Morgan Chase. From 2019 through 2021, Novakovic received a total compensation package worth over $680,000 from Abbott.

38. 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. Osborn was the Company's Lead Independent Director. He was the Chairman and CEO of Northern Trust Corporation and served on the boards of the Tribune Company, Caterpillar Inc., and General Dynamics Corporation. From 2019 through 2022, Osborn received a total compensation package worth more than $1.3 million from Abbott.

39. Defendant Michael F. Roman ("Roman") has served on the Abbott Board since April 2021. He serves on the Audit and Compensation Committees. Roman is the Chairman of the Board, President, and CEO of the 3M Company. From April 2021 through 2022 alone, Roman received a total compensation package worth more than $580,000 from Abbott.

40. 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. Starks was the Chairman, President, and CEO of St. Jude Medical, Inc. from 2016 to January 2017

when Abbott acquired the company. From 2019 through 2022, Starks received a total compensation package worth more than $1.2 million from Abbott.

41. Defendant John G. Stratton ("Stratton") has served on the Abbott Board since 2017. He serves on the Audit and Public Policy Committees. Stratton is the Executive Chairman of Frontier Communications Parent, Inc., a telecoms company. From 2019 through 2022, Stratton received a total compensation package worth more than $1.2 million from Abbott.

42. 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. Tilton was the Chairman and CEO of United Air Lines. Like many of his co-directors, he serves on the AbbVie board and the board of Phillips 66, a petroleum company. From 2019 through 2022, Tilton received a total compensation package worth more than $1.3 million from Abbott.

43. 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. White serves on the board of McDonalds Corporation and previously served on the board of Caterpillar, Inc. He was a chairman of the Federal Reserve Bank of Chicago and the Pharmaceutical Research and Manufacturers of America. From 2019 through 2021, White received a total compensation package worth more than $63.5 million from Abbott.

44. Defendants Ford, Alpern, Austin, Babineaux-Fontenot, Blount, Gonzalez, Kumbier, Liddy, McDew, McKinstry, Novakovic, Osborn, Roman, Starks, Stratton, Tilton, and White are current or former members of the Abbott Board and are collectively referred to herein as the "Director Defendants."

45. Defendants Austin, Gonzalez, Kumbier, McKinstry, Roman, Starks, Stratton, and Tilton also are collectively referred to herein as the "Audit Committee Defendants."

46. Defendants Alpern, Babineaux-Fontenot, Blount, McDew, Novakovic, and Stratton are also collectively referred to herein as the "Public Policy Committee Defendants."

47. Defendants Ford, Austin, McKinstry, Novakovic, Roman, Starks, and Stratton are also collectively referred to as the "Executive Committee Defendants."

48. Defendants Alpern, Blount, Gonzalez, McDew, and Stratton are also collectively referred to as the "Nominations and Governance Committee Defendants."

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

**D. Officer and Executive Defendants**

50. Defendant Hubert Allen ("Allen") has served as Abbott's Executive Vice President, General Counsel and Secretary since 2013. From 2019 through 2022, Allen received a total compensation package worth more than $29.8 million from Abbott.

51. Defendant Erica Battaglia ("Battaglia") has served as Abbott's Chief Ethics and Compliance Officer since June 2021.

52. Defendant Christopher J. Calamari ("Calamari") has served as the Senior Vice President of U.S. Nutrition which includes Abbott's portfolio of infant formula products, since 2021, and from 2017 to 2021 was Vice President of Pediatric Nutrition.

53. 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. From 2019 through 2022, Funck received a total compensation package worth more than $28.4 million from Abbott.

54. Defendant J. Scott House ("House") has served as Abbott's Senior Vice President of Quality Assurance, Regulatory and Engineering Services since March 2020. House joined Abbott in 1990. According to House's biography on Abbott's website, House and his team are responsible for "ensuring that Abbott's quality, regulatory and engineering values are consistently applied across the corporation, helping ensure the highest quality products for our customers, strict compliance with global regulatory requirements, and a safe environment…."

55. Defendant Joseph Manning ("Manning) has served as the Executive Vice President of Nutritional Products since 2021. Manning joined Abbott in 1995 and has held various positions within Abbott's Pharmaceutical and Nutrition organizations worldwide.

56. Defendant Lori J. Randall ("Randall") is the Division Vice President of Nutrition Quality Assurance. Randall joined Abbott in 1993. Randall has overall responsibility for quality operations for global Abbott Nutrition which includes, but is not limited to, oversight of manufacturing locations and food safety, product quality, supplier quality, compliance, complaint management, and corrective and preventive actions. *See* Complaint at ¶ 7, *United States v. Abbott Labs.*, No. 22-cv-00441 (W.D. Mich. May 16, 2022), ECF No. 1.

57. 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 that role he was "responsible for defining the strategic vision for both of these businesses and leading efforts to conduct innovative research and science-based products and medicines for people of all ages." From 2019 through 2022, Salvadori received a total compensation worth more than $26.6 million from Abbott.

58. Defendant James E. Young ("Young") has served as Abbott's Chief Ethics and Compliance Officer ("CECO") from July 2015 to May 2021.

59. Defendants Allen, Battaglia, Calamari, Ford, Funck, House, Manning, Randall, Salvadori, and Young are collectively referred to herein as the "Officer Defendants."

60. The Director and Officer Defendants are collectively referred to herein as the "Defendants."

61. As further described in Section VII, Defendants had fiduciary duties under Illinois law, along with obligations under the Company's governing documents, requiring them to oversee the Company's compliance with all regulations, along with its risk exposure and internal controls. Defendants' "oversight" duties (i.e., "*Caremark*" duties) required the directors and/or officers to make a good faith effort 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 way. Defendants' oversight duties also required them to take action when presented with "red flags" of illegal conduct. Here, Defendants utterly failed to fulfill their oversight duties under *Caremark's* Information Reporting System and Red Flags System theories as detailed below, causing significant harm to Abbott.

## IV. HISTORY OF QUESTIONABLE PRACTICES IN CONNECTION WITH ABBOTT'S SALE OF INFANT FORMULA

62. Abbott's leadership has enabled a culture to flourish that allows risky behavior in pursuit of sales of infant formula products in the U.S., at the cost of complying with laws and regulations, leading to myriad lawsuits alleging, among other things: (1) Abbott's use of anti-competitive conduct to secure contracts with and customers in the lucrative Women, Infant, and

Children ("WIC") program, and (2) Abbott's failure to warn about the risk of preterm infants developing NEC from consuming Abbott's cow-milk based formula.

**A. Abbott's Allegedly Anti-Competitive Conduct to Secure WIC Contracts**

63. Approximately 98% of formula consumed in the U.S. is also manufactured domestically because regulatory requirements make it difficult for foreign manufacturers to enter the U.S. market.

64. The WIC program, established in the U.S. in the 1970s, supplies infant formula to low-income families. WIC feeds about half of the nation's infants and is the largest buyer of infant formula in the U.S., making up more than half of annual formula sales, according to the United States Department of Agriculture ("USDA"). In 2022 alone, the USDA spent roughly $1.5 billion on infant formula.

65. 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 in its state. Importantly, if the state-contracted provider's brand is sold out, WIC recipients are not able to switch to a different brand.

66. WIC guidelines require stores to stock certain amounts of the winning "brand," which increases brand visibility on store shelves. Many stores, especially smaller ones with limited shelf space, *exclusively* stock the WIC-approved brand. As a result, non-WIC customers only have access to the formula sold by that state's WIC contract holder. WIC contracts therefore dramatically boost sales for the company that wins the contract, from both WIC and non-WIC consumers in that state.

67. Abbott has repeatedly secured a position as one of the biggest suppliers to the government-run WIC program.

68. Of the three infant formula producers who have bid on WIC formula contracts since 1996, Abbott has the largest share of WIC contracts, with contracts in 49 states, territories, or tribes. As a result, in 2022, 47% of the 1.2 million infants who receive formula through WIC can obtain only Abbott formula through that program.[2]

69. As noted in a *Wall Street Journal* article, "Baby Formula Makers Face FTC Investigation for Collusion," the FDA and academics have voiced concern 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.

70. In early 2022, the FTC initiated an investigation "into whether any participant in infant formula markets has engaged in collusion or coordination with any other market participant regarding the bidding for WIC contracts."[3] The FTC noted a "2015 USDA study examining WIC bidding between 2003 and 2013 [that] identified patterns potentially indicative of non-competitive bidding for WIC formula contracts."[4] That investigation is ongoing.

### B. Abbott Fails to Warn 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

71. Abbott has engaged in other deceptive and aggressive marketing tactics that have deceived consumers regarding the safety, efficacy, and equivalency of cow milk-based formula compared to breast milk, notwithstanding that these tactics may have violated potentially numerous truth in advertising, unfair trade practices, and consumer fraud laws, including Section

[2] Meredith Lee and Helena Bottemiller Evich, How the baby formula shortage links back to a federal nutrition program, Politico, https://www.politico.com/news/2022/05/19/baby-formula-shortage-federal-contracts-00033581 (last visited on October 15, 2023).

[3] https://www.ftc.gov/legal-library/browse/cases-proceedings/petitions-quash/infant-formula

[4] *Id.*

5 of the Federal Trade Commission ("FTC") Act, which provides that "unfair or deceptive acts or practices in or affecting commerce . . . are . . . declared unlawful." 15 U.S.C. § 45 (2006).

72. Specifically, for decades, Abbott has advertised its cow-milk-based infant formulas as "safe" for pre-term infants to consume.

73. Abbott's representations could not be farther from the truth. An abundance of two decades worth of well-designed clinical studies and medical literature showed that cow-milk-based formulas were unsafe and unreasonably dangerous for feeding premature infants and left babies susceptible to a dangerously high risk of developing NEC, which is potentially fatal. Abbott, however, has withheld this information from the public on its infant formula products' labels.

74. NEC is a fatal gastrointestinal disease in premature infants. NEC occurs when tissue in the large intestine, also known as the colon, becomes inflamed. This inflammation damages and kills tissue in the infant's colon leading to bacterial invasion causing cellular damage, cellular death, and necrosis of the colon and intestine. Unfortunately, even if an infant survives NEC, they are left with a lifetime of debilitating health problems that can severely restrict their long-term quality of life before they even speak their first words. NEC is among the top killers of preterm infants in hospital neonatal intensive care units. The mortality rate for NEC patients is astounding, ranging from 10% to 50%. In fact, NEC is almost 100% fatal for patients with the most severe form of the disease.

75. 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 based formulas and/or fortifiers lead to a significantly higher occurrence of NEC in preterm infants than human milk does. Moreover, studies have also shown that an

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

76. For example, over thirty years ago in 1990, a landmark study, the "Cole Study," was published linking cow-milk based formula to NEC. Then, nearly a decade later, in 1999, the "Schanler Study" found that there was a lower incidence of NEC and late onset of sepsis in infants fed fortified human milk as compared to those fed preterm formula, concluding that the unique properties of human milk promote an improved host defense and gastrointestinal function compared with the feeding of formula. About another ten years later, in 2012, the "Sullivan Study" found that extremely premature infants receiving an exclusively human milk diet had significantly lower rates of NEC and NEC requiring surgical intervention. In addition, a Cochrane Library meta-analysis Study, last updated in 2018, showed a higher risk of NEC in the formula-fed group when compared to the human milk-fed group.

77. Despite the plethora of scientific studies confirming for decades that cow-milk based products are unsuitable for premature infants due to increasing their risk for developing NEC, Abbott continues 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.

78. Abbott's failure to warn about the potential for premature infants to contract NEC on its cow-milk based infant formulas has led to a massive number of lawsuits against Abbott by the parents of deceased or disabled infants, who developed NEC after they ingested Abbott's formulas. In February 2023, in its annual report filed as Form 10-K to the SEC, Abbott disclosed that 399 of those lawsuits were pending in federal and state court, and Abbott also faced international lawsuits. Since then, the number of NEC-related lawsuits have only grown. Many of

those federal actions are now proceeding as a multi-district litigation ("MDL") in this Court with Chief Judge Pallmeyer presiding over the MDL.

79. Among other claims, these lawsuits allege that Abbott faces: strict liability for manufacturing and marketing a product that was defective in design (because cow's milk is inherently dangerous to premature infants due to the NEC risk); negligently marketing these products to infants' parents despite the well-known risks based on decades of research; and failing to warn parents of the dangers to their premature infants from ingesting these products. The complaint's allegations go far beyond negligence; rather, they allege that Abbott knowingly sought to "hook" parents onto their products, played on their feelings of guilt by implying that a diet without Abbott's formulas would be **unhealthy** for infants, including premature infants, and disregarded contrary research. Abbott's knowing disregard of the risks exposes the Company to even greater liability.

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

81. Notably, since Abbott has pursued a multitude of potentially deceptive marketing tactics for decades, they are now ingrained as part of the Company's culture, which has continued to flourish with Defendants at Abbott's helm today.

## V. ABBOTT HAS VIOLATED NUMEROUS FEDERAL FOOD SAFETY REGULATIONS IN ITS MANUFACTURING AND PRODUCTION OF INFANT FORMULA AT THE STURGIS PLANT

### A. Infant Formula Manufacturing is Highly Regulated

82. Abbott must comply with federal food safety regulations, among other laws, when manufacturing and selling its infant formula products in the U.S. Indeed, compliance with these 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. Non-compliance presents a significant legal, safety, and reputational risk for the Company.

83. Specifically, the Food, Drug, and Cosmetic Act of 1938 ("FDCA") provides the 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 has been prepared, packed, or held under insanitary conditions. . . whereby it may have been rendered injurious[.]" 21 U.S.C. §342(a)(3)-(4) (2005).

84. With respect to infant formula, 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 [i.e., "cGMP"] for infant formula" 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." ECF no. 1, *United States v. Abbott Labs.* (No. 1:22-cv-00441). Furthermore, the FDCA prohibits adulterated items from being "held for sale." 21 U.S.C. §331(k).

85. Federal regulations govern infant formula manufacturing, and any formula that does not comply with cGMPs for infant formula under the FDCA and its implementing regulations

is considered "adulterated." 21 U.S.C. § 350a; 21 C.F.R. § 106. The FDCA prohibits the introduction into interstate commerce of adulterated food and violations are punishable by fines or imprisonment. 21 U.S.C. §§ 331, 333. Under the FDCA's implementing regulations, infant formula manufacturers are required to comply with quality control procedures (21 C.F.R. § 106), recordkeeping and reporting requirements (21 C.F.R. § 106.100), labeling requirements (21 C.F.R. §§ 107.3-107.30), nutrient requirements (21 C.F.R. § 107.100), and recall requirements (21 C.F.R. §§ 107.200-107.280).

86. The cGMPs require an infant formula manufacturer, like Abbott, to implement a system of production and in-process controls that covers "all stages of processing, from the receipt and acceptance of the raw materials, ingredients, and components through the storage and distribution of the finished product[,]" and "is designed to ensure that an infant formula is manufactured in a manner that will prevent adulteration of the infant formula." 21 C.F.R. § 106.6(a), (b).

87. The cGMPs require process controls. An individual "qualified by education, training, or experience shall conduct a documented review" of any specifications the manufacturer fails to meet and decide whether to "reject the affected article, to reprocess or otherwise recondition the affected article, or to approve and release the article for use or distribution[.]" 21 C.F.R. § 106.6(c)(4). The manufacturer shall establish recordkeeping procedures. 21 C.F.R. § 106.6(c)(5).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 manufacturing. 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).

88. 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. §350a(b)(4); 21 C.F.R. §106.100(k) (2015).

89. General food safety regulations also apply to Abbott's production of infant formula products, including those related to "Processes and controls" (i.e., 21 C.F.R. § 117.80a (2105)) and "Manufacturing" operations (i.e., 21 C.F.R. §117.80c(2015)).

90. Record and reporting requirements for infant formula require specifically that, "[e]very manufacturer of infant formula shall maintain the records specified in this regulation in order to permit the FDA 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©.

91. 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) (2023).

(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 … [m]ay be …" "adulterated or misbranded." 21 C.F.R. §106.150(a) (2023).

92. The FDA monitors a company's compliance with the FDCA, by, in part, conducting periodic—usually annual—inspections of infant formula manufacturing plants. If the FDA inspectors "observe any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act [of 1938] and related Acts," such as failures to adhere to the cGMPs, the FDA issues the facility a Form 483 Letter directed to the site's senior management.

93. At the conclusion of each FDA inspection, the FDA investigators hold a "close-out meeting" with the company's management and share their observations. Again, if the FDA investigators observe significant deviations from the FDCA, they are recorded in a "Form 483," which 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 that "[a] copy [of the Form 483] should be sent to the top management of the firm." FDA Investigations Operations Manual, Ch. 5, § 5.2.3.6.

94. When a Form 483 is issued, it is accompanied by an Establishment Inspection Report ("EIR"). The EIR contains more detail than the Form 483 and may contain additional objectionable conditions in the manufacturing facility. The company has an obligation to respond to the FDA's observations within fifteen business days with a root cause analysis, impact assessment, and a set of corrective and preventative actions.

95. If a company's response is inadequate, the FDA may issue a warning letter to encourage voluntary compliance 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 that

may require extensive remedial action, even being forced to cease operations and implement costly and time-consuming corrective measures.

96. Accordingly, the failure to adhere to the FDCA and its regulations can have a tremendously negative effect on a company's ability to market and sell its products.

97. Abbott has a history of FDCA violations.

98. In 1999, after six years of compliance deficiencies despite repeated FDA warnings in Form 483s, Abbott agreed to a consent decree requiring it to pay a $100 million civil fine to the FDA, withdraw 125 types of medical diagnostic test kits from the market, destroy inventory, and cease manufacturing almost 300 medical testing devices until the Company brought facilities into compliance with federal regulations.

99. In 2004, Abbott's directors, including Defendant White, settled a related derivative litigation for $27 million to fund unspecified "regulatory/compliance activities" and adopt a new version of the Public Policy Committee's charter.

100. In 2010, the FDA found a flour beetle infestation at the Sturgis Plant that dated back to 2007. As a result, Abbott recalled 5 million containers of Similac, ceased production, and cleaned the plant. The recall cost Abbott $100 million. Abbott also replaced a Sturgis Plant manager, but instead of firing him, Abbott moved him to another position in the Company. Nine of the Director Defendants (Alpern, Austin, Blount, Liddy, McKinstry, Osborn, Tilton, Osborn, and White) served on the Board, and two Officer Defendants (Calamari and Randall) were Abbott officers when these FDCA violations occurred. [redacted]

Defendants Alpern, Blount, McKinstry, Calamari and Randall continued to serve as Abbott fiduciaries when violations of federal food safety laws occurred again at the Sturgis Plant from 2019 through 2022.

101. Then in 2012, Abbott pled guilty to a criminal misdemeanor violation of the FDCA related to its pharmaceutical division misbranding the drug 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. The settlement also required Abbott to enter into a Corporate Integrity Agreement with the Office of Inspector General of the Department of Health and Human Services ("OIG") to self-report any violations of the FDCA to the FDA and the OIG, required the CEO to certify compliance with this reporting requirement, and required the Board to report annually to the OIG on the effectiveness of the Company's compliance program, among other things. [redacted] When Abbott again violated the FDCA at the Sturgis Plant from 2019 through 2022, the same nine Director Defendants (Alpern, Austin, Blount, Liddy, McKinstry, Osborn, Tilton, and White) were serving on the Board at this time; further, three of those individuals, Alpern, Blount, and McKinstry, are still serving as Abbott directors.

### B. Two Whistleblowers Confirmed that For Years, Abbott's Production and Sale of Infant Formula Products at the Sturgis Plant Violated Federal Food Safety Regulations

102. According to whistleblower reports, for years, conditions at the Sturgis Plant violated the FDCA and created fertile grounds for bacterial contamination. Whistleblower #1 was

a former Quality Assurance Specialist at the Sturgis Plant from 2015 to August 2020. Whistleblower #2 was a former Sturgis Plant supervisor.

103. Whistleblower #1 described Sturgis' workplace culture as focusing on speed and meeting metrics at the expense of safety. He explained that "[m]eeting metrics frequently took precedence 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 known as 'quality assessment.'" Furthermore, Whistleblower #1 alleged that "[i]ncreasingly over the last 12 months of [his] time at Abbott, management directed him and others to misuse the SQE [Standard Quality Evaluation] procedure in order to meet metrics for the Sturgis site."

104. 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."

105. Whistleblower #1 further explained that the Sturgis Plant regularly engaged in spot cleaning, rather than cleaning the entire area, even when Abbott's policy would require the entire area to be cleaned, because "meeting metrics took precedence."

106. 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 certain metrics in terms of production."

107. 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.

108. Consistent with the Company's culture that encouraged potentially anticompetitive actions to obtain WIC contracts to maximize profits, Whistleblower #2 emphasized, "[m]anagement purposefully took the largest market share they could in a plant that they knew had issues, that they weren't funding properly – and then when they finally dropped the ball, they left these families that are on fixed incomes with babies completely out to dry[.]" Furthermore, Whistleblower #2 recounted how he "kept hearing over and over and over again, 'yeah, you've got to be careful if you start bringing stuff up. You can just disappear around here.'"

109. Whistleblower #2 further described plant management's obsession 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.'"

110. Both Whistleblowers #1 and 2 observed FDCA violations and other unsafe conditions at the Sturgis Plant.

111. For example, Whistleblower #1 observed "first-hand" many food safety violations and unsafe conditions, 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; understating or inaccurately describing events so as to limit or avoid oversight; issuing certifications of projection pages bereft of pertinent data; shipping packages with fill weights lower than represented on the labels; failing to maintain accurate maintenance records; and prematurely removing holds in the absence of all requisite approvals."
- "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')."

112. 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, 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.

113. In addition, the Sturgis Plant had other leaks from its 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 leak out and present another contamination risk.

114. 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 a replacement EleCare line had a defective can seamer, which seals formula cans.

115. 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 were already shipped out on the market rather than issue a recall. This tactic 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.

116. 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 was 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.

117. 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 where food safety is paramount."

118. For example, Whistleblower #1 identified 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 there being multiple episodes where management has consciously misled division officials as to [records] or the seriousness of a situation."

119. Furthermore, Whistleblower #1 also complained about the inability to report concerns confidentially. 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 a "protected activity" and "disclosures . . . will be treated as confidential." Nevertheless, "his identity was disclosed to others at that Sturgis site and retaliation soon followed."

120. 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."

121. Whistleblower #1 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 led 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."

122. 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, 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."

123. Whistleblower #1 also alleged "that members of management who are intimately involved with circumventing what exist [sic] 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."

124. Whistleblower #1 also noted that Sturgis personnel were filing false certifications of compliance with food safety regulations to secure rebates under the WIC program, which as discussed in Section IV, is a huge part of Abbott's infant formula business. Whistleblower #1 believed that the fact that Abbott falsely certified compliance also resulted in making false statements in its securities filings—filing for which Abbott's Board and senior management were responsible.

125. 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 Plant's 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, an "inspection" consisted largely of reviewing the plant's own records.

126. Finally, Whistleblower #1 described his belief, "This failure [to implement and actively enforce adequate controls] 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."

## VI. DEFENDANTS FAILED TO IMPLEMENT AN INFORMATION REPORTING SYSTEM TO MONITOR COMPLIANCE WITH FOOD SAFETY LAWS WHEN PRODUCING AND SELLING ITS U.S. INFANT FORMULA PRODUCTS, AND FAILED TO RESPOND TO RED FLAGS OF VIOLATION OF SUCH LAWS

127. The safety of its infant formula products is a central compliance issue for the Company. Its production and sale must comply with federal regulations. Abbott's infant formula production has an outsized reputational impact on the Company because of how frequently used and widely distributed Abbott's infant formula is in this nation and because a contaminated or unsafe product can cause catastrophic harm or death to babies.

128. The risks of food safety non-compliance are well known. In recent years multiple food companies have faced significant fines, litigation, and even criminal charges due to food contamination and attendant cover-ups. For example, in 2015, the former top executive of Peanut Corp. of America was sentenced to 28 years in prison after its peanut processing plant was found to be the source of a deadly salmonella outbreak.[5] A deadly listeria outbreak tied to Blue Bell Creameries LP's ice cream resulted in the company pleading guilty in 2020 to federal charges for distributing contaminated food, as well as $19 million in criminal fees and forfeiture, in addition to related civil litigation.[6]

129. Despite these business-specific and industry-wide risks, [redacted]

130. [redacted]

[5] https://www.foodsafetynews.com/2023/07/stewart-parnell-takes-habeas-corpus-petition-to-11th-circuit-court-in-atlanta/#:~:text=After%20jury%20conviction%2C%20Parnell%20was,6%2C%202019.

[6] https://www.houstonchronicle.com/business/article/fraud-charges-former-blue-bell-ceo-dismissed-17827684.php#:~:text=Brenham%2Dbased%20ice%20cream%20maker,Food%2C%20Drug%20and%20Cosmetic%20Act.

[redacted]

131. [redacted]

132. [redacted]

[redacted]

133. [redacted]

[redacted]

134. [redacted]

[redacted]

135. 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. Approximately 20% of all infant formula made domestically was manufactured at the Sturgis Plant. But from at least 2005 to the present, Abbott has faced multiple civil suits alleging that Cronobacter contamination at Sturgis had caused infant injury or death. 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 leaves 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, while surviving in a finished can for up to a year. 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.

136. Abbott's response to these lawsuits was not to clean up the Sturgis Plant (or any other plant), or to implement an information reporting system 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 has drawn judicial reprimands. For example, as described in a September 8, 2022 article a judge presiding over such a case 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."[7] He commented, for example, on how he was "shocked by what he read" in depositions, highlighting the "astounding" number of objections Abbott's counsel would lodge. The judge further stated that if he had presided over a "bench trial, [he] would have ruled for the plaintiffs in all likelihood[.]" Another judge criticized Abbott's counsel for making "nonsensical" claims that were "a waste of judicial resources."

137. Moreover, when Abbott settled certain cases related to Cronobacter associated with its infant formula product, it required non-disclosure agreements in the settlement terms, thus ensuring that the victims and their families remained silent. This practice drew the attention of Senator Elizabeth Warren who on October 12, 2022, sent Defendant Ford a letter challenging Abbott's litigation tactics and requesting that Abbott specifically provide:

[7] 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.

> [A] list of settlements Abbott Nutrition has entered into regarding alleged *Cronobacter* infections from powdered infant formula since 2003.
>
> i. For each settlement, please provide the following information:
>
> ii. 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.

138. Senator Warren 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."

139. It is currently unknown publicly whether Abbott complied with Senator Warren's requests.

### A. 2019: The FDA Issues a Form 483 for Violations of Federal Food Safety Laws at the Sturgis Plant

140. [redacted] Because the Board did not have a system to obtain timely and accurate information about infant formula safety and regulatory compliance, Abbott's Board could not mitigate or respond to risks that arose. As a result of Defendants' sustained failure to oversee whether Abbott manufactured and sold its U.S. infant formula products in compliance with FDCA regulations, Abbott repeatedly violated those regulations in 2019.

141. 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."

142. 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, Whistleblower #1 explained that 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.

143. According to the FDA's EIR for 2019, that year, Abbott received a complaint from a "Pediatric Nurse Practitioner. . . stat[ing] that there were 5 babies . . . that consumed Similac Sensitive Infant Formula," and that "all babies were projectile vomiting[]"for reasons that were not clear. In another complaint, a baby with confirmed Cronobacter was having seizures after consuming three types of Similac". In both cases, upon review of the complaint, Abbott did not find other medical complaints about the particular batches of formula at issue and closed the investigations.

144. [redacted]

145. [redacted]

[redacted]

146. [redacted]

147. [redacted]

148. [redacted]

[redacted]

149. Three months later, 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 reflective of 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, Whistleblower #1 stated, "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."

150. [redacted]

151. Between September 16-24, 2019, the FDA inspected the Sturgis Plant. That inspection resulted in the issuance of a Form 483 (the "2019 Form 483"). [redacted]

[redacted]

152. 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."

153. 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 Cronobacter, and was hospitalized for twenty-two days.

154. 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. The FDA found that Abbott only tested half 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."

155. Despite the fact that Form 483s from the FDA related to Abbott's production of its infant formula products in the U.S. and constituted critical information concerning how the Company was violating federal food safety laws, [redacted]

156. [redacted]

157. [redacted]

[redacted]

158. A[redacted]

[redacted]

159. [redacted]

[redacted]

160. On November 12, 2019, Defendant Ford replaced Defendant White, who had served as Abbott's CEO and Chair of the Board for over two decades, as the Company's CEO and was appointed to the Board, while Defendant White remained as the "Executive Chairman" of the Board, (and continued to reap millions of dollars in compensation on an annual basis).

161. [redacted]

[redacted]

162. [redacted]

**B. 2020: Violations of Federal Food Safety Laws at the Sturgis Plant Continue**

163. [redacted]

164. [redacted]

165. By March 2020, COVID-19 had overtaken the U.S., which caused the FDA to forgo its annual in-person inspection of Abbott's infant manufacturing plants. This made even more critical than ever that Abbott's directors and officers oversaw and ensured that Abbott safely manufactured and sold its infant formulas in compliance with federal food safety laws. [redacted]

[redacted]

166. [redacted]

167. [redacted]

168. [redacted]

- [redacted]

[redacted]

169. [redacted]

170. [redacted]

[redacted]

171. [redacted]

172. [redacted]

[8] 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.

[redacted]

173. Whistleblower #1 further alleged, "[i]t 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 yet continued certifying missing test results "multiple times." Whistleblower #1 further emphasized, "[d]espite 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."

174. 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."

175. [redacted]

[redacted]

176. [redacted]

177. [redacted]

[redacted]

### C. 2021: Whistleblower Complaint Is Filed About Sturgis Plant and The FDA Finds More Violations

178. [redacted] By this time, however, the Sturgis Plant's longstanding problems caught up with it, and its management could no longer hide them from regulators.

179. On February 16, 2021, Whistleblower #1 filed a complaint with the Occupational Safety and Health Administration of the Department of Labor ("OSHA"), detailing serious illegal activities at the Sturgis Plant (the "OSHA Complaint"). 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.

180. [redacted]

181. [redacted]

[redacted]

182. In April 2021, Abbott responded to Whistleblower #1's OSHA Complaint; by virtue of their roles, Officer Defendants Randall and Calamari, who both have direct oversight over the Sturgis Plant, and Defendant Allen would have been involved in such response. As a result, by no later than April 2021, Abbott's senior management, including the Company's most senior level legal officer who directly reported to Defendant Ford, Abbott's CEO and Chairman, should have been 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. [redacted] Indeed, Abbott's management had a fiduciary obligation to bring Whistleblower #1's OSHA Complaint to the Board's attention, yet Defendants Allen, Randall, and Calamari failed to do so.

183. [redacted]

[redacted]

184. [redacted]

[redacted]

185. [redacted]

[redacted]

[redacted]

186. [redacted]

187. 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. [redacted]

188. On September 24, 2021, the FDA issued another Form 483 to Abbott (the "2021 Form 483") and related EIR after its September 2021 inspection. The 2021 Form 483 stated, among other things, that Abbott "did not maintain a building used in the manufacture, processing, packing or holding of infant formula in a clean and sanitary condition[,]" and that "[a]n instrument [Abbott] used to measure, regulate, or control a processing parameter was not properly maintained." The 2021 Form 483 further – shockingly – stated: "**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). Clearly, the Sturgis Plant was not complying with the most basic precautions even though it had a history of microbial contamination.

189. [redacted]

[redacted]

190. A[redacted]

191. At this time, Abbott was engaged in another employment litigation case with Whistleblower #1. 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 Plant. [redacted]

192. On December 1, 2021, the FDA received a second complaint of a Cronobacter infection in an infant given Abbott formula; the infant later died.

193. Also in December 2021, the FDA interviewed Whistleblower #1.

194. The FDA further sought to schedule another inspection of the Sturgis Plant in January 2022 – now a "for cause" inspection, indicating the seriousness of the violations. But Abbott's management at the Sturgis Plant sought to delay this inspection, citing a COVID-19 outbreak at the plant.

195. [redacted]

[redacted]

196. 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 claimed 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," notwithstanding that the facts suggest otherwise as Whistleblower #1 recounts.

### D. 2022: The Board's Failure to Oversee Compliance Results in a Recall, Shutdown of the Sturgis Plant, and Tremendous Financial, Legal, and Reputational Harm to Abbott

197. In light of the mounting regulatory issues at the Sturgis Plant, it was even more critical that Defendants fulfill their oversight duties to ensure that the Company's infant formula products were manufactured and sold in the U.S. through safe and compliant means in 2022.

[redacted]

[redacted]

198. On January 5, 2022, the parents of a preterm infant, who had consumed Abbott's infant formula products, developed NEC, and died, began what became a flood 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 based 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.[9]

199. 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.

200. [redacted]

201. 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

[9] *Hall v. Abbott Laboratories*, Master Docket 1:22-cv-0071, transferred from MDL No. 3026 on April 8, 2022, 600 F.Supp.3d 1345.

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.

202. Significantly, the FDA's testing detected Cronobacter 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 Sturgis Plant. As such, Cronobacter was found in multiple locations in the Sturgis Plant because of unsafe and illegal practices that had been ongoing for years due to the focus on maximizing profits over compliance, consistent with the Company's longstanding culture.

203. Despite repeated requests from the FDA, Abbott resisted conducting a recall until the FDA forced its hand by issuing a consumer advisory regarding those products.[10]

204. Reflecting the FDA's level of concern, a day after FDA leadership learned of positive Cronobacter samples at Sturgis, the FDA's Food Program Leadership met and the FDA's Coordinated Outbreak Response Network began preparing a response.

205. Then on February 11, 2022, the FDA notified the WIC program of a "potential action that could impact the infant formula supply."

206. On February 13, 2022, the FDA sequenced six confirmed samples of Cronobacter collected from the Sturgis facility environment.

207. On February 14, 2022, an FDA intra-agency group convened and began "discussions of food safety, regulatory, and supply chain issues related to the response."

[10] The FDA's summary of key events can be reviewed at FDA, Timeline of Infant Formula Related Activities, https://www.fda.gov/media/158737/download.

208. On February 15, 2022, the FDA recommended that Abbott voluntarily recall its product. The FDA received additional Cronobacter sample results, met with the WIC program on the investigation, potential for recall, and supply chain issues. Under pressure from the FDA, Abbott ceased production on that day, but did not institute a recall. Abbott agreed to exclude and hold specialty metabolic products given the critical access need and Abbott's lack of a mitigation plan to produce these formulas at one of its other facilities.

209. On February 16, 2022, the FDA again recommended that Abbott voluntarily recall its product. The FDA submitted a report to U.S. government partners on potential recall and supply chain impacts given Abbott's significant market share and the Sturgis Plant's role as a critical producer of specialty metabolic and amino acid formulas. The FDA also met with the American Academy of Pediatricians to make them aware of a significant upcoming action involving infant formula that will have ramifications for supply chains.

210. On February 17, 2022, following a *third recommendation* that Abbott Nutrition voluntarily recall its product, shortly after the market closed on February 17, 2022, the FDA increased pressure by issuing 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 produced at the Sturgis Plant. The FDA highlighted that its investigation was "on-going."

211. Facing public scrutiny, Abbott finally initiated a recall. Abbott, however, misleadingly framed the recall as a "voluntary" and "proactive" action by the Company (as detailed further in Section IX). Abbott's press release failed to mention that the FDA's investigation was on-going or the existence of 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. Abbott also omitted the fact that it took multiple requests by the FDA before Abbott agreed to do the recall. 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 Plant. Moreover, Abbott, failed to mention the intensive testing mandated by the FDA when it found Cronobacter in product contact areas.

212. 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 40% 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 Califf 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."

213. Notably, during the weeks between the FDA's "for cause" inspection at the Sturgis Plant and its shocking results, the shutdown, and the February 17, 2022 recall, [redacted]

[redacted]

214. [redacted]

[redacted]

215. [redacted]

216. [redacted]

217. On February 18, 2022, before the start of trading, Abbott filed a Form 8-K confirming the recall. 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."

218. 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.

219. Analyst and media response was swift and concerned, with coverage in *The Wall Street Journal* and *The New York Times* that Cronobacter can be "lethal for infants" and "can cause severe, life-threatening infections or inflammation of the membranes that protect the brain and spine." However, Abbott's reassurances provided some comfort, with analysts initially assuming a relatively minor impact on operations. Indeed, a February 18, 2022 report from J.P. Morgan was titled "Nutrition Recall Less Impactful than Feared," stating that it will be hard to recover from the supply shortfall but "there will continue to be a decent supply of Similac in the market" and "Abbott is working with the FDA to get the affected plant up and running as fast as possible." RBC Capital stated that the recall's financial impact would "likely [] be immaterial at the total company level." In reaching these conclusions, analysts from Evercore ISI, J.P. Morgan, RBC Capital, and other well-regarded outlets emphasized the facts as they were told at the time that no *Cronobacter* was found near finished infant formula products and that the recall was "voluntary" and "proactive."

220. In response to those disclosures, and despite the Company's downplaying of their severity, the price of Abbott common stock declined precipitously, falling from a closing price of $120.58 per share on February 17, 2022 to a closing price of $116.79 per share on February 18, 2022, a decline of 3.14%.

221. 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.

222. 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 demanded that Abbott turn over internal documents related to the manufacture and sale of infant formula products from the Sturgis Plant, including information concerning Cronobacter.

223. On February 28, 2022, facing increasing public and regulatory pressure, 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, Michigan 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, while a spokesperson for Abbott merely stated that production at the Sturgis Plant was "paused" as it continued to work with the FDA. [redacted]

224. 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.

225. 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."

226. 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.

227. There was widespread coverage of the 483 reports, including a *Bloomberg* article on March 22, 2022 reporting that the FDA found "unsanitary conditions" at Sturgis "five months before the company conducted a recall of products associated with the deaths of two babies."

228. 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.

229. The FDA's release of the three Form 483s caused Senator Bob Casey to state, "[t]his is another troubling report establishing a pattern of Abbott Nutrition's inadequate efforts to keep its products safe." Likewise, Senator Patty Murray commented, "[t]his 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[.]"

230. 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.

231. 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 shutdown 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.

232. 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."

233. In April of 2022, Chief Judge Rebecca Pallmeyer of the Northern District of Illinois also 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.

234. Significantly, [redacted]

[redacted]

235. [redacted]

[redacted]

236. [redacted]

237. [redacted]

238. [redacted]

[redacted]

239. [redacted]

240. [redacted]

241. [redacted]

242. [redacted]

[redacted]

243. 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."

244. 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.

245. On May 15, 2022, in a virtual press briefing, FDA Commissioner Califf stated, "there are so many factors involved in this investigation and we're just not in a position yet to make any definitive statements."

246. On May 16, 2022, the DOJ, on behalf of the FDA, filed 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 sakazakii ("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).

247. 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.

248. 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.

249. On May 25, 2022, in testimony at the Congressional Hearing on "Formula Safety and Supply: Protecting the Health of America's Babies", FDA Commissioner Robert Califf testified that the Sturgis Plant was "egregiously unsanitary." Califf 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." Califf also rebutted Abbott's assertion that the FDA had exonerated it, 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."

250. 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" when in fact Abbott learned about it in early 2021 (as later revealed on June 8, 2022 by *The Wall Street Journal*). 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, and Abbott would have had notice 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. Whistleblower #1's counsel also sent a letter to Abbott's General Counsel (Defendant Allen) to retain documents related to his client's lawsuit, which 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.

251. 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 ever-evolving, ever-escalating allegations." Also the same day, *Food Safety News* announced that the FDA had received reports of nine infant deaths between December 1, 2021 and March 3, 2022 of babies that consumed infant formula produced by the Sturgis Plant. This article further reported twenty-five incidents of "Life Threatening Illness/Injury" and eighty 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.

252. [redacted]

253. [redacted]

254. [redacted]

255. [redacted]

256. 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.

257. 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. Incredibly, 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, effectively conceding the existence of serious institutional deficiencies that caused the contamination and recall. 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

258. 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.

259. 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 a 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 FDCA, 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 Abbott 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.

260. 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."

261. That same month, the FTC was also reported to be conducting an investigation related to Abbott's infant formula products. 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." The FTC soon after explained that it is investigating whether Abbott and the two other major formula manufacturers have "engaged in collusion or coordination with any other market participant regarding the bidding" for WIC contracts, as well as collusion in the broad market outside of the WIC programs, and how that collusion affects sales and supply of infant formula.

262. 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 co-defendant.

263. Despite these ongoing serious regulatory investigations and numerous lawsuits involving multiple aspects of the Company's production and sale of infant formula products,

Abbott's Board and management have allowed Abbott to consistently report positively on the business line. This includes taking the public position that 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 before the House Subcommittee on Health Care and Financial Services, 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.

264. In fact, during his March 28, 2023 Congressional 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.

265. In addition, Yiannas further clarified that while Abbott had represented that it had voluntarily recalled formula in an abundance of caution, Abbott was actually 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.

266. 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 in Section V, supra.

267. Yianna's public testimony and the allegations made by Whistleblowers #1 and 2 are [redacted] As a result, Defendants utterly failed to oversee whether the Company manufactured and sold infant formula products in the U.S. in a safe manner that complied with federal food safety regulations and Abbott's corporate governance policies.

268. Despite their breaches of fiduciary duty and other forms of misconduct that resulted in tremendous harm to Abbott (as detailed in Section X), Defendants Allen, Battaglia, Calamari, Ford, Funck, House, Manning, Randall, Salvadori, and Young were rewarded with lavish compensation and benefits that amounts to unjust enrichment.

## VII. DUTIES OF DEFENDANTS

269. Defendants' failure to develop and oversee an information reporting system and to attend to red flags breached their fiduciary duties under Illinois law as well as their duties as set forth in Abbott's bylaws, governance guidelines, and Board committee charters.

### A. Fiduciary Duties Under Illinois Law

270. Under Illinois law, as Abbott directors and/or officers, Defendants owe fiduciary duties of loyalty, good faith, and candor to the Company's shareholders. In this regard, the 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. 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.

271. By virtue of their fiduciary duties of loyalty, good faith, and candor, each 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.

272. In particular, Defendants owed "oversight" duties (i.e., "Caremark" duties) as part of their fiduciary duties. 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. Defendants' oversight duties further required them to take action when red flags of illegal conduct were waved in their faces.

### B. The Board, its Committees, and Senior Officers Were Charged with Overseeing Abbott's Legal Compliance, Risk Exposure, and Internal Controls

273. Abbott's bylaws, corporate governance guidelines, and 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 compliance with regulations, along with its risk exposure, and internal controls. Defendants, who were and are members of the committees of the Board, assumed the responsibility to carry out the functions of their respective committees.

#### a. Duties Under the Company's Bylaws

274. 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, "[t]he 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.

275. 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, "[e]ach 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 "[e]ach 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.

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

**b. Duties Under the Company's Governance Guidelines**

277. 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.

278. 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.

279. Abbott's Code of Business Conduct further states that it applies to "all officers, employees, contract workers and agents of Abbott[.]" Accordingly, Defendants were obligated to follow all provisions of the Company's Code of Business Conduct too.

280. Moreover, Abbott maintains a Comprehensive Ethics and Compliance Program, which includes relevant provisions as follows:

- The CECO provides regular briefings to our Chairman and CEO, executive leaders, the Board of Directors, and Public Policy Committee.
- The CECO chairs Abbott's Business Conduct Committee (BCC) — a team of executive-level leaders and Abbott's Chairman and CEO. The BCC meets regularly to discuss potential risk areas and mitigation measures, to review compliance program performance and metrics, including plans for improvements, and to evaluate legal and regulatory changes and best practices.
- 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.

281. Abbott's Board consistently boasted about 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 ingrained 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."

282. As noted in Section VII.B.f, the Board's Nominations and Governance Committee is responsible for reviewing Abbott's Corporate Governance policies.

283. 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 shareholder 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.

284. 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.** . . . . (Emphasis added).

285. Based on the Board's recommendation in the 2018 Proxy Statement, Abbott's stockholders voted down the shareholder proposal for an independent Board chair.

**c. Duties of Public Policy Committee Members**

286. 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.

287. 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[.]"

**d. Duties of Audit Committee Members**

288. 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.

289. 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.

**e. Duties of Executive Committee Members**

290. Article IV, Section 3 of the Bylaws requires that the Executive Committee must have a majority of its membership comprised of 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."

**f. Duties of Nominations and Governance Committee Members**

291. 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.

292. 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.

**g. Duties of Compensation Committee Members**

293. 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.

## VIII. THE PROXY DEFENDANTS VIOLATED SECTION 14(A) OF THE EXCHANGE ACT AND SEC RULE 14A-9 BY CAUSING THE COMPANY TO FILE MATERIALLY MISLEADING PROXY STATEMENTS

294. 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, among other things, (1) the Company manufactured and sold its infant formula products in the U.S. in violation of federal health and safety laws and regulations; and (2) the seriously deficient internal risk management and controls that allowed those unsafe and illegal conditions to proliferate at Abbott, exposing Abbott to significant legal, regulatory, and reputational risks.

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

295. 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.

296. 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.

297. 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."

298. 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.

299. 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."

300. 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.
>
> * * *
>
> All of Abbott's directors exhibit…Commitment to good corporate citizenship
>
> * * *
>
> In addition, Board members should have backgrounds that, when combined, provide a portfolio of experience and knowledge that will serve Abbott's governance and strategic needs.

301. 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."

302. 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."

303. 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:…
>
> - Abbott's accounting and financial reporting practices and the audit process,
> - The quality and integrity of Abbot's financial statements,
> - Legal and regulatory compliance relating to financial matters, including accounting, auditing, financial reporting, and securities law issues,
> - The performance of Abbot's internal audit function and internal auditors 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.

304. 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.

305. 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.

306. 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."

307. 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.

308. The statements outlined above from the 2021 Proxy Statement convey to its stockholders that Abbott's Board: (i) was comprised of members with sufficient relevant knowledge and experience to exercise proper risk oversight and maintained sufficient compliance, risk controls, review, and reporting systems to oversee enterprise risk and identify and address misconduct, including Abbott's legal, regulatory and healthcare compliance; (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; (iv) maintained risk management practices related to its production and sale of the Company's infant formula products in the U.S.; and (v) interacted meaningfully with Abbott's senior management to confirm that risk assessment, compliance and mitigation practices were consistent with Abbott's business strategy.

309. The 2021 Proxy Statement omitted any disclosures regarding: (i) Abbott's ineffective internal risk management controls, which exposed Abbott to serious and significant regulatory and legal risks; (ii) the existence of the 2019 Form 483 and a related EIR detailing violations of federal food safety regulations at the Sturgis Plant; (iii) Abbott's inadequate controls to manufacture and sell its infant formula products in the U.S. in compliance with federal food safety laws and regulations and the Company's corporate policies; (iv) the existence and failure to address Whistleblower #1's OSHA Complaint, along with 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 manufacture and sale of infant formula products in the U.S.

310. 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 re-elect the 2021 Proxy Defendants to the Board.

311. 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.

* * *

COMPENSATION PROGRAM IS DIRECTLY LINKED TO BUSINESS STRATEGY

Our compensation program is also linked directly to our business strategy, to ensure that officers are focused on those activities that drive our business strategy and create value for shareholders.

* * *

COMPENSATION LINK TO SUSTAINABILITY

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…

- Abbott's Code of Conduct to ensure adequate internal controls for financial reporting and compliance with applicable laws and regulations.

312. Contrary to those statements, Abbott's compensation system actually encouraged and rewarded extreme risk taking, turning a blind eye to 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 and failure to establish a system of board-level controls that would allow the Board to properly oversee Abbott's infant formula business.

313. Under this misrepresentation, 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 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 internal control deficiencies, and their continued failure to reform the Company's compensation structures to ensure they do not promote this misconduct.

314. 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).

315. 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 ignore their oversight responsibilities, and instead, created a culture that punished ground-level employees who reported safety violations, and enabled ongoing operations, where Abbott was manufacturing and selling infant formula products in the U.S. that violated federal food safety laws and the Company's corporate governance policies, creating unsafe and potentially fatal conditions for its infant consumers. In reality, Abbott's board structure allowed senior executives and the Board to forsake their oversight responsibilities and accountability to the Company and its shareholders and, instead, enabled ongoing, unsafe operations of the Sturgis Facility and the manufacture and distribution of infant powdered formula products that failed to meet FDCA quality and safety standards.

316. 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

317. On March 18, 2022, Director Defendants Alpern, Blount, Ford, Gonzalez, Kumbier, McDew, McKinstry, 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. As to each of these solicited votes, these Defendants issued materially false or misleading statements.

318. 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."

319. The 2022 Proxy Statement represented that: "The process used to identify and select nominees has resulted in a balanced, diverse, and well-rounded Board of Directors that possesses the skills, experiences, and perspectives necessary for its oversight role," and "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."

320. 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."

321. 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."

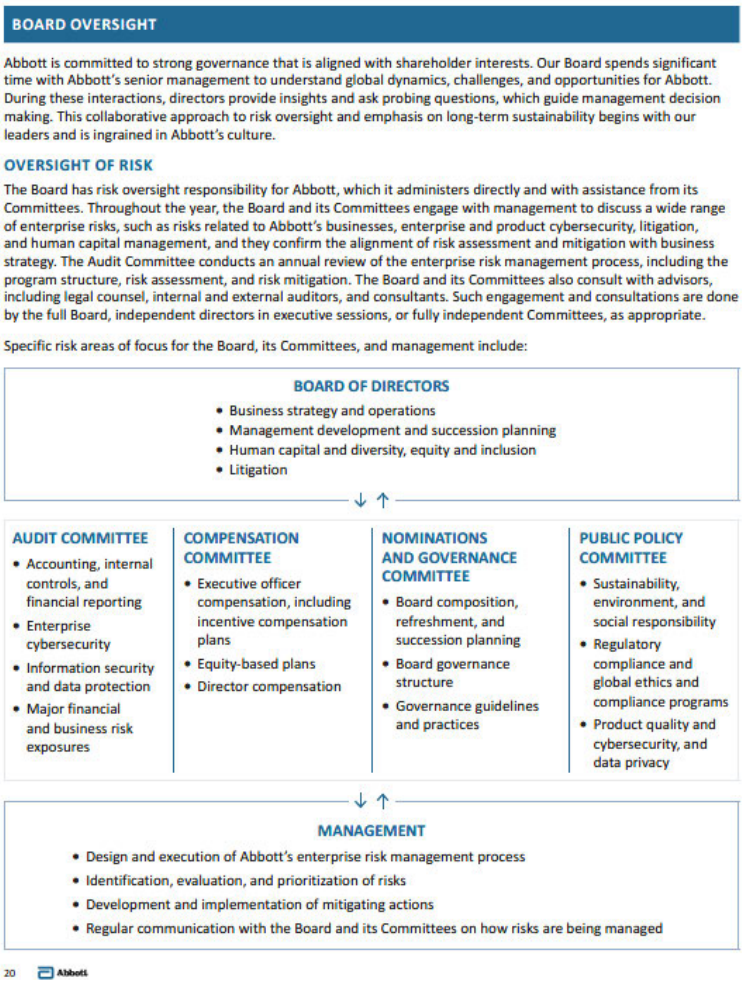
322. The 2022 Proxy Statement also represented in a Section entitled, "Nominations and Governance Committee" that:

> 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.

323. 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."

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



**BOARD OVERSIGHT**

Abbott is committed to strong governance that is aligned with shareholder interests. Our Board spends significant time with Abbott's senior management to understand global dynamics, challenges, 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 ingrained in Abbott's culture.

**OVERSIGHT OF RISK**

The Board has risk oversight responsibility for Abbott, which it administers directly and with assistance from its Committees. Throughout the year, the Board and its Committees engage with management to discuss a wide range of enterprise risks, such as risks related to Abbott's businesses, enterprise and product cybersecurity, litigation, and human capital management, and they confirm the alignment of risk assessment and mitigation with business strategy. The Audit Committee conducts an annual review of the enterprise risk management process, including the program structure, risk assessment, and risk mitigation. The Board and its Committees also consult with advisors, including legal counsel, internal and external auditors, and consultants. Such engagement and consultations are done by the full Board, independent directors in executive sessions, or fully independent Committees, as appropriate.

Specific risk areas of focus for the Board, its Committees, and management include:

**BOARD OF DIRECTORS**

- Business strategy and operations
- Management development and succession planning
- Human capital and diversity, equity and inclusion
- Litigation

**AUDIT COMMITTEE**

- Accounting, internal controls, and financial reporting
- Enterprise cybersecurity
- Information security and data protection
- Major financial and business risk exposures

**COMPENSATION COMMITTEE**

- Executive officer compensation, including incentive compensation plans
- Equity-based plans
- Director compensation

**NOMINATIONS AND GOVERNANCE COMMITTEE**

- Board composition, refreshment, and succession planning
- Board governance structure
- Governance guidelines and practices

**PUBLIC POLICY COMMITTEE**

- Sustainability, environment, and social responsibility
- Regulatory compliance and global ethics and compliance programs
- Product quality and cybersecurity, and data privacy

**MANAGEMENT**

- Design and execution of Abbott's enterprise risk management process
- Identification, evaluation, and prioritization of risks
- Development and implementation of mitigating actions
- Regular communication with the Board and its Committees on how risks are being managed

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325. 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:…
>
> - Abbott's accounting and financial reporting practices and the audit process,
> - The quality and integrity of Abbot's financial statements,
> - Legal and regulatory compliance relating to financial matters, including accounting, auditing, financial reporting, and securities law issues,
> - The performance of Abbot's internal audit function and internal auditors 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.

326. 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.

327. 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.

328. 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."

329. 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.

330. The statements outlined above from the 2022 Proxy Statement convey to its stockholders that Abbott's Board: (i) was comprised of members with sufficient relevant knowledge and experience to exercise proper risk oversight and maintained sufficient compliance, risk controls, review, and reporting systems to oversee enterprise risk and identify and address misconduct, including Abbott's legal, regulatory and healthcare compliance; (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; (iv) maintained risk management practices related to its production and sale of the Company's infant formula products

in the U.S.; and (v) interacted meaningfully with Abbott's senior management to confirm that risk assessment, compliance and mitigation practices were consistent with Abbott's business strategy.

331. The 2022 Proxy Statement omitted any disclosures regarding: (i) Abbott's ineffective internal risk management controls, which exposed Abbott to serious and significant regulatory and legal risks; (ii) the existence of the 2019 Form 483 and a related EIR detailing violations of federal food safety regulations at the Sturgis Plant; (iii) Abbott's inadequate controls to manufacture and sell its infant formula products in the U.S. in compliance with federal food safety laws and regulations and the Company's corporate policies; (iv) the existence and failure to address Whistleblower #1's OSHA Complaint, along with 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 manufacture and sale of infant formula products in the U.S.

332. 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 re-elect the 2022 Proxy Defendants to the Board.

333. 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.

* * *

COMPENSATION PROGRAM IS DIRECTLY LINKED TO BUSINESS STRATEGY

Our compensation program is also linked directly to our business strategy, to ensure that officers are focused on those activities that drive our business strategy and create value for shareholders.

334. Contrary to those statements, Abbott's compensation system actually encouraged and rewarded extreme risk taking, turning a blind eye to 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 and failure to establish a system of board-level controls that would allow the Board to properly oversee Abbott's infant formula business.

335. 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 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 internal control deficiencies, and their continued failure to reform the Company's compensation structures to ensure they do not promote this misconduct.

336. 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

[…]

**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).

337. 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 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.

338. 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

339. On March 17, 2023, Director Defendants Alpern, Babineaux-Fontenot, Blount, Ford, Gonzalez, Kumbier, McDew, McKinstry, 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) 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.

340. 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."

341. 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."

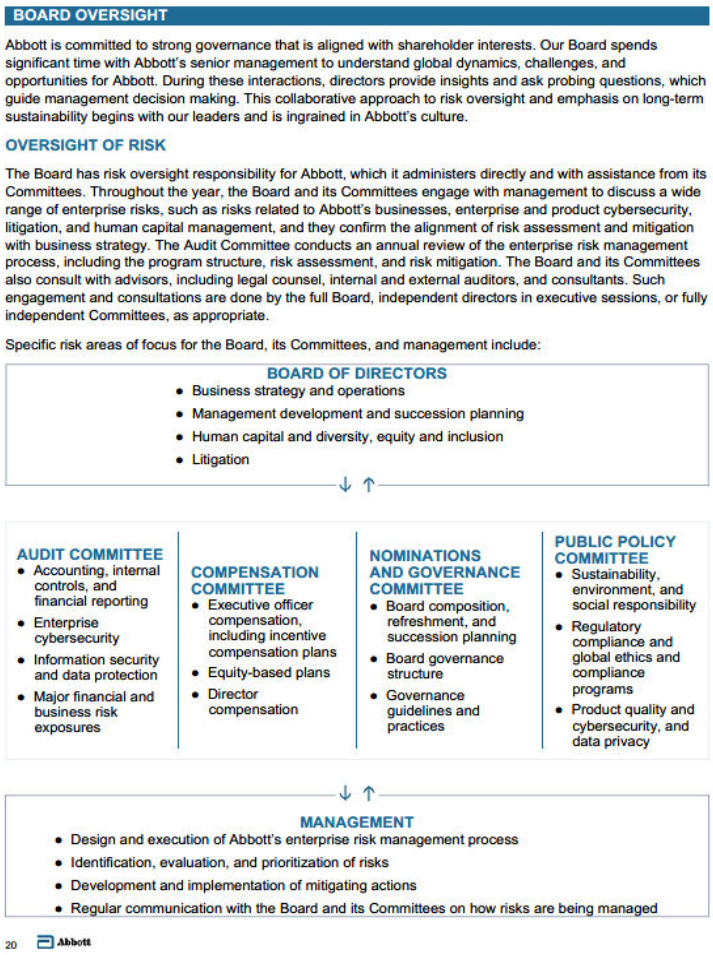
342. The 2023 Proxy Statement also represented in a Section entitled, "Nominations and Governance Committee" that:

> 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.

343. 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 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." 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 "[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 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."

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



**BOARD OVERSIGHT**

Abbott is committed to strong governance that is aligned with shareholder interests. Our Board spends significant time with Abbott's senior management to understand global dynamics, challenges, 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 ingrained in Abbott's culture.

**OVERSIGHT OF RISK**

The Board has risk oversight responsibility for Abbott, which it administers directly and with assistance from its Committees. Throughout the year, the Board and its Committees engage with management to discuss a wide range of enterprise risks, such as risks related to Abbott's businesses, enterprise and product cybersecurity, litigation, and human capital management, and they confirm the alignment of risk assessment and mitigation with business strategy. The Audit Committee conducts an annual review of the enterprise risk management process, including the program structure, risk assessment, and risk mitigation. The Board and its Committees also consult with advisors, including legal counsel, internal and external auditors, and consultants. Such engagement and consultations are done by the full Board, independent directors in executive sessions, or fully independent Committees, as appropriate.

Specific risk areas of focus for the Board, its Committees, and management include:

**BOARD OF DIRECTORS**
- Business strategy and operations
- Management development and succession planning
- Human capital and diversity, equity and inclusion
- Litigation

↓ ↑

**AUDIT COMMITTEE**
- Accounting, internal controls, and financial reporting
- Enterprise cybersecurity
- Information security and data protection
- Major financial and business risk exposures

**COMPENSATION COMMITTEE**
- Executive officer compensation, including incentive compensation plans
- Equity-based plans
- Director compensation

**NOMINATIONS AND GOVERNANCE COMMITTEE**
- Board composition, refreshment, and succession planning
- Board governance structure
- Governance guidelines and practices

**PUBLIC POLICY COMMITTEE**
- Sustainability, environment, and social responsibility
- Regulatory compliance and global ethics and compliance programs
- Product quality and cybersecurity, and data privacy

↓ ↑

**MANAGEMENT**
- Design and execution of Abbott's enterprise risk management process
- Identification, evaluation, and prioritization of risks
- Development and implementation of mitigating actions
- Regular communication with the Board and its Committees on how risks are being managed

20 Abbott

345. 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: [. . .]
>
> - Abbott's accounting and financial reporting practices and the audit process,

- The quality and integrity of Abbot's financial statements,
- Legal and regulatory compliance relating to financial matters, including accounting, auditing, financial reporting, and securities law issues,
- The performance of Abbot's internal audit function and internal auditors 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.

346. 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:

• Legal, regulatory, and healthcare compliance matters, including evaluating Abbott's compliance policies and practices and reviewing Abbott's compliance program, [. . .]

• Governmental affairs and political participation, including advocacy priorities, political contributions, lobbying activities, and trade association memberships, [. . .]

• Social, political, economic, and environmental trends and public policy issues that affect or could affect Abbott's business activities, performance, and public image.

347. 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.

348. 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 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."

349. 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.

350. The statements outlined above from the 2023 Proxy Statement convey to its stockholders that Abbott's Board: (i) was comprised of members with sufficient relevant knowledge and experience to exercise proper risk oversight and maintained sufficient compliance, risk controls, review, and reporting systems to oversee enterprise risk and identify and address misconduct, including Abbott's legal, regulatory and healthcare compliance; (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; (iv) maintained risk management practices related to the production and sale of the Company's infant formula products in the U.S.; and (v) interacted meaningfully with Abbott's senior management to confirm that risk assessment, compliance and mitigation practices were consistent with Abbott's business strategy.

351. The 2023 Proxy Statement omitted any disclosures regarding: (i) Abbott's ineffective internal controls, which exposed Abbott to serious and significant regulatory and legal risks; (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 and causing Abbott significant harm; (iii) the 2022 DOJ Consent Decree, which was required to restart production of infant formula products at the Sturgis plant; (iv) Abbott's inadequate internal controls related to ensuring that its manufacture and sale of infant formula products in the U.S. complied with federal food safety laws and regulations and the Company's corporate policies; (v) the existence and failure to address Whistleblower #1's OSHA Complaint, along with 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 manufacture and sale of infant formula products in the U.S.

352. 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 re-elect the 2023 Proxy Defendants to the Board.

353. 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.

354. Contrary to those statements, Abbott's compensation system actually encouraged and rewarded extreme risk taking, turning a blind eye to 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.

355. 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 $44.9 million, in 2022, without the benefit of material information concerning 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 internal control deficiencies, and their continued failure to reform the Company's compensation structures to ensure they do not promote this misconduct.

356. 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).

357. 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 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.

358. 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. THE 10(B) DEFENDANTS VIOLATED SECTION 10(B) OF THE EXCHANGE ACT AND SEC RULE 10B-5 BY KNOWINGLY OR RECKLESSLY ISSUING MATERIALLY FALSE AND MISLEADING STATEMENTS

359. In violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5, Defendants Alpern, Austin, Blount, Calamari, Ford, Funck, Gonzalez, Kumbier, Liddy, McDew, McKinstry, Novakovic, Osborn, Starks, Stratton, Tilton, and White (the "10(b) Defendants") issued, and caused the Company to issue, statements that, in light of the unsafe and illegal infant formula production detailed above, were materially false or misleading when made. The 10(b) Defendants' misrepresentations artificially inflated and/or maintained the price of Abbott shares, causing the Company to purchase shares at artificially high prices through its significant stock repurchase program.

360. The 10(b) Defendants' conduct caused Abbott to make share repurchases, signaling 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 and/or maintain at artificial levels Abbott's share price. The artificial inflation of Abbott shares was financially beneficial to the 10(b) Defendants, as the misrepresentations increased the value of stock and options they held; benefited those Officer Defendants whose compensation was tied to the Company's financial performance; and allowed the Insider Selling Defendants to sell shares at higher prices than they would have absent the artificial inflation.

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

361. Abbott's Board periodically authorizes the Company to repurchase its own shares of common stock. As members of the Board, Director Defendants Alpern, Austin, Blount, Kumbier, Liddy, McDew, McKinstry, Osborn, 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. These authorizations resulted in the following repurchases by Abbott:

| Month/Year of Repurchase | Number of Shares Repurchased | Weighted-Average Price per Share | Total Amount Paid ($) |
|---|---|---|---|
| Oct 2019 | 2,675,000 | $81.950 | $219,216,250 |
| Nov 2019 | 1,786,605 | $82.928 | $148,159,579 |
| Dec 2019 | 1,844,839 | $85.440 | $157,623,044 |
| **Total for 2019** | **6,306,444** | **$83.031** | **$524,998,873** |
| Jan 2020 | 2,957 | $85.890 | $253,977 |
| Apr 2020 | 76,831 | $98.000 | $7,529,438 |
| May 2020 | 9,188 | $92.100 | $846,215 |
| Jun 2020 | 791 | $90.900 | $71,902 |
| Sep 2020 | 28,423 | $109.470 | $3,111,466 |
| Dec 2020 | 1,600,411 | $107.999 | $172,842,788 |
| **Total for 2020** | **1,718,601** | **$107.445** | **$184,655,785** |
| Jan 2021 | 1,785 | $109.110 | $194,761 |
| Feb 2021 | 10,000 | $122.543 | $1,225,430 |
| Apr 2021 | 18,202 | $120.900 | $2,200,622 |
| Jun 2021 | 4,500,000 | $111.575 | $502,087,500 |
| Jul 2021 | 450,000 | $120.849 | $54,382,050 |
| Aug 2021 | 2,175,000 | $123.265 | $268,101,375 |
| Sep 2021 | 3,002,035 | $120.814 | $362,687,856 |
| Oct 2021 | 1,767,000 | $127.811 | $225,842,037 |

| Month/Year of Repurchase | Number of Shares Repurchased | Weighted-Average Price per Share | Total Amount Paid ($) |
|---|---|---|---|
| Nov 2021 | 4,750,000 | $127.486 | $605,558,500 |
| Dec 2021 | 135 | $141.000 | $19,035 |
| **Total for 2021** | **16,674,157** | **$121.283** | **$2,022,299,167** |
| Jan 2022 | 650,000 | $127.262 | $82,720,300 |
| Feb 2022 | 8,550,000 | $123.643 | $1,057,147,650 |
| Mar 2022 | 8,113,060 | $118.344 | $960,131,973 |
| Aug 2022 | 1,050,000 | $102.567 | $107,695,350 |
| Sep 2022 | 7,363,597 | $102.895 | $757,677,313 |
| Oct 2022 | 2,000,000 | $98.258 | $196,516,000 |
| **Total for 2022** | **27,726,657** | **$114.038** | **$3,161,888,586** |
| **Grand Total** | **52,425,859** | | **$5,893,842,411** |

362. In addition to the stock repurchase plan resulting in a 10(b) violation, its authorization by the Director Defendants constitutes corporate waste. No reasonable person would purchase Abbott common stock at prices artificially inflated by fraud, as they were here.

### B. The 10(b) Defendants Made False and Misleading Statements of Material Fact Regarding Abbott's Production and Sale of Infant Formula Products in the U.S.

363. The 10(b) Defendants knowingly or with reckless disregard made false or misleading statements of material fact and omitted material information concerning the Company's production and sale of infant formula or stood idly by as the Company disseminated false or misleading statements of material fact or omitted material information regarding issues over which they have oversight.

364. 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.

365. In its 2019 Form 10-K, Abbott further represented that: "Abbott's facilities are deemed suitable and provide adequate productive capacity."

366. The same representations were made in 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").

367. The same representations were made in 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").

368. The statements above (in the 2019, 2020 and 2021 Form 10-Ks) relating to Abbott's production and sales of infant formula were materially false and misleading including because:

- Abbott failed to manufacture and sell its infant formula products in a safe and legally compliant manner in the U.S.;
- Defendants knew or recklessly disregarded that employees, including those at the Sturgis Plant, were engaged in 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 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 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 they were presented with indicating an urgent need to oversee these issues;
- 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;
- 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), Defendants allowed the illegal activities to continue; and

- Contrary to Defendants' positive assertions that the production and sale of Abbott's infant formula is safe and in compliance with all laws, it was produced in violation of federal regulations and using unsafe practices.

369. Additionally, Abbott's Code of Business Conduct was in effect and available on Abbott's website throughout the relevant period and was signed by Defendant Ford. It stated, among other things, "[w]e produce and deliver safe, effective products that people trust . . . We are committed to timely identifying, evaluating, and addressing product safety issues . . . We adhere to all laws, regulations and Abbott requirements that apply to our work."

370. These statements were false and misleading because Abbott failed to adhere to the FDCA regulations and internal controls that would ensure a safe and effective product and, unfortunately, Abbott delivered infant formula manufactured at the Sturgis Plant that has been linked to the deaths of multiple infants. Rather than "timely" address issues, Abbott pushed back against whistleblower complaints, failed to adhere to confidentiality norms that promote whistleblowing, and failed to elevate key concerns to the Board. Additionally, the FDA's findings in Form 483s and the Congressional testimony of FDA representatives reflect Abbott's non-compliance with applicable laws and regulations.

371. Additionally, on July 16, 2021, Abbott published its Global Sustainability Report, affirmatively stating that its infant formula manufacturing processes were safe:

> Abbott's nutrition business ensures food safety through a tightly controlled manufacturing process that encompasses all steps from accepting materials from suppliers through to final product distribution. We monitor and verify microbiology, packaging integrity, and nutrient and lot control. We complete extensive finished product testing before releasing it for commercial distribution.

372. This statement was materially false or misleading because the Company did not ensure a "tightly controlled manufacturing process" that was "monitor[ed]" and "verif[ied]." Rather, the Sturgis Plant which produced a major portion of the Company's infant formula

experienced for years standing water throughout the facility (a known contamination risk), had insufficient staffing, failed to consistently comply with record-keeping requirements, and failed to rigorously test infant formula before distribution.

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

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

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

375. Abbott's November 15, 2021 "2020 Sustainability Report Summary" contained similar representations including that Abbott conducts quality control to "ensure that [its quality-system performance model and metrics] continue to assess relevant quality and compliance risks." It also stated:

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

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

377. Numerous false and misleading statements were also made following the February 17, 2022 recall.

378. The February 17, 2022, Abbott-issued press release (the "February 17, 2022 Press Release") stated:

> [Abbott] is initiating a proactive, voluntary recall of powder formulas, including Similac, Alimentum and EleCare manufactured in Sturgis, Mich., one of the company's manufacturing facilities . . .
> During testing in our Sturgis, Mich., facility, we found evidence of Cronobacter sakazakii in the plant in non-product contact areas.
> Importantly, no distributed product has tested positive for the presence of either of these bacteria, and we continue to test. Abbott conducts extensive quality checks on each completed batch of infant formula, including microbiological analysis prior to release. All finished products are tested for Cronobacter sakazakii, Salmonella Newport and other pathogens and they must test negative before any product is released. Additionally, retained samples related to the three complaints for Cronobacter sakazakii tested negative for Cronobacter sakazakii. . . . While Abbott's testing of finished product detected no pathogens, we are taking action by recalling the powder formula manufactured in this facility with an expiration of April 1, 2022, or later.

379. This statement was false or misleading because it omitted that the FDA had pushed for the recall and was conducting an ongoing investigation, as well as that the FDA inspection report dated March 18, 2022 and released publicly on March 22, 2022 stated that Cronobacter was found not only "in non-product contact areas" as asserted by Abbott but also on the "scoop hopper" that is "placed directly inside infant formula containers that contain product." As former FDA Deputy Commissioner Yiannis later testified on March 28, 2023 at a Congressional hearing, the "weight of the evidence" "supported a conclusion that [powdered infant formula] made at Abbott's

Sturgis plant was produced under insanitary conditions and [was] a likely source of ongoing, sporadic contamination of [powdered infant formula] with multiple strains [of Cronobacter] over time."

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

381. On May 25, 2022, Defendant Calamari testified to the U.S. Congressional House Oversight and Investigations Subcommittee, stating among other things that "[w]e [Abbott] became aware of the whistleblower complaint in the end of April, when it was made public by Congress" and claimed that it was the whistleblower's "choice to use that mechanism to raise the complaint," referring to Abbott having purportedly learned of the whistleblower's concerns from Congress rather than internally.

382. That Congressional testimony was false or misleading because it misrepresented when the whistleblower complaint occurred. In fact, the whistleblower had filed an OSHA complaint on February 16, 2021, which contained the same concerns as in the October 2021 whistleblower complaint filed with the FDA. OSHA sent the complaint to Abbott who responded on April 2021. The testimony also misrepresented the whistleblower's efforts to communicate concerns, suggesting that they were provided to Congress rather than to Abbott or the appropriate regulators.

### C. The 10(b) Defendants Made the Statements with Scienter

383. The facts, when viewed holistically and together with the other allegations in the Complaint, establish a strong inference of scienter that each of the 10(b) Defendants knew or was

severely reckless in not knowing that each of the alleged misrepresentations and omissions was false and misleading at the time that it was made.

384. The October 2021 Whistleblower Complaint was provided to Abbott prior to many of the alleged misstatements. It makes clear that severe and systemic violations of federal food safety regulations were occurring at the Sturgis Plant and had persisted for many years. That same information appeared in the Form 483s provided to Abbott. The 10(b) Defendants were severely reckless in ignoring this information. And even upon learning of the "voluntary" recall, the 10(b) Defendants failed to act promptly to address potentially fatal health and safety issues. Their narrow concern for short-term corporate financial impact and lack of concern for the potential impact on Abbott's consumers or the legal, regulatory, and reputational consequences for the Company gives rise to an inference of scienter.

385. Abbott entered into a Consent Decree with the DOJ on May 16, 2022. The Consent Decree, which was signed and submitted by Defendant Randall, requires Abbott to hire an independent expert; put in place testing, sanitation, environmental monitoring, and employee training programs; and requires the expert to certify that Defendants "have corrected all deficiencies." This effective admission of deficiencies and the fact of the DOJ investigation and Consent Decree support an inference of scienter.

386. Abbott's infant formula business line is critical to the business, and the reputational impact of a health and safety crisis in that division is calamitous. One in five babies relied on Sturgis formula for their nutrition; in 2021, Abbott's U.S. pediatric nutritionals revenue fell from $2.192 billion in 2021 to $1.562 billion in fiscal year 2022 – a 28.7% decrease that "reflects the impact of the voluntary recall and production stoppage of certain infant powder formula products manufactured at Abbott's facility in Sturgis, Michigan, partially offset by increased demand for

Abbott's Pedialyte products." The Company also reported a 60% decrease in operating earnings for the Nutritional Products segment, which it attributed to "the impact of the voluntary infant product recall and manufacturing stoppage." The Company also recorded $176 million of charges related to the 2022 voluntary recall. Misrepresenting and omitting information concerning Abbott's core operation supports an inference of scienter.

387. The significant governmental scrutiny further supports an inference of scienter. The U.S. DOJ launched a criminal investigation of Abbott, announced on January 20, 2023, in *The Wall Street Journal* among other news outlets. Abbott confirmed the DOJ probe, stating that "DOJ has informed us of its investigation and we're cooperating fully." A February 15, 2023 article in *Crain's Chicago Business* emphasized the risks of the DOJ investigation, noting that it could "deepen the damage from an episode that has already hurt the company's bottom line and brand name." Additionally, in its 2022 Form 10-K, Abbott announced a December 2022 subpoena from the SEC's Enforcement Division regarding Abbott's powder infant formula business and related public disclosures. And in January 2023, Abbott announced that it had received a civil investigative demand from the FTC seeking information in connection with its investigation of companies who participate in bids for WIC infant formula contracts. These civil and criminal investigations also contributes to an inference of scienter.

388. Congressional testimony of Frank Yiannis, the former FDA Deputy Commissioner, Food Policy & Response from November 2018 through February 2023 also supports an inference of scienter. In Yiannis's testimony before the U.S. House of Representatives Oversight Committee's Subcommittee on Health Care and Financial Services, he strongly pushed back against the claims that the Sturgis Plant was not the source of the reported infant illnesses, stating "Abbott Nutrition and some others have suggested that their products were not the source of

illnesses because the genetic strains of Cronobacter sakazakii were never found in product, nor in the Sturgis facility. This information is misleading." He further stated that "Abbott's Sturgis facility lacked adequate controls to prevent the contamination of powdered infant formula with C. sakazakii" and that "[t]here is also evidence that sporadic contamination of finished product actually did occur, and it is likely that other lots of PIF produced in this plant were contaminated with multiple C. sakazakii strains over time, which evaded end-product testing, were released into commerce, and consumed by infants."

389. Finally, insider sales throughout the relevant period support an inference of scienter. 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 false or misleading statements. The Insider Selling Defendants collectively sold or otherwise disposed of massive amounts of 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 Insider Selling Defendants' knowledge or reckless disregard of the unlawful practices detailed in this Complaint.

390. The Insider Selling 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 focused on maximizing profits over safety or compliance; and (iii) the Company lacked the requisite risk controls as wells as internal 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 Selling 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.

391. The following charts depict sales of the Insider Selling Defendants, each of whom sold 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 production and sale of infant formula products in the U.S.:

**Defendant Calamari**

| Date | Shares | Xcode | Price | Proceeds |
|---|---|---|---|---|
| 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:** | **3,643** | | | **$435,102.84** |

**Defendant Ford**

| Date | Shares | Xcode | Price | Proceeds |
|---|---|---|---|---|
| 8/25/2022 | 102,425 | S | $105.10 | $10,765,154.29 |
| 2/28/2022 | 26,579 | F | $122.41 | $3,253,535.39 |
| 2/26/2021 | 22,865 | F | $121.58 | $2,779,926.70 |
| 2/28/2020 | 16,638 | F | $79.19 | $1,317,563.22 |
| **Total:** | **199,249** | | | **$21,183,308.94** |

**Defendant Funck**

| Date | Shares | Xcode | Price | Proceeds |
|---|---|---|---|---|
| 2/28/2022 | 10,750 | 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 |
| **Total:** | **154,381** | | | **$16,827,223.65** |

**Defendant McKinstry**

| Date | Shares | Xcode | Price | Proceeds |
|---|---|---|---|---|
| 2/4/2022 | 1,614 | S | $116.42 | $187,901.88 |
| **Total:** | **1,614** | | | **$187,901.88** |

**Defendant Salvadori**

| Date | Shares | Xcode | Price | Proceeds |
|---|---|---|---|---|
| 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 |
| **Total:** | **200,178** | | | **$25,201,246.54** |

**Defendant Starks**

| Date | Shares | Xcode | Price | Proceeds |
|---|---|---|---|---|
| 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:** | **100,000** | | | **$11,118,041.85** |

**Defendant Manning**

| Date | Shares | Xcode | Price | Proceeds |
|---|---|---|---|---|
| 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 |
| **Total:** | **127,798** | | | **$13,336,100.68** |

**Defendant Allen**

| Date | Shares | Xcode | Price | Proceeds |
|---|---|---|---|---|
| 3/1/2022 | 1,450 | S | $118.17 | $171,347.95 |
| 2/28/2022 | 9,878 | F | $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 |
| **Total:** | **241,122** | | | **$29,045,492.48** |

### D. In Repurchasing Stock, Abbott Relied on 10(b) Defendants' False or Misleading Statements

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

393. The market for Abbott common stock was efficient during the relevant period because, among other reasons:

- Abbott's stock met the requirements for listing, and was listed and actively traded on the New York Stock Exchange, which is a highly efficient market, with an average daily trading volume of over 5 million shares;
- As a regulated issuer, Abbott filed periodic reports with the SEC;
- Abbott regularly communicated with public investors including by disseminating press releases over major newswire services and communicating with the financial press and widely available media outlets; and
- Abbott was followed by numerous analysts employed by major brokerage firms, including, but not limited to Barclays, Cowen and Company, Credit Suisse, J.P. Morgan, Morgan Stanley, RBC Capital Markets, UBS, and Wells Fargo, all of whom wrote reports about Abbott that were disseminated in the public domain.

394. As a result of the foregoing, the market for Abbott common stock promptly digested current information regarding Abbott from all publicly available sources and reflected such information in Abbott's stock price.

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

### E. The 10(b) Defendants' Misstatements and Omissions Caused Damages to Abbott

396. From 2019 through 2022, the price of Abbott's common stock was artificially inflated as a result of Defendants' materially false and misleading statements and omissions identified above. 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 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.

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

398. As detailed above, between February 17, 2022 and October 19, 2022, the revelation of the truth through a series of disclosures caused Abbott's stock price to plummet.

399. The decline in Abbott's share price was a direct result of the nature and extent of Defendants' fraud being revealed to the market. The timing and magnitude of the decline in the

Company's share price negates any inference that the losses suffered by Abbott were caused by market conditions, macroeconomics or industry factors, or Company-specific facts unrelated to the fraudulent conduct.

## X. ABBOTT HAS SUFFERED BILLIONS OF DOLLARS IN DAMAGES BECAUSE OF DEFENDANTS' MISCONDUCT

400. The fallout from Abbott's infant formula recall and Sturgis Plant shutdown has been dramatic, severe, and commercially destructive for Abbott. Defendants' oversight failures have reverberated across Abbott due to eroded consumer trust and confidence in the brands' safety and efficacy. As a direct and proximate result of the Defendants' conscious failure to perform their fiduciary duties, along with their violations of federal securities laws, Abbott has sustained significant damages both financially and to its corporate image and goodwill. Such damages to Abbott caused by the Defendants' misconduct include, and will include, operational cost increases, penalties, fines, damages awards, settlements, expenses, increased regulatory scrutiny, increased cost of capital, and other liabilities described herein.

401. Abbott also suffered significant loss in its market capitalization, as the price of its stock plummeted following revelations about the safety and compliance failures at the Sturgis Plant. Between February 17, 2022, the day the recall was announced, and June 8, 2022, when investors learned that Abbott was aware of the Whistleblower's complaint months earlier than previously reported, Abbott's stock price declined $8.30, or 6.7%, for a total market capitalization loss of more than $13 billion. Abbott's stock price continued to decline through October 19, 2022, in response to additional subsequent revelations and events relating to the unsafe conditions and repeated regulatory violations at its Sturgis Plant, resulting in a further loss in market capitalization of another approximately $30 billion.

402. For example, in its second quarter report to investors, filed with the SEC in August 2022, Abbott stated that sales of "infant powder formulas associated with the recall" were $393 million less in the first six months of 2022 than the first six months of 2021. Further, on October 19, 2022, Abbott reported its third-quarter 2022 results to investors, revealing a seismic and unprecedented decline in sales in its Nutrition division due to the Sturgis Plant shutdown 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. By the fourth quarter of 2022, sales were down by more than 20%.

403. Abbott also lost significant market share during the Sturgis Plant shutdown as competitors increased their infant formula output to help ease the national formula shortage crisis. Mead Johnson gained a market share of 60%, up from 35% before the recall, and Nestle Gerber also increased its output by approximately 50% in March and April 2022.

404. In addition, Abbott is currently expending an astronomical amount of money on litigation arising from Defendants' lack of oversight pertaining to the Sturgis shutdown, along with other issues in the infant formula business line. 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 co-defendant.

405. As a result of Defendants' knowing misconduct, Abbott engaged in an unlawful and deceptive scheme of violating federal 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.

406. Abbott has suffered significant costs to remediate the Sturgis Plant to comply with the Consent Decree, and faces potential civil fines of $30,000 per day, up to $5 million per year, for violations of the Consent Decree.

407. The recall caused a nationwide infant formula shortage that resulted in Abbott incurring costs to support a "market share recovery," including providing rebates to WIC recipients in states where Abbott held the WIC contract so recipients could buy competitor brands, costs to fly in formula from Abbott's facilities in Ireland and Spain, and a $5 million independently administered fund to help families reliant on Abbott's specialty formulas.

408. Abbott was also harmed by a massive stock repurchase program conducted at prices that were artificially inflated by the 10(b) Defendants' false and misleading statements regarding Abbott's manufacturing and sale of infant formula, its violation of food safety laws, and the absence of an information reporting system.

409. Finally, Abbott's business, goodwill, and reputation have been, and will continue to be, severely damaged by 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.

## XI. DEMAND ON THE BOARD IS FUTILE

410. Lead Plaintiffs have not made a pre-suit demand on the Board to assert the claims set forth herein against Defendants because such a demand would have been futile, and is thereby excused as a matter of law.

411. 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") (i.e., the "Demand Board"). There is no disinterested and independent majority of the Board (i.e., at least six current directors) that could impartially consider a demand as to any of the claims alleged in the complaint.

412. 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 potential personal liability in a securities class action that involves some of the same subject matter as this lawsuit. Ford is, thus, interested and cannot impartially consider a demand.

413. In addition to Ford, at least five other directors cannot impartially consider a demand as to any of the claims alleged in the complaint.

### A. Demand Is Futile for Count I Concerning Violations of Section 14(a) of the Exchange Act

414. Count I of the Complaint asserts derivative claims against the 2021, 2022, and 2023 Proxy Defendants (defined above) for violating Section 14(a) of the Exchange Act by issuing,

causing to be issued, and participating in the issuance of 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 are members of the Demand Board.

415. 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 and misleading stated that Abbott: (i) maintained sufficient compliance, risk controls, review, and reporting programs to identify and address misconduct, including Abbott's legal, regulatory and healthcare compliance; (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 or should have known that the 2021, 2022 and 2023 Proxy Statements violated Section 14(a) of the Exchange Act when they were issued. [redacted]

416. Accordingly, there is not a majority of the Demand Board that can impartially consider a demand to pursue Count I against the 2021, 2022, or 2023 Proxy Defendants. Specifically:

a. eight of the twelve Demand 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 Demand 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 Demand 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.

**B. Demand Is Futile for Count II Concerning Violations of Section 10(b) of the Exchange Act**

417. Count II of the Complaint asserts claims against the 10(b) Defendants (Defendants Alpern, Austin, Blount, Calamari, Ford, Funck, Gonzalez, Kumbier, Liddy, McDew, McKinstry, Novakovic, Osborn, Starks, Stratton, Tilton, and White) 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. The 10(b) Defendants include nine of the current members of Abbott's Demand Board.

418. Each of the currently serving Defendants served on the Board when they issued, caused to be issued, and participated in the issuance of materially false and misleading statements

in the 2019, 2020 and 2022 10-K's to stockholders, as discussed in Section IX.B above, during their respective Board tenure. While Abbott's stock price was artificially inflated due to Defendants' false and misleading statements, the 10(b) Defendants caused Abbott to repurchase millions of shares of its own common stock at prices that were artificially inflated due to Defendants' false or misleading statements and/or omissions. Accordingly, there is not a majority of the Demand Board that can impartially consider a demand to pursue Count II against the 10(b) Defendants.

### C. Demand Is Futile for Count III Concerning Breaches of Fiduciary Duty Claims Alleged Against the Director Defendants

419. Count III of the Complaint asserts claims against the Director 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 a safe manner that complied with federal food safety regulations.

420. 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[.]"

421. There is no majority of the Demand 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 a safe manner, and in compliance with federal food safety regulations. Because food safety is a central compliance concern of Abbott, and Abbott was found to have violated federal food safety laws, these directors cannot be expected to impartially investigate and bring claims against themselves.

422. 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 failed to comply with good manufacturing practices at the Sturgis Plant. Despite this, Defendants Ford, Alpern, Babineuax-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Starks, and Stratton failed to make a good faith effort to implement an information reporting system to oversee food safety related to Abbott's manufacture and sales of its infant formula products in the U.S. even though it is a central compliance concern, and ignored flags to which they were alerted. [redacted] 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, or other directors or officers of the Company on this issue.

423. [redacted]

424. [redacted]

425. [redacted]

426. [redacted]

[redacted]

427. [redacted]

428. Defendants Babineaux-Fontenot, Gonzalez, Kumbier, McKinstry, and Stratton currently sit on Abbott's Audit Committee. [redacted] 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. Based on these facts and as further alleged herein, the 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.

429. Defendants Alpern, Babineaux-Fontenot, Blount, McDew, Roman, and Starks currently sit on Abbott's Public Policy Committee. As described above, the Public Policy Committee Defendants violated its charter and failed to fulfill their charge to oversee regulatory compliance related to Abbott's production and sale of infant formula products in the U.S. [redacted] Based on these facts and as further alleged herein, the Public Policy 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.

430. 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 federal food safety regulations. As such, Executive 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.

431. 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 of Abbott's compliance with federal food safety laws concerning its production and sale of U.S. infant formula products. Based on these facts and as further alleged herein, the 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.

432. Defendants Alpern, Blount, Gonzalez, McDew, and Stratton currently sit on the Nominations and Governance Committee. The Nominations and Governance Committee Defendants violated its 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 of Abbott's compliance with federal food safety regulations when manufacturing and selling its U.S. infant formula products. Based on these facts and as further alleged herein, Nominations and Governance 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.

433. Defendants Alpern, Blount, and McKinstry were previously named as director-defendants in derivative lawsuits involving Abbott and agreed to settlement terms which did or should have put them on notice to exercise their oversight duties related to food safety issues, including Abbott's compliance with related federal regulations. Based on these facts and as further alleged herein, Alpen, Blount, and McKinstry 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.

434. The safety of infant formula is a central compliance issue for the Company because it has an outsized reputational impact on the Company given how frequently used and widely distributed Abbott's infant formula is in the U.S., and because a contaminated or unsafe product can cause catastrophic harm or death to babies. 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, potentially exposing the Company to stricter regulatory scrutiny, again heightening the need to have robust compliance systems in place.

435. [redacted]

436. [redacted]

437. [redacted]

[redacted]

438. [redacted]

439. [redacted]

440. [redacted]

441. 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.

442. 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.

443. 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. Demand Is Futile for Count IV Concerning Breaches of Fiduciary Duty Claims Alleged Against the Officer Defendants

444. Count IV alleges breaches of fiduciary duty of oversight against the Officer Defendants for consciously breached their fiduciary duties in at least the following ways: (a) repeatedly failing to implement and actively monitor or oversee a compliance and safety program related to Abbott's manufacture and sale of infant formula products in the U.S.; (b) disregarding their duty to investigate red flags and to remedy any misconduct uncovered; and (c) covering up the safety and compliance risks related to Abbott's manufacture and sale of infant formula products in the U.S.

445. Defendant Ford as Abbott's CEO and Chairman faces a substantial likelihood of personal liability for breaching his fiduciary duties as both an officer and a director, and is thus unable to impartially consider a demand to pursue Count IV against himself or the other Officer Defendants. Many of the factual allegations and legal arguments underlying Count IV also underlie other Counts of the complaint. Proving Count IV would require pursuing allegations that would tend to put the remaining directors at increased risk of personal liability on other counts. The remaining Demand Board defendants (Alpern, Babineaux-Fontenot, Blount, Gonzalez, Kumbier, McDew, McKinstry, Roman, Stark, and Stratton) are thus incapable of impartially considering Count IV, and demand is thus excused.

### E. Demand Is Futile for Count V Concerning Insider Trading

446. Count V 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 a majority of the Demand Board cannot impartially consider a demand to pursue Counts III and IV, neither can they consider a demand to pursue Count V.

**F. Demand Is Futile for Count VI Related to Corporate Waste**

447. Count VI alleges corporate waste against the Director Defendants for wasting Abbott's corporate assets by approving the stock repurchase program described above. Eleven Director Defendants remain on Abbott's Demand Board today. For the same reasons that a majority of the Demand Board cannot impartially consider a demand to pursue Count II, neither can they consider a demand to pursue Count VI.

**G. Demand is Futile for Count VII Concerning Unjust Enrichment**

448. Count VII demands disgorgement from Defendants Allen, Battaglia, Calamari, Ford, Funck, House, Manning, Randall, Salvadori, and Young arising from liability to Abbott caused by them being unjustly enriched by compensation in light of their misconduct alleged in the Complaint.

449. 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 VI would require pursuing allegations that would tend to put the remaining directors at increased risk of personal liability on other counts. The remaining Demand 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.

## CLAIMS FOR RELIEF

### COUNT I

### Violation of §14(a) of the Exchange Act Against All of the Proxy Defendants

450. Lead Plaintiffs incorporate by reference the allegations set forth above as if fully set forth herein, except this claim may be alleged on a negligence standard as further described below. In addition, Abbott's exculpation provision in its Articles of Incorporation is inapplicable to this derivative claim because such claim only applies to breach of fiduciary claims, and has no application to federal securities laws. Further, this count is asserted as a derivative claims on behalf of the Company by the Lead Plaintiffs, and not as a direct claim on behalf of shareholders.

451. 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).

452. The Proxy Defendants either knowingly or negligently 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 controls, including Abbott's legal, regulatory and healthcare compliance; (ii) the existence of the 2019 Form 483, the 2021 Form 483, the 2022 Form 483, and related EIRs detailing violations of federal food safety regulations at the Sturgis Plant, resulting in the shut-down of that 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) Abbott's inadequate controls related to ensuring that its manufacture and sale of infant formula products in the U.S. complied with federal food safety regulations and the Company's corporate policies; (v) the existence and failure to address Whistleblower #1's OSHA Complaint, along with 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 manufacture and sale of infant formula products in the U.S.

453. 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.

454. 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 voting regarding directors that were proposed for election to the Board. The proxy-solicitation process in connection with the Proxy Statements was an essential link in and proximate cause of: (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.

455. Lead Plaintiffs, on behalf of Abbott, thereby seek 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.

456. This action was timely commenced within three years of the date of each Proxy Statement and within one year from the time Lead Plaintiffs discovered or reasonably could have discovered the facts on which this claim is based.

**COUNT II**

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

457. Lead Plaintiffs incorporate by reference and reallege each and every allegation contained above, as though fully set forth in this paragraph. In addition, Abbott's exculpation provision in its Articles of Incorporation is inapplicable to this derivative claim because such claim only applies to breach of fiduciary claims, and has no application to federal securities laws. Further, this count is asserted as a derivative claims on behalf of the Company by the Lead Plaintiffs, and not as a direct claim on behalf of shareholders.

458. From 2019 through 2022, in connection with Abbott's repurchases of Abbott shares, Defendants disseminated or caused to be issued false or misleading statements about Abbott, which are specified in Section IX, which they knew or recklessly disregarded were false or misleading and were intended to deceive, manipulate, or defraud. Those false or misleading statements and Defendants' course of conduct were designed to artificially inflate the price of the Company's common stock.

459. At the same time that the price of the Company's common stock was inflated due to the false or misleading statements made by Defendants, they also caused Abbott to repurchase millions of shares of its own common stock at prices that were artificially inflated due to Defendants' false or misleading statements. The 10(b) Defendants engaged in a scheme to defraud Abbott by causing the Company to purchase nearly $6 billion in shares of Abbott stock at artificially inflated process.

460. The 10(b) 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.

461. The 10(b) 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, Defendants were in possession of material, adverse nonpublic information regarding Abbott's unsafe and illegal production and sale of infant formula products in the U.S.

462. 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.

463. As described above, 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 Defendants or were so obvious that Defendants should have been aware of them. Throughout 2019 to 2022, Defendants also had a duty to disclose new information that came to their attention and rendered their prior statements to the market materially false or misleading.

464. 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.

465. As a result of the 10(b) 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 Defendants' false or misleading statements.

466. As a direct and proximate result of the 10(b) 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 10(b) Defendants are liable to the Company pursuant to Section 10(b) of the Exchange Act and SEC Rule 10b-5.

467. Lead Plaintiffs brought this claim within two years of their discovery of the facts constituting the violation and within five years of the violation.

**COUNT III**

**Breach of Fiduciary Duty Against the Director Defendants**

468. Lead Plaintiffs incorporate by reference and reallege each and every allegation set forth above as if fully set forth herein.

469. At all times relevant hereto, each Defendant was the agent of the Company, and was at all times acting within the course and scope of such agency.

470. 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.

471. Defendants breached their fiduciary duties by failing to oversee whether Abbott complied with federal food safety regulations while producing and selling the Company's infant formula products in the U.S.

472. The Director Defendants consciously breached their fiduciary duties in at least the following ways:

i. Repeatedly failing to implement and actively monitor or oversee a compliance and safety program related to Abbott's manufacture and sale of infant formula products in the U.S.;

ii. Disregarding their duty to investigate red flags and to remedy any misconduct uncovered; and

iii. Covering up the safety and compliance risks related to Abbott's manufacture and sale of infant formula products in the U.S.

473. The Director Defendants' actions as detailed in this Complaint were not a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

474. As a direct and proximate result of the Director Defendants' breaches of their fiduciary duties, Abbott has been damaged, not only monetarily, but also with regard to its corporate image and goodwill.

475. Lead Plaintiffs, on behalf of Abbott, have no adequate remedy at law.

**COUNT IV**

**Breach of Fiduciary Duty Against the Officer Defendants**

476. Lead Plaintiffs incorporate by reference and reallege each and every allegation set forth above as if fully set forth herein.

477. The Officer Defendants owed Abbott and its shareholders the highest obligations of due care and loyalty in the administration of the affairs of the Company, including without limitation, operating the company in compliance with laws and without undue risk to public safety,

implementing and overseeing programs to comply with laws and regulations governing the manufacture and sale of Abbott's infant formula products in the U.S., and reporting significant risks to the Board, regulators, and shareholders. In addition, Abbott's exculpation provision in its Articles of Incorporation is inapplicable to the breach of fiduciary claims alleged against the Officer Defendants.

478. The Officer Defendants consciously breached their fiduciary duties in at least the following ways:

i. Repeatedly failing to implement and actively monitor or oversee a compliance and safety program related to Abbott's manufacture and sale of infant formula products in the U.S.;

ii. Disregarding their duty to investigate red flags and to remedy any misconduct uncovered; and

iii. Covering up the safety and compliance risks related to Abbott's manufacture and sale of infant formula products in the U.S.

479. Defendant Ford, as the CEO and President of Abbott since March 2020, was responsible for Abbott's failure to: (a) implement a Board-level information reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during his tenure; (b) maintain the Sturgis Plant in a safe and compliant manner; and (c) ensure its U.S. infant formula products were manufactured and sold in safe and compliant ways.

480. Defendant Allen, as Abbott's Executive Vice President, General Counsel and Secretary since 2013 of Abbott, is responsible for Abbott's failure to: (a) implement a Board-level information reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during his tenure; (b) maintain the Sturgis Plant in a safe and compliant manner; and (c) ensure its U.S. infant formula products were manufactured and sold in safe and compliant ways. Allen is also responsible for failing to inform the Board about Whistleblower #1's complaints, which he received copies of in 2021.

481. Defendant Erica Battaglia, as Abbott's Chief Ethics and Compliance Officer since June 2021, is responsible for Abbott's failure to: (a) implement a Board-level information reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during her tenure; (b) maintain the Sturgis Plant in a safe and compliant manner; and (c) ensure its U.S. infant formula products were manufactured and sold in safe and compliant ways.

482. Defendant Calamari, as Senior Vice President of U.S. Nutrition, is responsible for Abbott's failure to: (a) implement a Board-level information reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during his tenure; (b) maintain the Sturgis Plant in a safe and compliant manner; and (c) ensure its U.S. infant formula products were manufactured and sold in safe and compliant ways. Calamari is also responsible for providing misleading testimony before the House Committee in May 2022.

483. Defendant Funck, as Abbott's Executive Vice President, Finance and CFO since 2020, is responsible for the issuance of misleading proxy statements and Abbott's failure to implement a Board-level information reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during his tenure.

484. Defendant House, as Abbott's Senior Vice President, Quality Assurance, Regulatory and Engineering Services, is responsible for Abbott's failure to: (a) implement a Board-level information reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during his tenure; (b) maintain the Sturgis Plant in a safe and compliant manner; and (c) ensure its U.S. infant formula products were manufactured and sold in safe and compliant ways.

485. Defendant Manning, as Abbott's Executive Vice President of Nutritional Products since 2021, is responsible for Abbott's failure to: (a) implement a Board-level information

reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during his tenure; (b) maintain the Sturgis Plant in a safe and compliant manner; and (c) ensure its U.S. infant formula products were manufactured and sold in safe and compliant ways.

486. Defendant Randall, as Abbott Nutrition's Division Vice-President of Quality Assurance, is responsible for Abbott's failure to: (a) implement a Board-level information reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during his tenure; (b) maintain the Sturgis Plant in a safe and compliant manner; and (c) ensure its U.S. infant formula products were manufactured and sold in safe and compliant ways. Randall is also named as a defendant in the DOJ's Consent Decree.

487. Defendant Salvadori, as Abbott's Executive Vice President and Group President, Established Pharmaceuticals and Nutritional Products, is responsible for Abbott's failure to: (a) implement a Board-level information reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during his tenure; (b) maintain the Sturgis Plant in a safe and compliant manner; and (c) ensure its U.S. infant formula products were manufactured and sold in safe and compliant ways.

488. Defendant Young, as Abbott's Chief Ethics and Compliance Officer until May 2021, is responsible for Abbott's failure to: (a) implement a Board-level information reporting system related to the Company's manufacture and sale of infant formula products in the U.S. during his tenure; (b) maintain the Sturgis Plant in a safe and compliant manner; and (c) ensure its U.S. infant formula products were manufactured and sold in safe and compliant ways.

489. As a direct and proximate result of the Officer Defendants' breaches of their fiduciary duties, Abbott has been damaged, not only monetarily, but also with regard to its corporate image and goodwill.

490. Lead Plaintiffs, on behalf of Abbott, have no adequate remedy at law.

**COUNT V**

**Breach of Fiduciary Duty for Insider Selling Against Defendants Allen, Calamari, Ford, Funck, Manning, McKinstry, Salvadori, and Starks**

491. Lead Plaintiffs incorporate by reference and reallege each and every allegation set forth above as if fully set forth herein.

492. 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. In addition, Abbott's exculpation provision in its Articles of Incorporation is inapplicable to the breach of fiduciary claims for insider selling alleged against the officers charged with this claim.

493. 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, using that information for their own benefit and to the detriment of the Company.

494. 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.

495. Because the use of material nonpublic 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.

## COUNT VI

### Corporate Waste Against the Director Defendants

496. Lead Plaintiffs incorporate by reference and reallege each and every allegation set forth above as if fully set forth herein.

497. The Director Defendants have an obligation to protect Abbott's assets from loss or waste.

498. By approving the stock repurchase program, the Director Defendants have caused Abbott to waste its corporate assets on the repurchase of stock at artificially inflated prices. They caused Abbott to pay prices for Abbott stock that were disproportionately high relative to the actual value of the stock had the truth been fully revealed to the market and therefore that no reasonable person would have paid under the circumstances. In addition, Abbott's exculpation provision in its Articles of Incorporation is inapplicable to the corporate waste claim.

499. As a result of the Director Defendants' corporate waste, the Company has suffered damages.

## COUNT VII

### Unjust Enrichment Against Officer Defendants Allen, Battaglia, Calamari, Ford, Funck, House, Manning, Randall, Salvadori, and Young

500. Lead Plaintiffs incorporate by reference the allegations set forth above as though fully restated herein.

501. Defendants Allen, Battaglia, Calamari, Ford, Funck, House, 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, receiving lavish compensation under circumstances that in equity and good conscience they should not be allowed to take given their

roles in fostering an environment that failed to ensure safe and legally compliant production of infant formula, 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 damages of billions of dollars. The award of this lavish and undeserved compensation was unjust under the circumstances. In addition, Abbott's exculpation provision in its Articles of Incorporation is inapplicable to the unjust enrichment claim.

502. 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 Abbott.

**PRAYER FOR RELIEF**

WHEREFORE, Lead Plaintiffs demand judgment as follows:

A. Declaring that this action is a proper derivative action maintainable under the law and that demand was excused;

B. Declaring that Defendants have breached their fiduciary duties 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 Defendants, jointly and severally;

D. Awarding to Abbott restitution from the Defendants and ordering disgorgement of all salaries, profits, benefits, and other compensation obtained by them, including all salaries, profits, special benefits, compensation, 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, stock option grants, or any other form of compensation), and common stock sale proceeds;

E. Directing Abbott to cancel the votes to re-elect the Director Defendants in connection with the annual shareholder meeting in 2023, and ordering Abbott to revise its 2023 Proxy to correct its false and misleading statements, distribute the revised 2023 Proxy Statement to Abbott's shareholders, and allow its shareholders to re-vote at a special shareholder meeting prior to the annual shareholder meeting in 2024.

F. Directing Defendants to perform all necessary actions to reform and improve Abbott's corporate governance and internal procedures, to enable the Company to comply with its 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 establish and maintain an information reporting system to the Board regarding compliance with food safety standards and manufacturing regulations;

(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 sole approval of the Company's Senior Vice President and Chief Financial Officer or Vice President and Controller, along with implementing additional corporate governance procedures related to the Company's repurchases of its common stock; and

G. Awarding to Lead Plaintiffs the costs and disbursements of the action, including reasonable attorneys' fees, accountants' and experts' fees, costs, and expenses;

H. Awarding pre- and post-judgment interest; and

I. Granting such other and further relief as the Court deems just and equitable.

**JURY DEMAND**

Lead Plaintiffs demand a trial by jury.

Dated: October 16, 2023

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I hereby certify that on October 16, 2023, I electronically filed the Consolidated Amended Verified Stockholders' Derivative Complaint with the Clerk of the Court using the ECF, who in turn sent notice to all counsel of record.

Dated: October 16, 2023

*/s/ Carol V. Gilden*
Carol V. Gilden

**VERIFICATION TO CONSOLIDATED AMENDED STOCKHOLDERS' DERIVATIVE COMPLAINT**

I, Michael O'Malley, Administrator of the International Brotherhood of Teamsters Local No. 710 Pension Fund ("Teamsters Local 710 Pension Fund"), hereby declare and verify that Teamsters Local 710 Pension Fund is a shareholder of Abbott Laboratories as alleged in the attached Consolidated Amended Verified Stockholders' Derivative Complaint ("Amended Complaint"). I have reviewed the Amended Complaint and authorized its filing on behalf of Teamsters Local 710 Pension Fund. I verify that as to those allegations in the Amended Complaint of which I have personal knowledge, I believe those allegations to be true to the best of my knowledge, information, and belief. As to those allegations in the Amended Complaint of which I do not have personal knowledge, I believe those allegations to be true, based on the discussions with and reliance upon my counsel and to the best of my knowledge, information, and belief.

Teamsters Local 710 Pension Fund has not received, been promised or offered, and will not accept any form of compensation, directly or indirectly, for prosecuting this action or serving as a representative party in this action except: (i) such fees, costs, or other payments as the Court expressly approves to be paid to Teamsters Local 710 Pension Fund; or (ii) reimbursement, by its attorneys, of actual and reasonable out-of-pocket expenditures incurred directly in connection with the prosecution of this action.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: October 13, 2023

Michael O'Malley
Administrator
Teamsters Local 710 Pension Fund

**VERIFICATION TO CONSOLIDATED AMENDED STOCKHOLDERS' DERIVATIVE COMPLAINT**

I, Gino Benedetti, General Counsel of Southeastern Pennsylvania Transportation Authority ("SEPTA"), hereby declare and verify that SEPTA is a shareholder of Abbott Laboratories as alleged in the attached Consolidated Amended Verified Stockholders' Derivative Complaint ("Amended Complaint"). I have reviewed the Amended Complaint and authorized its filing on behalf of SEPTA. I verify that as to those allegations in the Amended Complaint of which I have personal knowledge, I believe those allegations to be true to the best of my knowledge, information, and belief. As to those allegations in the Amended Complaint of which I do not have personal knowledge, I believe those allegations to be true, based on the discussions with and reliance upon my counsel and to the best of my knowledge, information, and belief.

SEPTA has not received, been promised or offered, and will not accept any form of compensation, directly or indirectly, for prosecuting this action or serving as a representative party in this action except: (i) such fees, costs, or other payments as the Court expressly approves to be paid to SEPTA; or (ii) reimbursement, by its attorneys, of actual and reasonable out-of-pocket expenditures incurred directly in connection with the prosecution of this action.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: October 13, 2023

Gino Benedetti

Gino Benedetti, General Counsel
Southeastern Pennsylvania Transportation Authority