UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re Perrigo Company PLC Securities Litigation	Case No. 1:25-cv-09596 CLASS ACTION **CORRECTED AMENDED COMPLAINT** JURY TRIAL DEMANDED

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Glossary of Key Terms

Term	Definition / Meaning
CAPA	Corrective and Preventive Action
cGMP	Current good manufacturing practice
C.s.	*Cronobacter sakazakii*
***Cronobacter* spp.**	Cronobacter species generally
CSCA	Consumer Self-Care Americas (Perrigo reporting segment)
EH&S	Environmental Health and Safety
EIR	Establishment Inspection Report
ER	Exceptional Release
FDA	U.S. Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act of 1938
FEs	Former Employees of Perrigo
GDP	Good Documentation Practices
GMP	Good manufacturing practices
HHS	U.S. Department of Health and Human Services
HRA	HRA Pharma (company acquired by Perrigo in May 2022)
KPI	Key Performance Indicator
ODIRs	Operational Deviation Incident Report
ODR	Outside Deviation Report
PID or PI&D	Piping and Instrumentation Diagram (referenced as plant "PID drawings")
PM	Preventative Maintenance
QA	Quality Assurance
QC	Quality Control
RDO	Results Delivery Office
WGS	Whole Genome Sequencing

Lead Plaintiff International Brotherhood of Teamsters Local No. 710 Pension Fund ("Lead Plaintiff"), by and through its undersigned attorneys, Cohen Milstein Sellers & Toll PLLC, brings this action under Sections 10(b), 20(a), and 20A of the U.S. Securities Exchange Act of 1934 (the "Exchange Act"), and U.S. Securities and Exchange Commission ("SEC") Rule 10b-5 promulgated thereunder, on behalf of itself and all persons and entities who or which purchased or otherwise acquired the publicly traded common stock of Perrigo Company PLC ("Perrigo" or the "Company") during the period from November 1, 2022 through November 5, 2025, inclusive (the "Class Period"), subject to certain exclusions (the "Class"), against Defendants Perrigo, Patrick Lockwood-Taylor, Murray Kessler, and Eduardo Bezerra (the "Individual Defendants," together with Perrigo, "Defendants").

The allegations herein are based on Lead Plaintiff's personal knowledge as to its own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of Lead Counsel, which includes a review of SEC filings by Perrigo, securities analysts' reports about the Company, press releases and other public statements issued by the Company, media reports about the Company, interviews of former employees of Perrigo ("FEs") with knowledge of the matters alleged,[1] review of related litigation, and consultation with experts in the areas of U.S. Food and Drug Administration ("FDA") compliance, current good manufacturing practices, due diligence, accounting standards, loss causation, and damages. Lead Counsel's investigation into the matters alleged is ongoing and many relevant facts are known only to, or are exclusively within the custody

[1] Individuals referenced herein as "FE" or "Former Employees" refer to former Perrigo employees interviewed as part of Lead Counsel's investigation of the claims. To protect their identities, all FEs are referred to with male pronouns regardless of their gender. The exact titles and reporting structure of certain FEs have been made less specific in light of those FEs' concerns regarding identification and retribution.

or control of, the Defendants. Lead Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth after a reasonable opportunity for discovery. On behalf of itself and the Class it seeks to represent, Lead Plaintiff alleges as follows:

I. INTRODUCTION

1. This case arises out of Perrigo and its leadership's materially false and misleading statements regarding the Company's most significant product line: infant formula. In reality and unbeknownst to investors, Perrigo's manufacturing facilities and infant formula were frequently contaminated with dangerous bacteria and metal fragments, and produced in facilities where workers stripped to their underwear in 110-degree heat to hand-clean a dryer that the FDA discouraged using for infant formula production. Defendants concealed the true state of their infant formula business and acquisition of the "Gateway" infant formula facility located in Wisconsin ("the Gateway facility" or "Gateway") – artificially inflating the Company's stock price while Defendants personally enriched themselves through insider sales and bonuses tied to the formula business's perceived success, and ultimately destroying over $3.4 billion in shareholder value once the truth was finally revealed.

2. At the start of the Class Period, on November 1, 2022, Perrigo announced the acquisition of the Gateway facility from Nestlé, promising investors it would add 36 million pounds of formula production capacity and be "immediately accretive to net sales, gross margin, and earnings per share." But Defendants concealed that Gateway was a facility that Nestlé had run into the ground in the year leading up to the acquisition and, in the words of a former employee, "dumped" after years of deferred maintenance. Gateway's key piece of equipment, the dryer that converted liquid formula slurry into powdered formula, was over 30 years old and riddled with expanding micro-cracks that created harborage sites for deadly *Cronobacter* bacteria (referred to herein as "*Cronobacter*," '*Cronobacter sakazakii*," or "C.s."); its roof leaked into high-sanitation

areas during rainstorms; and just months before the acquisition, the FDA issued a Warning Letter to the plant after finding eleven separate *Cronobacter* positives, water leaking into sensitive processing zones, and that the plant "did not establish a system of process controls . . . designed to ensure that infant formula does not become adulterated."

3. Throughout the Class Period, Defendants repeatedly assured investors that Perrigo was "achieving industry-leading quality control at near historical record production levels"; and that the Company's plants were "extremely well-disciplined well-run plants with GMPs that drive quality production." In reality, both Gateway and Perrigo's pre-existing Vermont formula facility were in violation of FDA regulations and did not reliably produce safe, sanitary infant formula at the levels touted by Defendants. Gateway produced at only 40-50% of expected capacity in 2024 and operated for only approximately six months out of twelve in 2025, crippled by frequent *Cronobacter* contamination, equipment failures, and emergency shutdowns. Although Defendants reassured investors that they were taking remedial action and the plant was "reset," the FDA concluded Perrigo was not taking ***any*** proactive actions to address the resident strains of *Cronobacter* at Gateway. As for the Vermont facility, it was a converted dairy facility ill-suited for infant formula production that used a standard industrial boiler rather than the culinary-grade boiler required for powdered infant formula production; had porous dairy-brick flooring that fostered bacterial growth; had a fire on the roof due to a poorly maintained HVAC system;[2] and prior to the Class Period had consultants advise Perrigo that its dryers were beyond repair and needed to be replaced, which Perrigo ignored.

4. Over the course of the Class Period, *Cronobacter* contamination escalated from positives in the environment and on equipment to positives in actual finished product, forcing

[2] "HVAC" refers to the Heating, Ventilation, and Air Conditioning system.

Perrigo to scrap massive volumes of formula. Metal shards contaminated the formula so frequently that there was a period when employees worked full-time filtering formula under microscopes in a desperate effort to salvage portions of contaminated batches. Perrigo's employees believed the metal contamination was caused by something shredding inside a machine and asked management to slow down and figure out the cause of the problem, but Perrigo refused in order to keep production moving forward. Over the Class Period, Perrigo had to recall formula on multiple occasions due to *Cronobacter* or errors in the formulation. By 2024, Perrigo's chronic inability to fill orders cost it a crucial customer: Target.

5. While making consistent positive statements, Defendants knew and had access to information that contradicted their representations about the Gateway acquisition, Perrigo's infant formula business, and their impact on earnings per share and production capacity. Defendant CEO Patrick Lockwood-Taylor ("Lockwood-Taylor") told investors he was "very close to the remediation work" and personally chaired Perrigo's Steering Committee. Defendant Lockwood-Taylor was promptly notified every time there was a positive *Cronobacter* hit at one of the formula facilities. He personally selected an outside consulting firm to bring in, Validant, at a cost of approximately $27 million, and visited Gateway to announce its shutdown for a "reset." Those consultants produced detailed reports – shared directly with Lockwood-Taylor and the Steering Committee – documenting systemic failures in Gateway's environmental monitoring program, food code violations, sanitation deficiencies, and inexperienced Quality Department personnel. But rather than make the capital investments needed to fix the root causes – replacing the cracked dryers, repairing the leaking roofs, redesigning contamination-prone processes – Defendants ignored the consultants' recommendation and directed money toward superficial cleaning and then repeatedly told investors the plants were "reset" and that costs were "one-time" only. As late as

February 2025, Defendants doubled down, announcing a $240 million "strategic investment" in the infant formula business and projecting it would generate $100 million in annual free cash flow by 2028. Just nine months later, Perrigo abandoned the business entirely.

6. The truth was gradually revealed to investors through a series of partial disclosures – including unexpected remediation costs of $35 to $45 million, lower-than-expected earnings per share, and millions of dollars in scrapped product – but each time, Defendants falsely reassured investors with claims that the facilities were "fully compliant and operationally reliable," and that the "big intervention[s]" were "largely done." And Perrigo blamed low production or lost sales on changes due to the FDA's "evolving industry guidelines" rather than Perrigo's own systemic failures. These claims were false comfort; the Gateway and Vermont facilities were in violation of FDA regulations long before a competitor's Cronobacter contamination triggered a nationwide recall and formula shortage, and Perrigo continued to fail to comply with the FDA's specific requests for heightened attention to controlling water and implementing appropriate corrective actions after that event.

7. Finally, to investors' surprise, on November 5, 2025, Perrigo announced a "strategic review" of the infant formula business – effectively abandoning the enterprise – and slashed its earnings guidance. On this news, Perrigo's stock price fell $5.09, or 25.2%, to close at $15.10 per share, a loss of approximately ***$1 billion*** in market capitalization in a single day. Just a few months after the Class Period ended, Perrigo recognized a $1.3 billion goodwill impairment and eliminated infant formula from "CORE Perrigo," its "go-forward business," while the FDA issued yet another Form 483 to Gateway.

8. While Defendants concealed the truth from their investors, they personally profited. Defendants Lockwood-Taylor and Bezerra's bonuses were tied to the perceived success of the

Gateway acquisition and the infant formula business, creating a strong motive to conceal the fundamental problems. And Defendant Kessler sold over $7 million of his Perrigo common stock at artificially inflated prices just two weeks after the FDA issued a non-public Form 483 identifying multiple *Cronobacter* positives and serious systemic failures at Gateway.

9. As a consequence of Defendants' fraud, and following the series of disclosures of corrective information, Perrigo's stock price collapsed from its Class Period high of $40.11 on the first day of the Class Period to $15.10 after the final corrective disclosure, a difference of $25.01 or a -62.35% decline that inflicted massive losses on Perrigo's investors.

II. JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1331.

11. Venue is proper in the Southern District of New York pursuant to 28 U.S.C. § 1391 and Section 27 of the Exchange Act, in that many of the acts, transactions and occurrences alleged herein occurred in this District, and all of the Defendants conducted business here in connection with the events described herein. Defendants directly or indirectly made use of the means or instrumentalities of interstate commerce including the mails in connection with the conduct alleged herein.

III. PARTIES

A. Lead Plaintiff

12. Lead Plaintiff International Brotherhood of Teamsters Local 710 Pension Fund is a Taft-Hartley defined benefit pension fund located in Mokena, Illinois, with approximately 21,000 active participants and over $3.5 billion in plan assets. Lead Plaintiff purchased or acquired Perrigo common stock during the Class Period and was harmed by the misconduct alleged in this matter, as set forth in Exhibit A.

B. Defendants

13. Defendant Perrigo is a consumer products company that manufactures, produces, and distributes private and generic over-the-counter self-care products. Perrigo is incorporated under the laws of Ireland and maintains its corporate headquarters in Dublin. Perrigo trades on the New York Stock Exchange ("NYSE") under the ticker "PRGO" and did so throughout the Class Period.

14. Defendant Patrick Lockwood-Taylor ("Lockwood-Taylor") has been Perrigo's Chief Executive Officer ("CEO") since June 30, 2023.

15. Defendant Murray Kessler ("Kessler") was Perrigo's Chief Executive Officer from October 2018 to June 30, 2023.

16. Defendant Eduardo Bezerra ("Bezerra") has been Perrigo's Chief Financial Officer ("CFO") and Executive Vice President since May 2022.

C. Relevant Non-Parties

17. FE1 was employed at Perrigo from February 2024 through October 2024. FE1 was employed as a Quality Specialist – Plant Hygienist. He worked at the Gateway facility. FE1 worked twelve-hour shifts on the facility floor and moved across every area of the facility, so had direct insight into quality and sanitation across the whole Gateway facility. FE1 joined Perrigo right as the transition was taking place following Perrigo's takeover of Gateway from Nestlé. During the recruiting and interviewing process, he had a positive impression of Perrigo and moved across the country for the position. But upon arrival, FE1 quickly realized that the plant was not in great condition and required extensive work. In his view, Perrigo did not seem interested in taking on that work. FE1 reported to Lacy Niebruegge, a hygiene supervisor who in turn reported to a separate Quality team leader.

18. FE2 was employed by Perrigo from October 2022 through April 2024. FE2 served in the Maintenance group. FE2 worked at Perrigo's plant in Vermont, supporting production of infant formula. In this role, FE2 was responsible for overseeing installation and maintaining machinery, instrumentation, and hardware and software. In FE2's role, he was directly involved in the infant formula production process from start to finish, including working with machinery at Perrigo's pilot plant where formula was tested and produced at small scale, and full-scale production from raw inputs to finished product including the dryers, packaging lines, cleaning systems, maintenance, and process controls. Prior to this role, FE2 had experience in the design and certification of clean and sanitary environments.

19. FE3 worked for Perrigo at the Vermont infant formula facility during the entire Class Period. In his role, FE3 worked directly with the infant formula, including to support its quality and consistency.

20. FE4 was employed at the Gateway facility in Eau Claire, Wisconsin, starting in 2013, when Nestlé owned the facility. He continued working at the facility through the transition to ownership by Perrigo, before leaving in December 2025. During his time at the Gateway facility, FE4 worked as a dryer operator, a production supervisor, and then in a new role as production manager from approximately June 2024 until his departure. In his role as production manager, FE4 oversaw all day-to-day operations associated with the liquid processing systems and spray-drying lines. FE4 managed approximately fifty to fifty-five employees, both direct and indirect. A second production manager oversaw warehousing, packaging, and logistics with a similar number of personnel. In his role as production manager, FE4 reported directly to Operations Manager Omar Mendez starting in the fall of 2024.

21. FE5 was employed at Perrigo from November 2022, when Perrigo acquired the Gateway facility, until his retirement in June 2024. FE5 spent his entire career – approximately 30 years – at the Gateway facility and Nestlé's "sister factory," also located in Eau Claire, Wisconsin. From approximately 2019 onward, however, FE5 worked exclusively at Gateway. FE5 worked as a Senior Quality Systems Expert (also known as a Senior Quality Systems Specialist). FE5 described his primary responsibilities as focused on quality systems. FE5's role included internal audits, document control, change management, recall and traceability management, and managing corrective action systems arising from audit findings and gaps. FE5 explained that he was heavily involved whenever the facility was audited, including FDA inspections, and served as a principal point of contact for assembling and reviewing quality system documentation. During audits, he would walk regulators through records, provide supporting materials, and participate alongside management. While deeply involved in audit preparation and execution, FE5 clarified that formal regulatory communications with the FDA were handled by Quality Manager Kristi Knudtson ("Knudtson"),[3] not by FE5 directly. Besides FE5, Knudtson and Victoria Neuman ("Neuman"),[4] a Quality Supervisor, would be in attendance for the entirety of an inspection. As needed, they would also bring in other specialists to answer particular audit questions. Throughout his tenure, FE5 reported to Knudtson, who served as Quality Manager during the later Nestlé years and continued in that role following Perrigo's acquisition. As a result, FE5's reporting line remained consistent before and after the ownership transition.

22. FE6 worked at Perrigo from January 2025 to January 2026. FE6 was a Chemistry Lab Supervisor, working at the Vermont infant formula facility. FE6's role was in Quality Control

[3] Senior Quality Manager at Gateway.
[4] Quality Assurance Manager at Gateway.

and involved chemical testing to ensure that the infant formula product met the label claims, including with respect to vital minerals and nutrients. This process ensured that the formula that went out to customers was as represented on the label. His role included review of the results of in-process testing during the manufacturing process, release testing at the end of the manufacturing cycle, and stability testing after the product had been completed and rested. FE6 also oversaw the laboratory and employees involved in this testing process.

23. FE7 was employed at Perrigo in the Gateway facility from September 2023 until January 2026. FE7's last title before he left was as an Associate Manager – Food and Safety Validation. FE7's first role at the Gateway facility was as a Quality Specialist, later titled a Quality Engineer. In that role, FE7's responsibilities included conducting investigations of deviations in the infant formula manufacturing process. FE7 reported to Senior Quality Assurance Manager Kristi Knudtson. Knudtson, in turn, reported to a Senior Director of Quality named Brent (FE7 does not recall his last name) for the first 6-7 months of FE7's employment. Brent was later replaced by Guillermo Guillen ("Guillen").[5] Knudtson was promoted to a role external to Gateway in 2024, although he continued to report to Guillen. Neuman was promoted to Quality Manager, and FE7 began reporting to her. In December 2024, Jesus Hernandez ("Hernandez")[6] was hired as Director of Quality, replacing Knudtson.

24. FE8 worked at Perrigo from 2016 to April 2024. He worked at Perrigo's infant formula facility in Vermont. He was hired as the Environmental Health and Safety ("EH&S") engineer and advanced to EH&S Manager by the time he left. FE8's role focused on employee health and safety at the plant. This included OSHA logs, workmen's compensation, employee

[5] Senior Director of Quality.
[6] Director of Quality.

injuries, and security at the plant. Because health and safety were implicated by all significant projects and engineering projects, FE8 was involved in all major projects at the plant. Additionally, his role included walking external vendors and consultants around when they were at the plant, to ensure physical safety.

25. FE9 was employed by Perrigo for many years before the Class Period until March 2024. During the Class Period, he worked in project management. In his role, FE9 interacted with the Results Delivery Office ("RDO"). The RDO is responsible for overseeing and tracking improvement programs and initiatives across the organization which during the Class Period included the Supply Chain Reinvention Program.

26. FE10 was employed by Perrigo from 2005 until November 2022. He worked at the Vermont facility. In his final role, he served as a Director of Nutrition Research and Development.

27. FE11 was employed by Perrigo from October 2022 through April 2024. FE11 served as a senior process engineer. FE11 worked at Perrigo's plant in Vermont, supporting production of infant formula. FE11's role focused on processes to ensure safety and compliance. His duties included leading the Clean-in-Place validation work, supporting and creating necessary continuous improvement initiatives, project management and support of upgrades during annual shutdown of the tub filler line, and beyond. FE11 has an engineering degree and prior experience in Clean-in-Place Validation, which is a process for verifying and confirming the accuracy and reliability of contaminant detection. At Perrigo, the primary concern was *Cronobacter*, and other bacteria that can cause fatal infections in infants after consuming infant formula containing this bacteria species and others. In prior engineering roles, FE11 learned of the necessary activities to verify and validate Clean-in-Place processes. The same methodology must be used to eliminate

the risk of *Cronobacter* contamination in infant formula manufacturing facilities. FE11 wrote numerous Requests for Proposals ("RFP") for work to be performed by consultants.

IV. SUMMARY OF THE FRAUD

A. Perrigo Enters the Infant Formula Business

28. Perrigo is a consumer products company that manufactures, produces, and distributes private and generic over-the-counter self-care products. Perrigo's North American Corporate Headquarters is in Michigan.

29. Perrigo first entered the infant formula business in 1998.

30. In 2010, Perrigo acquired PBM Holdings, Inc., the leading store-brand infant formula manufacturer.[7]

31. The U.S. infant formula industry is highly concentrated, with a small number of companies manufacturing most formula products on the market: Abbott Laboratories ("Abbott"), Mead Johnson (owned by Reckitt Benckiser), Nestlé, and Perrigo.

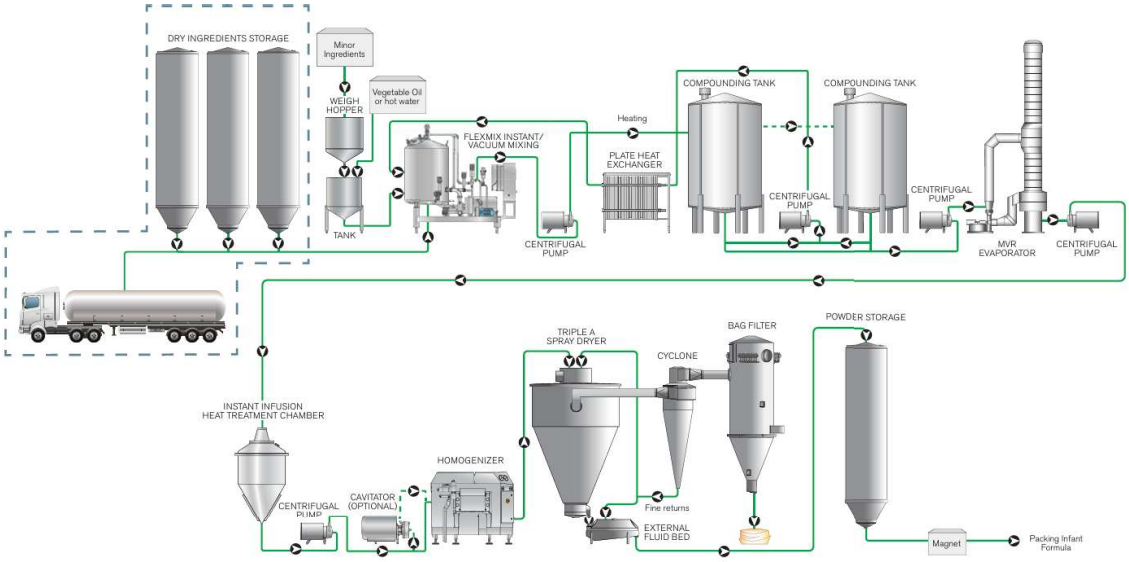
32. In its financial statements, Perrigo reports infant formula within the Consumer Self-Care Americas ("CSCA") segment, under the "Nutrition" product category.

33. During the Class Period, infant formula accounted for 85% to 95% of the Nutrition category and was a critical cash generator for the Company's higher-growth segments. Defendants regularly discussed how Perrigo's "unique complementary businesses enables each individually to play a specific reinforcing role" where "store brands and infant formula generate cash investments for the Company's key higher margin, higher growth or 'High Grow' brands."

[7] Certain FDA documents refer to PBM Nutritionals, LLC, in connection with the Vermont facility.

B. The Infant Formula Manufacturing Process

34. The following graphic depicts the typical steps in the infant formula manufacturing process:[8]



35. Specific conditions must be maintained during the manufacturing process to ensure the infant formula is safe, sanitary, and meets product specifications (such as the specific claims regarding amount of vitamins and nutrients in the formula). Different risks are present at each stage of the process.

36. First, after ingredients are prepared and weighed, dry ingredients are solubilized in water in tanks. Those ingredients must be kept at a specific temperature and mixed in a specific way. Wet ingredients are mixed in large tanks and must be kept at a specific temperature. The liquid product then undergoes pasteurization, a process of heating to reduce microbes in the product. The liquid product is fed to a vacuum evaporator to reduce the moisture content in order to increase the percentage of the total product that is solid and prepare the product for spray drying.

[8] *Full Production Cycle*, HIPLAC (last visited April 28, 2026), https://hiplac.eu/full-production-cycle. (graphic under heading "From Base Powder to Infant Food").

The key equipment for these steps includes stainless steel tanks, mixers, piping, pumps, and heating for the tanks. Particular risks at this phase include the use of improper ingredients, adding the incorrect amount of ingredients, incorrect temperature, improper mixing, leaks, improper vacuum or low evaporation rate, exposure of the product to the environment, and contamination from the environment, personnel, or equipment.

37. Second, the liquid product is fed to a spray dryer, which uses heat and hot air to convert the thick liquid formula product (referred to as "slurry") into a powder. The key equipment for this step is the spray dryer and associated equipment (air blowers, heaters, fluid bed, cyclone separator, bag filter). Dryers used in modern infant formula manufacturing are typically multiple stories tall with platforms at each story allowing access for cleaning and maintenance, as depicted below:

38. Dryers are typically closed to the external environment to maintain sanitation. There are heightened risks here due to the maintenance needs and complexity of the equipment; spray dryers are subject to cracking, as well as problems with drying and the Clean-in-Place cycle.[9] This can result in serious issues including contamination, insufficient drying, scorching or burning, clumping, breach of the equipment making it open to the environment, leaks of water or air, improper flow rates, and insufficient spray dispersion.

39. Third, after the powdered formula is dry, it is cooled, sifted, and packaged. The risks at this stage include exposure to the environment, metal or bacterial contamination, poor sifting, low or high fill in the can, and improper closure.

40. Particular attention to cleanliness and sanitation must be taken with powdered formula because it does not go through a heat sterilization process and so is considered non-sterile. Accordingly, powdered formula manufacturers must do "environmental monitoring" which tests the equipment and surrounding surfaces to make sure the environment is kept clean, and "finished product testing" to make sure the powdered formula is pathogen free.

41. The FDA's efforts to ensure "pathogen free" formula focuses particularly on two bacteria: the *Cronobacter* species and *Salmonella* species.[10] These two species are known to cause foodborne illnesses in sensitive infants, and thus FDA requires testing for these two specifically in

[9] "Clean-in-Place" refers to an automatic process of cleaning the interior of industrial machinery by circulating cleaning, rinsing, and sanitizing solutions from within the machinery, without disassembling the machinery. When done properly, this reduces the time and labor of disassembling and reassembling machinery and attendant potential contamination, and reduces worker exposure to cleaning chemicals.

[10] FDA, Compliance Program Manual, Program 7321.006, *Infant Formula Program – Inspection, Sample Collection and Examination*, Transmittal No. 2023-CPM-HFP-004 (Sept. 28, 2023) (pen and ink changes made Aug. 5, 2025).

every batch of infant formula before release for sale.[11]

42. While infections from *Cronobacter* are rare, they can be deadly for infants, causing necrotizing enterocolitis and invasive infections such as meningitis, pneumonia, and sepsis.[12] *Cronobacter*'s ability to form biofilms – structured communities of bacteria that adheres to a surface and are encased in a protective extracellular matrix – renders it particularly problematic. The bacteria can establish, grow, and persist in so-called "harborage" sites, becoming a recurring source of contamination in a plant. Biofilms also render the protected bacteria more resistant to cleaning agents.

43. Most bacterial contamination, including *Cronobacter*, comes from people or water. It is therefore critical for manufacturers to implement sufficient controls to prevent and mitigate moisture and water; regulate the movement of people, ingredients, and equipment into and around the plant to prevent *Cronobacter* from traveling with them; and ensure proper gowning.

C. The Regulatory Framework and Inspection Process

44. The manufacturing process for infant formula is highly regulated. As a manufacturer of infant formula, Perrigo must comply with federal food safety regulations, among other laws. Non-compliance presents a significant legal, safety, and reputational risk for the Company.

45. The Food, Drug, and Cosmetic Act of 1938 ("FDCA") provides the statutory framework for regulating food safety, including Perrigo's infant formula products. The FDCA's purpose is to protect consumers from adulterated food, defined as food that "consists in whole or

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[11] FDA, *Handling Infant Formula Safely: What You Need to Know*, https://www.fda.gov/food/buy-store-serve-safe-food/handling-infant-formula-safely-what-you-need-know (last visited May 1, 2026).

[12] *About Cronobacter Infection*, Ctrs. for Disease Control & Prevention (Sep. 29, 2025, https://www.cdc.gov/cronobacter/about/index.html.

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).

46. Under the FDCA's implementing regulations, infant formula manufacturers must 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).

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

48. The cGMPs require an infant formula manufacturer, like Perrigo, to implement a system of production and process controls that cover all stages of the manufacturing process, from receiving raw materials, to manufacturing, to storing and distributing the finished formula product. 21 C.F.R. § 106.6(a), (b).

49. Manufacturers are required to have trained and experienced personnel to ensure the formula meets certain specifications. 21 C.F.R. § 106.6(c)(4); 21 C.F.R. § 106.6(c)(5).

50. Manufacturers are required to keep records and have procedures for handling and investigating all complaints that indicate a possible health hazard; failure to comply renders infant formulas adulterated. 21 U.S.C. §350a(b)(4); 21 C.F.R. §106.100(k) (2015).

51. The FDA monitors compliance with the FDCA, but is not a substitute for a company's own quality and compliance systems.

52. The FDA generally inspects infant formula plants once a year, but can inspect more frequently. In a more routine inspection, the FDA identifies "management discussion items,"

typically related to risk areas or industry standards. These items are discussed with the firm and written down in an Establishment Inspection Report ("EIR").

53. If the FDA observes conditions that may constitute violations of the FDCA, they can issue a Form 483, which contains a list of the specific violations called "observations."

54. If a Form 483 is issued, the company is required to formally answer the FDA's observations within fifteen business days with a root cause analysis, impact assessment, and proposed corrective and preventative actions.

55. If a company's response is inadequate, the FDA may issue a Warning Letter.

56. Pursuant to the FDA Investigations Operations Manual, if a Form 483 is issued, it is provided to "the most responsible person available at the close of the inspection[,]" and "[a] copy [of the Form 483] should be sent to the top management of the firm." FDA Investigations Operations Manual, Ch. 5, § 5.2.3.6.

57. As a practical matter, FDA inspections are not exhaustive. In the industry, this is described as not being a "100% inspection." There simply is not enough time or resources to inspect every potential issue in a facility and inspectors may not have sufficient training and experience to identify and understand all concerns. Inspectors cover a broad range of food products from canned to dried to imports to infant formula, all of which have different requirements, risk factors, science, and applicable laws, regulations, policies, guidelines, and inspection guides. As a result, cGMP and FDCA violations can be missed – making a company's own quality systems all the more critical.

D. Perrigo Announces Expansion of Vermont Formula Facility

58. Prior to the start of the Class Period, Perrigo had two infant formula manufacturing facilities: one in Georgia, Vermont ("the Vermont facility") and one in Covington, Ohio.

59. The Vermont facility was Perrigo's legacy plant, employing nearly three times as many people as its Ohio counterpart (420 employees in Vermont compared to 120 employees in Ohio). The Ohio plant was in significantly better condition than the Vermont facility. According to FE8, the Ohio facility had a brand-new floor, made significant improvements to many of their processes, and their wet process was significantly different than the Vermont facility. The different flooring made a huge difference in the cleanability of that facility compared to Vermont.[13]

60. Perrigo and then-CEO Defendant Kessler frequently touted infant formula as a strategic focus and core growth opportunity for the Company. Perrigo and its leadership repeatedly described infant formula and the Nutrition category as one of five "product growth priorities" or "growth pillars" for the Company, as well as a "key platform for . . . investment."

61. The Company told investors that demand for its infant formula was outpacing the production capability at its two facilities and that the Company was "maxed out" and having "major capacity issues."

62. Accordingly, Perrigo, under the leadership of Defendant Kessler, obtained authorization from Perrigo's Board of Directors for a $300 million investment to build a new infant formula facility in Vermont. Kessler acknowledged that the Company's existing Vermont facility was "nearing the end of its useful life" and that to date, the Company had not "appropriately invested to ensure we have the most state-of-the-art infant formula plants which are capable of meeting demand" but with the new facility investment, "[t]hat has changed."

[13] FE8 had counterparts in similar EH&S roles in Perrigo's formula plants in Ohio and Wisconsin and traveled regularly to Ohio to assist and train his counterpart there, who was more junior.

63. Perrigo's plan was to build the new facility on the same large parcel of land where its current infant formula facility was situated, and the construction timeline was approximately two-and-a-half years with formula production at the site expected to begin in 2023.

E. The Abbott Recall Triggered a Nationwide Formula Shortage and Opened U.S. Markets to Foreign Formula Manufacturers

64. On February 17, 2022, Abbott, one of Perrigo's few competitors, announced a massive recall after potential *Cronobacter* contamination at its main infant formula manufacturing plant in Sturgis, Michigan, and multiple deaths or illnesses in infants who consumed Abbott's formula manufactured there.[14] This triggered a massive increase in demand for infant formula from other U.S. manufacturers, like Perrigo.

65. While Perrigo received an initial boost in market share due to the Abbott recall, the Company was unable to fully satisfy the heightened demand. Defendant Kessler explained that despite the Company's plants running "around the clock" and at "117% of [their] normal full capacity . . . we won't keep up with all of the demand."

66. A nationwide infant formula shortage followed. Within months, the federal government issued new guidance allowing foreign-manufactured formula into the U.S. market, and then-President Joe Biden launched "Operation Fly Formula" to speed the importation of foreign-manufactured infant formula. Additionally, then-President Biden invoked the Defense

[14] *See* Fed. Trade Comm'n, *Market Factors Relevant to Infant Formula Disruption 2022: A Report of the Federal Trade Commission*, (Mar. 13, 2024), https://www.ftc.gov/system/files/ftc_gov/pdf/infant_formula_report_final.pdf.

Production Act to ensure formula manufacturers would be given priority for necessary ingredients.

F. In Spring 2022, the FDA Issues a Form 483 to Gateway; Perrigo Conducts Due Diligence in Connection with a Potential Acquisition of Gateway for "Well Over a Year"

67. Just a few weeks after the Abbott recall announcement, on March 5, 2022, the FDA initiated an inspection of the Gateway facility (at the time still under Nestlé ownership). The eight-member team was unusually large for a routine inspection and included six FDA investigators, one national expert, and a milk specialist. The inspection lasted for over a month.

68. At the end of the inspection, on April 14, 2022, the FDA team issued a Form 483 (the "April 2022 Form 483" at Exhibit B), addressed to then-Factory Manager Dominik Painter ("Painter"). The April 2022 Form 483 set forth significant concerns related to *Cronobacter* contamination in the facility and inadequate sanitation systems and processes.

69. The FDA identified multiple "objectionable conditions and practices," including that the Gateway Plant "did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment." Additionally:

a. The FDA identified *Cronobacter sakazakii* in environmental swabs collected by the FDA and four sister swabs, including in high hygiene areas such as the dryer or dryer area, and even in a batch of infant formula;

b. The FDA observed water leaks or pooling in the processing environment, including the dryer or dryer area while actively drying infant formula powder; and

c. The FDA identified personnel who were working directly with infant formula but were not wearing required protective apparel.

70. The FDA's issuance of the April 2022 Form 483, combined with information known or available to Perrigo at the time of the acquisition and the accounts from FEs of the state

of the facility, reflected the systemic failures at the Gateway facility and its key equipment that limited the facility's ability to reliably produce safe and sanitary formula and meet production metrics. Significantly, the problems at Gateway observed by FEs *(e.g.*, micro-cracks in the dryer and a leaking roof) and documented by the FDA *(e.g.*, systemic *Cronobacter* contamination in the dryer area, water dripping from equipment in sensitive areas) – matched the problems at the Abbott plant where the formula giving rise to the company's massive recall was manufactured. According to FE1, those problems had persisted at Gateway for years, as reflected in maintenance logs and Form 483s that were maintained.

71. Unbeknownst to investors at the time, in this very same period that the FDA issued the April 2022 Form 483 with its alarming findings, Perrigo was conducting due diligence on the Gateway plant. *See infra* ¶¶ 76, 638. In the spring of 2020, FE10 went to the Nestlé Gateway facility to perform due diligence for Perrigo before they purchased the facility. They made product trials in the fall of 2020. FE10 visited the facility in his role as part of the Research and Development team to look at the Gateway facility's operations. Perrigo also sent a larger Quality team to review the Gateway facility. According to FE10, Perrigo was aware of the problems at the Gateway facility before purchasing it. The facility was 40 years old and had many of the same problems as the Vermont facility. Older facilities such as Gateway are notoriously difficult to keep running and maintain cleanliness. They are also capital-intensive, requiring huge multi-million-dollar investments every year for routine maintenance alone. After visiting the Gateway facility and conducting due diligence, FE10 was surprised that Perrigo opted to purchase Gateway.

72. Soon after, on September 14, 2022, there was a regulatory meeting between the FDA and Gateway.

G. The Class Period Begins: Perrigo Announces the Gateway Plant Acquisition

73. A few weeks later, at the start of the Class Period, on November 1, 2022, Perrigo

announced its bold plan to increase the Company's formula production capacity: the acquisition of the Gateway infant formula plant in Eau Claire, Wisconsin plant from Nestlé, along with the U.S. and Canadian rights for Nestlé's Good Start® branded formula.

74. In the press release that day announcing their "Strategic Investment to Expand and Strengthen U.S. Manufacturing of Infant Formula." Perrigo claimed the Gateway facility would add "***a total of 36 million pounds of capacity to Perrigo***" within just 18 months (*e.g.*, by May 2023). Perrigo also told investors that it "expects the purchase of the Gateway infant formula plant, along with the rights to the Good Start® infant formula brand, to be ***immediately accretive to net sales, gross margin, and earnings per share***."[15]

75. On November 8, 2022, Perrigo held an earnings call for the third quarter of 2022 (the "Q3 2022 Call"), which Defendants Kessler and Bezerra participated in. During the call, Defendant Kessler explained that the Company abandoned its previously announced plan to increase formula capacity with the construction of a new plant in Vermont because the "greenfield project . . . ***didn't pass the environmentals***." Defendant Kessler touted the switch from the new construction plan to the Gateway acquisition as a positive development, explaining it "***finally solves the capacity problem and at nearly half the cost."***

76. Defendant Kessler reassured investors that the Gateway acquisition was not a hasty decision but rather they had been "working on this for well over a year" – before the Abbott recall and nationwide formula shortage, and before the April 2022 Form 483.

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[15] This announcement followed a spree of acquisitions that Perrigo undertook between 2020 and 2022: Steripod, a toothbrush accessory/protector brand for $26 million; Dexsil, a silicon supplement brand, for approximately $8 million; the oral care assets of High Ridge Brands for $106.2 million (2020-11-05 – 10Q); three European OTC dermatological brands for $62.3 million; and Heras SAS ("HRA Pharma"), a consumer self-care company for approximately $1.6 billion. As with the Gateway acquisition, Kessler consistently touted each deal as "revenue-accretive and "key drivers" of Perrigo's growth strategy.

77. Defendant Kessler touted the acquisition's near-term benefits, emphasizing that the "***Gateway and Good Start brand infant formula acquisition is the primary driver***" of an expected $50 to $70 million in incremental operating income next year, and that "***[t]his purchase is highly accretive with an expected operating profit contribution in 2023 of more than $50 million***, part from the Good Start brand and an equal part from additional volume we can now run through this network to support our current customers."

78. Defendant Kessler noted lower formula sales in the third quarter due to quality issues at the Vermont facility. He explained those issues were caused by increased production runs in response to the nationwide formula shortage, but reassured investors that "***[t]o remedy this situation we paused the Vermont facility for three weeks to do proper maintenance***" and "***[t]he facility is back up and running*** . . ."

79. Analysts reacted positively to these claims about the Gateway acquisition and Perrigo's infant formula business. For example, Wells Fargo commented that, while Perrigo had suffered a "painful" quarter, the stock was nevertheless "an attractive long over the next 12+ months at <12x earnings," in part because the "Gateway investment should help to resolve existing plant issues." J.P.Morgan similarly averred it was maintaining the stock's "overweight" rating, citing Perrigo's increased sales estimates "due to the recently acquired infant formula plant."

80. But unbeknownst to the market, Perrigo and Defendant Kessler's claims were false and misleading. Their November 1 and 8 representations that Gateway and Good Start acquisition would add 36 million pounds of production capacity, be immediately accretive to net sales, gross margin, and earnings per share," and drive "$50 million to $70 million in incremental operating income next year" concealed that the Gateway and Vermont facilities suffered from systemic defects limiting production capacity and thus infant formula's ability to drive Perrigo's finances

and earnings per share. Their claims also concealed certain material reasons for the acquisition.

1. Gateway's Violations of FDA Regulations and cGMPs

81. In the "well over a year" that Perrigo was working on the acquisition, there were clear red flags about the systemic quality and sanitation issues at Gateway and its violations of FDA regulations and cGMPs.

82. Most blatantly, the FDA issued the April 2022 Form 483 to Gateway just months before the acquisition, flagging several regulatory violations and concerning conditions, including positive *Cronobacter* hits in high-hygiene areas and water leaks.

83. ***Nestlé's deferred maintenance and disinvestment.*** According to multiple former employees, Nestlé ran the facility into the ground before the acquisition.

84. FE4 started working at Gateway in 2013, nearly a decade before the acquisition. He described the final twelve to eighteen months under Nestlé ownership as a period of clear disinvestment in the facility in preparation to sell it. FE4 explained that during this time, the company started to run the factory 24 hours a day, seven days a week, while at the same time failing to backfill roles or conduct regular maintenance. The facility was operating with extremely lean staffing, at one point having only three supervisors, plus one "float" supervisor, to cover the constant operation. FE5, who spent his entire 30-year career at the Gateway facility and Nestlé's "sister factory," also located in Eau Claire, Wisconsin, and had been at Gateway exclusively since 2019, corroborated that in the year or two prior to Perrigo's acquisition of Gateway, Nestlé stopped conducting annual shutdowns of the plant in order to perform maintenance work. After the maintenance manager quit because his "hands were tied" by the inadequate maintenance budget, Nestlé refused to fill the role. As a result, key tasks including tracking and conducting regular preventative maintenance, calibrating and monitoring equipment, and conducting root cause analyses for equipment issues were neglected.

85. In the spring of 2020, FE10 went to the Nestlé Gateway plant to perform due diligence for Perrigo before they purchased the plant. They made product trials in the fall of 2020. FE10 visited the plant in his role as part of the Research and Development team to look at the Gateway plant's operations. Perrigo also sent a larger Quality team to review the Gateway plant. According to FE10, Perrigo was aware of the problems at the Gateway plant before purchasing it. The plant was 40 years old and had many of the same problems as the Vermont plant. Older facilities such as the Gateway plant are notoriously difficult to keep running and maintain cleanliness. They are also capital-intensive, requiring huge multi-million-dollar investments every year for routine maintenance alone. After visiting the Gateway plant and conducting due diligence, FE10 was surprised that Perrigo opted to purchase the Gateway plant.

86. According to FE3, key people did not lay eyes on the plant until after it was purchased. Then, when the plant-level personnel took stock of the plant's condition and the equipment, they had significant concerns. FE3 learned this from colleagues in Vermont who regularly met with Perrigo employees at the other plants. One colleague who spent time at Gateway expressed to FE3 that the scope and number of problems was overwhelming, including problems he had not even imagined could exist.

87. ***Micro-cracks in the dryer***. According to FE1, who joined Perrigo right as the transition was taking place following Perrigo's takeover of the Gateway plant from Nestlé, from the outset, he came to learn about serious problems at the Gateway facility. He had visibility into these problems because he worked with many different departments including hygiene, sanitation, and operations. These included micro-cracks in the dryer, the central piece of production equipment at the facility. Micro-cracks are a big concern because they create harborage areas – essentially nooks and crannies where pathogens can grow. In the sanitation industry FE1 explained

we describe those as impossible to truly clean, even when one does a deep clean. Additionally, they create a risk that biofilms will grow – essentially a protective layer that the bacterium forms over itself particularly with *Cronobacter*, listeria, and salmonella. When cleaning is done, those biofilms can be broken off and spread. These are often not visible to the eye. These micro-cracks had been repeatedly scanned by professional contractors, with each scan showing worsening conditions. FE1 knows this because there was at least one scan done when he worked at the facility and the hygiene team had to train and monitor contractors entering the sanitary space. He also spoke regularly with the head of utilities, Bill, and the dryer expert, Randy, both of whom had been at the plant for many years, long before Perrigo owned it. From these conversations and his role, he learned that the dryer was over 30 years old, though its typical operational lifespan was only 25 years. FE1 learned from other staff that they had concerns that Perrigo had said it was going to make significant investments, but in reality, was not making necessary fixes on the equipment.

88. ***Widespread and recurring leaks across the facility, including leaking roofs***. FE5 confirmed that there were significant, recurring issues with roof leaks. FE5 explained that whenever there was heavy rain or snow melt, Quality personnel would often be present in high-sterile zones, such as the dryer or packaging filler rooms, managing active leaks. Those high-sterile or "high-hygiene" zones were areas where there was direct contact with infant formula product and therefore required the highest possible levels of sanitation; the powdered product was not yet contained within cans, and as such, was at higher risk for contamination. These leaks were believed to contribute to microbiological contamination issues. From a quality systems perspective, the leaks resulted in constant cleaning, sanitization, and follow-up testing, creating substantial additional work. He recalled that microbiological "positives" requiring batch rejection occurred a few times per year and often involved significant numbers of batches. According to FE5, these

issues existed while the plant was under Nestlé ownership and continued after Perrigo acquired the facility.

89. These systemic quality and sanitation issues and in particular the April 2022 Form 483 were red flags that any reasonable due diligence would have uncovered. Instead, Perrigo made reckless claims about the acquisition's benefits.

2. The Vermont Facility's Violations of FDA Regulations and cGMPs

90. ***Perrigo ignored its consultant's recommendation and continued using unsafe and unsanitary dryers***. The Vermont facility had two dryers: a vertical Stork dryer and a box dryer called the Marriott Walker. As early as 2016, employees understood that the FDA did not approve of the use of Marriot Walker-type dryers for infant formula and there was regular discussion of phasing it out, but nonetheless, Perrigo continued using it for another decade.

91. In 2020 a consulting group, Relco, did an assessment of the Vermont facility and concluded that both of the dryers at the plant were unsafe and unsanitary and drastic change was needed to get the plant into compliance with health and safety standards. As to the Marriott Walker, Relco concluded it was outdated and there was no way to update or repair it to meet modern safety and quality standards. As to the Stork dryer, Relco raised concern about the lack of fire suppression in the Stork dryer. Infant formula creates a very fine powdered dust that can cause a combustible dust explosion; if that happens, the machine can explode – akin to a bomb on the plant floor. Relco told Perrigo that it needed to add fire suppression. Specifically, it recommended adding fire suppression canisters inside the Stork dryer – but to do that, numerous holes would need to be drilled into the dryer.

92. But Perrigo ignored its consultants' recommendations. Instead, Perrigo continued operating the Vermont facility with their outdated, unsafe dryers with the predictable result of frequent breakdowns causing delay and regular contamination forcing them to scrap millions of

dollars of product.

93. Neither dryer could be adequately cleaned.

94. The Stork dryer's Clean-in-Place process did not fully flush the equipment, leaving chemicals and powder residue behind. This caused the formula batches going through the machine to get wet, creating a heightened risk for *Cronobacter* contamination. According to FE11 who started at the plant in October 2022, when he started the plant had a CIP process but there was a lot of variation in how the process was implemented, as reflected in the fact that it could take anywhere between 8 and 12 hours to complete. Additionally, there were many Standard Operating Procedures that contradicted each other thus needed to be fixed prior to the ability to validate said process.

95. Additionally, the Marriott Walker dryer had to be cleaned by hand. Workers had to climb inside the machine, which was 90 degrees when it was cooled down and could be as high as 110 degrees inside during the cleaning process. Given the extreme heat, workers would strip down to their underwear and a safety suit to do this work, with sweat dripping onto the machine they were trying to clean and sanitize to dry infant formula, as reported by FE8.

96. ***Key materials and equipment did not meet infant formula standards.*** The Vermont facility had been a dairy-grade facility before its conversion to an infant formula plant. As such, the plant design and materials were not suitable for the more sensitive process of manufacturing formula. Much of the flooring was dairy-grade brick; because this material was more porous than the flooring used for infant formula facilities, it created a heightened risk of mold and bacterial growth. Perrigo replaced small sections of the flooring over a period of many years, but during the Class Period there were still large areas of the Vermont facility with dairy-grade flooring.

97. Additionally, the boiler at the Vermont facility produced steam that was not rated at the safety level necessary for manufacturing infant formula. The plant's engineering schematics, which were reviewed by the FDA during inspections, were inaccurate – representing the boiler as producing culinary grade steam, when it only produced industrial grade steam.

98. When pressurized vessels like the boiler or heat exchanger needed repair, rather than hiring certified specialized welders, Perrigo would use its in-house maintenance workers to fix the machinery. Their patch work would fail quickly; on multiple occasions, a patch or repair welded to a pressurized machine would fail within a week or short period, dumping dirty steam into a high-hygiene environment. Additionally, the boiler was dangerous; components of the shell were missing so the boiler could accumulate hot spots or eventually rupture.

99. FE11 was also troubled by Perrigo's lack of standards or a scientific theory regarding acceptable leakage in the infant formula tubs. Leakage can create dangerous conditions where bacteria can thrive. From years of work in the safety and compliance field, FE11 had never seen anything like it.

100. There were no specifications on what size of leak was the threshold that would determine if the finished packaged product would be compromised. Nor was there any differentiation in leakage standards based on the different conditions that the formula traveled in. This was highly problematic because if, for example, formula was shipped by air, there were different pressure conditions than if it was shipped by truck, and so there is a different likelihood and risk of leakage. Temperature differentials should also be considered in determining leakage specifications.

101. The plant had a leak detection system that could detect anything larger than 500 microns, but the process was also to periodically take a tub off the line and immerse it in water; if

they saw bubbles come out of the tub they concluded that there was a leak and if they did not observe bubbles, they concluded there was not any leakage. That test was done to identify if there were any issues with the leak detection system or if there was a leak smaller than the 500 microns. It is unacceptable to have a quality system that is included in the HACCP which does not have a specific requirement, i.e. there was no evidence or scientific studies to support that a 500 micron or less leak is acceptable and does not introduce risk for the life of the product prior to being purchased from the customer. From a safety and compliance perspective, this does not follow any legitimate scientific principles, and does not provide any information regarding the size of the leak. A Senior Director at Perrigo suggested that the plant take a different approach of checking for leakage using infrared Technology. FE11 has extensive experience using IR technology and told the Senior Director that the gun would not be able to spot leakage, just anomalies of the seal interface.

102. ***Frequent deviations***. Deviations were a frequent occurrence at the Vermont facility. "Deviation" refers to an error in the process or product – for example, a critical step in the manufacturing process was missed or the incorrect amount of an ingredient was added. When a deviation is identified, a report would be generated. FE7 drafted operational deviation incident reports (referred to as either "ODIRs" or "ODRs") and exceptional releases ("ERs"). An ODIR was drafted in response to a deviation in the process stream that did not present as severe a risk of causing harm. An ER would be drafted in response to a deviation causing a food safety risk (either physical, chemical, or microbiological) of such gravity that it may cause harm if consumed; an ER required signoff by the most senior onsite Quality personnel before the product could either be released or destroyed. For example, an ODIR would be required if an operator put the incorrect expiration date on a can of infant formula, but an ER would be necessary if indicator tests for

vitamin levels in the process stream were outside the normal process ranges.

103. Following a deviation, product may be isolated for re-testing (referred to as placing "on hold"). At Vermont, the frequency of deviations meant that a huge volume of product was "on hold" for as long as three or four months and delayed in shipping to customers. According to FE4, at Vermont, there was a specific individual in charge of re-testing; due to volume of re-testing, it would take a very long time to re-test product, even as long as three or four months, so orders could be very delayed. Plant leadership constantly told the employees that they were behind schedule on producing formula needed for orders, plus so much product was on hold. People at the plant always wondered if the on-hold product was counted in the plant numbers even though it couldn't be sent out yet.

104. ***HVAC system and filtration were not adequate for infant formula***. One of the major issues that FE2 observed was with the HVAC system at the Vermont facility. The system was enclosed and would dump into the dryer systems. The dryer system was negatively pressurized and would pull in outside air. The Stork dryer produced the more sensitive powder, and then there was a Walker dryer for the less sensitive powder. The interior of the Stork dryer was considered in the red zone – the highest level of sanitation. Air from lower sanitation zones, such as orange and block, was pulled into the Stork, which could introduce bacteria to the dryer and HVAC system.[16] Additionally, FE2 had concerns about the filtration of the HVAC system. The HEPA filters were significantly upstream from where air contacted product, and that air was then pumped through ducting that was not balanced and was not cleaned sufficiently, which would undermine the filtration process and could introduce bacteria or other contamination. That air was then

[16] FE2 knew that this was problematic because his education and training in prior roles included focusing on air balancing and pressurization issues, which are critical points of protection and maintaining sterility for clean environments.

pumped into the room around the Stork dryer and into the Stork dryer in a cold process.

105. Further, the HVAC system was poorly maintained – eventually resulting in a fire on the roof of the Vermont facility.

106. ***Leaks and water spilling into sanitary environments***. There were regular and systemic leaks, which Perrigo addressed simply by placing buckets in the ceiling. There was a Preventative Maintenance ("PM") cycle to empty and replace those buckets, but that task was frequently skipped. As a result, buckets would overflow or fall, spilling contaminated water into clean environments. These incidents required up to 30 hours of cleaning and sanitizing the high-hygiene environments.

107. ***Limited production***. According to FE2, on a good day, the Vermont facility could produce 2,000 to 5,000 units an hour. But in FE2's experience, they could not maintain that rate consistently because there were frequent breakdowns, problems, and equipment failures. As a result, according to FE2, the Vermont facility usually produced around 1,000 to 3,000 units an hour. FE2 knew about this because there was a board in the packaging environment room that displayed target rates and net rates.

3. Perrigo's Concealed Reasons for the Acquisition

108. Defendant Kessler claimed that the Company decided to abandon the plan to construct a new plant in Vermont because the Gateway acquisition offered a cheaper path to expand capacity and because the Vermont site "didn't pass the environmentals." Perrigo's announcement of the Gateway acquisition was the first time that Defendants indicated that they were not going through with the Vermont facility buildout or that there had been an "environmentals" problem with the chosen site. Furthermore, these claims misleadingly omitted certain of Perrigo's reasons for the acquisition.

109. ***Perrigo did not realize the planned expansion site in Vermont was contaminated***. Perrigo owned a large parcel of land in Georgia, Vermont, where its current formula facility was located and where it planned to build the new formula facility. Perrigo's Board approved a $300 million plan to do the construction, which Perrigo announced publicly and moved ahead. According to FE2, Perrigo had even purchased equipment for that facility and was paying to store much of that equipment.

110. But when Perrigo went to break ground, they realized that they had overlooked a major problem: the site was contaminated and the ground was full of concrete and other building materials. According to FE8, a prior owner of the land had demolished a building and rather than removing the materials, had simply buried them in the ground. FE2 noted that Perrigo discovered asbestos. That site previously had a whey factory, which had been connected by underground tunnel to the Vermont formula facility where FE2 worked and the wastewater treatment plant.

111. Given the contamination and the state of the site, it would be significantly more expensive than anticipated to remediate and complete the planned expansion.

112. The contamination and difficulties of remediating the site contributed to Perrigo abandoning its plans to overhaul the Vermont facility.[17]

113. Some of the pricey machinery that had been purchased for the new formula facility was abandoned outside and used for spare parts.

114. ***Anti-competitive motivation.*** As alleged by P & L Development ("PLD") in an antitrust lawsuit filed in the Eastern District of New York against Perrigo and Nestlé, PLD's multi-year efforts to negotiate a contract to acquire Nestlé excess formula product were foiled when

[17] FE2 learned this when he would ask others at the plant why Perrigo wasn't building a new formula-specific facility.

Nestlé revealed that it already had an agreement with Perrigo giving the Company a right of first refusal to excess formula that Nestlé, manufactured.[18] Years later, it was alleged that Perrigo's decision to purchase Gateway – Nestlé's only U.S. infant formula plant – was in furtherance of Perrigo's illegal anticompetitive strategy to lock up the market for the manufacture of store-brand infant formula.[19]

H. Defendants' False and Misleading Statements Concealed Systemic Problems That Limited Production Capacity, Sales, and Earnings Per Share

115. During the Class Period, Defendants continued to stress the benefits of the infant formula business and Gateway acquisition to analysts and investors. Perrigo's Investor Day Presentation on February 28, 2023 proclaimed that Gateway and the Good Start brand "***are significantly margin accretive and driving an immediate uplift*.**" In reality, within a day of completing the acquisition, *Cronobacter* was detected in the Gateway facility, forcing Perrigo to switch the facility's status to "maximum control." Even after that switch, Perrigo identified *Cronobacter* in both the dryer and other high-hygiene areas. Moreover, the Gateway facility had already produced multiple batches of infant formula contaminated with Cronobacter, which had resulted in discarded batches and production delays to allow for Clean-in-Place operations.

116. Separately, the FY22 10-K issued that same day warned that results "could" or "may" be impacted by the "failure of one of these [manufacturing] facilities to comply with applicable laws and regulations" or infant formula products being "found or alleged to have suffered contamination or deterioration." These claims misleadingly framed events that were

[18] *P&L Development, LLC v. Gerber Products Company, et al.*, No. 1:21-cv-05382, ECF No. 44 at 17 (E.D.N.Y. Feb. 1, 2022).

[19] *Id.*, ECF No. 150 at 3, 19 (E.D.N.Y. June 25, 2024). The Court denied the motion to dismiss as to Perrigo and Gerber (excluding Nestlé due to lack of jurisdiction) and the case is ongoing.

already occurring as hypothetical future risks.

117. These representations were significant to the market, with Canaccord Genuity issuing a report titled "Restocked and ready to go: Perrigo emerges from the pandemic with a focus on high-growth self-care" and initiating coverage of Perrigo with a Buy rating and a $49 price target, specifically citing the purchase of the Gateway facility and U.S./Canadian rights to the Good Start brand.

118. But Perrigo's claims concealed the ongoing systemic problems, including the troubled transition of Gateway from Nestlé to Perrigo. According to FE7, experienced personnel largely left Gateway before it transitioned to Perrigo, and there was a major gap in leadership at the plant level. Perrigo failed to sufficiently staff key teams, including the Quality team; as a result, there was no one to do critical tasks like identifying the high-risk zones in the plant where contamination was most likely and establishing processes for operators to properly move between high- and low-risk areas. Additionally, the switch from Nestlé's sophisticated database to Perrigo's outdated system resulted in loss of key manufacturing records and required manual entry of critical information.

119. On March 6, 2023, the FDA published a letter directed to "Infant Formula Manufacturers" like Perrigo and others in the industry. It discussed the Abbott recall and made specific requests to formula manufacturers to prevent *Cronobacter* contamination and "help protect our most vulnerable population":

> Specifically, FDA asks that you:
> 1) Evaluate your established system of production and in-process controls (which must cover 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 ensure that appropriate controls are implemented in accordance with 21 CFR 106.6(c) at any point, step, or stage in the production process where control is necessary to prevent adulteration of infant formula;
> 2) Ensure full compliance with all relevant regulations – including the Infant Formula

> Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications rule (21 CFR part 106) and the Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food rule (21 CFR part 117);
> 3) Consider the concerns shared in this letter when evaluating your established system of production and in-process controls, including when taking corrective actions; and
> 4) Ensure adherence to the notification requirement of an adulterated or misbranded infant formula any time product has left the facility, in accordance with 21 CFR 106.150.
> Lastly, FDA asks that firms voluntarily notify the Agency any time a product sample is found to be positive for Cronobacter spp. or Salmonella, even if the affected lot(s) have not been distributed.

120. Further, the letter called manufacturers (including Perrigo's) attention to specific "areas for improvement across the infant formula industry":

> 1. Controlling water in dry production areas
> 2. Verifying the effectiveness of controls through environmental monitoring
> 3. Implementing appropriate corrective actions following the isolation of a pathogen from an environmental sample or a product sample
> 4. Implementing effective supply-chain controls for biological hazards
> 5. Identifying all relevant biological hazards

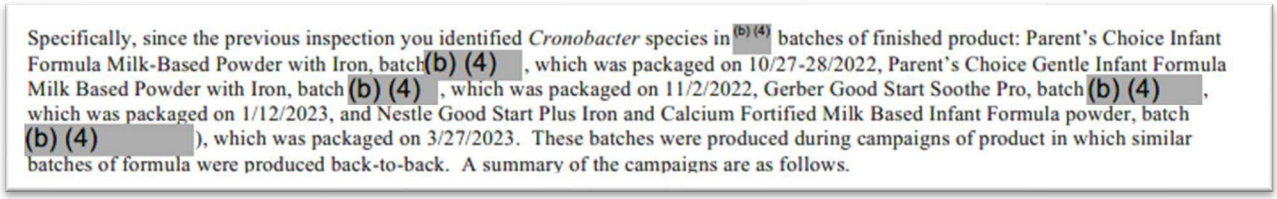
121. Just a few weeks after Perrigo claimed the Gateway and Good Start acquisition was "significantly margin accretive and driving an immediate uplift" and framed non-compliance with FDA regulations as a potential, future risk, on March 17, 2023, Perrigo was forced to recall Gerber Good Start SoothePro infant formula due to potential presence of *Cronobacter*.

122. Given the attention to the Abbott recall and attendant impact on that firm, the market was unsurprisingly focused on whether Perrigo had similar risk. Perrigo personally reassured analysts that Perrigo was fundamentally different. Following meetings with Defendants Kessler and Bezerra, analysts at Canaccord Genuity reported on April 5, 2023 that "Perrigo runs a much tighter ship" than Abbott and "[w]e believe that PRGO's facilities do not have the same issue as Abbott's Sturgis facility at all."

123. But what the analysts and the market did not know – because Defendants concealed it – was that Gateway had the very same problems that the Department of Justice

("DOJ") cited in its complaint against Abbott, namely micro-cracks in the dryer and a leaking roof that create heightened risk for *Cronobacter* contamination, and positive findings of *Cronobacter* in the environment and in finished product.[20]

124. Nor did the market know that an FDA inspection of Gateway was currently underway, which resulted in the FDA issuing another Form 483 to the Gateway facility on April 26, 2023 (the "April 2023 Form 483" at Exhibit C). This resulted from another lengthy inspection, from March 6 to April 26, 2023. Like the April 2022 Form 483, the FDA again identified several positive *Cronobacter* hits, including in actual product batches and high-hygiene areas including the dryer and dryer area. Troublingly, the April 2023 Form 483 reflected that even after Perrigo conducted a major Clean-in-Place, there were positive *Cronobacter* swabs, indicating the Clean-in-Place process was not adequate. Perrigo had to destroy multiple batches of formula due to the positive *Cronobacter* hits.


Specifically, since the previous inspection you identified *Cronobacter* species in (b) (4) batches of finished product: Parent's Choice Infant Formula Milk-Based Powder with Iron, batch (b) (4), which was packaged on 10/27-28/2022, Parent's Choice Gentle Infant Formula Milk Based Powder with Iron, batch (b) (4), which was packaged on 11/2/2022, Gerber Good Start Soothe Pro, batch (b) (4), which was packaged on 1/12/2023, and Nestle Good Start Plus Iron and Calcium Fortified Milk Based Infant Formula powder, batch (b) (4), which was packaged on 3/27/2023. These batches were produced during campaigns of product in which similar batches of formula were produced back-to-back. A summary of the campaigns are as follows.

125. The April 2023 Form 483 also cited metal fragments found on the "packaging magnet" and on the "dryer magnet," after which the dryer was the focus – "a decision was made to stop production and start a major CIP of the dryer" over the course of March 28 to 30, 2023.

126. The FDA further found that Perrigo failed to "employ sufficient qualified personnel to perform all operations in the manufacture, processing, packing and holding of each infant formula" and failed to "ensure that all surfaces that contacted in-process materials and infant

[20] Compl. for Permanent Inj. at 11, *United States v. Abbott Labs.*, No. 1:22-cv-00441 (W.D. Mich. May 16, 2022), ECF No. 1.

formula were cleaned and sanitized and maintained to protect infant formula from being contaminated by any source."

127. The FDA would later characterize these findings as "significant violations" of its rules and regulations on infant formula.

128. Despite the concerning findings in the April 2023 Form 483, just two weeks later, Perrigo issued a press release for first quarter 2023 earnings, claiming that the "***integrations of HRA, the Gateway facility and the Good Start® brands are on track.***"

129. Analysts believed Perrigo's reassurances. J.P.Morgan reported the latest earnings were "another step in the right direction," and the Supply Chain Reinvention Program was "starting to progress."

130. That day, Perrigo also unexpectedly announced that Defendant Kessler planned to retire, effective that summer. Two days later, on May 11, 2023, Defendant Kessler personally enriched himself with the sale of 197,646 shares of his Perrigo common stock, for over ***$7 million*** in proceeds.

131. On May 16, 2023, Perrigo submitted a corrective action response to the FDA, purporting to address the issues raised in the April 2023 Form 483.

132. On July 31, 2023, Defendant Lockwood-Taylor succeeded Defendant Kessler as CEO.

133. In July 2023, unbeknownst to the market, Perrigo had to recall roughly two months of product manufactured at the Vermont facility that had not yet reached customers. The Vermont facility was also struggling after years of deferred maintenance and Perrigo's refusal to invest in meaningful remediation. The facility rarely produced at its actual capacity due to frequent machine malfunctions and unplanned repairs. According to FE10, the quality of the Vermont facility

declined after then-plant director Sean Walsh was let go in 2020. The new senior management Perrigo put in place tried to run the Vermont facility on an extremely limited budget, to the facility's detriment.

134. That summer, Perrigo shut down the Gateway facility for a few weeks to complete certain projects, including replacing certain flooring and crack inspection and repairing the dryer. But they did not conduct an adequate root cause analysis to prevent adulteration, as the FDA had asked of the industry in its March 6, 2023 Letter to Industry and had urged Perrigo specifically in the April 2023 Form 483. Following the shutdown, Gateway continued having environmental positives for *Cronobacter*, demonstrating the shutdown did not resolve the fundamental problems.

135. Nonetheless, on August 8, 2023, in response to an analyst question, Defendant Bezerra claimed that they were "***already seeing the significant value accretion*** . . . in the Nutrition business because of the Gateway facility integration" and Defendant Lockwood-Taylor claimed the infant formula business was "***getting to normalization***" and seeing "a particularly strong recovery early in quarter 4."

136. The market credited these statements. J.P.Morgan wrote that it exited "the [quarter] with greater conviction in the company's continued path to margin/EPS [earnings per share] recovery through 2025."

137. That month, on August 30, 2023, the FDA issued a formal Warning Letter to the Gateway facility ("August 2023 Warning Letter" at Exhibit D).

138. The August 2023 Warning Letter made clear that the inspectors' findings in the April 2023 Form 483 constituted "significant violations" of FDA rules, that Perrigo was still in violation of cGMPs and FDA regulations, and that Perrigo's May 16, 2023, corrective action response was unacceptable. The FDA identified numerous "areas that still require corrective

actions." The FDA found that Perrigo improperly released batches of formula to market that had potential exposure to *Cronobacter* and that Perrigo was narrowly focused on cleaning and sanitization without conducting a meaningful root cause analysis to identify and eradicate the cause of the frequent *Cronobacter* contamination – as a result, the same strains of *Cronobacter* were detected multiple times over the course of the past year, proving that Perrigo's "sanitation procedures have been inadequate to significantly minimize or prevent the presence of *C. sakazakii* in your facility."

139. In strong words, the FDA stated:

> [Y]our response does not indicate that you are taking ***any*** proactive actions to address the resident strains of *C. sakazakii* present within the facility. We strongly encourage you to conduct a root cause analysis to identify any potential niche or harborage areas and to address facility practices or conditions that may contribute to the persistence of these harborage sites and potential routes of contamination. (Emphasis added).

140. The letter closed with a warning that the FDA would "inspect the adequacy of [Perrigo's] corrective action during [their] next inspection of [the] facility."

141. FE7 joined Perrigo at the Gateway facility in September 2023, and his observations echoed the FDA's concerns. According to FE7, although the dryer was supposed to be fully enclosed, during the Clean-in-Place process it would leak and water would pour out of one of the doors near the top of the dryer; at another spot in the dryer, water would leak inward. FE7 echoed that during the Clean-in-Place process, the dryer would "leak like a sieve" and water would pour out of the dryer's "level five" door.[21] At level one, there was leaking inward. This led to moisture in the dryer itself and in the areas around it.

142. After a leak from a Clean-in-Place, operators would have perform a "wet clean" or sanitation break cleaning by spraying chemical foam on to the dryer and then rinsing that foam

[22] Vice President of Operations for the infant formula business.

off. A "wet clean" would, intuitively, introduce more water and more risk for *Cronobacter* contamination. According to FE7, the leaks from the Clean-in-Place would not have occurred if Perrigo had invested in realigning the Clean-in-Place hookup lines and dryer pipes so that the junctions fit together. According to FE7, this problem was well known, but Perrigo did not opt to make that investment.

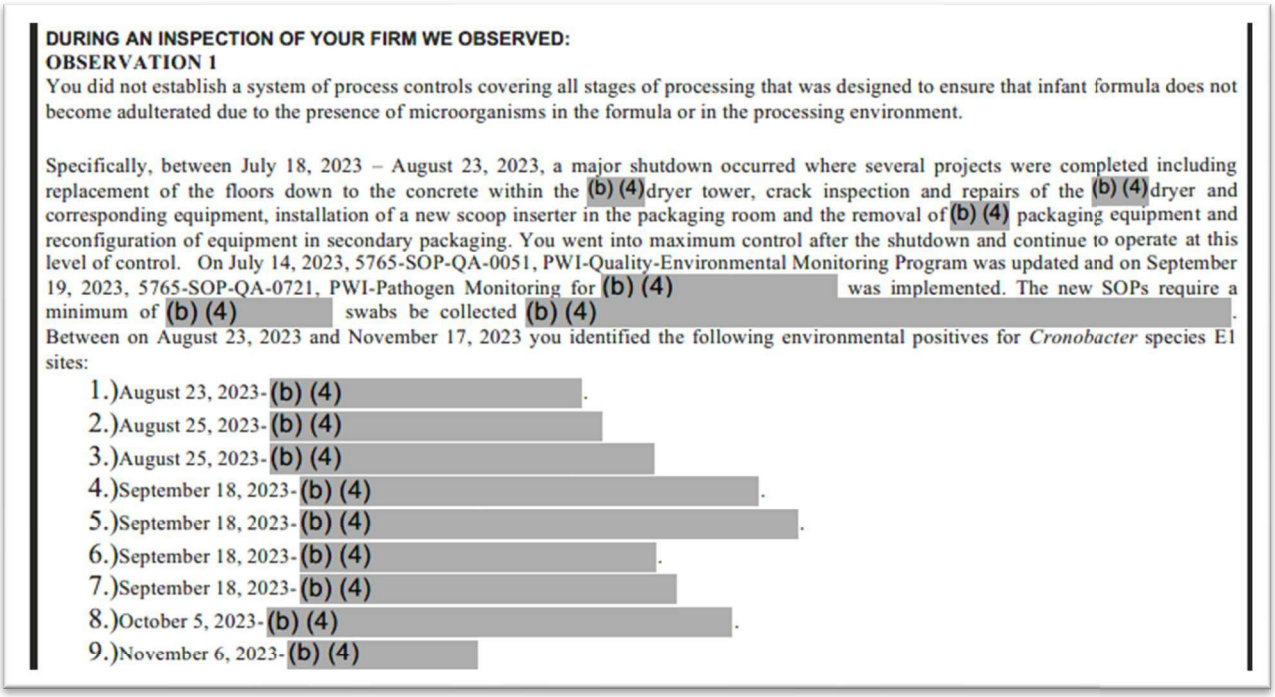
143. Additionally, according to FE7, the extensive leaking also prevented operators from following FDA procedures for documenting cleaning procedures in the dryer itself. Specifically, the FDA requires that cleaning procedures be documented on paper in real time as they take place. But due to the leaks and the subsequent need to perform wet cleans, operators could not bring their paperwork into the dryer during cleaning operations and instead had to document their work after the fact. This delay sometime caused operators to fail to update their paperwork. This was an issue that FE7 was told by a production manager were communicated up to senior leadership, all the way to Lockwood-Taylor. That production manager, in turn, was aware because he had regular meetings with Reno Thomas ("Thomas")[22] and Anthony Freve ("Freve")[23] discussing the documentation issues.

144. On September 18, 2023, there were four environmental positives for *Cronobacter* at Gateway, followed by another environmental positive for *Cronobacter* on October 5, 2023.

145. Then on November 29, 2023, the FDA issued a ***third Form 483 to the Gateway facility*** (the "November 2023 Form 483" at Exhibit E), following an inspection that took place between November 6 and November 29, 2023.

[22] Vice President of Operations for the infant formula business.
[23] Senior Vice President of Operations and Supply Chain Consumer Self-Care Americas.

146. Once again, the FDA criticized Perrigo for its "failure to establish a system of process controls . . . designed to ensure that infant formula does not become adulterated," and included a list of ***nine positive Cronobacter hits*** in high-hygiene areas of the Gateway facility between August and November 2023:



DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
OBSERVATION 1
You did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.

Specifically, between July 18, 2023 – August 23, 2023, a major shutdown occurred where several projects were completed including replacement of the floors down to the concrete within the (b) (4) dryer tower, crack inspection and repairs of the (b) (4) dryer and corresponding equipment, installation of a new scoop inserter in the packaging room and the removal of (b) (4) packaging equipment and reconfiguration of equipment in secondary packaging. You went into maximum control after the shutdown and continue to operate at this level of control. On July 14, 2023, 5765-SOP-QA-0051, PWI-Quality-Environmental Monitoring Program was updated and on September 19, 2023, 5765-SOP-QA-0721, PWI-Pathogen Monitoring for (b) (4) was implemented. The new SOPs require a minimum of (b) (4) swabs be collected (b) (4).
Between on August 23, 2023 and November 17, 2023 you identified the following environmental positives for *Cronobacter* species E1 sites:

1.) August 23, 2023- (b) (4).
2.) August 25, 2023- (b) (4)
3.) August 25, 2023- (b) (4)
4.) September 18, 2023- (b) (4).
5.) September 18, 2023- (b) (4).
6.) September 18, 2023- (b) (4).
7.) September 18, 2023- (b) (4)
8.) October 5, 2023- (b) (4).
9.) November 6, 2023- (b) (4)

147. Inspectors additionally noted environmental positives for *Cronobacter* in ***ten other sites*** throughout the Gateway facility.

148. In that same period of time, the report noted, Perrigo identified 10 separate water leaks in the facility, with two leak locations testing positive for *Cronobacter*.

149. The report noted that this constituted a "repeat observation from the previous inspection(s) conducted on 4/26/2023 (written observation), [and] 4/12/2022 (written observation)."

150. Shortly thereafter, in early December 2023, according to FE7, Perrigo brought in the consulting company IEH to conduct thousands of swabs throughout the Gateway facility to establish the "footprint" of *Cronobacter* and understand where the "resident" and "transient"

strands of the bacteria were located in the facility. The swabs produced hits for *Cronobacter* throughout the facility. The Company shut the facility down soon after, for the so-called "Gateway Reset."

151. According to FE4, who was present, Defendant Lockwood-Taylor went to the facility to announce the shutdown, which he said was meant to "reset the site" and address a "deficient culture of quality" and introduce a consulting team, Validant, that he had personally selected. Employees including FE4 strongly disagreed that the issue was "cultural" – that ignored the systemic equipment and maintenance problems at the facility that they had no control over.

152. The consulting company, Validant, did extensive documentation of violations of cGMPs, Good Documentation Practices ("GDP"), the food code, and sanitation policies. The Quality and Production Departments would sign off on the consultants' summaries (including FE7 for certain summaries), which were then provided to Valerie Gill ("Gill"),[24] Perrigo's Vice President of Regulatory Affairs.

153. FE7 was told by Knudtson and Gill that the write-ups were presented to Defendant Lockwood-Taylor and the Steering Committee.

154. Validant also interviewed fifty employees at Gateway and produced a lengthy assessment of the problems at the facility identified during the interviews. The assessment was then shortened to a 15-page summary of six recommended changes for Perrigo to make the Gateway facility successful. According to FE7, who viewed the summary, Validant's key findings included that Quality personnel lacked experience in infant formula and were not effective at their roles and that there was not sufficient cooperation across Quality and the other Departments at Gateway.

[24] Vice President of Regulatory Affairs.

155. Validant also created a report and presentation on the frequent deviations at Gateway to present to Defendant Lockwood-Taylor and the Steering Committee, along with other reports including one that FE7 recalled analyzing the failures of Gateway's environmental monitoring program.

156. According to FE4 and FE5, Validant did not focus on equipment or facility design, and Perrigo did not use the shutdown to conduct any preventative maintenance, upgrade equipment, or redesign factory processes to align with new FDA regulations – instead, the primary focus of the shutdown was cleaning the facility.

157. Perrigo's approach ignored the fundamental problem driving the repeat contamination: deteriorating equipment, leaks, and ineffective Quality personnel. Perrigo's narrow focus on cleaning was particularly shocking in light of the August 2023 Warning Letter, where the FDA specifically told Perrigo that cleaning was insufficient and it needed to identify and address the root cause of the persistent *Cronobacter* contamination.

158. Unsurprisingly, the shutdown and "reset" that was largely just a deep clean did not solve Perrigo's problems. Gateway continued to have positive *Cronobacter* hits forcing production to halt for extended periods of time and product to be discarded. FE5 recalled that even after the post-warning-letter shutdown and remediation efforts, there were at least two periods following microbiological positives where the facility was shut down to clean the entire building.[25]

159. According to FE4, the Gateway reset had significant commercial consequences. Before the shutdown, the facility had meaningful market share. Once the facility was shut down,

[25] FE5's primary role at this time was to review the documentation.

Perrigo could not supply its customers and they went to other companies, so even after restarting production Perrigo had lost business.[26]

160. The Vermont facility similarly struggled to fill orders due to persistent equipment failures and contamination forcing Perrigo to scrap product. Customers lost confidence and reduced the volume they were ordering from Perrigo. Employees were regularly updated on the production forecasts which declined over time, with fewer orders, fewer production runs happening, fewer samples being pulled into the laboratories for testing, and less work across the facility.

161. According to FE11, one of the dryers had significant problems in the ductwork. Because of the plant design, they could not see inside or easily reach the ductwork, let alone properly clean it. Powder was regularly left behind and caked onto the dryer even after it was supposedly cleaned where visual inspection was available, causing them to need to rework the existing CIP process. As a result of these issues, the facility had to scrap a large volume of product that went through that dryer in 2023 and 2024.

162. Reflecting the lost customers and ongoing equipment failures and *Cronobacter* contamination that forced extended shutdowns and scrapping product, Perrigo's projected formula production for 2024 was only 40-50% of expected annual capacity.

163. According to FE11, who worked at the Vermont facility, Perrigo's safety and contamination and equipment issues meant they regularly scrapped formula and were running well below the plant's production capacity. It was well known at the Vermont facility that production

[26] In his role as production manager, FE4 would sit with the scheduling team to discuss production expectations for the following weeks to meet order volumes. Through those meetings and reviewing the scheduling team's forecasts, FE4 became aware of substantial declines in customer orders and lost customers.

was down; there were updates on production and sales and other metrics at the monthly all-hands meetings. At the end of 2023, no one received a bonus or even standard merit increases because the Company was struggling so much. The workers and operators were very frustrated.

164. Like Gateway, in this period the Vermont facility was also undergoing extensive consulting work. In 2024, Perrigo had another consulting group, LaPorte, assess the Vermont facility. According to FE11, in January 2024, after roughly a year of work and analysis, LaPorte prepared a report and preliminary action plan. The report recommended extensive renovation and replacement of equipment, as well as updates to processes. The report had photos in it of issues across the Vermont facility, including powder remaining in machines even after they were supposedly cleaned and sanitized – creating a huge risk for bacterial contamination. Much of the recommended work was identical to the study that was performed in 2020.

165. Further according to FE11, LaPorte's recommendations included replacing the spray balls used in the cleaning process; ensuring that swabbing for potential contamination was happening in areas that were difficult to see and access; improving the process for monitoring and managing humidity; removing areas of the Vermont facility with poor or no drainage; major overhaul to Standard Operating Procedures ("SOPs") and checklists; redesigning the cyclone outlet because there was regularly powder remaining in the cyclone even after it was cleaned; more frequent manual cleaning and adding valves and bypasses to one of the kitchens that was frequently dirty and had many blind spots; adding conductivity checks to confirm that detergent has been fully rinsed from machinery; replacing connections in hoses to proper sanitary connectors; and updating the Piping and Instrumentation Diagram ("PID" or "PI&D") drawings so they conformed to the actual layout and machinery in the facility.

166. Additionally according to FE11, a company was hired to perform some of the most important work that LaPorte recommended on the dryer. But ultimately, they could not actually perform it because the infrastructure was unsafe and not as required for a safe work environment per safety regulation standards. The tower spray dryer did not have a release mechanism in place in the event of a dust/powder explosion, which means if there was a significant enough one, any of the employees within the vicinity of the fallout would have high risk to injury (shrapnel where the most vulnerable points are).

I. Defendants Disclose Unexpected Remediation Costs and 50% Drop in Earnings Per Share, but Falsely Assure Investors of a "Reset"

167. The truth began to emerge on February 27, 2024. That day, with the announcement of fiscal year 2023 earnings, Perrigo disclosed that it would need to make $35 to $45 million in investments to remediate the infant-formula business, and that earnings per share was down roughly 50% year over year, largely due to the Gateway remediation costs – the very thing Defendants claimed would drive earnings per share. The Company also revealed the infant formula's full year adjusted operating income was less than half the expected normalized run rate of $140 million, and that full year 2024 adjusted operating income was expected to be below that of 2023.

168. On this news, the Company's share price fell from a closing price of $32.17 on February 26, 2024 to close at $26.41 on February 28, 2024, a decline of $5.76, or 17.90%, on unusually heavy trading volume.

169. Analysts were caught off guard. J.P.Morgan described the update as "disappointing" and that "the magnitude of the impact (~$0.65 EPS headwind in 2024 vs. prior guidance) is far larger than anticipated."

170. But Defendant Lockwood-Taylor doubled down, assuring investors that Perrigo

had "***made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs and added additional quality personnel";*** the Gateway facility "***has recently completed its plant-wide reset, and is now back in production"***; and "***what we're doing is probably ahead of what is being done by many other manufacturers."***

171. Similarly, at the UBS Global Consumer & Retail Conference held just a few weeks later on March 13, 2024, Defendant Lockwood-Taylor assured investors that Gateway was "***fully compliant and operationally reliable and producing and moving through different batches, ahead of our expectation"*** and that Perrigo ***"finished the root cause analysis in Vermont"*** and ***" we are moving very well . . . towards quality compliant, reliable supply operations, and we will be there within a few weeks."***

172. The market was reassured. Canaccord Genuity "believed management has been conservative with the nutrition business, and if the transition goes smoothly, we could see an upside in their estimates" and Piper Sandler characterized the stock reaction as "a bit overdone," noting management was "trying to be ultra-prudent in addressing" issues.

173. But Defendant Lockwood-Taylor's claims omitted that despite any claimed enhancements and "reset," Gateway still suffered from systemic safety and quality deficiencies in equipment, processes, and staffing that had not been addressed and would continue to limit production capacity and attendant impact on sales and EPS.

J. Defendants Disclose Drop in Infant Formula Sales, But Misleadingly Conceal Persistent *Cronobacter* Contamination

174. The truth continued to partially emerge on May 7, 2024, during the earnings announcement for the first quarter of 2024 when Perrigo disclosed that margins were further

compressed and "net sales of $91 million decreased 34.5% due primarily to lower shipments to customers as the company works through its infant formula plant remediation plans."

175. Perrigo's stock price fell $3.28, or 9.8%, to close at $30.15, on unusually heavy trading volume.

176. But once again, Perrigo reassured investors that the worst was over, claiming that "***any planned large-scale plant resets have been completed."*** In response to an analyst pressing Defendant Lockwood-Taylor's "level of confidence" that the fundamental issues had been resolved, Defendant Lockwood-Taylor reiterated that "***[t]he big intervention in terms of root cause analysis, corrective and preventative actions the translations of that into new GMPs, protocol, staffing levels, et cetera, is largely done"*** across the three formula facilities. Defendant Bezerra echoed this confidence, stating lower shipments in the quarter were due to "***onetime impacts***" that would not be repeated.

177. The market accepted these claims. J.P.Morgan reported that "PRGO's large-scale plant resets are now completed, with all three factories back in production and quality compliant" and it "continue[d] to see significant upside for shares to the extent this segment normalizes, which [J.P.Morgan] feel[s] increasingly comfortable with following today's results."

178. But in the weeks that followed, the problems continued. A deteriorating fire sprinkler line in the dryer at Gateway had a positive *Cronobacter* hit. A campaign at Gateway to produce soy formula resulted in deviations in nearly every batch due to known temperature issues in production tanks, forcing Perrigo to discard roughly half of every soy formula batch it produced that summer.

179. Nonetheless, Defendants continued their positive claims to reassure the market that the infant formula business was performing reliably and Perrigo had completed the necessary

maintenance and "reset." At the June 11, 2024 Oppenheimer Consumer Growth and E-Commerce Conference, Defendant Lockwood-Taylor claimed "***We have made outstanding progress, in line, if not ahead, really, of our expectations"; "[t]he large-scale plant reset . . . is now behind us"*** and ***"[w]e are achieving industry-leading quality control at near historical record production levels."***

180. The market credited these claims. The next day, Piper Sandler issued a report titled "Forecasting Formula: Fears Overdone, Future Looks Favorable," noting that "Perrigo has been intentional and thorough in taking proactive measures to make sure its infant formula meets FDA regulatory requirements" and "[w]ith production ready in all sites as of the end of Q1 . . ."

181. On August 2, 2024 press release in conjunction with the Form 10-Q for the second quarter of 2024 (the "Q2 2024 10-Q"), Perrigo claimed that all of the infant formula sites "***are up and running and have returned to reliable, quality-assured production with recent output across the network near 2023 levels***" and that "***[w]e do not expect these continuing improvements to result in extended shutdowns beyond typical planned maintenance activities***." In response to an analyst question, Defendant Lockwood-Taylor elaborated that he had been "***very close to the remediation work***" in infant formula, and that it was "***executed extremely well across all three sites***" and "all the key performance indicators show that we are ***fully compliant***."

182. While analysts noted the overall results were "disappointing," they were largely mollified. J.P.Morgan "walk[ed] away from today's update with greater confidence in the 2H24+ [second half of 2024] recovery of PRGO's infant formula business . . . and ability to reach $3+ of EPS in 2025 as a result"; described infant formula recovery as "the key focus for the story"; and stated that all of Perrigo's infant formula sites "are up & running with volumes having significantly normalized thus far." Morningstar reported that infant formula "recovery is progressing quicker

than anticipated" and "[m]anagement's reiteration of earnings per share guidance despite a mid-single-digit sales expectation cut is encouraging."

183. Just six days later, on August 8, 2024, Perrigo announced a major infant formula recall due to elevated levels of Vitamin D in the product.[27] The recall covered three lots within one batch, totaling 16,500 cans of formula that had been shipped out to stores in twelve different states.

184. That Perrigo sent infant formula with an incorrect formulation out to market reflected a major breakdown at two different points: introducing excess vitamin D during the manufacturing process, and failing to detect the excess levels before shipping it.

185. Additionally, there were quality issues with certain formula that was manufactured at Gateway and shipped to Vermont for packaging, leading to additional discarded product. According to FE2, the formula frequently arrived with clumps in it, indicating moisture had come in contact with the product. This creates heightened risk for bacterial contamination. Workers at the Vermont facility would simply use sifters to remove the clumps before packaging the formula. Additionally, the process by which the formula was brought into the Vermont facility raised quality and sanitation concerns. It was moved around the facility from the truck through increasingly high-hygiene environments by high school kids and temporary labor who lacked basic training and experience in proper gowning or maintaining sanitary environments. Trained employees at Vermont frequently saw poor sanitation practices and would try to jump in to correct errors, but there was not adequate supervision to maintain the necessary sterility.

[27] *Perrigo Issues Voluntary Recall of One Batch of Premium Infant Formula with Iron Milk-Based Powder Due to Elevated Levels of Vitamin D*, FDA (Aug. 8, 2024), https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/perrigo-issues-voluntary-recall-one-batch-premium-infant-formula-iron-milk-based-powder-due-elevated.

186. Perrigo was unable to keep up with customer orders due to low production, frequent deviations putting formula on hold for months, and high levels of product scrap. FE7 attended weekly meetings with employees and leaders spanning the entire Perrigo formula network where members of the supply chain or procurement scheduling team would direct the facilities as to which batches needed to be prioritized for release so that they should be shipped on time to customers. These meetings emphasized the critical problem that frequent deviation was delaying batches and the company was losing customers. FE7 also recalled that participants in the meetings would review planned downtime for maintenance work; on many occasions, leadership, including Thomas, would instruct plant managers to prioritize fulfilling orders, thereby postponing maintenance work.

187. But deferred maintenance meant problems were getting worse. The Gateway dryer was scanned by professional contractors in 2023 and 2024, who documented that the micro-cracks in the dryer were expanding.

188. By fall 2024, Perrigo lost one of its key clients – Target – due to Perrigo's repeated failure to fill orders.[28] Order volume dropped off dramatically going into 2025.

189. Also in 2024, Perrigo had another consulting group, LaPorte, assess the Vermont facility. According to FE11, LaPorte largely re-did the analysis that Relco had performed a few years prior. Additionally, per another Request For Proposal, LaPorte consulted on validating the cleaning process.

[28] FE4 specifically recalls someone mentioning at a scheduling meeting in the fall of 2024, that the company had lost Target as a customer. Others at the meeting indicated that they had lost the customer because they could not fulfill orders. After losing that key customer, order volume dropped off drastically beginning in 2025.

190. And LaPorte reached the same conclusion that Relco had reached four years earlier: that the two dryers were unsafe and inconsistent with safety and quality standards, and patches and repairs could not make them safe or effective. Like Relco before it, LaPorte concluded that the Marriott Walker was outdated and there was no way to update or repair it to meet modern safety and quality standards. Also like Relco before it, LaPorte raised concern about the lack of fire suppression in the Stork dryer and risk of an explosion, and recommended fire suppression by drilling holes and adding internal fire suppression canisters.

191. But again, Perrigo did not act on its consultant's recommendations. Perrigo leadership pushed the plants to keep running production to try and fulfill orders, forcing them to postpone maintenance work.

192. Meanwhile, starting in late 2024, there was an ongoing problem of metal fragments in the infant formula produced at Vermont. According to FE6, employees sifted through thousands of discrete portions of formula batches trying to find salvageable areas that did not have metal contamination, and at one point, there were four batches in a row that had to be discarded in their entirety due to metal contamination. Employees believed the metal contamination was caused by something shredding inside a machine and asked to slow down and figure out the cause of the problem, but Perrigo refused.

193. Despite these serious problems, in November 2024, Defendant Lockwood-Taylor continued telling the market that the business was recovering and that remediation was successful: "Job number one in infant formula was to ***recover and complete our self-remediation actions so that all our sites produce reliable, quality-assured infant formula. We have done this and are now achieving high attainment of quality, production and packaging***." Lockwood-Taylor also described the plants as "***extremely high quality***," highlighting that "***we're running higher quality***

plants more efficiently than we have done historically and we are seeing store recovery and store brand consumer recovery completely in line with our expectation, and that will accelerate."

194. However, production was significantly down. By the end of the first quarter 2025, Vermont was producing about a quarter of its capacity. Workers on the packaging line were frequently sent home because there was not enough work to do. During 2025, Perrigo shut down one of the dryers and a tank used for sterilizing equipment at Vermont because they did not work. Further, there were not enough janitors and maintenance staff so bathrooms and laboratory floors were not cleaned as frequently as needed, and the bathrooms smelled terrible.

195. On February 10, 2025, a major fire occurred at the Vermont facility. The Georgia Fire Department called for and received additional assistance from the nearby Milton Fire Department. The Georgia Fire Department's report reflected that the cause of the fire was "failure of equipment or heat source" and the "[f]ire included a belt, bearings, and an oiler within the unit." FE8 explained that the fire stemmed from a belt in the HVAC system, which was poorly maintained. Given the smoke, soot, and potential contamination, Perrigo had to shut the facility down to do a deep clean and inspect equipment and instrumentation.

K. Perrigo Announces $240 Million "Strategic Investment" in Infant Formula

196. Later that month, on February 28, 2025, Perrigo announced a large "strategic investment": $240 million investment for the infant formula business, signaling confidence in a business that supposedly was remediated and on track.

197. In the 2024 Annual Report submitted with the 2024 Form 10-K, Perrigo confirmed the stability and success of the infant formula program:

> ***Currently, all our infant formula manufacturing sites are up and running and have returned to reliable, quality-assured production with recent output across our infant formula network near historical levels***. Our focus now lies in continuing to rebuild customer service levels and getting these critical products back on the shelves for

> consumers who need high-quality, affordable infant formula. ***With production now stabilized***, we're driving strategic investments to strengthen the infant formula operations network to ensure the long-term sustainability of a key component of our CSCA business.

198. On the earnings call, executive Ron Janish ("Janish") described the investment as "a tremendous opportunity to transform our free cash flow performance" that "also helps ensure the long-term sustainability of a key component of our North American business" and was expected to provide substantial cash returns and secure this business over the long term. He explained that Perrigo believes the infant formula business "can generate $100 million or more of annual free cash flow beginning in 2028" and that the Company "anticipate[s] recouping our investment within two years post project completion."

199. The market reacted positively. Piper Sandler commented on the Company's "solid plan to build toward LT [long-term] recovery," resulting in an "incrementally more positive" outlook and Morningstar noted the "path to continued recovery remains intact," in part due to "high-teens growth from infant formula sales."

200. A week later, on March 6, 2025 (less than a month after the fire), a local news outlet reported that Perrigo would phase out and shut the Vermont facility down by 2027. A communications manager for Perrigo said the facility's age and evolving regulatory requirements meant it was no longer "cost-effective" to invest in the facility.[29]

201. The market believed this was an orderly wind-down. Specifically, a Canaccord Genuity report published on March 11, 2025, after the analysts met with Defendants Lockwood-Taylor and Bezerra noted that Perrigo "will be consolidating manufacturing from three facilities to two" but emphasized that Perrigo was also "upgrading manufacturing capacity at the two

[29] Corey McDonald, *Perrigo to shut down Vermont Facility, affecting more than 400 employees*, VT Digger, Mar. 6, 2025, 3:51 PM), https://vtdigger.org/2025/03/06/perrigo-to-shut-down-vermont-facility-affecting-more-than-400-employees/.

facilities" and that "[t]he business is highly profitable and expected to generate $100+M in [free cash flow] by FY28.The report concluded "it appears the worst is behind with infant formula," and "[m]anagement expects a highly profitable, cash-generating infant formula business poised for share gains."

202. At the March 12, 2025 UBS Global Consumer & Retail Conference, Defendant Lockwood-Taylor explained euphemistically that they were "retir[ing]" one of the plants but claimed all were still performing well, stating "***[t]hese are extremely well-disciplined well-run plants with GMPs that drive quality production, quality issue production.*** I couldn't be happier with where we ended up . . . ***it is a very attractive business. It's highly reliable, it's highly predictable. It is significantly margin accretive.***"

203. Unbeknownst to the market, and in clear contrast to the claims of having "returned to reliable, quality-assured production with recent output across our infant formula network near historical levels" and having "extremely well-disciplined well-run plants with GMPs that drive quality production," the underlying problems remained unresolved. According to FE4, in or around March 2025, a positive *Cronobacter* hit at Gateway forced the facility to shut down for over a month and discard approximately $10 to $15 million dollars' worth of product – an amount FE4 viewed as direct evidence that the shutdown and consultant intervention had not addressed core issues. FE4 and other employees learned about the product loss at a town hall with plant leadership. Additionally, in April or May 2025, according to FE7, there was a large rainstorm that caused leaks throughout the Gateway facility, which led to outside water entering multiple places in Level Six of the dryer, where the liquid slurry is introduced.[30]

[30] FE7 viewed the rain leak register and was told by Neuman that reports of the leak were shared with upper management, including Thomas and Thomas's boss, Anthony Freve. Neuman

204. As for Vermont, after Perrigo told Vermont it was shutting down the facility over the next two years, employees rapidly fled. Within weeks, the three labs lost employees with over 120 cumulative years of experience, and manufacturing was also hard hit. Perrigo could not or did not fill vacancies, leading to continued problems and production limitations in clear contrast to the orderly wind-down that the Company represented to investors.

205. And the summer 2025 soy formula campaign failed again – Perrigo insisted on going forward with the campaign even though the temperature-deviation problem had not been addressed. Predictably the same problems persisted and Perrigo had to discard roughly half of the soy formula product it manufactured.

206. Despite these significant equipment, quality, and sanitation issues that forced frequent shutdowns and product scrap, at the June 10, 2025 Oppenheimer Consumer Growth and E-Growth Conference, Defendant Lockwood-Taylor reiterated: "***Our production attainment, packaging attainment, customer service levels are at historical highs. These are more reliable, more efficient, more quality assured operations than we've ever had before. And in our view, they're market-leading***."

207. The next month, the post-storm cleaning of Gateway was complete and the plant was ready to come back online. Plant leadership insisted on restarting it over the weekend; a senior employee objected to this plan because there would not be the correct personnel at the facility, but leadership went ahead anyway. An error was made that resulted in more flooding at the plant, and another multi-day delay in production.

208. Around this time, Perrigo cancelled necessary planned upgrades for the dryer.

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told FE7 that he had escalated the report up the chain to demonstrate the severity of the problem; there had been several documented rain leaks in the past, which the FDA was aware of. When the FDA had questioned Neuman, he could only respond that it would require a capital project to fix.

L. Perrigo Discloses Drop to Gross Profits Due to Increased Product Scrap, But Claim the Infant Formula Business is "Progressing"

209. This truth about Perrigo's infant formula business was partially revealed to investors on August 6, 2025, when Perrigo announced that adjusted gross profit of $403 million was decreased $30 million, or 6.9%, due in part to ***"production variability in infant formula, leading to an increase in product scrap in the quarter."*** Additionally, reported gross margin was 34.4%, a decrease of 260 basis points "due primarily to the same factors."

210. On the same day, Perrigo hosted an earnings call regarding the Company's financial results for the second quarter ending June 28, 2025. During the earnings call, Defendant Bezerra revealed that the "production issue" with infant formula "led to scrapping approximately $11 million of inventory." Bezerra further stated that the Company's "gross profit declined $23 million, largely due to the previously mentioned isolated production variability in infant formula." Specifically, during the earnings call, Bezerra stated as follows, in relevant part:

> Second quarter gross profit of $403 million declined $30 million year-over-year, primarily due to an $18 million impact from divestitures and exited businesses, partially offset by favorable currency translation. ***Organic gross profit declined $23 million, largely due to the previously mentioned isolated production variability in infant formula. This production issue led to scrapping of approximately $11 million of inventory.*** Additionally, we experienced lower plant overhead absorption in OTC and Oral Care. These factors more than offset benefits from our accretive initiatives, Project Energize and Supply Chain Reinvention, which continue to deliver meaningful efficiencies.

211. On this news, the Company's share price fell from a closing price of $26.62 on August 5, 2025 to close at $22.83 on August 7, 2025, a decline of $3.79 or 14.24%, on unusually heavy trading volume.

212. Nevertheless, Defendant Bezerra reassured investors that even as near-term results were pressured, the business was on track: "While we experienced production variability in the quarter, I want to emphasize that ***the infant formula business is progressing***, and the actions we have taken are moving us in the right direction."

213. Analysts accepted Bezerra's reassurances. J.P.Morgan modestly reduced its estimate but explained "we are leaving our margin estimates largely unchanged as we view the scrapped infant formula product as more 1x in nature" – exactly as Defendants had framed it.

M. The Class Period Ends: Perrigo Discloses it is Abandoning the $240 Million "Strategic Investment" and Commencing a "Strategic Review," While Slashing Earnings Per Share

214. On August 12, 2025, Defendants Lockwood-Taylor and Bezerra attended the Canaccord Genuity Growth Conference. When asked where he saw the "biggest opportunity throughout the company," Defendant Lockwood-Taylor pointed to infant formula, characterizing its recovery as a "***revenue builder***."

215. Just three months later, Perrigo reversed course entirely.

216. On November 5, 2025, before the market opened, Perrigo issued a press release announcing the Company *"**is initiating a strategic review of its infant formula business**,"* including "a full range of alternatives." The press release revealed Perrigo is "reassessing the Company's previously announced investment in this business of $240 million."

217. Perrigo further revealed that "due primarily to infant formula industry dynamics," Perrigo was slashing its fiscal year 2025 outlook. The Company cut its reported net sales growth guidance to -2.5% to -3%, a negative turn from the previously expected 0% to 3%. Further, the Company cut its expected adjusted diluted EPS to a range of $2.70 to $2.80, a significant cut from the previously announced range of $2.90 to $3.10.

218. Defendant Lockwood-Taylor claimed that "[w]hile our infant formula operations have stabilized, the external environment has quickly changed, making a fit with our consumer health OTC [over the counter] businesses less strategic."

219. On this news, Perrigo's stock price fell $5.09, or 25.2%, to close at $15.10 per share

on November 5, 2025, for a loss of approximately $1 billion in market capitalization, on unusually heavy trading volume.

220. Over the course of the Class Period, Perrigo's stock price fell from a high of $40.11 to this low of $15.10, a loss of over $3.4 billion in market capitalization.

221. Although Perrigo phrased this process as a "review," the market finally understood what had been true all along – that the infant formula business and Gateway acquisition were not "stabilized," "reset," and "immediately accretive" as Defendants had claimed. One analyst noted that it was now ***"[u]nclear what value Perrigo ultimately realizes from the asset***." J.P.Morgan concluded that while they "expect this strategy review will take some time to complete . . . ***ultimately we believe PRGO is likely not the best owner of this asset"*** and expected "choppy" results from Nutrition in the meantime. *Reuters* emphasized that the announcement came alongside a cut to the profit forecast, reinforcing that infant formula challenged near-term results and created earnings risk and had reversed from a turnaround story that the Company had under control to a major drag on earnings.

222. Perrigo made a flimsy excuse for the abrupt reversal, claiming that "the external environment has quickly changed," referring to the U.S. government allowing foreign formula manufacturers enter the market. But Defendants had tracked, discussed, and publicly minimized that supposed catalyst for years, noting in the Q1 2023 10-Q the FDA's efforts to "strengthen *and diversify the market,*" referring to new market participants, including foreign entrants; on the Q3 2024 earnings call, Defendant Lockwood-Taylor acknowledged disruption from "new foreign brand entrants into the market"; in winter 2025, Perrigo executive Thomas went to the Vermont facility and talked to employees about increased competition from Canadian and European formula; at the 2025 Investor Day, concurrent with the announcement of Perrigo's $240 million

investment in infant formula, Schmelte noted recent "disruptions" including "[a]llowing foreign manufacturers to market and sell in the US market." And most recently, at the June 10, 2025, Oppenheimer 25th Annual Consumer Growth & E-Commerce Conference, Defendant Lockwood-Taylor dismissed foreign formula as merely a "short-term competitive risk."

223. The sudden reversal from viewing foreign formula as a mere "short-term competitive risk" to it necessitating a total "strategic review" and pause of the $240 million investment underscores the dubious nature of that excuse.

224. That was further evidenced just a few months after the Class Period, on February 26, 2026, when Perrigo recognized a $1.3 billion goodwill impairment leading to diluted EPS, due to "lower expected cash flows principally related to infant formula market dynamics" among other reasons, and eliminated infant formula from "CORE Perrigo," its "go-forward business." That month, the FDA inspected the Gateway facility and issued another Form 483.

V. ADDITIONAL ALLEGATIONS OF FORMER EMPLOYEES

A. Perrigo Retained Pricey Consultants but Ignored Their Recommendations

225. During the Gateway "reset," according to FE4, Perrigo hired Validant to provide quality consulting at a cost FE4 heard was approximately $27 million dollars. FE4 worked directly with Validant consultants over the course of the shutdown. According to FE4, Validant consultants were on the factory floor all the time, "looking over everyone's shoulder" to report even minor deviations in quality processes. According to FE4, the general consensus among the Gateway employees was that the Validant consultants were "not telling them anything they did not already know."

226. According to FE7, the Validant consultants would write shift recaps of problem they were observing, such as issues with Good Documentation Practices ("GDP") or Good

Manufacturing Practices ("GMP"), food code violations, or sanitation issues, among others.[31] The Quality and Production Departments would sign off on the consultants' recaps; FE7 viewed some of these recaps, and on occasion, was asked to sign off on recaps himself. Validant would then pass the write-ups to Valerie Gill ("Gill"),[32] Perrigo's Vice President of Regulatory Affairs. FE7 was told by Knudtson and Gill that the write-ups were being presented to the Steering Committee – and to Lockwood-Taylor himself.

227. According to FE7, Validant had frequent meetings with Perrigo's Steering Committee. Knudtson, Bohl and Gill would attend those meetings, which occurred on a bi-weekly basis through 2025. FE7 was told by Knudtson that Validant's findings were shared with Lockwood-Taylor during those meetings. FE7 recalled that some of the Validant summary's key findings included that Quality Department employees lacked experience; most had two or fewer years of experience in infant formula and so were not effective at their roles. Additionally, it found that there was not sufficient cooperation across Quality and the other Departments at Gateway, and that Quality did not allow other Departments to have buy-in on the procedures.

228. At one point in 2024, early in Validant's tenure at the Gateway facility, a consultant named Caitlin (FE7 does not recall her last name) arranged to meet with employees at the plant, pulling 50 employees across different departments for individual interviews. FE7 was one of the employees interviewed. At the start of the interview, Caitlin informed FE7 that she was using this information to draft a report that would be going to the Steering Committee and to Lockwood-

[31] Initially, FE7 did not work directly with the Validant consultants, who worked primarily on the floor with operators. The intent had been for the consultants to train the operators on food safety best practices while the plant's Quality team was too understaffed to conduct that training itself. But by the fall of 2024, FE7 was working with the Validant consultants on a day-to-day basis, after Knudtson assigned him to serve as the point of contact within the Quality team for the consultants.

[32] Vice President of Regulatory Affairs.

Taylor. Additionally, Caitlin informed FE7, a summary of her findings would be shared with onsite management. During the interview, FE7 was asked many questions about personnel, including and especially Knudtson. The interview did not, to FE7's memory, include questions about equipment or mechanical issues.

229. The consultants revised certain written programs and built out a more formal micro-monitoring program, but according to FE4 they did not address the critical engineering deficiencies that required capital investment. He believed the necessary investments should have been focused on engineering solutions that would eliminate high-risk points and reduce human interaction, for example, redesigning and automating wet clean processes; adding automatic samplers; and upgrading control systems and automation. These were the types of investments that would have mattered to enhance sanitation and safety and to the FDA after the Abbott recall. Instead, Perrigo directed money toward a third-party consultant and toward a second evaporator that, as of his departure, had not been turned on.

230. FE8 interacted with multiple consultants that came to the Vermont facility over the years to analyze the plant and make recommendations to Perrigo on changes to address the quality and sanitation issues. The last two consultants during his tenure were Relco and LaPorte. Both Relco and LaPorte made recommendations to Perrigo that their current dryer situation did not work and to make it work, significant renovations and changes would be necessary to equipment and processes. One of the concerns with the Stork dryer is that due to the lack of adequate fire suppression, if there was any kind of combustible dust explosion in the machine, it would create a serious explosion hazard. This concern came up multiple times from multiple consultants between roughly 2020 and 2024.

231. Both Relco and LaPorte concluded that the dryer situation at Vermont just did not work. They recommended that Perrigo add fire suppression cannisters to the Stork dryer so it had CO2 fire suppression. But the only way to make that work was drilling numerous holes into the dryer – the problem was that due to the layout and how the Stork dryer was positioned in the plant, one could not do Project Maintenance (PMs) because to get to these holes one would need to build platforms and elaborate infrastructure around the dryer. As to the Marriott Walker dryer, there was no viable way to update it and make it safe and consistent with quality standards – there simply was not the space inside the plant to build another vertical dryer like the Stork dryer without extensive changes that would be difficult on an old plant.

232. FE11 reiterated that in 2020, a consultant named Relco prepared a report for Perrigo that identified numerous issues with the Vermont plant, including issues that impacted safety and quality of the formula being produced. But Perrigo did not take action or implement Relco's recommendations.

233. The consultants' findings regarding the dryers, along with their recommendations that they need to be completely overhauled or replaced were well known across Perrigo, including its leadership. FE8 personally discussed these findings and recommendations with numerous people including Rob Somers ("Somers")[33] the EH&S Director or VP and Todd Shuttleworth ("Shuttleworth")[34] who was in leadership at the plant. FE8 also attended numerous meetings where these topics were discussed, and which were attended by folks in leadership including Somers and Shuttleworth.

[33] Global Senior Director of Environment, Health and Safety.
[34] Director of Operations.

234. At one point, Shuttleworth told FE8 to not tell employees that there was a significant combustible dust hazard because of the dryer. He did not want employees to know that this was a potential safety hazard on the floor. Infant formula is a very fine powder, so that can create this heightened risk for combustible dust. Indeed, when FE8 did a walkaround of the plant with the combustible dust analysts, he was specifically told by Shuttleworth to not tell the workers that they were doing a combustible dust analysis.

B. Perrigo's Leadership Had Access to Data and Visibility into Plant Problems

235. FE9 described Perrigo as a company with deeply embedded, extensive reporting processes, requiring monthly updates to the C-suite on demand forecasts, production planning, and financial assessments. FE9 explained that these processes were time-consuming and involved many departments across the Company.

236. FE1's role focused primarily on non-batch-quality issues for the environmental monitoring program, such as environmental pathogen hits, sanitation failures, and contamination-related events. He performed root cause investigations, compiled historical quality data, and authored investigative reports that would be reviewed during FDA investigations. Through this work, he regularly accessed and relied on historical maintenance records (via SAP), quality data stored in NeoGen (a newly created tracking tool), Excel spreadsheets, older FDA Form 483 letters dating back to the Nestlé era, and document-control files stored in OpenText. FE1 observed that if someone at his level could access these systems, he assumed that senior leadership – including corporate-level quality and engineering – could also review them.

237. FE2 was aware of both the Vermont and other Perrigo formula plants receiving numerous FDA "yellows" or Warning Letters. FE2 knows this because information about FDA yellows or Warning Letters for all of the Perrigo formula plants was shared at the monthly all-hands meetings. Additionally, FE2's job took him throughout the Vermont facility and satellite

facilities where he would speak to other employees, who often would let him know if their department received a yellow or a Warning Letter.

238. According to FE9, the Supply Chain Reinvention Program touched on the entire CSCA business, which includes infant formula. In connection with the Supply Chain Reinvention Program, the RDO developed a dashboard which was a standard set of slides to update information on project status, capital investments, anticipated return on those investments, changes in overall capacity, major milestones that had been completed, timeline for remaining milestones, whether spending was on track, and more. That information would be presented to Janish at least monthly to provide updates and answer questions. Additionally, this information was presented to Executive Vice Presidents and others in leadership.

239. Infant formula was a frequent topic of attention for Perrigo's senior leadership. FE9 and colleagues would have timelines set to gather information and update slide decks in advance of their review by Janish and presentation at executive leadership meetings. It was FE9's understanding that those executive leadership meetings typically were attended by the CEO (Murray Kessler and then Patrick Lockwood-Taylor), the CFO Eduardo Bezerra, operations leader Janish, commercial leader Catherine "Triona"[35] Schmelter ("Schmelter") and others. It was also FE9's understanding that the CEO visited the formula plants.

240. FE4 shared that Perrigo executives were informed of and aware of the major issues, such as positive *Cronobacter* tests or equipment breakdowns causing significant downtime at the Gateway facility. Executives including Reno Thomas, Guillermo Guillen, Anthony Freve, and Maria McCaffrey were aware of major issues. Thomas was the Vice President of Operations for

[35] Executive Vice President & President of the Consumer Self-Care Americas and Global Portfolio Optimization.

the infant formula business, Guillen was Senior Director of Quality, Freve was the Senior Vice President, Operations and Supply Chain Consumer Self-Care Americas, and McCaffrey was Senior Vice President Global Quality. Also, according to FE4, CEO Patrick Lockwood-Taylor was notified the most recent time that the plant had a positive *Cronobacter* hit. A quality manager drafting the report told FE4 that the report would go all the way up the reporting chain to the CEO.

241. FE1 recalled that Perrigo's CEO visited the facility at least once or twice during his tenure. He said some senior personnel visited more frequently and he observed them at the facility. They had an all-hands-on-deck approach the few days before senior personnel would come to try and spruce up the facility.

242. According to FE11, at monthly all-hands meetings, employees also regularly raised concerns about infant formula contamination. FE11 observed that the necessary actions were not being prioritized as need be and no meaningful steps were progressing to address such problems.

243. FE2 went to Shuttleworth and told him about his concerns including that the equipment was contributing to *Cronobacter* being present in the plant, specifically the HVAC and boiler issues. FE2 spoke directly to Shuttleworth in person, over multiple conversations, about these concerns. In response, FE2 was either told that he was wrong or reassured that his concerns would be looked into or were handled by an outside company, but during his tenure at the plant the problems were not resolved. FE2 also sent emails to Health and Safety and Engineering teams at the plant regarding the HVAC and boiler issues.

244. FE8 received reports and information from the consultants because their work implicated EH&S issues like fire safety. He directly told Somers and Shuttleworth about the information they received from the consultants, quotes for fire suppression and other measures that

were recommended, and what we need to fix. There were many meetings on the problems, but no meaningful steps were taken by Perrigo to address the big problems.

245. In winter 2025 before the fire, FE6 recalled Reno Thomas coming to the Vermont facility for an onsite. There was another senior corporate leader onsite with him, as well. FE6 recalled Thomas talking about market invasion of formula from Canada and Europe creating competition. FE6 also recalled a worker directly asking Thomas about the future of the Vermont facility; Thomas was very reassuring and said they were such a reliable team and he wouldn't think of getting rid of them. Weeks later, they were told the plant was getting shut down.

246. FE9 recalled that demand for formula was very high, particularly after the Abbott recall. Perrigo regularly evaluated its production capacity, how to maximize capacity, and how to increase output to respond to heightened demand. FE9 recalled a desire among leadership to increase production. Perrigo was also regularly evaluating capital investments in an effort to maximize production.

C. Perrigo Mismanaged Gateway's Transition from Nestlé

247. Once the transition happened, Perrigo lacked sufficient personnel in key roles.

248. According to FE7, experienced personnel largely left Gateway before it transitioned to Perrigo, and there was a major gap in leadership at the plant level.

249. FE3 understood that before Perrigo purchased Gateway from Nestlé, it had been staffed by Nestlé employees who possessed years – sometimes decades – of institutional knowledge. When the sale occurred, few of those people stayed on at the plant, meaning Perrigo inherited the machinery but not the expertise required to operate it efficiently or understand its nuances and challenges.

250. FE4 saw a clear contrast between Perrigo's capabilities and those of Nestlé. Under Nestlé, the company had extensive technical resources and a deep bench of experts who could be dispatched to the site when needed. By comparison, Perrigo had only a handful of food scientists and lacked the expertise necessary to support a complex, highly automated infant formula facility. FE4 believed this gap was obvious from early in the transition and contributed substantially to ongoing operational difficulties.

251. ***Deferred maintenance and key positions left vacant***. According to FE4, from 2020 until after Perrigo's acquisition of the plant, Nestlé failed to conduct an annual shutdown. Prior to that, for the first eight years that FE4 worked at the Gateway facility, the company conducted a two-week shutdown every year for major maintenance work on equipment such as the boilers. FE4 emphasized that the highly automated and technical systems required regular investment that Nestlé had stopped providing.

252. Similarly, FE7 heard from other operators who worked at the plant during Nestlé's ownership that the company stopped spending any money on the plant, and the amount that Perrigo would have needed to invest so that the plant would meet the standards necessary to manufacture infant formula would be substantial.

253. FE4 was told by his supervisor that Nestlé had scaled back maintenance budgets to such an extent that the maintenance manager, Michael Bischel ("Bischel"),[36] resigned, telling colleagues that his "hands were tied." Instead of hiring a new maintenance manager, Nestlé had its engineering manager, Andres Alvarado, take on Bischel's responsibilities as well as his own. These roles were the second highest at the plant level, right below the factory manager. Additionally, by approximately 2021, the Gateway facility had no maintenance supervisors and

[36] International Logistics Manager.

Nestlé declined to backfill their roles, instead handing off their responsibilities to production supervisors, including FE4. As a result, tasks that had previously been the responsibility of maintenance supervisors, such as tracking and conducting regular PMs, calibrating and monitoring equipment, and conducting root cause analyses for equipment breakdowns, were severely neglected.

254. According to FE4, the first several months after the acquisition were intended to be a transition period in which Nestlé agreed to work hand-in-hand with Perrigo as it took control of operations. FE4 instead observed a failed leadership transition. Nestlé's factory manager, Dominik Painter ("Painter"),[37] was supposed to train a Perrigo-appointed successor during this time. However, Perrigo failed to hire anyone into the role before Paintner left. Perrigo attempted to persuade Paintner to remain longer, but he declined, leaving the site without a factory manager for an extended period. A corporate supply chain vice president named Shannon Qualls ("Qualls")[38] was temporarily assigned to cover oversight responsibilities, but he was rarely present at the facility. FE4 recalls Qualls present at the factory only once. Within four to six weeks, Qualls was replaced by a new hire, Luis Mar-Silva ("Mar-Silva").[39] However, by that point there had been no transition from Nestlé personnel, leaving Mar-Silva without institutional support or guidance.

255. In the period leading up to Nestlé's sale of the facility, FE5 noted that employees had no advance knowledge that Nestlé intended to sell but, at the same time, the announcement was not entirely surprising given the operational challenges. FE5's impression was that Nestlé "dumped" the facility because of the difficulty, cost, and regulatory burden of producing infant formula.

[37] Factory Manager of Infant Formula at Nestlé Nutrition North America.
[38] Vice President of Supply Chain and Operations Integration.
[39] Senior Director of Operations at Gateway.

256. ***Loss of critical data during recordkeeping system transition***. According to FE1, Nestlé had a version of SAP and then during his tenure they transitioned to Perrigo's SAP. It was a really rough transition. A lot of maintenance and recordkeeping information was lost in that transition. These issues were brought up in some of the larger staff meetings at the facility that FE1 attended. Perrigo sent its employees to the facility to try and help with the problems.

257. Similarly, FE5 explained that Nestlé had used more updated and integrated digital systems for inventory management, auditing, and corrective action tracking. Under Perrigo, the facility relied on older, more manual systems, including legacy SAP and inventory platforms. As a result, many quality and audit functions required manual data entry, often by FE5 himself, which slowed corrective actions, audits, and operations workflows. FE5 stated that this regression added friction to quality operations and daily production activities. FE7 also noted that the switch from Nestlé's sophisticated database to Perrigo's outdated system resulted in loss of key manufacturing records and required manual entry of critical information.

258. ***Overestimated production capacity***. FE4 observed that Perrigo was surprised by the number and extent of problems they uncovered after the acquisition. Site-level staff who had worked at the plant under Nestlé's ownership immediately recognized that Perrigo did not fully understand what they had purchased and had not examined maintenance history, operational realities, or infrastructure condition in sufficient detail. For example, Perrigo misunderstood the production capacity of the factory. FE4 was present during a scheduling meeting sometime in 2024 in which someone mentioned that Perrigo thought they had purchased a "27-million-pound factory," meaning a plant that could produce up to 27 million pounds of infant formula product per year. The operations manager, Jim Nesterick, responded, "Yes, but of Good Start." The comments gave FE4 the impression that Perrigo did not understand that the 27 million capacity

number was limited to exclusive production of the Good Start formula – and only when the factory was operating under ideal conditions, i.e., with well-maintained equipment and a full staff. FE4 explained that when the plant was producing exclusively the company's "Good Start" formula, the plant could run for 64 hours straight without needing a Clean-in-Place to sanitize equipment. That did not work for Perrigo's infant formula products, so-called "intact protein" formulas, which required more frequent cycles and breaks for Clean-in-Places (approximately every 30 hours), reducing practical production capacity to approximately seventeen to eighteen million pounds annually.

259. FE4 believed that Perrigo did not ask the questions that would have uncovered this discrepancy. Had Perrigo asked basic questions about, for example, the facility's turnover rate, staffing levels, or the assumptions underlying its production capacity, it would have been apparent to the company that those numbers were not feasible.

D. Perrigo Failed to Address Critical Quality and Sanitation Issues at the Gateway Plant

260. ***Deteriorating dryers.*** According to FE7, the dryer was tested by an external company in 2023, 2024, and 2025 – microcracks were found each time and their size expanded over time – by December 2025, the largest crack measured 32 inches long.[40]

261. FE5 corroborated that Gateway experienced recurring issues with the eight-story dryer, which contained micro-cracks, and with *Cronobacter* contamination events. FE5 described the facility as very costly to operate due to microbiological controls. FE5 explained that whenever a test was positive for microbiological contamination, entire batches had to be rejected and discarded. Given that individual batches could be worth hundreds of thousands of dollars, this

[40] Pictures were taken of the cracks, which FE7 viewed. Hernandez shared with FE7 a report drafted by the external company.

made the plant extremely expensive to operate.

262. According to FE7, in approximately June 2025, at the request of Hernandez and Guillen, FE7 and Neuman created a PowerPoint presentation on the *Cronobacter* investigation and potential root causes, including the dryer leak issue. The presentation was shared with Guillen and Maria McCaffrey ("McCaffrey").[41] Finally, in response, Perrigo adjusted the Clean-in-Place process to prevent it from leaking into the dryer.

263. ***Widespread leaks.*** FE1 also observed widespread leaks, occurring all over the facility including in sanitary areas. There was at least one leak in the dryer area. There were rain leaks through the roofs in the warehouse and packaging areas. If rain or a storm was in the forecast, employees knew they'd have five to ten leaks to deal with. They had to put buckets out to catch water. There were also condensation issues with water dripping from pipes throughout the plant due to poor humidity control.

264. FE1 dealt with structural failures on the roof and dryer in his role. For leaks, he'd fill out a form with time and date of the leak, the containment efforts, who did the containment, information about swabbing and the results, put in a maintenance / utilities request through SAP, and attempt to do a root cause investigation. For dryer issues, if there were contractors coming in especially for patching and the fireline partial removal, it was FE1's job to try and prevent environmental contamination – training contractors on how to interact the environment, creating transition stations, teaching how to clean up, preparing the area, and then how the final environmental swabbing would be done afterwards.

265. FE1 knew that both of these issues – the dryer micro-cracks and the leaks – had persisted for years, because they appeared throughout maintenance logs and Form 483s that he

[41] Senior Vice President of Global Quality.

reviewed in the course of his work.

266. These issues were consistent with a common theme FE1 observed at the plant: ongoing problems with known root causes, repeated over many years, without corrective action. FE1 felt that Perrigo was doing band-aids instead of real fixes. This included patching the dryers, and the use of rain leak containment tarps and patching by the utilities team as opposed to getting a real roofing professional to fix the roof problem.

267. ***Flooding from poorly managed plant restart***. Perrigo had intended to restart plant operations in July 2025 following a *Cronobacter* investigation – they were under pressure to restart quickly given how long they had been out of production. At the time, FE7 was working from home on the investigation, and was receiving messages from Neuman about plant leadership wanting to start up again over a weekend. FE7 and others, including the production manager and sanitation manager, discouraged starting on a weekend; all management needed to be there when the facility restarted so that operators on the floor would have the support they needed. The request was ignored; the plant restarted on a Sunday, and during a Clean-in-Place, massive flooding occurred in the "bag house" area of the plant, where waste product is moved. That resulted in a subsequent three to four-day production hold as they needed to reclean the environment in the dryer.

268. ***High temperatures and poor humidity control throughout the plant***. FE7 personally observed condensation form on the tower, a three-story structure where the dried powdered product would be slowed down and probiotics added prior to packaging. FE7 similarly reported that he was told by operators that there was also condensation in the filler, the last piece of equipment before formula would go directly into the can.

269. Multiple operators also told FE7 that the high temperature in the facility, combined with the heat from the disposable smocks worn during cleans, would cause operators to sweat

directly onto the very equipment they were attempting to clean.

270. ***Inadequate sanitation and zoning program***. According to FE7, Gateway's sanitations and zoning programs were not where they were supposed to be. A zoning program is intended to define physical areas in the plant from lowest to highest risk of possible contamination, with Zone 1 as an area where there is immediate product surface contact and therefore the highest risk to contamination. Because the facility's Quality team was severely understaffed, there was no dedicated hygiene team to delineate these zones or put in place processes for operators to move from areas of high risk to low risk, or vice versa, according to best practices, as reported by FE7.

271. With respect to sanitation, FE7 also observed that the plant did not follow best practices when cleaning equipment that was high-hygiene. According to FE7, under best practices, such equipment should be cleaned in a designated area directly adjacent to the Zone 1 or "high-hygiene" area, and the equipment must be dried immediately after washing in order to avoid water at ambient temperatures remaining on the equipment and increasing the risk of contamination. Instead, at Gateway, operators would disassemble and transport high-hygiene equipment into a separate warehouse area, into a room called the "tote wash," where all equipment, whether high-hygiene or not, would be washed and then left to air dry over extended periods of time.

272. ***Contaminated fire suppression lines***. FE1 identified a major recurring contamination hotspot in the fire sprinkler system located inside the dryer, which he discovered was visibly deteriorated and in uncleanable condition. From the platforms around the dryer, one could look up and see the lines and just with the naked eye one could see that sections of the sprinkler line were heavily degraded, and see paint chipping onto the floor, portions of the lines coated in black grime, and surfaces that could not be sanitized. The line contained evident pathogen harborage. Portions of line ultimately had to be removed because the condition of the system posed

contamination and safety risks. FE1 stated that this issue should have been addressed much earlier, given the dryer's advanced age and the apparent, obvious deterioration of the equipment. This problem did not happen overnight – it was the kind of problem that takes a long time to get to this state. This was common knowledge of the dryer operators and anyone could see bright red paint chips on the floor – the only red thing in that area was the fire line. It was FE1's understanding that it was hugely expensive to replace the sprinkler line altogether.

273. When he discovered this issue, FE1 made a big stink, escalating it aggressively by bringing his findings – and the supporting evidence – to Neuman, and then into meetings that included the plant manager, Luis Mar-Silva. This occurred in late summer or early fall of 2024. FE1 explained that this was so important to him because when he looked at the historical logs and results, the area where they'd swab and have bacteria present were frequently in the areas of degraded equipment. Once they started swabbing that fire line they were getting bacterial hits. It screamed out as a root cause and serious problem.

274. Similarly, FE7 observed that the fire sprinkler line at the dryer was visibly deteriorating. In approximately April 2024, Perrigo removed that sprinkler line in response to the 2024 *Cronobacter* finished product hit and informed the FDA that this constituted the preventative maintenance to address the problem. However, according to FE7, there were several other fire sprinklers throughout the plant that were not possible to clean – they were positioned such that if someone got too close to a sprinkler, they would get triggered and go off. Perrigo did not report this issue to the FDA, nor did they adjust the sprinkler lines such that they would be easier to clean without being triggered.

275. ***Improper cleaning processes***. According to FE7, equipment that came in direct contact with the infant formula was considered "high hygiene" and required the highest levels of

sanitation to prevent contamination. But rather than follow proper protocol of cleaning high-hygiene equipment directly adjacent to its zone and immediately drying it, at Gateway, operators would disassemble and transport high-hygiene equipment to a separate warehouse area, where many different types of equipment was washed and left to air dry.

276. ***Lack of a deviation tracking system***. Additionally, Gateway lacked basic systems for tracking key information like deviations. A "deviation" occurs when a critical step in the manufacturing process was missed, the formulation is incorrect, or a problem is identified with the formula (such as metal shards). When a deviation is identified, an Outside Deviation Report ("ODR") is generated and the product has to be re-tested, discarded, or recalled. According to FE7, he developed the first such system for the plant a month and half after being hired, on an Excel spreadsheet. FE7 created a deviation-tracking spreadsheet in Microsoft Excel for the Quality team to monitor deviations across Gateway. Prior to this, there was no consolidated tracking system for deviations; instead, individual reports were simply saved in a shared folder. A co-worker expanded upon FE7's original framework, and eventually, the tracker was adopted for use not just in the Quality department, but also in Operations. The tracker started to be shared on a biweekly basis during operational meetings, with managers relying upon the tracker to analyze the cause of deviations and utilizing the tracker as a continuous improvement tool. According to FE7, the tool and its analysis was shared with Guillermo Guillen and VP of Operations Thomas in order to assess the time required to close out deviations. This was a matter of significant operational importance given that unresolved deviations delayed the release of product.

277. ***Dryer repair made over employee objection created more metal contamination, post-Class Period***. In late December 2025, FE7 attended a meeting between members of the Gateway Quality department and leadership, including Neuman, Guillen, Thomas, Head of

Reliabilities and Maintenance Dave Rosenthal and the Gateway maintenance manager. The Quality team informed leadership that something had to be done about the cracks in the dryer before the FDA returned for another inspection. Leadership decided to weld a patch on the dryer. FE7 was concerned about the decision to patch the dryer as opposed to replace it. FE7 previously worked as a welder; he knew that parts of the dryer were getting thin and that patching new metals to older metals could lead to additional problems, such as microcracks forming over the weld itself and frequent repairs around the patch being needed. Once the metal is as worn and cracked as what FE7 observed on the Gateway dryer, it needs to be replaced entirely. FE7 expressed concern about the welding in the meeting, but Neuman pushed back that the problem just needed to be fixed.

278. Ultimately, plant leadership opted to cut out entirely the cracked section of the dryer and replace it; but this caused the same challenge identified by FE7 with welding new metal over old. Moreover, this "fix" ended up causing a three-week delay to restarting production due to the introduction of metals into the dryer, which posed a severe food safety risk. The metal shavings left behind by cutting out and replacing the dryer section were then "chewed up" by the dryer's rotary valves, thereby creating even more metal pieces. Due to the challenges with removing the metal introduced in the dryer, the plant was still shut down by the time the FDA came for its next inspection, in late January 2026.

E. Perrigo Failed to Address Critical Quality and Sanitation Issues at the Vermont Plant

279. ***Deteriorating dryers***. According to FE2, the Vermont facility was originally designed as a dairy facility, so many of the materials and aspects of the layout were not designed to meet the sterility requirements of infant formula. When it was converted to an infant formula facility they retrofitted instead of completely rehauling so there were design problems.

280. Similarly, according to FE8, one of the other issues that came up was the fact that the Vermont facility had dairy-grade brick for its flooring. Because of the more porous nature of that material, it contributed to the mold and *Cronobacter* issues that the plant was struggling with. Perrigo started replacing certain areas of the plant in 2022 or 2023. By the time FE8 left Perrigo, they were replacing very small sections. For the most part, the wet processing area still had dairy brick.

281. According to FE6, from the start of his time at the plant, it was clear to FE6 that there was significant deferred maintenance on important machines and instrumentation. For example, the dryers had been there for decades and would break down frequently.

282. Similarly, FE8 reported that one of the areas with significant issues was the dryers. The Vermont facility had two dryers – the Stork dryer (vertical) and the Marriott Walker (an old box dryer). When FE8 started working at Vermont back in 2016, he was told the Marriott Walker dryer should not be in operation because it was very old and FDA did not approve of that type of dryer for this purpose, but year after year Perrigo continued using it.

283. The Stork dryer had frequent quality issues, particularly related to cleaning. The Clean-in-Place process did not work successfully in the dryer, resulting in chemicals and powder remaining in the dryer even after the cleaning process was complete. This caused the formula to get wet, which created frequent issues with *Cronobacter* growth. Additionally, the Stork dryer lacked adequate fire suppression.

284. The Marriott Walker dryer also had significant issues. It used steam suppression, which can be a means of fire suppression, but is a non-traditional method that does not work well. Additionally, it was not possible to clean the Marriott Walker sufficiently. To clean it, workers had to go physically inside of the dryer and clean it by hand. It was between 90 degrees when it

cooled down and 110 degrees at its highest temperature. The workers would strip down to their underwear and put on a Tyvek suit and climb inside to clean it, and were sweating all over a machine they were trying to clean and ensure was sanitary.

285. ***Recurring metal contamination***. According to FE6, there were metal shreds found in the infant formula frequently; FE6's group was responsible for looking at microcards which involved filtering the formula and looking under a microscope for metal filaments or fragments, in an effort to salvage some portion of a batch where metal had been found. The frequency with which there was metal in the formula product suggested that something was shredding in a machine that was leading to these fragments. People from across the facility including in the quality group and in the manufacturing team asked and pushed to stop or slow down the process to really diagnose the problem. These requests were shut down by leadership, who instead kept pushing production to meet quotas and get product out.

286. During FE6's time at the Vermont facility, there was a period of about two months when they were seeing tons of metal in the formula product. He remembered a period when there were four batches back-to-back where he pushed to discard the entire batch and not even try to filter and salvage it due to significant amount of metal in the product. For other batches, they pushed through thousands of microcards with people working full-time examining the product under a microscope to try and find formula that was not contaminated and could be sold.

287. ***Unsafe industrial steam used in formula production.*** According to FE2, another issue was with the boiler system. The system was old; the exterior was damaged and posed a significant hazard for employee safety because components of the shell were missing and the boiler could accumulate hot spots or lead to a rupture eventually; and the boiler system was a standard industrial boiler not suitable for coming in direct contact with infant formula. Despite this lack of

proper equipment, the infant formula production process had boiler steam go across a single culinary filter and be directly injected into the infant formula, in contradiction to the PI&D drawings which showed that the steam was culinary-rated steam – not standard industrial steam.

288. FE2 took it on himself to read the applicable standards, and additionally in his typical job functions frequently had to read the PID drawings. He observed that many of the PID drawings were highly inaccurate, showing processes and systems the plant did not actually have. For example, there had previously been a culinary steam system but that had been removed and now was the industrial boiler. He frequently sent emails that we need to get PIDs updated because they were used for regulatory and conformance checks. FE2 would get ignored when he raised these concerns; and no one ever acknowledged the PID problems.

289. Similarly, FE11 noted that there were incorrect PI&Ds and missing or misleading PI&D tags on components across the company. PI&D are instrument diagrams that show all of the equipment and component parts. But the plant's PI&Ds were not consistent with the equipment and components that were actually in the plant. FE11 was asked to update the PI&D drawings during his tenure at Perrigo but he had not had training in the latest AutoCad software. Having inaccurate PI&Ds is a huge issue, and FE11 was surprised the Company had not received a Form 483 for this and for the contradictory work instructions/SOP's.

290. A boiler technician told FE2 that Perrigo used a boiler cleaner at the plant that was banned by the FDA for use in machinery that comes in contact with infant formula; this went on for 4-5 years despite knowing it was banned, according to this technician.

291. According to FE2, the Vermont facility had a heat exchanger that would take steam across the water loop to increase the temperature of the water. That heat exchanger was old and poorly maintained and would frequently leak steam into the environment.

292. According to FE2, when pressurized vessels like the boiler or heat exchanger needed repair, they were supposed to be fixed by specialized welders who held particular certifications for these types of repairs. Perrigo used in-house workers who were not professional welders and did not hold these certifications. Their patch work would fail quickly; FE2 recalls that on multiple occasions, there would be a patch or repair welded to a pressurized machine that would fail again within a week or short period – dumping dirty steam into an elevated sanitation environment.

293. ***Inadequate air filtration***. Additionally, according to FE2, the culinary filter that was part of this process was not sufficient or adequately monitored due to its location and because the instrumentation that monitored the integrity of the filter was not part of any calibration cycle. The Quality department in the facility was responsible for setting calibration cycles. This culinary filter was hard to get to and the gauges responsible for monitoring if the filter failed were not even in the system or part of a calibration cycle.

294. According to FE2, the system should have been set up to have culinary steam go across a culinary filter and then get directly injected. That was what was reflected in the plant's PID drawings. But in reality, the culinary filter was filtering industrial grade steam. That process was below what FE2 understood to be required by the FDA and could result in machine oils, lubricants, or metallic debris contaminating the formula product.

295. According to FE2, an additional concern was that the culinary filter's gauges weren't calibrated, so the plant did not have clear visibility into how the filter was performing or if it had failed. When FE2 asked why the gauges were not in the calibration cycle, he was told that it was because they were part of the PM cycle coordinated by a different group. So, when FE2 asked the department that handled the PM what was the PM for these gauges? He was told that the

maintenance cycle was every three months, they would just look up at the gauges which were about 15 feet up in the air, and see if the readings seemed correct. That was not an adequate way to read this particular type of gauge; these were mechanical dial face gauges so the dial goes back and forth across a series of numbers. Looking up at it from below would necessarily mean the reading would be higher than if one was looking at the gauge correctly. FE2 reported to his department and multiple other department supervisors and managers the issue of the layout and location of the gauges and the nature of the PM and was ignored.

296. ***Contamination risks in formula shipped from Gateway to Vermont***. FE2 recalls that Perrigo told the Vermont facility employees that the new Wisconsin plant would produce formula but then ship it to Vermont, because Wisconsin did not have the capability to package on site. This raised concern for FE2 and others at the plant because shipping created additional contamination risks that were mitigated by just double-bagging the formula, which is not adequate for the level of handling the formula was receiving. Then, there were concerns about how the product was handled once it got to Vermont. FE2 worked on equipment that was involved in conveying the powder so he saw the process and often helped the teams out with this process. The material would arrive to Vermont in a truck on wooden pallets, which is a black zone; then those wooden pallets were unloaded from the truck into a green zone; then brought with a pallet jack to a blue zone where they were squirted with a cleaning fluid that is not sufficient to truly clean a wooden pallet; then brought to the freight elevator which is a yellow zone; then through the silo room to an orange zone where the formula was pumped into the powder conveying system, in a red zone. Perrigo heavily relied on high school kids and temporary labor to move the powdered formula through the facility. These workers did not have basic training or experience in things like proper gowning or how to maintain a sanitary environment. FE2 often jumped in to correct

sanitation errors that occurred during this process such as improper gowning and improper product handling and sanitation practices.

297. FE2 observed that shipments of formula from the Wisconsin plant that arrived at the Vermont facility were often clumped, which would be due to moisture coming in contact with the product. Moisture in contact with the product can create an environment where bacteria grow. FE2 would get called when this happened because the equipment was not designed for clumped formula and could not handle it. Employees at the Vermont facility used sifters to remove clumps before packaging the final product.

298. ***Defective tanks***. Another problem that FE6 observed was with the tanks used for sterilizing and other important pieces of the manufacturing process. One of the tanks was shut down for the entirety of FE6's tenure at the plant because they could not fix it. There was also a dryer that was shut down for the entirety of his tenure; FE6 heard from colleagues that the dryer had numerous issues and was extremely unreliable, so eventually they just shut it down.

299. Additionally, according to FE7, another topic of conversation that came up more than once during meetings spanning Perrigo's infant formula network was an ongoing issue with equipment used in the production of soy-based products. There were known issues with surge tanks, also known as batch tanks, running at temperatures far above their internal specifications. However, the Company refused to invest in fixing the equipment because, according to Thomas, "we don't know what the future of soy is." When the supply chain team requested that Gateway "run a campaign for soy," i.e., manufacture soy formula, during the summer of 2024, every batch produced had a deviation due to the temperature, causing delays and resulting in approximately half of the campaign, or half of the total product manufactured, being thrown away.

300. ***Leaks and water contamination***. FE2 was also aware of PMs to replace buckets in

the ceiling to deal with leaks. There were frequent misses of these PMs and buckets would fall, spilling contaminated water into clean environments. This meant the plant would have to spend as much as 30 hours to decontaminate an entire room. This happened at least three to four times in his tenure, along with frequent near misses that almost resulted in buckets overflowing or falling.

301. ***Insufficient janitorial staff***. According to FE6, they did not have enough janitors to clean the bathrooms and floors as frequently as needed. As a result, the bathrooms smelled terrible and chemistry lab floor didn't get cleaned regularly. FE6 heard from colleagues that this was because Perrigo was not paying wages sufficient for people to want the job. Other businesses in the area paid multiple dollars per hour more than Perrigo was willing to pay.

302. ***HVAC fire from deferred maintenance***. In the early months of 2025, there was a significant fire at the facility that FE6 understood to stem from an issue with the HVAC system. Employees had to be evacuated and the fire department spent two days at the scene. There were concerns about soot contamination in the facility, so Perrigo had to shut down the facility to do a deep clean and inspect the equipment and verify instruments and tools used in the formula production process.

303. FE8 corroborated that there was a fire in February 2025. The Georgia Fire Department responded to the call and asked for mutual aid from the Milton Fire Department. The fire started on the roof. The cause of the fire was the belt in the HVAC system. The HVAC system was poorly maintained, and Perrigo was not fixing the system the way they should.

F. Perrigo's Formula Production Collapsed and Customer Orders Went Unfilled

304. FE7 first became aware of the facility's struggles to fulfill customer orders in August 2024, when he began attending weekly scheduling meetings that spanned the entire Perrigo infant formula network. These meetings, held to discuss scheduling and supply chain needs for the

upcoming weeks, were attended by representatives across all three of Perrigo's infant formula manufacturing sites, as well as Guillen, Thomas, and Renata Melo, Senior Director of Infant Formula Supply, among others.

305. During these meetings, members of the supply chain or procurement scheduling team would direct the plants as to which batches needed to be prioritized for release so that they should be shipped on time to customers. The hope was that the operations teams on the ground at each plant would understand the criticality of deviations – the company would begin to lose customers if more deviations occurred and batch releases were further delayed.

306. According to FE7, during these meetings, attendees would also review facility scheduling and discuss any planned downtime for maintenance work at the plant that might prevent orders from being fulfilled. On many occasions, FE7 recalls that leadership, including Thomas, would instruct plant managers to prioritize fulfilling orders, thereby postponing maintenance work.

307. During his tenure, FE1 observed that production runs would get cut short when there were positive bacterial test results to do a sanitation break on an emergency basis. Additionally, because there were so many *Cronobacter* hits throughout the environment, there were pretty regular sanitation breaks. The dryer would leak during the Clean-in-Place process when it should be fully enclosed, which would mean the platforms and other areas in the environment would get wet as well and have to be cleaned. Introducing moisture to what should be a dry area created more risks for bacterial growth.

308. FE1 also noted that the company's projected production for 2024 was only 40–50% of expected annual capacity.

309. According to FE7, in 2025, Gateway only ran for approximately six months out of the year.

310. In the winter of 2024, FE7 attended a meeting where Supply Chain leadership informed attendees that Perrigo had lost the Target contract due to their repeated failures to fulfill orders. Order volume dropped off dramatically going into 2025.

311. In FE6's role, he had access to the production numbers and observed that Vermont was not performing anywhere near production expectations.

312. During FE3's time at Perrigo, he observed a significant spike in demand for Perrigo's formula following the 2022 Abbott recall, but Perrigo struggled to fill orders. Many customers lost confidence and reduced the volume they were ordering from Perrigo as a result. FE3 learned this because plant leadership would tell employees about production forecasts. Additionally, over time, he observed fewer production runs happening, less samples being pulled to the labs, and less work happening across the plant.

313. According to FE2, at the monthly meeting for the whole plant, people in plant leadership would go over joint rates across all shifts. Joint rates were also part of the monthly all-hands PowerPoint. Those PowerPoints included information from across Perrigo, including the Michigan plant, on topics such as HR performance, upcoming events, hire/fire rates, and production rates. The numbers in the PowerPoint for the Vermont facility never matched what FE2 saw on the board in the packaging environment room. FE2's shift always had a point of contention because the numbers did not reflect the production rates that FE2's shift met. There would be applause for the shift that hit high rates and it was always a day shift, but that didn't match the numbers on the board that showed FE2's night shift producing far more. It was a frequent point of conversation that it seemed like the numbers were off.

314. According to FE6, production volume at Vermont really slowed down during his time at the facility. By the end of quarter one 2025, they were producing about a quarter of capacity

the plant was capable of. FE6 learned this from chemists who were long-time employees and had seen the drop in production over their decades with the company. There were nights fairly frequently when they would send people home, especially in the packaging department, because there was not enough work to do.

315. FE6 regularly attended the monthly all-hands meeting, where management addressed the state of the plant, production metrics, future objectives, and production-related updates. He learned from these meetings and conversations with colleagues that the plant was not hitting sales numbers, production volume was not meeting demand, operations were slow, and employee attrition and turnover was very high. Long-time employees remembered a time when there was very low attrition and turnover at the plant; they would regularly ask about the attrition and turnover numbers during these all-hands meetings.

316. According to FE2, frequent recalls and outside deviation reports ("ODR") were common. ODRs were generally initiated when a critical process is missed or something is outside of defined boundaries, like if they find metal on the magnets or someone missed a check at an X-ray. Depending on the type of ODR and when it was caught and filed, it would result in recalls, or isolation and extensive re-testing on the product to verify it was within conformance.

317. The Vermont facility had numerous recalls due to bacteria or other contamination in the product. One recall in July 2023 was for two months of products that had not yet reached distributors.

G. Perrigo Abandoned its Plan to Expand in Vermont After Realizing the Site was Contaminated and Blindsided Employees with the Vermont Closure and "Strategic Review"

318. According to multiple former employees, the purchase of the Wisconsin plant felt like it came out of nowhere to FE8 and employees in Vermont.

319. According to FE8, for many years, Perrigo leadership told the Vermont employees that the plan was to expand in Vermont. Perrigo owned the land that the Vermont formula facility sits on, and it is quite a large plot.

320. According to FE8, Perrigo had gone so far as to start excavating and purchasing equipment for the facility when suddenly they announced that they were not going forward. Similarly, FE2 noted that Perrigo had even purchased equipment for that facility and was paying to store much of that equipment.

321. FE8 did daily walks at the site and was heavily involved in the construction process. According to FE8, once Perrigo started digging, they discovered that there were significant remnants of a prior factory in the ground. There had been a whey factory at the site and the owner of that factory rather than demolishing it and removing the building materials from the site, just dug a hole and buried concrete and other building materials. As a result, Perrigo was running into these materials and was going to need to do extensive remediation of the site to make it viable. FE2 corroborated and expanded on this accounting, stating that before Perrigo went to break ground, they did a soil survey and other inspections and discovered asbestos. That site previously had a whey factory, which had been connected by underground tunnel to the Vermont formula facility where FE2 worked and the wastewater treatment plant. The asbestos finding and difficulties of remediating the site contributed to Perrigo abandoning its plans to overhaul the Vermont facility. This information was known to these former employees because FE8 observed aspects of the construction process because it implicated EH&S issues in his scope of work, and FE2 would ask others at the plant why Perrigo wasn't building a new formula-specific facility, plus some of the machinery that had been purchased for the new formula plant was left sitting outside and used for spare parts for machinery at the facility.

322. According to FE8, this all happened in 2021 or early 2022. About a year after they discovered this major obstacle, Perrigo suddenly announced that they were purchasing the Gateway Wisconsin facility from Nestlé. Everyone in Vermont was surprised and severely disappointed because they had been told for years that things were going well, the company was going to continue investing in Vermont, and their future was secure.

323. FE6 recalled that when he was hired, FE6 was told the Vermont facility was there to stay and very stable. But in March 2025, shortly after the fire, Perrigo abruptly informed employees that the Vermont facility would be shut down. This announcement was unexpected and very destabilizing; FE6 observed that even some of the factory-level management seemed surprised when the message was delivered. There was an emergency all-hands meeting during first shift when this news was delivered and then news spread to the second shift. FE6 recalled that a week or two prior to this announcement, all the department heads had traveled to Perrigo's Michigan headquarters. Quickly, many veteran employees began leaving. Within weeks, the three labs (chemistry, instrumental, and microbial) lost employees with over 120 years of experience, cumulatively. The same deluge of departures happened across the plant. Manufacturing was also hard hit, with many packaging and other line workers quickly departing. Perrigo either could not or would not backfill many positions, leaving lots of holes across the facility.

324. In late summer or early fall of 2025, FE7 was informed by the project manager in charge that planned upgrades to the facility – specifically the installation of two new cyclones in the dryer – were being cancelled. At the time, FE7 was told by Hernandez that money was being diverted to fund the expansion of the plant's packaging lines. However, in November 2025, Lockwood-Taylor announced that the company was going to "reevaluate" the infant formula business. According to FE7, the flow of money stopped to the plant and any projects at the plant,

such as fixing their totes – a consistent generator of deviations – was abandoned. Hernandez informed FE7 that "everything was on hold until further notice."

325. In Vermont, according to FE6, when Perrigo made the November 2025 announcement of a "strategic review" of the infant formula business, the internal reaction was complete chaos and pandemonium. Employees felt blindsided and unmoored.

H. Perrigo's Culture Discouraged Raising Concerns

326. Over FE1's time, he observed a culture shift toward discouraging quality staff from initiating improvements. Whereas at the beginning of his tenure he had been permitted to propose document and program changes, by late 2024, his role had been reduced to completing checklists and submitting reports without input into remediation.

327. In FE3's experience, Perrigo had a culture of discouraging employees from raising concerns about the formula product. In FE3's experience, when he raised concerns about product quality or safety, he was met with skepticism rather than a desire to understand if there was a problem and fix it if there was. This included concerns he raised at meetings and in direct communications with managers. This stood out particularly because it was different than how the company would react if someone raised a concern about a workplace hazard (such as a poorly placed ladder). It troubled FE3 that the same level of responsiveness was not granted to a sensitive product like infant formula.

328. According to FE8, when employees asked leadership at the Vermont facility about the *Cronobacter* issues or large volume of formula that was on hold, the response would be that they were wrong and Perrigo was selling formula steadily. But then employees would see news articles or FDA letters that formula had been discarded or had to be recalled.

329. According to FE8, the Vermont facility had regular *Cronobacter* positive hits. They had to dispose of thousands of pounds of formula and huge quantities of formula were regularly

on hold. Employees regularly asked about these issues and what the company was doing to address them at all-hands meetings and leadership would just brush them off by saying things like we are working on it, but they never made the necessary changes to prevent the problems.

330. FE8 would also hear frequently as a response to concerns about the cleaning process or others processes that the plant had always done things a certain way and was going to continue following that process, even though the consultants were recommending dramatic change. That was the culture on the floor.

331. FE6 had concerns about the company pushing production at the expense of his team's quality control process. As one example, there was a batch that management said really needed to get out at the end of 2025. The Head of Production was sitting in his laboratory pressuring the team to finish its testing and get the results so he could push out the product. FE6 was very concerned about interference with the testing process and that the additional pressure would cause more mistakes in the process. He called a meeting with his manager and Head of Quality on site and said they cannot come into his laboratory to push them to go faster because it creates pressure and can interfere with the scientific process. Nothing changed after that meeting.

332. According to FE6, Perrigo lacked a clear and effective system to escalate and respond to concerns that arose for FE6 and his team. When FE6 and his team were working second shift (the overnight shift), there were not the right people on site to handle problems that arose. In particular, there were not Quality Assurance personnel on site at all on certain nights a week and other nights they were sorely understaffed. As a result, when FE6 and his team needed input from Quality Assurance on decisions like whether to do an Operational Deviation Report ("ODR") or other processes to comply with good manufacturing process, there simply were not the people that needed to be part of that decision or decisions were pushed to people who were not qualified to

make them. If FE6 pushed to wait until the next shift when more personnel would be available to participate in those decisions, he was met with frustration.

333. According to FE11, he would bring up his concerns about safety and sanitation to engineering director Alvaro Lascorz Muzas and his supervisor and engineering manager Christopher Amadon. He also escalated these items that needed to be addressed to the director of operations at the Perrigo Vermont facility, Todd Shuttleworth. He would tell FE11 to talk to his direct boss. None of the necessary items were addressed from the concerns that were raised by not only FE11, but also the outside consultants.

334. According to FE11, he heard from other employees that the Head of Quality at the Vermont plant had a good relationship with the FDA inspector, and that is what kept the plant from getting in bigger trouble despite the many safety and sanitation issues.

335. FE1 emphasized that the Quality department was extremely fragmented, with responsibilities spread across siloed sub-groups that did not coordinate well.

336. FE1 observed that many employees who had been with the plant during the Nestlé years were deeply familiar with the problems, but that leadership was not prioritizing remediation. He believed the resistance to addressing issues stemmed from higher levels of management, above the on-site Quality team. He referred to a senior on-site quality leader named Kristi Knudtson, who followed corporate direction rather than advocate internally for needed corrective actions. FE1 also identified Victoria Neuman, whom he described as a rapidly promoted quality manager pushing certain approaches without taking a step back and focusing on the problems. FE1 emphasized that Neuman also lacked real authority to carry out the major capital projects the facility required. Neuman had limited experience or knowledge in food safety and sanitation. FE1 was aware of these issues from his own experiences requesting to make program changes and

being shot down without considering the needs of the plant. FE1 would also hear from colleagues that Knudtson's employees were intimidated and afraid to express concerns.

337. FE2 asked for an updated manual on Sanitary Plumbing regulations for plant equipment, but they did not provide one, so he had to buy his own manual.

VI. EXPERT ANALYSIS

338. John R. Godshalk, M.S.E. is a Chemical and Biochemical Engineer with over twenty years of professional experience in the biologics regulatory field, including work experience at the FDA, the biopharmaceutical industry, and as an expert consultant. While at the FDA, Mr. Godshalk served as a reviewer and investigator in the Division of Manufacturing and Product Quality at FDA's Center for Biologics Evaluation and Research. In that role, Mr. Godshalk led cGMP inspections of manufacturing facilities and received an FDA-wide plaque award for Excellence in Review Science. Following his employment at the FDA, Mr. Godshalk has worked as a quality and regulatory consultant, including to pharmaceutical and biologics companies worldwide. Mr. Godshalk's consulting work has included acting as an interim quality director, leading remediation projects for FDA Warning Letters and inspection reports, performing mock FDA inspections and quality system audits, providing training programs on cGMP and quality issues, and performing cGMP evaluations of manufacturing facilities.

339. Mr. Godshalk reviewed the Form 483 Letters, August 2023 Warning Letter, first-hand accounts from the Former Employees, the DOJ's complaint against Abbott regarding infant formula contamination ("DOJ Complaint"), and the FDA Form 483s for inspections of Abbott's Sturgis facility dated September 24, 2019, September 24, 2021, and March 18, 2022.

340. Based on his review of those materials and his knowledge and experience with chemical and biochemical engineering, FDA inspections, cGMP, and quality systems, Mr. Godshalk reached the following conclusions.

A. April 2022 Form 483

341. The April 2022 Form 483 documented the observations by the FDA inspectors during their 2022 inspection of the Gateway facility ("2022 Inspection"), including the following:

a. *Cronobacter sakazakii* was identified in environmental swabs collected by the FDA and four sister swabs, including in high hygiene areas such as the dryer or dryer area;

b. *Cronobacter sakazakii* was identified in a batch of finished infant formula product;

c. water leaks or pooling were observed in the processing environment, including the dryer or dryer area while actively drying infant formula powder; and

d. personnel working directly with infant formula did not wear necessary protective apparel.

342. The 2022 Inspection was conducted by an unusually large team of eight investigators, including a national expert and milk specialist. The size of the team and inclusion of specialists indicates that the FDA considered the inspection to warrant additional resources.

343. The April 2022 Form 483 documented inadequate manufacturing conditions and practices at the Gateway facility that required corrective and preventive action, including repair or replacement of equipment, to ensure that the facility complied with safety, quality, and regulatory requirements.

344. The April 2022 Form 483 was issued shortly after the FDA issued a Form 483 to competitor Abbott's Sturgis facility, which led to a Complaint and Consent Decree in May 2022 between Abbott and the DOJ. The FDA's observations at Gateway were similar in kind and severity to the FDA's findings at Abbott's Sturgis facility, including:

a. *Cronobacter sakazakii* or *Cronobacter* spp. was identified in environmental swabs collected by the FDA and Abbott from low, medium, and high care areas, including

the dryer or dryer area;[42]

b. *Cronobacter sakazakii* was identified in finished infant formula product; and

c. water was observed in or around the dryer or dryer area while the dryer was running infant formula powder. [43]

345. It is my understanding that the April 2022 Form 483 was issued a few months before Perrigo announced in November 2022 that it was acquiring the Gateway facility. In connection with acquisitions of manufacturing facilities that are regulated by the FDA and required to follow cGMP, it is standard industry practice for the acquiring company to review recent Form 483s and other correspondence with the FDA.

B. April 2023 Form 483

346. The April 2023 Form 483 and the August 2023 Warning Letter document the following observations and findings by FDA investigators during their inspection in March and April 2023:

a. From November 2, 2022 to April 5, 2023, Perrigo identified *Cronobacter* species (spp.) in multiple batches of finished product and twenty locations in the Gateway facility, including eight locations defined to be areas with "a high potential for product contact."

b. The FDA and Perrigo also collected additional environmental swab samples on March 7 and 8, 2023 from high hygiene areas, including the dryer and dryer area, which tested positive for either *Cronobacter sakazakii* or *Cronobacter* species.

c. FDA investigators observed bubbling and cracking on the floor of the dryer, which had been previously identified as a harborage area for Cronobacter species.

d. Perrigo's root cause analysis identified only potential sources of contamination and did not include further investigation, such as Whole Genome Sequencing ("WGS"),

[42] FDA Form 483, Inspectional Observations, Abbott Nutrition, Sturgis, MI (Jan. 31 – Mar. 18, 2022), at 1-3; Compl. for Permanent Inj. at 11, *Abbott Labs.*, ECF No. 1.

[43] *Id*. at 3-4; *Id*. at 11-13.

to determine the source of contamination and whether the same strains of *Cronobacter* were contributing to multiple contamination event.

e. The FDA conducted WGS testing of environmental samples that investigators collected during their March 2022 and March 2023 inspections, which found the presence of the same two strains of *Cronobacter*, indicating resident pathogens or harborage sites in the facility since 2022.

347. A root cause analysis is the use of various methods to discover the underlying cause of a problem, rather than pointing at symptoms or contributing causes.

348. The FDA investigators' observation of bubbling and cracking on the floor of the dryer is consistent with the accounts from multiple FEs that report water leaks throughout the Gateway facility, including the dryer and roof, as well as cracks in the dryer, which are potential harborage sites for bacterial contamination. During its 2022 inspection of the Abbott Sturgis facility, FDA investigators identified evidence of similar water leaks throughout the Sturgis facility, including the roof and dry-production areas, as well as cracks in the dryer. [44] In the DOJ Complaint, the government explained that cracks in food-contact surfaces of equipment, in conjunction with an uncontrolled wet environment in processing areas and presence of *Cronobacter sakazakii,* create an unacceptable risk of bacterial contamination.[45]

349. The FDA's findings and accounts from FEs support the conclusion that by March and April 2023, Perrigo did not have a system of process controls covering all stages of processing that was designed to ensure that infant formula did not become adulterated due to the presence of microorganisms in the formula or in the processing environment.

[44] FDA Form 483, Abbott Nutrition, (June 31 – Mar. 18, 2022), at 3; Compl. for Permanent Inj. at 13, *Abbott Labs.*, ECF No. 1.

[45] *Id*. at 11-12.

C. August 2023 Warning Letter

350. The August 2023 Warning Letter documents that in response to the January 18, 2023 positive test of finished product, Perrigo destroyed the batch that tested positive and three additional batches produced immediately before or after the positive batch, but released the remaining twenty batches manufactured during the same production campaign. Perrigo justified its release of those twenty batches based on negative test results of those batches and its assertion that its root cause analysis "did not find an ongoing condition that [led] to the *Cronobacter* finding that would impact these batches."

351. The FDA rejected this explanation. As the FDA explained in the August 2023 Warning Letter, Perrigo's release of those twenty batches violated the FDCA, because when a batch of finished product tests positive, all batches produced during the same production campaign are deemed adulterated unless a root cause investigation conclusively identifies when the production system became contaminated and that all product before or after that time was not subjected to the insanitary conditions created by the contamination. Because Perrigo had not conducted an adequate root cause investigation of the positive tests of finished product, the remaining batches that Perrigo initially released to the public were deemed adulterated.

352. While cGMP requires testing, testing alone is not adequate to ensure safety and quality, because testing can typically be performed only on a small sample of a batch. For that reason, a positive test is conclusive evidence that a batch is contaminated, but a negative test is not conclusive evidence that a batch is uncontaminated. Perrigo's sample testing of finished product, without an adequate root cause investigation that identified a definitive root cause for a contaminated batch, is what the FDA terms "testing into compliance," which FDA regulations make clear is not permitted. This approach is not sufficient to ensure that every batch of infant formula meets safety, quality, and regulatory requirements.

353. The August 2023 Warning Letter documents that Perrigo did not notify the FDA that product that may be adulterated had left control of its facility and conducted a voluntary recall of the impacted batches of product released to the public only after the FDA's review of the Company's sanitation records and subsequent discussions with the agency. These findings indicate that Perrigo did not have rigorous protocols to protect the safety and quality of infant formula.

354. Third, the FDA's findings documented in the April 2023 Form 483 and August 2023 Warning Letter required corrective and preventive action that included identifying and elimination of potential sources of contamination and insanitary conditions, including water leaks and cracks in the dryer.

355. The August 2023 Warning Letter states that Perrigo submitted corrective actions in response to the April 2023 Form 483, which included the following responses:

a. Perrigo updated its finished product release procedures "to now hold the entire campaign of products (which is defined by sanitation breaks at the start and end of production) until all microbiological testing for pathogens has been completed" and that product would be "released only after confirmation that there are no *Cronobacter* positives in any of the line or finished product samples";

b. Perrigo "increased the frequency of sanitation breaks to minimize the amount of product on hold"; and

c. Perrigo conducted investigational swabbing, performed cleaning and sanitizing activities, conducted environmental swabbing to verify the effectiveness of cleaning, made plans to repair cracked floors, and would be conducting employee retraining activities.

356. But in the August 2023 Warning Letter, the FDA noted that for each finished product positive event, Perrigo had not identified a definitive root cause and "assumed that cross-contamination events had occurred between personnel and/or the environment with either food

contact surfaces or the product stream within high hygiene zones of the dry production areas."[46] In addition, Perrigo's response did not indicate that it was "taking any proactive actions to address the resident strains of *C. sakazakii* present within the facility." [47]

357. The FDA advised that Perrigo's corrective actions should include review of Perrigo's sanitation and hygienic control procedures and practices, as well as a root cause analysis to identify potential niches or harborage areas and address facility practices or conditions that may contribute to the persistence of these harborage sites and potential routes of contamination. The FDA stated that it would assess the adequacy of Perrigo's corrective actions during its next inspection of its facility.

358. From July 18 to August 23, 2023, Perrigo shut down the Gateway facility, during which several projects were completed, including replacement of floors within the dryer tower, crack inspection, and repairs of the dryer and corresponding equipment.[48]

D. November 2023 Form 483

359. The findings by the FDA investigators during their November 2023 inspection indicate that even after the summer 2023 shut down of the Gateway facility and completion of certain projects, Perrigo continued having environmental positives for *Cronobacter*. That indicates that Perrigo's corrective actions were inadequate to ensure that the manufacturing conditions and practices at the Gateway facility adequately ensured that infant formula did not become adulterated due to the presence of microorganisms in the formula or in the processing environment.

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[46] Ex. D, FDA Warning Letter to Perrigo Wisconsin, LLC, from Human and Animal Food West 1 Compliance Branch (dated Aug. 30, 2023), at 2.

[47] *Id*. at 6.

[48] Ex. E, FDA Form 483, Inspectional Observations, Perrigo Wisconsin, LLC, Eau Claire, WI (Nov. 6-29, 2023).

360. The November 2023 Form 483 documented the findings of FDA investigators, which included the following:

a. From August 23 to November 17, 2023, Perrigo identified *Cronobacter* species in samples taken from nine E1 locations and multiple E2 locations, including areas in or around the dryer.

b. During the same time period, Perrigo identified ten water leaks in or around the dryer and *Cronobacter* species were found in swabs collected from two of the leak locations.

361. These observations support the FDA investigators' finding that as of November 29, 2023, Perrigo still did not have system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment.

362. Public statements by Perrigo and its executives, as well as accounts from FEs, indicate that following the November 2023 Form 483, Perrigo shut down the Gateway facility for a "plant-wide reset."

363. Accounts from FE4 and FE5 indicate that during the plant-wide reset of the Gateway facility, Perrigo conducted cleaning and sanitation activities, but did not perform preventative maintenance, equipment upgrades, or redesign of manufacturing processes to comply with cGMP and regulatory requirements.

364. That approach is not effective or consistent with the customary approach. A customary approach would be to do an extensive engineering and equipment audit to fully determine what repairs and replacements are needed (such as addressing dryer cracks, leaks, water systems, and so on), in addition to cleaning and examining policies and procedures. A fulsome examination including of engineering and equipment is necessary for a real root cause analysis, which is the predicate to an effective CAPA. If the root cause is old or poorly maintained

equipment, extensive cleaning and consultants analyzing policies and procedures will not solve the problem.

365. In addition, accounts from multiple FEs report that following the plant-wide reset of the Gateway facility, there were still widespread leaks throughout the facility, including rainwater leaks through the roof and leaks in the dryer, cracks in the dryer that expanded over time, and repeated positive tests for *Cronobacter* species.

366. These accounts indicate that Perrigo had not undertaken sufficient corrective action and the Gateway facility was not fully compliant with industry and regulatory standards.

367. Additionally, FE4 noted that Perrigo's CEO Patrick Lockwood-Taylor attributed the problems at Gateway to a deficient culture of quality. Based on the Form 483s, Warning Letter, and accounts of the former employees, that characterization appears to be wrong or, at minimum, incomplete. The plant had multiple problems: deferred maintenance, old equipment, high turnover, leaks, and more. Blaming the problem on culture ignores those systemic issues that also need attention to truly identify and address the underlying problems.

E. Additional Observations Regarding Former Employee Statements

368. *Dryer cracks*: FE7 reported microcracks in the Gateway dryer that expanded over time and by December 2025, the largest crack measured 32 inches long and was large enough to harbor product. This is particularly concerning given that *Cronobacter* was identified near the dryer, suggesting a potential link. Cracks in the dryer are serious issues because they are a known harborage site for bacterial growth, including *Cronobacter*, and are very difficult to clean and sanitize. Continuing to run a dryer with micro-cracks, when there have been findings of *Cronobacter* in the environment (including near the dryer) and in product, can lead to contaminated infant formula, which is a serious health and safety issue for infants, and the sale of which violates FDA regulations and cGMPs.

369. *Ineffective cleaning processes*: FE7 also reported that the Clean-in-Place at Gateway did not work successfully for the dryer at Gateway, with inward leaking at level one and outward leaking at level five. The leakage resulted in moisture in and around the dryer. Inward leaks are particularly serious because they can introduce contamination. The leaks and the added moisture are significant concerns that certainly qualify for a Form 483 observation and could be a Warning Letter issue.

370. FE8 reported that to clean the Marriot Walker dryer at Vermont, employees had to strip down to their underwear, put on a Tyvek suit, and climb inside, causing them to sweat on the machinery. This was highly unusual in a food plant and does not comply with modern industry practices. While equipment is sometimes cleaned by hand, that is typically smaller equipment like small tanks. Cleaning a piece of equipment as large as a dryer by hand is not common practice; typically, a Clean-in-Place system would be installed.

371. FE8 also noted that the Clean-in-Place process did not work successfully for the Stork dryer at the Vermont facility, leaving chemicals and powder residue behind. There should not be any water or residual product left in the dryer after the Clean-in-Place. The FDA requires that the Clean-in-Place process be validated as working effectively, including for wash cycles, rinse cycles, and drying. Water or residual product remaining after a Clean-in-Place would cause the validation to fail. This account reflects that Perrigo did not have an up to date, validated Clean-in-Place process.

372. FE7 stated that high-hygiene equipment was not cleaned and immediately dried, but instead was moved to a different warehouse and left to air dry for extended periods of time. While this method may be allowed for liquid products that are heat sterilized, it is not allowed in cGMP for powder products. This happens when a company does not fully understand and

appreciate the different requirements of powder products versus heat treated products and implement procedures to ensure appropriate handling.

373. *Metal contamination in formula*: FE6 and FE7 both discussed the problem of metal contamination in infant formula manufactured at Vermont. Metal in the formula product is a major issue and clear violation of FDA regulations and cGMPs.

374. FE6 reported that Perrigo would analyze thousands of microcards to look for salvageable formula that was not contaminated. This is akin to batch bracketing – trying to isolate a time in the batch when there are no metal particles. While it may be possible to filter out the metal, it should be treated as a major issue that the plant needs to address and prevent from reoccurring.

375. FE6 also reported that Quality and other departments asked to stop or slow down the manufacturing process to identify the cause of the metal fragmentation, and that Perrigo declined that request in order to push production forward. The tension between Quality and production is inherent in this type of manufacturing – that is why cGMPs require that Quality has authority and responsibility for Quality decisions and cannot be pressured in this manner by operations teams. From the FDA perspective, Perrigo's response is a failure of management controls. It also reflects an improper effort to "test quality into product" rather than ensuring a compliant product from the start; this approach violates well-established FDA cGMP principles.

376. *Leaks and water*: Multiple FEs discussed leaks in the facilities. FE7 reported a large rainstorm causing outside water to enter the dryer in multiple places, and that Perrigo had several documented rain leaks in the past that the FDA was aware of. Similarly, FE5 reported significant, recurring issues with roof leaks and that Quality personnel had to manage the leaks during heavy rains or snow melts. FE2 and FE1 reported that Perrigo dealt with leaks by placing buckets in the

ceilings and sometimes the buckets would fall, spilling contaminated water into clean environments. FE5 also explained that in response to the leaks, there was constant cleaning, sanitization, and testing, often resulting in microbiological "positives" that forced them to reject batches.

377. These former employee accounts are consistent with the Form 483s and Warning Letter. Water is a major concern at this plant because it is a primary source of contamination. Accordingly, rain leaks into high hygiene areas like the dryer is a serious issue and could result in an FDA Warning Letter. Perrigo's approach of buckets and cleaning is insufficient; it reflects a band-aid approach that does nothing to prevent the problem from reoccurring and does not comply with cGMPs.

378. *Sprinkler lines*: FE7 noted that the fire sprinkler line at the dryer was visibly deteriorating and the site of *Cronobacter* positives. Sprinkler lines are a known source of contamination. Water typically sits in these lines for a long time, then when the sprayer is activated, contaminated water spreads. This can present a major issue.

379. *Boiler*: FE2 noted that Perrigo's Vermont facility had an industrial-grade boiler rather than a culinary-grade boiler, and that the plant's PIDs (also referred to as process flow diagrams) were not accurate. FE2 reported that Perrigo used a boiler cleaner that was not permitted for use in infant formula for multiple years. FE2 reported that Perrigo used in-house, non-specialized welders to repair pressurized equipment including the boiler and heat exchanger, and their work frequently failed quickly, dumping dirty steam into high-sanitation environments. These accounts raise numerous significant concerns. Industrial stem has chemicals in it that should never be in contact with food, including a cleanout chemical. That, plus an error in the process flow

diagrams in a critical system like steam, violates cGMP and would be a major concern if the FDA was aware of it that could result in a critical classification for the inspection.

380. *Retesting*: FE2 noted the high frequency of ODRs requiring re-testing, and a lengthy backlog to complete the re-testing. There is a limit as to how much re-testing can be done to release product. If the can is already sealed, then sampling is called "destructive testing" because you cannot reseal the product. It is well established by FDA and Quality that you cannot test quality into a product, and this is also against cGMPs.

381. *High pressure, poor culture, and high turnover*: Multiple former employees shared accounts reflecting pressure from the operations side of the business on the Quality side of the business. FE2 noted that plant leadership constantly told employees they were behind schedule on production, and that a large volume of product was on hold. FE6 recounted concerns about the Company pushing production at the expense of his team's quality control processes, including a specific incident where the Head of Production sat in his lab pressuring the team to finish testing and get results so he could push out the product. Both of these accounts are problematic for Quality. Quality and sanitation problems are often traced to employees being pressured, because Quality tends to be compromised when people are pushed for production. Additionally, when there is a large volume on hold, that is likely due to deviations – different types of deviations present different quality issues, which require sufficient time and attention to understand and test. For these reasons, it is a violation of cGMPs for Operations to tell Quality Assurance what to do, as appeared to be happening here.

382. FE3 described Perrigo as having a culture of discouraging employees from raising concern about the formula product and being met with skepticism rather than a desire to understand and fix problems. This is troubling from a Quality perspective. FDA expects all companies to have

"management controls" which means that Quality Assurance and Quality Control information is shared with managers so they can allocate resources (spend money, hire people, assign people) to fix problems. This is a basic and required cGMP function. The whole idea of cGMP is to find problems (often as deviations, but also from audits/inspections and QA personnel) and to fix them with a CAPA. This is a core function of quality assurance and a core expectation in cGMP. When a Company instead responds by discouraging employees from raising problems, it often reflects a refusal or inability to spend the necessary funds to fix the problem, or a mindset that does not appreciate the sensitivity of the product being manufactured. The latter concern can happen at companies that make different products of varying sensitivity – for example, liquid products that can be heat treated versus dry products that cannot be heat treated and so require significantly greater care and caution to prevent contamination. Regardless of the reason, this approach creates significant risk and violates cGMPs.

383. FE2, FE3, and FE6 indicated that there was high turnover at Perrigo. Environments where employees are frustrated, pushed, or do not feel that they have a say often experience high turnover.

384. FE6 noted that shortly after the Vermont facility closure was announced, many veteran employees left the Company, leaving holes that Perrigo could not or did not fill. In my experience, that is a common occurrence when a plant shutdown is announced. In a plant that is already struggling with Quality and sanitation issues it can create significant issues, given inadequate skilled and experienced personnel.

VII. DEFENDANTS' MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS OF MATERIAL FACTS

385. Throughout the Class Period, Defendants made a series of materially false and misleading statements and omissions of material facts. Among other things, Defendants initially

touted the value of the acquisition of Gateway, representing that that it would be "immediately accretive" of margin and EPS, despite the fact that any standard due diligence would have uncovered numerous red flags indicating that the facility's production capacity was seriously diminished—including the recently issued April 2022 Form 483 listing multiple regulatory violations and environmental contamination. After conducting a cursory "reset" that failed to address any of the true root causes of production capacity constraints, Defendants claimed that the remediation efforts were "done" and "behind them," and that the plants were now fully compliant and producing high-quality formula. In reality, the Vermont and Gateway facilities were not producing anywhere close to their full capacity, remained out of compliance with relevant cGMPs and FDA rules, and continued to detect bacteria—and, at times, even metal shreds—inside finished product or the surrounding environment, leading to recalls, product scrap, and extended shutdowns. Defendants' claims about the strength and recovery of the infant formula category were also false or, at a minimum, misleading, since the Company continued to lose business the wake of the 2024 "reset," including Target, a major customer at the time. And whenever that the Company did acknowledge problems with the Gateway acquisition or infant formula business as a whole, it misleadingly attributed those challenges to industry-wide reverberations from "evolving" FDA regulations, not its own failures to address the serious infrastructure, process, and personnel challenges plaguing its facilities.

386. Each statement in this Section by or attributed to Defendants Kessler, Lockwood-Taylor, and Bezerra is also attributable to Perrigo because each statement was made in their capacity as a representative of Perrigo and can properly be deemed Perrigo's statement.

A. November 1, 2022

387. On November 1, 2022, the Class Period begins with Perrigo's announcement of a major development in its infant formula business – an acquisition of a plant from a competitor and

the rights to one of its highly popular brands.

388. That day, the Company issued a press release entitled, "Perrigo Announces Strategic Investment to Expand and Strengthen U.S. Manufacturing of Infant Formula." The press release revealed that Perrigo had purchased Nestlé's "Gateway" infant formula plant ("the Gateway Plant") located in Eau Claire, Wisconsin, along with the U.S. and Canadian rights to Nestlé's Good Start brand of infant formula. The press release claimed that the Company's investment in the Gateway facility would add "a total of ***36 million pounds of capacity*** to Perrigo" within just 18 months (*e.g.*, by May 2023).

389. The press release represented to investors that "Perrigo expects the purchase of the Gateway infant formula plant, along with the U.S. and Canadian rights to the Good Start® infant formula brand, to be ***immediately accretive to net sales, gross margin, and earnings per share***."

390. These statements were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they conveyed an impression that the Gateway facility ran reliably and would immediately generate significant additional production, sales, margin, and earnings per share, when in reality according to multiple FEs and as reflected in the April 2022 Form 483, Gateway's production capacity was limited by its serious equipment problems, ongoing *Cronobacter* contamination, and numerous violations of FDA regulations and cGMPs. The statements misleadingly omit highly material information including that Gateway (1) had frequent unplanned shutdowns, failures, and scrapped product due to the degraded equipment and conditions at the facility; (2) had significant deferred maintenance; (3) had lost substantial personnel, particularly in the Quality and Maintenance Departments; (4) relied on an aging, cracked dryer that could harbor *Cronobacter* and leaked during Clean-in-Place operations; (5) suffered from systemic roof leaks; (6) lacked proper humidity and temperature

control, leading to excess condensation on equipment; (7) contained sprinkler lines that were not accessible for cleaning and, in some cases, visibly deteriorating. The statements further omit that Gateway was in violation of critical FDA regulations and cGMPs as made clear in the April 2022 Form 483 issued just months earlier, including water leakage and substantial *Cronobacter* contamination in sensitive processing areas—observations with alarming parallels to Abbott's Sturgis facility at the time of its shutdown — which were not remediated by the time of the Defendants' positive statements. The observations documented by the FDA made clear that substantial repair and, in some cases, replacement of equipment and infrastructure would be needed in order for Gateway to reliably produce infant formula and comply with FDA requirements.

B. November 8, 2022

391. On November 8, 2022, before trading opened, Perrigo hosted the Q3 2022 Call.

392. During the Q3 2022 Call, leadership elaborated on the $170 million "strategic investment" to expand the Company's infant formula manufacturing footprint, including the $110 million purchase of Gateway and an additional $60 million investment in the plant to expand capacity.

393. As depicted in the slides accompanying the presentation, Perrigo claimed the Gateway acquisition would ***"[e]xpand[] overall U.S. infant formula production by 7M pounds, or more than 100M 8-ounce bottle equivalents, within 18 months, adding 36M pounds of total capacity to Perrigo***."

394. On the call, Defendant Kessler explained the initiative's near-term benefits driven by infant formula:

> Our third strategic initiative is the Supply Chain Reinvention Program, which ***we expect to deliver $50 million to $70 million in incremental operating income next year. The Gateway and Good Start brand infant formula acquisition is the primary driver***, but our portfolio design and SKU optimization actions will also contribute. ***So let me repeat myself. We expect the incremental operating income from these strategic initiatives in 2023 to replace the lost operating income from the second half of 2022.***

395. Defendant Kessler also expanded on the reasoning behind the purchase of the Gateway Plant:

> My nutrition team had been working to solve our infant formula capacity constraints for several years. And you may remember that in 2018, the Perrigo Board of Directors authorized and we announced that we would invest up to $300 million to expand our formula capacity with a greenfield project, which did not occur. ***The acquisition of the***

> ***Gateway facility finally solves the capacity problem and at nearly half the cost. . . . This purchase is highly accretive with an expected operating profit contribution in 2023 of more than $50 million, a part from the Good Start brand and an equal part from additional volume we can now run through this network to support our current customers….***
>
> And we have been facing challenges with very old equipment in Vermont for years. Like in my first month joining Perrigo, at the first Board meeting, we had gone in and asked for, I think, of somewhere around $250 million and in the next Board meeting, we raised it to over $300 million to build a facility, but we weren't able to build that because it ***didn't pass the environmentals***, et cetera.

396. Defendant Kessler also noted that Perrigo's Vermont facility had been running at "117% of normal output" in light of the nationwide formula shortage and so "***running this older equipment that hard for that long resulted in an abnormal amount of formula placed on quality hold . . . To remedy that situation, we paused the Vermont facility for 3 weeks to do proper maintenance. The facility [was] back up and running***, but Q3 shipments could have been higher without this constraint."

397. The statement that there were quality hold issues at the Vermont facility because it had been running at increased capacity is materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it omits the significant unremediated problems at the Vermont facility and suggests that the "proper maintenance" performed meant that the facility was "back up and running," at normal production capacity. In reality, the Vermont facility had serious, ongoing quality issues long before the nationwide infant formula shortage caused Perrigo to increase production runs at the plant. The Company did not perform proper maintenance on the Vermont facility, which continued to run far below its maximum production capacity. Specifically, Perrigo (1) failed to replace the porous, bacteria-harboring flooring that was dairy grade and not suited for infant formula production; (2) failed to replace the Marriott Walker dryer, *even after that was recommended by consultants three*

years earlier; (3) failed to replace the industrial boiler system with one suitable for use in the production of infant formula; (4) failed to hire properly trained personnel to conduct technical repairs of pressurized vessels in the facility; (5) failed to install a fire suppression system in the Stork dryer; and (6) failed to repair the roof and leaks in the facility to prevent water contamination and reliance on a precarious, ad hoc system of tarps and buckets to catch leaks.

398. And the claim that Perrigo reversed course from expanding in Vermont to acquiring Gateway because the Vermont expansion site "didn't pass the environmentals" was materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it concealed that an illegal anticompetitive motivation was also behind locking up the Gateway facility to block entrants to the formula market and that the shift in strategy from the Vermont expansion was due to Perrigo's oversight of a major contamination issue on the site.

399. Defendant Kessler elaborated:

> The opportunity came to purchase [the Gateway facility], and it sort of solves the entire problem***. Now this is not something that came up in the last month or so. We've been working on this for well over a year, long before the infant formula shortage.***
>
> ***. . . And we can put millions of more pounds.*** We will also invest about 60 million into that facility, which will allow us to make more than the 4 products that we already make there. . . . ***We can start putting more poundage. We can get that. That allows us in Vermont or some of our premium national brand customers, we can now meet their demand*** because we're only satisfying about half of what they want or less than half of what they want and we can do that.
>
> . . .
>
> ***[L]isten, 170 million for 50 plus. I'm usually relatively conservative, [but] 50 million-plus in additional operating income is a big deal.***

400. The statements that the Gateway acquisition would allow Perrigo to "put millions or more pounds"; "meet [customer] demand"; and add $50 million plus in operating income were materially false or, at a minimum, misleading when made and omitted material facts necessary to

make the statements not misleading because at the time of the statements, Defendants knew, should have known or recklessly disregarded, based on typical due diligence of an acquisition like the Gateway Plant prior to purchase, that (1) the plant was in such poor condition that it could not allow the Company put out "millions more pound[s]" of product and "meet [the] demand" of premium national brand customers, and therefore (2) it could not give the Company the opportunity to "slow down" production at the Vermont facility and give "more time for breaks, for maintenance."

401. Defendant Kessler's claim of "50 plus" million in operating revenue in the next year alone was also materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because he had no reasonable basis for making such a representation**.** ***First,*** standard due diligence of the engineering, quality, and personnel aspects of the Gateway facility would have revealed that the facility (1) had not undergone necessary annual maintenance; (2) had lost substantial personnel, particularly in the Quality and Maintenance Departments; (3) housed an aging, cracked dryer that was a consistent harborage site for *Cronobacter* and leaked *during* Clean-in-Place operations, preventing proper documentation of cleaning processes; (4) suffered from systemic roof leaks; (5) lacked proper humidity and temperature control, leading to excess condensation on equipment; (6) contained sprinkler lines that were not accessible for cleaning and, in some cases, visibly deteriorating. ***Second,*** standard due diligence would have included review of any inspection reports, Form 483s, or Warning Letters issued to the facility by the FDA. Here, mere months before Perrigo completed the acquisition, the Gateway facility was inspected by an unusually large team of FDA inspectors. The resulting April 2022 Form 483 detailed multiple objectionable conditions and practices through the plant, including water leakage and substantial *Cronobacter* contamination in sensitive

processing areas—observations with alarming parallels to those observed in Abbott's Sturgis facility at the time of its shutdown. As set forth in further detail in Section VI, Expert Analysis, the observations documented by the FDA made clear that substantial repair and, in some cases, replacement of equipment and infrastructure would be needed in order for Gateway to reliably produce infant formula and comply with relevant FDA requirements. ***In addition***, in the two weeks before Defendants made these statements, Gateway had multiple batches of infant formula contaminated with *Cronobacter,* resulting in production delays to allow for Clean-in-Place operations and forcing Perrigo to discard batches. Moreover, on November 2, 2022, ***six days before these statements were made***, Perrigo switched the plant's status to "maximum control" after detecting *Cronobacter* which required additional environmental testing. That testing revealed *Cronobacter* in both the dryer and other high-hygiene areas.

402. Analysts credited management's positive claims about the Gateway acquisition and factored those claims into their recommendations. For example, a Wells Fargo analyst commented that, while Perrigo had suffered a "painful" quarter, the stock was nevertheless "an attractive long over the next 12+ months at <12x earnings," in part because the "Gateway investment should help to resolve existing plant issues." Analysts at J.P.Morgan similarly concluded that despite the "disappointing" quarterly results they were "*increasing* [their] 2023 sales estimate due to the recently acquired infant formula plant" and maintaining the stock's "overweight" rating.

C. February 28, 2023

403. On February 28, 2023, the Company filed its Form 10-K with the SEC reflecting its annual report for the fiscal year ended December 31, 2022 ("FY22 10-K"). The FY22 10-K was signed by Defendants Kessler and Bezerra.

404. The FY22 10-K included representations regarding regulatory compliance and quality assurance:

Infant Formula

> Before marketing a particular infant formula, the manufacturer must provide regulatory agencies assurance of the nutritional quality of that particular formulation consistent with the FDA's labeling, nutrient content, and manufacturer quality control requirements. A manufacturer must notify the FDA at least 90 days before the marketing of any infant formula that differs fundamentally in processing or in composition from any previous formulation produced by the manufacturer. ***We actively monitor this process and make the appropriate adjustments to remain in compliance with current FDA rules regarding cGMP, quality control procedures, quality factors, notification requirements, and reports and records for the production of infant formulas.***

405. These statements were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because, in fact, Perrigo's Gateway facility and Vermont facility had significant violations of current FDA rules and the Company ***did not*** make appropriate adjustments to get into or remain in compliance with current FDA rules or cGMP. The Gateway facility had received the April 2022 Form 483 identifying several compliance violations including that the Gateway facility "did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment." The April 2022 Form 483 further noted multiple instances of water dripping or leaking into sensitive processing areas for powdered formula and multiple instances of positive hits for *Cronobacter* in the environment, including in high-hygiene areas such as the dryer and dryer area. In the months since acquiring the facility, Perrigo had not remediated those violations: as would be reflected in the April 2023 Form 483, the same problems persisted a year later and new problems had developed. Gateway also: (1) lacked a structured process for tracking deviations in the formula; (2) had a dryer with micro-cracks and that leaked during Clean-in-Place operations, preventing operators from properly documenting cleaning procedures; (3) lacked proper humidity and temperature control, leading to excess condensation on equipment and

causing operators to sweat directly onto equipment or surfaces they were attempting to clean; (4) contained sprinkler lines that were not accessible for cleaning and, in some cases, visibly deteriorating; (5) lacked an adequate zoning program; (6) did not employ sufficient Quality personnel; and (7) failed to follow FDA regulations and cGMPs to clean high-hygiene equipment. Collectively, these conditions are referred to hereinafter as the "Unremediated Gateway Problems".

406. The Vermont facility was also in violation of FDA regulations and cGMPs that it had not remediated, including: (1) inaccurate PID drawings that reflected the facility had equipment graded for infant formula, when in fact it was using improper industrial-grade equipment; (2) incorrect flooring, which created heightened risk for mold and bacterial growth; (3) the "Marriott Walker" dryer remained in use despite Company knowledge that the FDA did not approve and a 2020 recommendation from consultant Relco that it was beyond repair; (4) both the Stork and Marriott Walker dryers posed serious quality and safety hazards because they could not be cleaned properly and lacked adequate fire suppression ; (5) the boiler system was old, damaged, and, as a standard industrial model, not appropriate for use in an infant formula production facility, which instead required a culinary-grade steam system; (6) personnel at the facility used a chemical cleaner on the boiler that was explicitly banned by the FDA; (7) the Company did not employ specialized welders when repairing pressurized vessels (*e.g.*, boilers, heat exchangers) who were certified to conduct those types of repairs, but rather non-certified in-house workers whose "patches" to the systems inevitably failed; (8) the Company relied on untrained temporary labor, including high school students, to move product throughout the facility and perform tasks that required experience and training to avoid contaminating product or clean environments; and (9) the facility relied on a system of temporary buckets and tarps to catch water

leaking from the roof—a system which regularly failed when buckets full of contaminated water would fall and spill into previously clean environments. Collectively, these conditions are referred to hereinafter as the "Unremediated Vermont Problems."

407. The FY22 10-K also warned of certain risks which "could" or "may" impact the Company's results, including the following:

> U.S. and global regulatory agencies regularly inspect our manufacturing facilities and the facilities of our third-party suppliers for GMP and other regulatory compliance. ***The failure of one of these facilities to comply with applicable laws and regulations may lead to a breach of representations made to our customers, or to regulatory or government action against us related to the products made in that facility,*** including suspension of or delay in regulatory approvals and product seizure, injunction, recall, suspension of production or distribution of our products, loss of licenses or other governmental penalties, or civil or criminal prosecution, which could result in increased cost, lost revenue, or reputational damage.

> With respect to our powdered infant formula products, a risk of contamination or deterioration may exist at each stage of the production cycle, including the purchase and delivery of raw materials, the processing and packaging of food products, and the use and handling by consumers, hospital personnel, and healthcare professionals. ***If certain of our infant formula products are found or alleged to have suffered contamination or deterioration, whether or not under our control, our reputation and our infant formula product category sales could be materially adversely affected.***

408. These statements were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they warned of potential future risks that were, in reality, already occurring. At the time the statement was made, Perrigo was not complying with applicable laws and regulations, and both the Vermont and Gateway facility had regular problems with contaminated formula including positive *Cronobacter* hits in both the environment and the product, as noted above, which required product to be scrapped.

409. At the Investor Day presentation held that same day, Defendants Kessler and Bezerra were listed as presenters. The slides in conjunction with the presentation included the following statement:

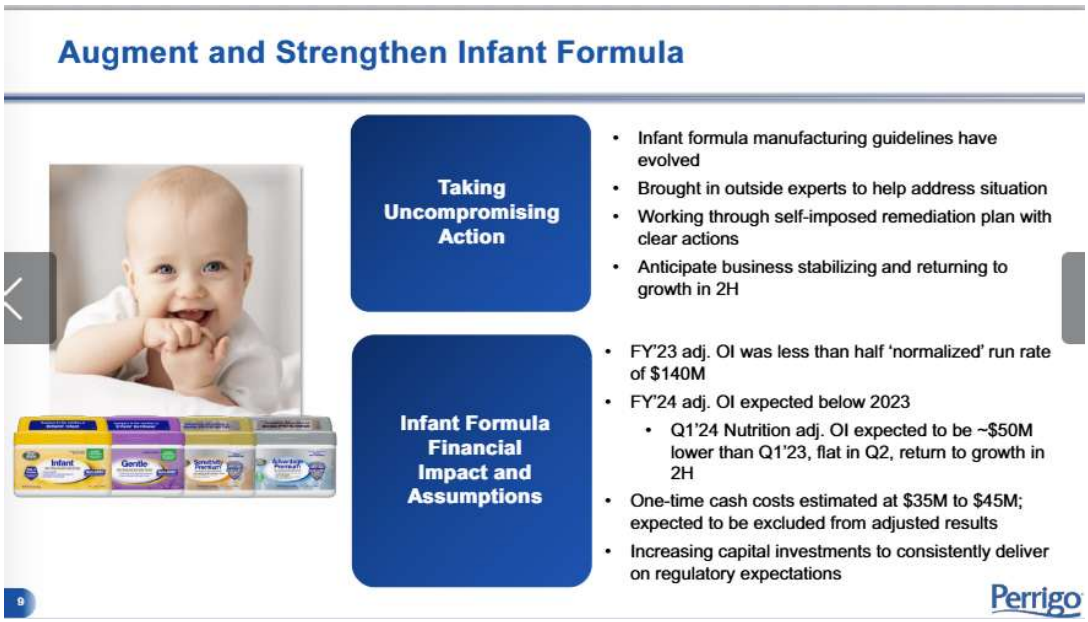
> ***HRA and Gateway & U.S. & Canadian Good Start® brand rights are significantly margin accretive and driving an immediate uplift***

410. These statements were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because at the time of the statements, Defendants knew, should have known or recklessly disregarded, based on typical due diligence of an acquisition like the Gateway Plant prior to purchase, that it was in such poor condition that it was not "significantly margin accretive and driving an immediate uplift." The production capacity of the Gateway Plant was seriously diminished. The Gateway Plant suffered from significant deferred maintenance and inadequate personnel – and, as a result, was experiencing regular production pauses and even producing contaminated powder that required scrapping entire batches. Further, typical due diligence conducted on the acquisition would have revealed the Gateway facility's deteriorated condition, recurrent product disruptions, history of producing contaminated powder, and unremediated violations of FDA regulations and cGMP that made Gateway a drain on gross margin, given the substantial expenditures that would be necessary to remediate it. ***First,*** standard due diligence of the engineering, quality, and personnel aspects of the Gateway facility would have revealed that the facility (1) had not undergone necessary annual maintenance; (2) had lost substantial personnel, particularly in the Quality and Maintenance Departments; (3) housed an aging, cracked dryer that was a consistent harborage site for *Cronobacter* and leaked *during* Clean-in-Place operations, preventing proper documentation of cleaning processes; (4) suffered from systemic roof leaks; (5) lacked proper humidity and temperature control, leading to excess condensation on equipment; (6) contained sprinkler lines

that were not accessible for cleaning and, in some cases, visibly deteriorating. ***Second,*** standard due diligence would have included review of any inspection reports, Form 483s, or Warning Letters issued to the facility by the FDA. Here, mere months before Perrigo completed the acquisition, the Gateway facility was inspected by an unusually large team of FDA inspectors. The resulting April 2022 Form 483 detailed multiple objectionable conditions and practices through the plant, including water leakage and substantial *Cronobacter* contamination in sensitive processing areas—observations with many parallels to those observed in Abbott's Sturgis facility at the time of its shutdown. As set forth in further detail in Section VI, Expert Analysis, the observations documented by the FDA would have indicated that substantial repair and, in some cases, replacement of equipment and infrastructure would be needed in order for Gateway to reliably produce infant formula and comply with FDA requirements. Further, as confirmed by the April 2023 Form 483, the Gateway Plant had already produced multiple batches of infant formula contaminated with *Cronobacter* – batches which were packaged on October 27-28, 2022, November 2, 2022, and January 12, 2023, respectively. Each positive test had resulted in production delays to allow for Clean-in-Place operations and required discarding batches. Moreover, on November 2, 2022, after *Cronobacter* was detected in a batch, Perrigo switched the plant's status to "maximum control," requiring additional environmental testing – but even after that switch, Perrigo identified *Cronobacter* in both the dryer and other high-hygiene areas. Environmental tests carried out in January 2023 also identified *Cronobacter*.

411. The slides presented with Investor Day underscored that Perrigo had addressed issues and the formula business had stabilized, claiming Perrigo was "Taking Uncompromising Action"; "[w]orking through self-imposed remediation plan with clear actions"; and therefore it "[a]nticipate[d] business stabilizing and returning to growth in 2H." The slides also stated that

there were only "[o]ne-time cash costs estimated at $35M to $45M; expected to be excluded from adjusted results" and claimed Perrigo was "[i]ncreasing capital investments to consistently deliver on regulatory expectations":



412. But these statements were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because Perrigo was not "Taking Uncompromising Action" or "clear actions" or "[i]ncreasing capital investments to consistently deliver on regulatory expectations." On the contrary, Perrigo refused to make the necessary investments to ensure a safe, sanitary, and reliable facility to manufacture infant formula by fixing the Unremediated Gateway Problems and Unremediated Vermont Problems.

413. Relatedly, the statements that Perrigo had "[o]ne-time costs" limited to "$35M to $45M" and the business was "stabilizing" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because in reality, a massive overhaul of facilities and equipment would be necessary to get Perrigo's facilities into compliance with FDA regulations and cGMPs, and able to reliably fill customer orders. Perrigo's failure to take the necessary steps to replace troubled equipment and implement

proper process controls necessarily prevented the business from "stabilizing" – they continued suffering frequent shutdowns, had to scrap huge volumes of product due to deviations, metal, or *Cronobacter* contamination, and could not meet production targets or reliably fill customer orders.

414. The market credited Defendants' materially false and misleading statements in the FY22 10-K and in remarks and the presentation for the earnings call, and analysts factored them into their recommendations. On March 7, 2023, in a report titled "Restocked and ready to go: Perrigo emerges from the pandemic with a focus on high-growth self-care," Canaccord Genuity initiated coverage of Perrigo with a Buy rating and a $49 price target, specifically citing the $170 million strategic investment made in formula, including the purchase of Gateway and U.S./Canadian rights to the Good Start brand, which the analyst expected to generate $50 million or more in operating income in 2023. Canaccord noted Perrigo's current situation of demand outpacing supply and that it was one of just a few manufacturers of store-label formula, so had great potential for higher margins with the increased scale from the Gateway investment.

D. March 17, 2023

415. On March 17, 2023, Perrigo issued a recall of certain batches of infant formula due to potential *Cronobacter* contamination. The Company Announcement issued by Perrigo and which appeared on the FDA's website stated:

> Importantly, no distributed product has tested positive for the presence of this bacteria, no adverse events have been reported and no other products manufactured at this facility or any other of Perrigo's facilities are affected by this recall.
>
> * * *
>
> For over 130 years, Perrigo has been committed to meeting the needs of consumers – and the quality and safety of our products is our highest priority. ***We have numerous regulatory approved procedures throughout the manufacturing process to control for Cronobacter sakazakii. Every batch of infant formula is tested to make certain it meets stringent nutritional, safety, quality, and regulatory requirements. As part of our rigorous protocols to protect the safety of families and infants, we are proactively taking this action.***

416. These statements were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because Perrigo did not follow "regulatory approved procedures . . . to control for *Cronobacter*." To the contrary, an FDA inspection of the Gateway facility that occurred concurrently with the issuance of this recall would conclude that there were "significant violations" of FDA rules and regulations, including: (1) failing to "establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment," as evidenced by multiple positive tests for *Cronobacter* in both batches of product and the surrounding environment as well as the detected presence of metal shards in already-packaged product; (2) failing to "employ sufficient qualified personnel to perform all operations in the manufacture, processing, packing and holding of each infant formula," as evidenced by multiple employees handling products and equipment in an unsanitary manner; (3) failing to "clean, sanitize, and maintain equipment and utensils used in the manufacture of infant formula at regular intervals," as evidenced by visible powder residue buildup on equipment surfaces, the plant floor, and electrical conduits; (4) failing to "ensure that all surfaces that contacted in-process materials and infant formula were cleaned and sanitized and maintained to protect infant formula from being contaminated by any source," as evidenced by a lack of documentation confirming that equipment was cleaned and sanitized prior to being introduced into the dryer system for interventions such as removing clumps of powder; and (5) the "record of a production aggregate of infant formula [failing to] include the deviations from established specifications and corrective actions taken as a result of the monitoring operation," as evidenced by the total lack of documentation of events surrounding the discovery of particles resembling metal dust in the final sifter through which product is filtered

prior to packaging.

417. Furthermore, the statement that the Company was "proactively taking this action" to recall the product "as part of [their] rigorous protocols" was materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it was only *after* the FDA evaluated Perrigo's sanitation records (as part of the inspection that led to the issuance of the April 2023 Form 483) and engaged in subsequent discussions with Company officials that the Company initiated the recall. In short: it was not the Company's "rigorous protocols" that caught the error, but rather the FDA's fortuitously timed review of Perrigo's own records.

E. May 9, 2023

418. On May 9, 2023, Perrigo issued a press release filed on Form 8-K with the SEC along with Form 10-Q (the "Q1 2023 10-Q") announcing earnings for the first quarter of 2023. The Q1 2023 10-Q was signed by Defendants Kessler and Bezerra.

419. The press release included the following statements:

> During the quarter we also made meaningful progress against our strategic initiatives. In our Supply Chain Reinvention Program, we have completed pilot programs of the enhanced Perrigo work system, which is already delivering increased productivity. This work system is now being rolled out across our global manufacturing footprint. Additionally, ***integrations of HRA, the Gateway facility and the Good Start® brands are on track,*** and HRA synergies are slightly ahead of initial expectations.

420. The "on track" statement was materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it conveyed an impression that the Gateway facility was operating reliably and was "on track" to meet the targets Perrigo had set forth, including increasing Perrigo's capacity by 36 million pounds and adding $50 million in incremental operating margin. To the contrary, just two months prior, in March 2023, Perrigo had to recall formula due to potential presence of *Cronobacter* and just

two weeks prior, unknown to the market, the FDA issued a Form 483 for violations at Gateway including positive *Cronobacter* hits, metal fragments in the formula, and failure to employ sufficient personnel and even after that, Perrigo repeatedly failed to establish a system of process controls, as reflected in the information Perrigo provided the FDA in May 2023. Additionally, the transition from Nestlé to Perrigo was difficult, including having lost experienced personnel, inheriting a plant that had not undergone any meaningful maintenance in over two years, declining to backfill maintenance supervisor roles, losing maintenance logs and other record-keeping in the transition from Nestlé's version of SAP to Perrigo's, and challenging integration between Nestlé's updated digital systems for inventory management, auditing, and corrective action tracking, and that of Perrigo (requiring many quality and audit functions to rely on manual data entry). Moreover, Perrigo's representation of the possible capacity of the Gateway facility was fundamentally wrong. While the Gateway facility could theoretically produce up to 27 million pounds of product (assuming the plant was fully operational and not frequently paused due to poor maintenance), that capacity was only possible if the plant was operating reliably and producing *exclusively Nestlé's Good Start brand* – something Perrigo did not intend to do, and did not do.

F. August 8, 2023

421. On August 8, 2023, Perrigo issued a press release filed on Form 8-K with the SEC along with Form 10-Q (the "Q2 2023 10-Q") announcing earnings for the second quarter of 2023. The Q2 2023 10-Q was signed by Defendants Lockwood-Taylor and Bezerra.

422. The earnings call included the following statements:

> The market was confident coming out of this call, with J.P.Morgan stating "we exit the [quarter] with greater conviction in the company's continued path to "***We recently completed the Gateway facility and Good Start brand acquisition, and that integration remains on track***. In the second quarter, this acquisition contributed $44 million of net sales in our nutrition category, which was partly offset by $5 million from a discontinued product line, and $45 million of lower net sales from pediatric drinks."

* * *

> Additionally, ***recent changes to FDA guidelines are impacting the entire industry, resulting in lower manufacturing volumes, higher production costs and higher risk of scrap***.
>
> * * *
>
> The healthy growth of our youngest consumer is our utmost priority. ***Our team is working relentlessly to ensure families have the nutritionally equivalent store brand formula that they need at the lowest price on shelf***.

423. The "on track" statement was materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it conveyed an impression that the Gateway facility was operating reliably and was "on track" to meet the targets Perrigo had set forth, including increasing Perrigo's capacity by 36 million pounds. To the contrary, on April 26, 2023 the FDA issued a Form 483 for violations at Gateway including positive *Cronobacter* hits, metal fragments in the formula, and failure to employ sufficient personnel and even after that, Perrigo repeatedly failed to establish a system of process controls, as reflected in the information Perrigo provided the FDA in May 2023. Additionally, the transition from Nestlé to Perrigo was difficult, including having lost experienced personnel, inheriting a plant that had not undergone any meaningful maintenance in over two years, declining to backfill maintenance supervisor roles, losing maintenance logs and other record-keeping in the transition from Nestlé's version of SAP to Perrigo's, and challenging integration between Nestlé's updated digital systems for inventory management, auditing, and corrective action tracking, and that of Perrigo (requiring many quality and audit functions to rely on manual data entry). Moreover, Perrigo's representation of the possible capacity of the Gateway facility was fundamentally wrong. While the Gateway facility could theoretically produce up to 27 million pounds of product (assuming the plant was fully operational and not frequently paused due to poor maintenance), that capacity was only possible if the plant was producing *exclusively Nestlé's Good Start brand* – something Perrigo did not intend to do, and did not do.

424. The second statement claiming that "recent changes to FDA guidelines" were the reason for Perrigo's lower manufacturing volume, higher costs, and higher scrap was also materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it omitted direct causes of these problems were the substandard condition the plant was in when Perrigo acquired it and Perrigo's subsequent failure to properly maintain its equipment and develop functional quality and sanitation systems, all of which led to frequent deviations and contamination that forced the Company to regularly shut down and scrap product. Perrigo's choice to not address the Unremediated Gateway Problems or Unremediated Vermont Problems, wholly apart from the FDA or any evolving regulations, directly contributed to the lower manufacturing volume, higher costs, and higher scrap.

425. Finally, the statement that the Perrigo team was "working relentlessly" to ensure supply of store brand infant formula was materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because, as the FDA concluded, the Company had not taken "***any proactive actions to address the resident strains of [cronobacter] present within the facility"*** in the months since receiving the April 2023 Form 483, with its laundry list of bacterial positives in the environment and other objectionable conditions and practices.[49]

426. Analysts credited Defendants' statements and assurances. J.P.Morgan wrote, "we exit the [quarter] with greater conviction in the company's continued path to margin/EPS recovery through 2025."

[49] This information was reflected in the August 2023 Warning Letter, issued a few weeks after this statement was made and which was responsive to Perrigo's conduct since April 2023.

G. August 9, 2023

427. The next day, Perrigo participated in the Canaccord Genuity Growth Conference. Executives Lockwood-Taylor and Bezerra attended the conference.

428. An analyst asked about the status of the integrations with HRA and Gateway, and Bezerra responded:

> On the Gateway side, [] we're working now to integrate our operations, order to cash is one of the key things that we expect to roll out now in the beginning of the fourth quarter that we're going to be integrating 100%. But ***we see already the significant value accretion to our results that took place in the second quarter in Nutrition business because of the Gateway facility integration.***

429. Then, an analyst asked, "just a follow-up on the infant formula business with the changes with the FDA, what they're making, how does that impact your business and managing that business?" Defendant Lockwood-Taylor responded:

> It's been a volatile category for quite some time. ***I think it's getting to normalization***. . . . ***The new regulations essentially introduced more stringent cleaning protocols***. How scientific that is, debated, but okay, ***they are the protocols and that's meant more disrupted operation. It's essentially meant more costs, less capacity***.

430. But the Company was not seeing the promised "significant value accretion" or a "normalization" of production. Those claims were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because the Gateway facility's production capacity was seriously diminished by the time Perrigo acquired it, and in the months since completing the acquisition, Perrigo had not undertaken the steps necessary to come close to achieving the conditions necessary to meet those production numbers. Specifically, Perrigo had not addressed the Unremediated Gateway Problems and, as a result, was experiencing regular production pauses, batch or environmental contamination, and product scrap. Defendants knew that, in fact, the Gateway facility was a drain on both gross margin and earnings per share, given the substantial capital and operational expenditures not disclosed at the

time that would be necessary to remediate the Gateway facility such that it was reliably producing infant formula at the levels necessary to add the promised millions of pounds of annual capacity and incremental operating margin.

431. The second statement claiming that "new regulations" with "more stringent cleaning protocols" caused "more disrupted operation" with "more costs, less capacity" was also materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it omitted that direct causes of these problems were the substandard condition the Gateway facility was in when Perrigo acquired it and Perrigo's subsequent failure to address the Unremediated Gateway Problems, all of which led to frequent deviations and contamination that forced the Company to regularly shut down and scrap product. Perrigo's choice to not address the Unremediated Gateway Problems or Unremediated Vermont Problems, wholly apart from the FDA or any evolving regulations, directly contributed to the lower manufacturing volume, higher costs, and higher scrap.

432. Analysts credited Defendants' statements and assurances and factored them into their recommendations. On September 13, 2023, Morningstar Equity Company issued a report, initiating coverage on Perrigo with a fair-value estimate of $40 per share. Morningstar emphasized the acquisition of Gateway and U.S. and Canada rights to the Good Start infant formula brand, concluding "[i]nfant formula is one of the largest revenue drivers for Perrigo, and we believe with the right execution the company will be able to enjoy an increased production capacity and capabilities to continue growing the category."

H. November 7, 2023

433. On November 7, 2023, the Company submitted a press release filed on Form 8-K with the SEC along with Form 10-Q announcing earnings for the third quarter of 2023. The Form 10-Q was signed by Defendants Lockwood-Taylor and Bezerra.

434. The press release included the following statements:

Nutrition

Net sales of $131 million increased 5.1% due primarily to the Gateway acquisition. This benefit was partially offset by lower net sales in legacy infant formula due to ***lower manufacturing productivity stemming from the FDA's evolving industry guidelines on infant formula manufacturing and exited product lines***.

435. The slide deck from that presentation in the section on infant formula emphasized "Stabilization Expected Mid-2024" and "***Production is improving and becoming more efficient each week***" (Slide 7).

436. But these statements were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because the claim that Perrigo was experiencing "lower manufacturing productivity" due to "the FDA's evolving industry guidelines" omitted that direct causes of these problems were the substandard condition the Gateway facility was in when Perrigo acquired it and Perrigo's subsequent failure to address the Unremediated Gateway Problems, all of which led to frequent deviations and contamination that forced the Company to regularly shut down and scrap product. Perrigo's choice to not address the Unremediated Gateway Problems or Unremediated Vermont Problems, wholly apart from the FDA or any evolving regulations, directly contributed to the lower manufacturing volume, higher costs, and higher scrap.

437. As was later reflected in the November 2023 Form 483, at the time of this statement, Perrigo had identified environmental positives for *Cronobacter* between August 23 and November 6, 2023, in over a dozen different locations in the plant, including the dryer and dryer areas. Moreover, on several occasions, there were delays between the date of collection for the initial environmental swab and the date of collection for the verification swab. In that same period of time, there were 10 identified water leaks, two of which resulted in positive

environmental *Cronobacter* tests. The November 2023 Form 483 further reported that Perrigo failed to "clean, sanitize and maintain equipment and utensils in the manufacture of infant formula at regular intervals," and failed to "employ sufficient qualified personnel to perform all operations in the manufacture, processing, packing, and holding of each infant formula." Similarly, Perrigo failed to address the Unremediated Vermont Problems. Perrigo's choice to not address the Unremediated Gateway Problems or Unremediated Vermont Problems, wholly apart from the FDA or any evolving regulations, directly contributed to the lower manufacturing volume, higher costs, and higher scrap.

438. Similarly, the claim that "***[p]roduction is improving and becoming more efficient each week***" was materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it suggests Perrigo had a functional infant formula manufacturing program and could reliably fill customer orders for safe, quality infant formula. In truth, even after Perrigo concluded certain repairs to Gateway on August 20, 2023, they identified *Cronobacter* in the environment *three days later* (with many more positives to follow, as elaborated above). Moreover, Perrigo had not addressed the Unremediated Gateway Problems or Unremediated Vermont Problems that continued to contribute to production disruptions.

439. The market believed management's reassurance that stabilization in infant formula was on track. For example, a Morningstar Equity Analyst Note issued on November 7, 2023 titled "Perrigo Earnings: Weak Sales but Margin Recovery Well Underway with Strong Momentum" noted that in light of heightened FDA guidelines, Perrigo "implemented enhanced quality control in its facilities that halted production and weighed down the top line" and while it expected those dynamics to continue playing out, "we expect conditions to improve, and

management expects operations to normalize by the middle of 2024." Additionally, the report stated:

> On the backdrop of challenging dynamics in the U.S. infant formula business, management lowered sales guidance to 4%-6% from a previously stated 7%-11%. However, we also saw margins showing great momentum and improving much faster than we had initially anticipated. After slightly lowering our sales forecast for the year and upping our margin assumptions, we maintain our fair value estimate of $40 per share.

I. February 27, 2024

440. The truth began to partially emerge on February 27, 2024, before the market opened, when the Company submitted its annual report for the fiscal year ended December 31, 2023 on a Form 10-K filed with the SEC (the "FY23 10-K") revealing an unexpected $35 to $45 million in investments to remediate the infant-formula business and 50% drop in earnings per share, largely due to the Gateway remediation costs.

441. But Defendants reassured investors that it had the problem well in hand; that Gateway had undergone a "reset"; and that these were cabined, fixed costs. The FY23 10-K stated:

> *Infant Formula*
>
> As part of its efforts to prevent supply interruptions and future *Cronobacter* spp. illnesses associated with powdered infant formula, in March 2023, the FDA released an "Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market" and issued a letter to the powdered infant formula industry to share information to assist the industry in improving the microbiologic safety of powdered infant formula. ***In response to those changes, we made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs and added additional quality personnel.*** These changes resulted in lower manufacturing output and production yields across our infant formula network.
>
> * * *
>
> The Company also bolstered its internal resources and brought in additional outside expertise to help revise, enhance and strengthen comprehensive standards and processes across our infant formula network. ***As part of this plan, each of our infant formula manufacturing facilities are undergoing a site-specific evaluation and a plant wide reset***, which may entail a pausing of production for comprehensive cleaning, infrastructure improvements and further enhancements to quality protocols and manufacturing processes. ***Perrigo Wisconsin has recently completed its plant-wide reset, and is now back in***

> ***production.*** Our other two infant formula facilities are under evaluation or set to begin a reset in the first quarter of 2024.
>
> * * *
>
> We have incurred and expect to incur certain extraordinary non-recurring costs associated with the evolving U.S. infant formula regulatory landscape, including consulting and legal fees relating to the Company's responses to the FDA and the development and institution of new protocols across our infant formula manufacturing sites, as well as other costs relating to the extended cleaning and sanitization and the pausing and restarting of production. We also expect higher ongoing operating costs at our infant formula manufacturing sites moving forward as we implement our enhanced program with additional internal capabilities. ***Cash costs in 2024 to achieve this remediation plan are estimated at $35 to $45 million.*** Due to these costs and the unabsorbed overhead and depressed sales volumes resulting from these actions, infant formula results in 2024 is now expected below 2023 levels.

442. The FY23 10-K also emphasized Perrigo's active monitoring and compliance practices:

> *Infant Formula*
>
> Before marketing a particular infant formula, the manufacturer must provide regulatory agencies assurance of the nutritional quality of that particular formulation consistent with the FDA's labeling, nutrient content, and manufacturer quality control requirements. A manufacturer must notify the FDA at least 90 days before the marketing of any infant formula that differs fundamentally in processing or in composition from any previous formulation produced by the manufacturer. ***We actively monitor this process and make the appropriate adjustments to remain in compliance with current FDA rules regarding current Good Manufacturing Practice ("cGMP"), quality control procedures, quality factors, notification requirements, and reports and records for the production of infant formulas.***

443. This message was reinforced on the earnings call on that same day in remarks from Defendants Lockwood-Taylor and Bezerra.

444. Defendant Lockwood-Taylor explained:

> During 2023, our team h[as] been working to adapt to the evolving U.S. infant formula regulatory landscape, which triggered a major overhaul of long-standing industry standards. ***In response to these changes, we made considerable investments in our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs and added additional quality assurance personnel***. These changes resulted in lower manufacturing output and production yields across our network. Then, in late November of last year, the FDA issued a Form 483 to our Wisconsin facility, which we acquired in November 2022. This followed

> the receipt of a warning letter issued to this facility earlier in the year**.** Now it was clear to me as a new CEO with over 20 years of experience regulated industries such as health care, and having led other good manufacturing process plant remediations that we need to put ourselves on an accelerated plan to augment and strengthen this business by investing and making facility enhancements and revising our quality protocols to ensure quality assured manufacturing in line with these new regulatory expectations. ***As a result, we bolstered our internal resources and brought in additional outside expertise to help revise, enhance, strengthen and accelerate comprehensive standards and processes across our infant formula network, which we believe will position us well for the future. I personally chair the Steering Committee that oversees these efforts. As part of this plan, our manufacturing facilities have either undergone or are undergoing a site-specific evaluation, which may entail a pausing of production for comprehensive cleaning, infrastructure improvement, a future enhancement to quality protocols and manufacturing processes. Our Wisconsin facility has recently completed a plant-wide reset and is now back in production.*** Our other 2 infant formula facilities are under evaluation were set to begin a reset in the coming weeks. ***Cash cost to achieve this critical remediation plan are estimated at $35 million to $45 million***. Due to unabsorbed overhead and depressed sales volumes resulting from these resets, interim formula operating income in 2024 is now expected to be below 2023 levels, but previously, we expected a recovery.
>
> * * *
>
> we're dealing in the most sensitive of categories . . . ***There has to be a final indication of a quality controlled manufacturing environment. With these investments, there is no doubt that, that moves us to that. . .*** I know what we've had to do. I think we were operating at normal industry standards. I think what we're doing is probably ahead of what is being done by many other manufacturers.

445. In response to an analyst question about the "bumpy ride" and what level of comfort they could have that this was "the last iteration we're going to be kind of seeing on nutritionals"? Lockwood-Taylor responded that by the end of November 2023, he recognized that "a more significant definitive intervention" was needed and in Wisconsin it has been a "***very significant intervention with a different level of protocol, corrective actions, preventative actions, quality assurance application and environmental monitoring and cleaning and sanitization***" and "***so far, so good. That site is up. It's a different level of adherence*** . . ."

446. Relatedly, as the following slide from the presentation reveals, the core message was that Perrigo is "Taking Uncompromising Action" to "Augment and Strengthen Infant Formula"; the additional cash costs were "***one-time"*** only; and that the Company still

"***anticipate[s] business stabilizing and returning to growth in 2H***":

447. But these statements were materially false and misleading and omitted material facts.

448. Claims that Perrigo had "***made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs and added additional quality personnel"*** and "bolstered its internal resources and brought in ***additional outside expertise to help revise, enhance and strengthen comprehensive standards and processes*** across our infant formula network" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest the Company is investing appropriately and making necessary changes to have a safe and reliable manufacturing process. In fact, Perrigo declined to address the Unremediated Gateway Problems and Unremediated Vermont Problems that were key causes of contamination, product scrap, and production delays – problems that external consultants, FDA inspectors, and on-the-ground plant personnel alike had already flagged

for Defendants.

449. Claims that the "***remaining work is well understood and within the cost ranges we have guided to***"; that the cash costs "***to achieve this remediation plan are estimated at $35 to $45 million***"; that additional cash costs were "***one-time***" only; and that the infant formula actions are "***planned investments that we expect to complete as we move through this year***" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest the costs are known, fixed, and cabined. In reality, the actual costs of bringing the Company into full compliance (*i.e.*, by addressing the Unremediated Gateway Problems and Unremediated Vermont Problems) were not limited to a discrete, one-time expenditure of $35 to $45 million for deep cleaning and process consultants but rather required a massive overhaul of facilities and equipment that would cost far in excess of those estimates. Both the Unremediated Gateway Problems and the Unremediated Vermont Problems could not be remedied with the cleaning protocols and personnel additions Defendants described – a fact that the FDA had explicitly highlighted in its August 2023 Warning Letter.

450. Those statements were bolstered by claims that Gateway had "***completed its plant-wide reset***" and that "***[t]he majority of the significant remediation actions are behind us***" and that they "***anticipate business stabilizing and returning to growth in 2H***" that erroneously suggest the work to get the facilities producing at levels to generate growth in the infant formula business.

451. In fact, Perrigo declined to address the Unremediated Gateway Problems and Unremediated Vermont Problems that were key causes of contamination, product scrap, and production delays—problems that external consultants, FDA inspectors, and on-the-ground plant personnel alike had already flagged for Defendants.

452. Claims that the Company is "mak[ing] the appropriate adjustments to remain in

compliance with current FDA rules" and "operating at normal industry standards" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they convey an impression that the Company is making necessary changes to have a safe and reliable manufacturing process. In fact, the changes that the Company was pursuing did not address the known issues at the plant – a fact that the FDA had raised to Defendants in the August 2023 Warning Letter. The Company was *not* addressing the Unremediated Gateway Problems or the Unremediated Vermont Problems. Instead, the Company hired external consultants to sanitize Gateway room by room—an exercise the FDA had explicitly warned would be insufficient, on its own, to bring the facility into compliance—as well as monitor production processes on the ground and report back to the Steering Committee.

453. In light of these reassurances, analysts at J.P.Morgan emphasized the company's "confiden[ce] in its ability to recover customer share given the industry's need to supply store-brand infant formula & the capacity constrained environment." Similarly, analysts at Canaccord Genuity accepted management's misleading statements about the future of the business: "[I]t will take a couple of quarters to get the infant nutrition business back on track. However, we believe management has been conservative with the nutrition business, and if the transition goes smoothly, we could see an upside in their estimates. . . . [We] remain buyers as we believe [Perrigo] will get back on track once past the nutrition issues." Finally, analysts at Piper Sandler characterized the stock reaction as "a bit overdone," explaining that they "struggle to fault management" for the need to make rapid facility enhancements and overhaul quality protocols when this was an "industry-wide issue[]" which Perrigo management was "trying to be ultra-prudent in addressing."

J. March 13, 2024

454. On March 13, 2024, Perrigo participated in the UBS Global Consumer & Retail Conference. Defendants Lockwood-Taylor and Bezerra attended.

455. An analyst asked about the progress of remediating the infant formula plants. Defendant Lockwood-Taylor responded:

> So with Wisconsin with the FDA, we clearly needed to accelerate and augment our work that is do more faster to get that to quality complaint and operation[ally] reliable, very positive story, okay? ***So we have[sic] done remediated that plant.*** [T]he start-up was faster than expected. And the throughput is better than expected and better than quarter 1, quarter 2 a year ago. Now a different formulation. So it's not completely apples-to-apples, but it's extremely encouraging. ***So we are fully compliant and operationally reliable and producing and moving through different batches, ahead of our expectation, okay?*** And whilst I'm not going to talk about what that means in terms of the EPS guidance that we gave at this stage because we're only 4 weeks in, we need a bit more data. It's very encouraging...
>
> On Vermont and Ohio, we had also seen issues. And again, we want quality compliant manufacturing and operational reliability. We scrapped over $50 million of product last year, okay? We had to change our GMPs, our protocols, our processes, our training, our culture, the number of quality people that we have working on the lines, et cetera, which is what we've done. So [] Vermont and Ohio [are] much less complex than the Wisconsin challenge that we had. ***We finished the root cause analysis in Vermont. We are still producing in Vermont and we know precisely what we need to do in terms of corrective actions and preventative actions. . . . So we are moving very well . . . towards quality compliant, reliable supply operations, and we will be there within a few weeks. The Wisconsin [plant is] done. Vermont partially done.*** Ohio to be done, but they will be done much faster than what we did at Wisconsin in part because we bring that know-how now to those plants. Right thing to do, okay? And we think positions us very well in the industry.

456. Defendant Bezerra added:

> [T]he way we're thinking about the infant formula business going forward, this normalized basis of $140 million of operating income, right? . . . [In the] third and fourth quarter [of 2024], we expect a significant recovery mainly on volume, right, because we had a lot of hiccups there. And also, we couldn't fully realize the price increase. ***We took significant price during last year given the new regulations and the impact they had in our overall production cycles, et cetera***.

457. Claims that the Company had "***remediated that plant***," referencing Gateway; that it is "***fully compliant and operationally reliable and producing and moving through different batches, ahead of our expectation" and that impact on EPS is "very encouraging***" and that the Company has "***finished the root cause analysis in Vermont***" and "know[s] ***precisely what we need to do in terms of corrective actions and preventative actions" so is "moving very***

well . . . towards quality compliant, reliable supply operations, and we will be there within a few weeks" and that "[t]he Wisconsin [plant is] done" *w*ere materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggests that the work is behind the Company; its factories are "remediated" and "fully compliant" with relevant FDA rules and cGMPs; and production rates are where they need to be to drive EPS. To the contrary, by the time Defendants made these statements, not one but two separate consultants had warned Perrigo that the Marriott Walker dryer at its Vermont facility was beyond repair, and the FDA had warned the Company that merely sanitizing the Gateway facility would not address the likely root causes of systemic *Cronobacter* contamination. Nonetheless, the "remediation" activities that the Company undertook during its facility "resets" were merely deep cleaning and hiring process consultants, and so did not meaningfully address the Unremediated Gateway Problems or Unremediated Vermont Problems.

458. The claim that the Company "***took significant price during last year given the new regulations and the impact they had in our overall production cycles"*** was also materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because the statement omitted Perrigo's own responsibility for these problems—namely, acquiring a facility that was in serious disrepair, and declining to address the Unremediated Gateway Problems and the Unremediated Vermont Problems, which caused the contamination, facility shutdowns, and product scrap.

459. A March 13, 2024 analyst report from Canaccord Genuity reflected the market's acceptance of Defendants' reassurances from the very title: "Perrigo's infant formula in recovery mode with plenty of upside going forward." The report reflected that the market believed the

following:

- *Remediation costs were fixed*: "This will require another $35-45M in capital investment to get all their infant manufacturing facilities up to the evolving FDA guidelines around infant nutrition."
- *The work was largely behind Perrigo*: "We note that PRGO has already implemented these updates with their Wisconsin Gateway facility in 4Q and have two more facilities to work on in calendar 1Q. These updates should be resolved faster due to taking learnings from the Wisconsin Gateway facility. . . ."
- *Unlike competitor Abbott, Perrigo would quickly get into compliance with FDA requirements and grow sales*: "We believe this reset will be much faster than Abbott's 2+ year timeframe to get back up to 'pre-recall' levels, which started in February 2022. PRGO's challenges are not as drastic as what Abbott underwent as Abbott's facilities were not up to prior FDA compliance standards . . . As a result, we believe PRGO will have a much quicker turnaround of its facilities and be able to start to grow sales again in 2H24 . . . **Abbott's full recovery took 2 years, but PRGO is not in as dire of a situation.** We note it took Abbott roughly 2 years after their major recalls, plant shutdown, and managing new FDA guidelines to get to 90% of the market share it had previously. . . Perrigo is expected to recover a lot quicker and we believe management's commentary is realistic as they have already successfully completed updating one of their three facilities, giving guidance and expertise on how to better update their remaining two. Additionally, we don't expect Perrigo to lose as much share as Abbott, given they did not have a recall. Management had noted that the nutrition adj. operating income will be ~$50M lower in 1Q24 vs. 1Q23, which

matches with management's commentary of a -$0.30 EPS headwind in 1Q as management stabilizes the business. For the full year, management indicated around -$0.65 of EPS headwinds compared to prior expectations given in November 2023."

- *EPS would recover:* "As PRGO laps these issues in FY25 and regains the incremental sales lost, we believe PRGO can see about $0.80 in EPS contribution in FY25 as sales come back to normal levels ($500M range) and EBIT [earnings before interest and taxes] margins of high-20s as costs are levered. This would be driven by lapping a one-time investment ($0.23) and seeing sales growth/leverage ($0.66). This would indicate around $0.80 in EPS contribution from the infant formula business in FY25, up from our estimate of $0.40 in contribution in FY23 and -$0.09 in FY24 and implied normalized rate of $0.80+. For details, see our EPS bridge below. Longer term, we believe the business could contribute $1.00+ to EPS."

460. Canaccord's report included the slide referenced above, titled "Augment and Strengthen Infant Formula," underscoring its significance to the market.

461. An April 23, 2024 analyst report from J.P.Morgan issued ahead of the first quarter earnings, similarly reflected investors' focus on infant formula and belief that the remediation was complete and a success, stating "***we see results taking a backseat to commentary on the progress of infant formula manufacturing plant remediations*** . . . Thus far, the ***remediation process appears to be going ahead of schedule based on recent company commentary – its Wisconsin facility is back online (& fully compliant) with volumes increasing faster than expectations*** while its ***Vermont & Ohio facilities should be relatively simpler processes***. And with PRGO likely to be largely through remediations by 1Q earnings, we expect a clearer line of sight to the volume ramp through the rest of the year and into 2025 and believe

greater clarity could allow for investors to return to the story."

K. May 7, 2024

462. The truth continued to partially emerge on May 7, 2024, when Perrigo disclosed that margins were further compressed and net sales down by 34.5% due primarily to lower infant formula shipments.

463. But the Form 10-Q announcing earnings for the first quarter of 2024 (the "Q1 2024 10-Q"), which was signed by Defendants Lockwood-Taylor and Bezerra, also reassured investors that the recovery was well in hand and costs were contained:

> *Infant Formula*
>
> As part of its efforts to prevent supply interruptions and risk of *Cronobacter* spp. illnesses associated with powdered infant formula, in March 2023, the FDA released an "Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market" and issued a letter to the powdered infant formula industry to share information to assist the industry in improving the microbiologic safety of powdered infant formula. ***In response to those changes, we made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs and additional quality personnel.*** These changes resulted in higher costs and lower manufacturing output and production yields across our infant formula network.
>
> * * *
>
> ***Currently, any planned large-scale manufacturing plant resets have been completed, and we are progressing the next phase of our quality enhancements.***
>
> This next phase of enhancements includes further protocol, process and procedural improvements at the site level, and we are making additional investments to upgrade infrastructure. ***We do not expect these continuing improvements to result in extended shutdowns beyond normal maintenance activities*** . . . ***Maintaining quality compliance is core to Perrigo's business and culture. We will continue to invest in quality, capacity, and other enhancements as we bolster quality-controlled, reliable manufacturing across our network.***
>
> * * *
>
> We have incurred and expect to incur certain extraordinary non-recurring costs associated with the evolving U.S. infant formula regulatory landscape, including consulting and legal fees relating to the Company's responses to the FDA and the development and institution of new protocols across our infant formula manufacturing sites, as well as other costs relating to the extended cleaning and sanitization and the pausing and restarting of production. ***Cash costs in 2024 to achieve this remediation plan are estimated at $35 to $45 million***. . . .

464. Similarly, on the earnings call that same day, Defendant Lockwood-Taylor reassured investors, stating:

> ***Looking at our 2024 operational priorities, I'm pleased to say we remain well on track. First, we are making good progress augmenting and strengthening our infant formula business and are working to recover manufacturing volumes***…
>
> * * *
>
> ***Over the past few months, we have made significant progress to augment and strengthen our infant formula manufacturing network. . . . At this point, any planned large-scale plant resets have been completed, and we are progressing to the next phase of our quality and operational enhancements. This next phase includes further policy and procedural enhancements at the site level. In addition, we are making further investments in infrastructure and people as appropriate***.
>
> * * *
>
> ***Importantly, we do not expect this continuing body of work to result in extended shutdown beyond normal maintenance activities***. The recovery of manufacturing volumes is expected to continue to build throughout 2024, stemming from longer quality hold times and faster, shorter campaign-style production runs. Sales volumes are expected to improve during the second half of the year, followed by market share recovery. All if this is in line with our original outlook. Stabilization of infant formula will remain a journey and I'm pleased with the progress we have made.

465. An analyst asked about Defendants' confidence that the remediation had actually solved the problems: "what's your level of confidence that the [] remediations have solved issues with these segments? . . . [W]ere these plant shutdowns the most challenging piece of the process? Or is it the work going forward to make sure you can . . . stay in compliance representing the biggest hurdle . . . ? And then . . . , if you could comment at all on just what portion of the $0.65 or so of impact from the remediation, do you think you're going to be [patient] to regain as we look out to 2025[?]" Defendant Lockwood-Taylor responded:

> ***The big intervention in terms of root cause analysis, corrective and preventative actions the translations of that into new GMPs, protocol, staffing levels, et cetera, is largely done, okay, across the 3 sites. As we executed in Wisconsin, we are able to accelerate the application of the know-how to the other 2 facilities back in production mode, okay?*** [A]nd as I suggested in my commentary, really putting start-up times and throughputs at or slightly ahead of our expectations. So we're very encouraged by that. To the point that you might flip back to a permanent watch, and we have to make sure that environmental cleanliness, monitoring, and GMPs keep us at all-time quality compliance. So ***we're not***

> ***getting any positive hits and therefore, having to stop production. We're not and we're not***.

466. Another analyst asked about the near-term forecast for the infant formula business: "What should we expect for the gross margin impact from infant formula in Q2? If Q1 was a minus 520 basis point impact, and we got earlier shipments, what should we expect in Q2 and if we're going to lose those shipments??" To which Defendant Bezerra responded:

> Well, so we expect in Q2 margins to be in a much better situation. ***Remember, we had the 2 key effects there, right? So we had first [] lower shipments, but also we had the variances that impacted because we had some stoppages in our manufacturing operations. We do not expect those onetime impacts [to] take place in Q2.*** And so our margins should rebound significantly versus Q1. . . . [A]s we look . . . into the second versus last year, volumes are not going to be at the same level of last year, but we should see an improvement on margins on a gross profit level as compared to what we did last year.

467. The slides in connection with the earnings call echoed that message, stating "***Large-scale plant resets completed where necessary***"; "Continue to expect volumes to ramp in 2H24; and they "***[d]o not expect further extended shutdowns beyond normal maintenance activities.***"

468. The claims that "***any planned large-scale manufacturing plant resets have been completed, and we are progressing to the next phase of our quality enhancements***"; "***any planned large-scale plant resets have been completed***"; "***[t]he big intervention in terms of root cause analysis, corrective and preventative actions the translations of that into new GMPs, protocol, staffing levels, et cetera, is largely done, okay, across the 3 sites***"; and "***We do not expect these continuing improvements to result in extended shutdowns beyond normal maintenance activities***" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest the work is done, that the problems that had previously caused *Cronobacter* hits and productions slowdowns had been addressed and would not be recurring, and that needed improvements in the future would not substantially disrupt operations. To the contrary, the few steps taken—specifically, deep cleaning the Gateway facility—*did not* address key causes of production slowdowns: the Unremediated Gateway Problems and Unremediated Vermont Problems. The critical fixes needed at both facilities remained unaddressed—and if they ever were to be addressed in the future, would cause substantial interruptions in production.

469. The claims that *"**we made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs and additional quality personnel***"; "***[i]n addition, we are making further investments in infrastructure and people as appropriate***"; and "***[m]aintaining quality compliance is core to Perrigo's business and culture. We will continue to invest in quality, capacity, and other enhancements as we bolster-quality-controlled, reliable manufacturing across our network. . . .***" were also materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they convey an

impression that Perrigo's investments in the plant "resets" appropriately invested in infrastructure and personnel such that the Company was "maintaining quality compliance," when, in fact, the Unremediated Gateway Problems and Unremediated Vermont Problems (the vast majority of which related to insufficient infrastructure and personnel) remained unaddressed after the resets. In fact, as of early-to-mid-2024, Defendant Lockwood-Taylor and Perrigo's Steering Committee responsible for reviewing production and quality records from the Gateway facility's consultants had received a report that recommended, among other critical changes, the Quality team hire more experienced personnel and that the Company terminate the employment of the then-Quality Manager, Kristi Knudtson. Again, Perrigo did not follow its consultants' advice, instead choosing to promote Knudtson and declining to backfill critical Quality roles.

470. The claim that "[c]ash costs in 2024 to achieve this remediation plan are estimated at $35 to $45 million. . . ." was also materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it suggests the costs are known, fixed, and cabined, when, in fact, true remediation *(i.e.*, fixing the Unremediated Gateway Problems and Unremediated Vermont Problems) would require a massive and expensive overhaul of facilities and equipment.

L. June 11, 2024

471. At the June 11, 2024 Oppenheimer Consumer Growth and E-Commerce Conference, Defendant Lockwood-Taylor made specific remarks about improvement in environmental stability and production. Specifically, he stated:

> Infant formula has been a significant focus for us this year. ***We have made outstanding progress, in line, if not ahead, really, of our expectations. The large-scale plant reset, three plants that went through significant remediation, that is now behind us***. ***It's been completed some months ago***, very good.
>
> We have seen significant improvement in quality control, production, packaging, and lease attainment. Just to put some numbers around that, we've seen a tenfold improvement in

> our environmental stability, which is outstanding. And while it's still early in the post remediation production ramp up, early results are very encouraging where ***we have seen significant improved production versus pre remediation levels***. ***We are achieving industry-leading quality control at near historical record production levels.***

472. The infant formula business was a key focus of analysts attending the conference. One analyst asked the executives to "talk about your evolution to One Perrigo in your current focus on deliver and deliver. Can you talk about how you see the One Perrigo strategy evolving over the longer term?" Defendant Lockwood-Taylor responded: "As we've mentioned several times, ***we continue to work to return infant formula to stable, profitable operations. That has gone extremely well and we are well on track***. And in our U.S. store brands business, that's about us focusing on driving growth and margin expansion."

473. Another analyst asked when infant formula will normalize and whether the business can deliver more than $3 EPS, and Bezerra responded: "***Yes.*** So the short answer is yes, right? . . . There are three major components that give us confidence on that. Firstly, ***the infant formula rebound***. So that's why it's so critical that in the fourth quarter [we] get back to a normalized state. ***Remember, when we talked about our earnings guidance, we expected a $0.65 impact related to infant formula into our results for 2024. We expect to see a significant portion of that rebound next year***."

474. The claims that Perrigo made "outstanding progress," that "[t]he large-scale plant reset, three plants that went through significant remediation, ***that is now behind us***" and that the Company would see a "significant portion" of a $0.65 "rebound" from infant formula the following year were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it suggests the work is done, that the plants were, in fact, remediated, and that production levels would pick up such that it would have a significant impact on earnings per share. Yet Perrigo had declined to address

either the Unremediated Gateway Problems or the Unremediated Vermont Problems during their facility "resets," thereby leaving in place the very obstacles to production capacity that had previously plagued the facilities. Indeed, in May 2024, the Gateway facility had additional positive *Cronobacter hit,* indicating that the "reset" had not eliminated bacteria from the environment.

475. The claims that "[w]e are achieving industry-leading quality control at near historical record production levels" and the claim, in response to an analyst question about whether Perrigo's strategy can deliver, the response that Perrigo's "work to return infant formula to stable profitable operations . . . has gone extremely well and we are well on track" were also materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest Perrigo had a functional infant formula manufacturing program and could reliably fill customer orders for safe, quality infant formula. In truth, even after Perrigo concluded certain repairs to Gateway on August 20, 2023, they identified Cronobacter in the environment *three days later* (with many more positives to follow, as elaborated above). Moreover, Perrigo had not addressed the Unremediated Gateway Problems or the Unremediated Vermont Problems that continue to contribute to production disruptions. In truth, projected capacity for 2024 was only 40-50% expected annual capacity given the extended shutdowns and product scrap, which, in turn, had led to a loss of customers.

476. J.P.Morgan report issued on May 7, 2024, praising Perrigo's "Encouraging Progress on Infant Nutritional Recovery," and proclaiming that "we walk away from today's updates more confident that PRGO's infant formula remediations (which we see as the core issues for shares in 2024) are on track and if anything slightly ahead of schedule."

477. The report further emphasized that the hard work was behind Perrigo:

> **PRGO now in the process of ramping production with focus on continued quality compliance**. **PRGO's large-scale plant resets are now completed, with all 3 factories back in production and quality compliant. From here, PRGO does not expect any more extended shutdowns** (i.e. beyond normal maintenance) with a focus on continued quality compliance / increased reliability. **As a result, mgmt. is confident in reaching a $140mm run-rate for operating income in 4Q**. We anticipate a modest step up in sales in 2Q followed by a more significant improvement in 2H24. **Importantly, we see this normalized nutritional profitability supporting $3+ in EPS in 2025**, which would imply a <10x 2025 PE multiple (a steep discount to consumer peers). **JPM View: We continue to see significant upside for shares to the extent this segment normalizes, which we feel increasingly comfortable with following today.**

478. Similarly, on June 12, 2024, Piper Sandler issued a report titled "Forecasting Formula: Fears Overdone, Future Looks Favorable." They concluded:

> We remain buyers of PRGO and believe recent share weakness resulting from the current infant formula challenges has been overdone, creating a nice buying opportunity . . . RGO has taken proactive steps to minimize the impact of additional infant formula regulatory requirements, which has led to some plant shutdowns and share loss. . . . Perrigo has been intentional and thorough in taking proactive measures to make sure its infant formula meets FDA regulatory requirements. Management has communicated its considerable investment in facility enhancements and revised quality protocols, which have subsequently lowered manufacturing output and production yields. While Perrigo has been working to implement an action plan related to the infant formula business, ongoing pressures throughout 2023 and into 2024 have had significant impacts on both the top and bottom lines. That said, with management calling out that it has taken extensive measures compared to many other industry players to get ahead of potential issues, we see room for share recapture as production begins to normalize for Perrigo and other players start to follow suit. With production ready in all sites as of the end of Q1, as well as start-up and throughput both ahead of where they were anticipated, we view management's expectations for re-acceleration by 2H this year as largely achievable. . . . While we see some room for share gains in 2025, we think the bulk is likely to be realized in 2026 when safety stock levels are fully recovered.

479. Finally, analysts at Canaccord Genuity noted that infant formula results were "better than expected," given the $0.06 benefit from the timing of infant nutrition formula shipments. The analysts further reported, in relevant part:

> [T]here still was a $0.30 headwind YOY due to the decline of infant nutrition sales. ***PRGO is working on getting the infant nutrition business back up to speed by the end of the year.*** The infant nutrition headwinds not only impact topline, but is also expected to have a $0.65 headwind on EPS this year as well due to losing out on higher- margin revenue along with investment needed to update their manufacturing facilities.

* * *

> PRGO stock ended -8.5% as we believe investors were hoping for a guidance raise if the infant nutrition business came in better than expected, but we believe management still wants to remain conservative given the business is a ways from being back on track still. However***; we believe PRGO is on track to getting the infant nutrition business back up to speed by the end of the year*** and continues to see growth outside of that business, even with the inventory destocking headwind. With PRGO trading at under 9.4x our FY2 EPS estimates, we believe the pullback presents a good buying opportunity due to an unbalanced risk/reward proposition and multiple growth drivers for the business longer-term. We reiterate our Buy rating and $42 PT.

M. August 2, 2024

480. On August 2, 2024, Perrigo issued a press release filed on Form 8-K with the SEC along with the Q2 2024 10-Q. The Form 10-Q was signed by Defendants Lockwood-Taylor and Bezerra.

481. The Q2 2024 10-Q included the following statements:

> *Infant Formula*
>
> As part of its efforts to prevent supply interruptions and risk of *Cronobacter* spp. illnesses associated with powdered infant formula, in March 2023, the FDA released an "Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market" and issued a letter to the powdered infant formula industry to share information to assist the industry in improving the microbiologic safety of powdered infant formula. ***In response to those changes, we made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs, enhanced quality oversight and increasing the number of quality and operations personnel. . . . The Company also bolstered its internal resources and brought in additional outside expertise to help revise, enhance and strengthen comprehensive standards and processes across our infant formula network,*** including in some instances, pausing production for comprehensive cleaning and infrastructure improvements. ***Any planned large- scale manufacturing plant resets have now been completed,*** and the Company is implementing the next phase of our quality enhancements, including further protocol, process and procedural improvements at the site level, and additional investments to upgrade infrastructure. ***We do not expect these continuing improvements to result in extended shutdowns beyond typical planned maintenance activities***.

> ***Currently, all sites are up and running and have returned to reliable, quality-assured production with recent output across the network near 2023 levels.*** . . . ***Cash costs in 2024 to achieve this remediation plan are estimated at $15 to $20 million, of which approximately $10.5 million were incurred during the first two quarters.***

482. On the earnings call held that day, Defendants made a number of highly positive statements in an effort to reassure investors.

483. Defendant Lockwood-Taylor stated:

> Now to infant formula. ***All sites are up and running, producing reliable, quality assured infant formula***. Our focus now lies on rebuilding customer service levels and swiftly getting these critical products back on the shelves to serve consumers to need high-quality, affordable infant formula***. We are currently making significant progress in quality control, production, packaging and release attainment. On a weekly basis, production volumes through the first four months of this year were approximately half of 2023's average weekly levels. During May-June, as we ramped up production following the remediation efforts with our new protocols in place, we immediately achieved production volumes of 90% of the prior year levels. And our latest data available for July reveals that production is on a path to return fully to prior year levels. Furthermore, manufacturing efficiencies and are recovering faster than expected, stemming from reductions in production stoppages and product scrapping, giving us confidence in the recovery of our second half profitability.***
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> * * *
>
> ***As you may recall, the genesis behind Perrigo acquiring its Wisconsin facility from Nestlé in 2022 was to bolster our network and eventually replace an aging facility through this cost-effective acquisition. Now that we are producing reliable, quality assured infant formula across the network***, we will now start the work on optimizing our production footprint over time.
>
> * * *
>
> ***These are extremely high-quality plants and really set benchmark of the industry. We are seeing production and packaging at or above historical levels***. So we're running higher quality plants more efficiently than we have done historically and we are seeing store recovery and store brand consumer recovery completely in line with our expectation, and that will accelerate.

484. Defendant Bezerra stated:

> Our second half earnings per share is expected to be more than double our first half. Let me provide some color here. ***There are three key drivers of this expected growth. First is the recovery of the infant formula business, starting with the absence of significant remediation costs, including extended client shutdowns that took place in the first half of the year.***
>
> * * *

> Our infant formula self-remediation actions began in January of this year, following updated manufacturing guidelines introduced by FDA last year. The focus of this initiative is to ensure all infant formula sites are producing reliable, quality assured infant formula. ***We now project a cash outflow of approximately $25 million in 2024 related to these initiatives, which again, as good news, this outflow is below our original projection of $35 million to $45 million***.

485. An analyst asked the following question regarding the Nutrition business: "It seems like you're making progress here. But just at this stage, how confident are you that you're fully through this process and that there won't be any meaningful setbacks in terms of the recovery in nutritionals? I mean, at this point, are you confident to say that the remediation that was put forth was successful and this business is kind of in a good place going forward?" To which Defendant Lockwood-Taylor responded:

> Yes. I've been very close to the remediation work. As you know, I chair the steering committee. ***The remediation work has been executed extremely well across the three sites***. ***All the key performance indicators show that we are fully compliant. I've not seen any backslide in terms of those KPIs [key performance indicators] as we've been through the remediation effort, and we're on the other side of that. So really now, it is into normal manufacturing operations, but in a much more quality compliant way***.

486. Claims that "any planned large-scale manufacturing plant resets have been completed, and we are progressing the next phase of our quality enhancements" and "any planned large-scale plant resets have been completed" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest that the work is done and that the plants were, in fact, remediated. Yet Perrigo had declined to address either the Unremediated Gateway Problems or the Unremediated Vermont problems during their plant "resets," opting instead to pay consultants merely to deep-clean the facilities and draft reports of their quality processes. In fact, in May 2024, the Gateway facility had additional positive *Cronobacter hit,* indicating that the "reset" had not eliminated bacteria from the environment. Moreover, during the summer of 2024, Gateway had to scrap half of all soy

formula product created during a lengthy production campaign due to known temperature deviations in aging equipment.

487. Claims that the "[c]ash costs in 2024 to achieve this remediation plan are estimated at $35 to $45 million" were also materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest the costs are known, fixed, and cabined when, in fact, the true cost of remediation would require addressing the Unremediated Gateway Problems and Unremediated Vermont problems, both of which would require massive and expensive overhaul of infrastructure and equipment.

488. Claims that Perrigo has "made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs and additional quality personnel"; Perrigo is "making further investments in infrastructure and people as appropriate"; and that they "do not expect these continuing improvements to result in extended shutdowns beyond normal maintenance activities" because "[m]aintaining quality compliance is core to Perrigo's business and culture. We will continue to invest in quality, capacity, and other enhancements as we bolster-quality-controlled, reliable manufacturing across our network" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest the Company is investing appropriately and making necessary changes to have a safe and reliable manufacturing process. In truth, Perrigo's failure to address the Unremediated Gateway Problems and Unremediated Vermont problems ensured that the Company remained out of compliance with cGMPs and FDA rules, as evidenced by the continued positive *Cronobacter* hits and product scrap made clear.

489. Analysts once again noted that Perrigo's results were "disappointing" and "below [] expectations," per a Morningstar report issued the same day. At the same time, analysts were largely mollified by the Company's reassurances about the recovery of the infant formula business and the announcement of early shipments to customers. The same Morningstar report indicated that analysts "expect improvement on both [sales and margin] through the year as the costly infant formula restart fully ramps up . . . ." It continued, "we think the firm's recovery plans are well underway, and we see signs of promise despite today's weak numbers. On infant formula, Perrigo noted that recovery is progressing quicker than anticipated manufacturing efficiency rebuilding is well underway with July production volume mirroring last July's. We expect material sequential improvement in the business starting next quarter and should continue improving throughout the year . . . Management's reiteration of earnings per share guidance despite a mid-single-digit sales expectation cut is encouraging."

490. Also on August 2, 2024, J.P.Morgan issued an analyst report titled "2Q Takeaways – Infant Formula Ramp Trending Ahead of Expectations, Company Remains Confident in $3+ of '25 EPS." They explained "we walk away from today's update with greater confidence in the 2H24+ recovery of PRGO's infant formula business (which we see as the core issue for shares) and ability to reach $3+ of EPS in 2025 as a result. Additionally, while the company's top-line guidance was adjusted for a recent contract loss with one of PRGO's customers, this appears to have been a strategic decision by the company (had become too dilutive to margins) and is more than offset in 2025 by other contract wins, which will also carry higher margins. And overall, with a still very achievable path for earnings to recover to the low to mid $3-range in the near-term and the business generally becoming less controversial, we continue to see a strong oppty for multiple expansion from current levels (~9x 2025 EPS)." They continued,

"Infant formula recovery trending ahead of expectations, which we continue to view as the key focus for the story. All infant formula mfg. sites are up & running with volumes having significantly normalized thus far; here, volumes have recovered from ~50% of 2023 avg. weekly volumes through the first 4 months of the year to ~90% in May – June & on path to 100% in July."

491. An August 4, 2024 report from Canaccord Genuity maintained its Buy rating and was titled "Near-term topline headwinds but 2H positioned for infant formula recovery and PRGO well positioned for trade down" and emphasized that "On 8/2 before the open, PRGO reported mixed 2Q24 results but provided commentary that their largest thorn, infant formula manufacturing, is recovering faster than anticipated. This helps set up a good 2H recovery to offset other near-term weakness around cough/cold and US destocking."

N. August 14, 2024

492. On August 14, 2024, Perrigo participated in the Canaccord Genuity Conference. Defendants Lockwood-Taylor and Bezerra attended. Defendant Lockwood-Taylor made the following remarks:

> ***We completed the remediations really by May . . . We're achieving incredible levels of quality compliance and environmental cleanliness with these new requirements. We're getting production levels at or ahead of what we were achieving previously***. So we're ramping up now in terms of production, in terms of re-pipelining and we will be going state in quarter four. ***So a big undertaking, executed extremely well***.

493. The claim that remediations were "completed . . . by May" and the "big undertaking" of the reset was "executed extremely well" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it suggests the work is done. In reality, Perrigo failed to address the Unremediated Gateway Problems and Unremediated Vermont Problems, all of which continued to plague the

manufacturing process, resulting in positive *Cronobacter* tests, production delays, and product scrap.

494. The claims that "[a]ll three plants are in normal manufacturing mode now" and they were "achieving incredible levels of quality compliance and environmental cleanliness" were also materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest that Perrigo had a functional infant formula manufacturing program and could reliably fill customer orders for safe, quality infant formula. In truth, even after Perrigo concluded certain repairs to the Gateway facility on August 20, 2023, they identified Cronobacter in the environment *three days later* (with many more positives to follow, as elaborated above). Moreover, Perrigo had not addressed Unremediated Gateway Problems and Unremediated Vermont Problems that continued to contribute to production disruptions. In truth, projected capacity for 2024 was only 40-50% expected annual capacity given the extended shutdowns and product scrap, which, in turn, had led to a loss of customers. Furthermore, six days before Lockwood-Taylor's statements, on August 8, 2024, Perrigo had announced a major infant formula recall due to elevated levels of Vitamin D in the product.

O. November 6, 2024

495. On November 6, 2024, Perrigo issued a press release filed on Form 8-K with the SEC along with Form 10-Q announcing earnings for the third quarter of 2024. The Form 10-Q was signed by Defendants Lockwood-Taylor and Bezerra.

496. The Form 10-Q included the following statements:

Infant Formula

As part of its efforts to prevent supply interruptions and risk of *Cronobacter* spp. illnesses associated with powdered infant formula, in March 2023, the FDA released an "Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market" and issued

a letter to the powdered infant formula industry to share information to assist the industry in improving the microbiologic safety of powdered infant formula. ***In response to those changes, we made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs, enhanced quality oversight and increasing the number of quality and operations personnel.*** These changes resulted in higher costs and lower manufacturing output and production yields across our infant formula network.

* * *

The Company also bolstered its internal resources and brought in additional outside expertise to help revise, enhance and strengthen comprehensive standards and processes across our infant formula network, including in some instances, pausing production for comprehensive cleaning and infrastructure improvements. ***All planned large-scale manufacturing plant resets have now been completed,*** and the Company is implementing the next phase of our quality enhancements, including further protocol, process and procedural improvements at the site level, and additional investments to upgrade infrastructure. We do not expect these continuing improvements to result in extended shutdowns beyond typical planned maintenance activities.

Currently, all sites are up and running and have returned to reliable, quality- assured production with recent output across the network near 2023 levels. Our focus now lies in rebuilding customer service levels and getting these critical products back on the shelves for consumers who need high-quality, affordable infant formula.

We have incurred and expect to incur certain extraordinary non-recurring costs associated with the remediation and enhancement actions described above and the evolving U.S. infant formula regulatory landscape, including consulting and legal fees relating to the Company's responses to the FDA and the development and institution of new protocols across our infant formula manufacturing sites, as well as other costs relating to the extended cleaning and sanitization and the pausing and restarting of production. ***Cash costs in 2024 to achieve this remediation plan are estimated at $15 to $20 million, of which approximately $17.9 million were incurred during the first three quarters.***

497. On the earnings call that day, Defendant Lockwood-Taylor states as follows:

Job number one in infant formula was to recover and complete our self remediation actions so that all our sites produce reliable, quality-assured infant formula. We have done this and are now achieving high attainment of quality, production and packaging.

* * *

First, ***we recognize the importance of stabilizing key areas of our business, namely infant formula,*** US Store Brand and core brand share growth in our international markets. ***Most of these stabilization efforts are well underway and delivering good results, including high attainment levels for quality production and packaging in infant formula***, increasing service levels, better joint business planning with customers and driving demand creation, which is a critical differentiator for our US store brand business.

498. And on the call, Defendant Bezerra stated:

> Our infant formula self remediation actions began in January of this year, following updated manufacturing guidelines introduced by FDA last year. ***The focus of this initiative is to ensure all infant formula sites are producing reliable, quality assured infant formula. We now project a cash outflow of approximately $25 million in 2024 related to these initiatives, which again, as good news, this outflow is below our original projection of $35 million to $45 million***.

499. An analyst asked a question regarding the infant formula recovery, demand, and competition. Defendant Lockwood-Taylor responded:

> We are recovering store brand share with consumers, largely in line with our expectations. We have modeled out a certain amount of new mothers who enter the category every month or see exit . . . And we will continue to see that store brand share grow as we introduce innovation next year and new SKUs, we actually hope share will actually recover beyond historical levels. That will be at some point through 2025. ***So that remediation has gone extremely well. These are extremely high-quality plants and really set benchmark of the industry. We are seeing production and packaging at or above historical levels. So we're running higher quality plants more efficiently than we have done historically, and we are seeing store recovery and store brand consumer recovery completely in line with our expectation, and that will accelerate***.

500. Defendant Lockwood-Taylor concluded the call:

> We've made a lot of progress this year, and it was a challenging year on stabilizing important parts of our business, including infant formula, ***which recovery is excellent and fully in line with expectations at a lower cost than we had first outlooked***. We are back to a competitive position in our US store brand business. As we mentioned last quarter, we are winning tens of millions of dollars of business, and we will see that growth playing through in '25 in the second half. ***This work of stabilizing these core businesses, I'm pleased to say it's now largely behind us***.

501. Claims that "[a]ll planned large-scale manufacturing plant resets have now been completed"; "[c]urrently, ***all sites are up and running and have returned to reliable, quality-assured production with recent output across the network near 2023 levels***"; "[j]ob number one in infant formula was to recover and complete our self remediation actions so that all our sites produce reliable, quality-assured infant formula. ***We have done this and are now achieving high***

attainment of quality, production and packaging; "high attainment levels for quality production and packaging in infant formula"; and that the "***work of stabilizing these core businesses, . . . it's now largely behind us***" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest that the work is done and that the facilities were truly remediated when, in fact, Perrigo declined to address the Unremediated Gateway Problems and Unremediated Vermont Problems that were key causes of contamination, product scrap, and production delays. Furthermore, contrary to the statement that the facilities were "achieving high attainment of . . . production" and that "output across the network [is] near 2023 levels," production levels were forecasted for 2024 to be only 40-50% of expected capacity given the extended shutdowns, product scrap, and resulting lost customers.

502. Claims that "[i]n response to those changes, we made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs, enhanced quality oversight and increasing the number of quality and operations personnel" and that "remediation has gone extremely well. These are extremely high-quality plants and really set benchmark of the industry. We are seeing production and packaging at or above historical levels. ***So we're running higher quality plants more efficiently than we have done historically, and we are seeing store recovery and store brand consumer recovery completely in line with our expectation, and that will accelerate***" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest Perrigo had a functional infant formula manufacturing program and could reliably fill customer orders for safe, quality infant formula. In truth, even after Perrigo concluded certain repairs to Gateway on

August 20, 2023, they identified Cronobacter in the environment *three days later* (with many more positives to follow, as elaborated above). Moreover, Perrigo had not addressed the Unremediated Gateway Problems or Unremediated Vermont Problems that had previously caused contamination, product scrap, and production disruptions. Perrigo focused on deep cleaning its facilities rather than investing to address the root causes of bacterial presence in the facilities—the Unremediated Gateway Problems and Unremediated Vermont Problems. As a result, the Company was not, in fact, "running higher quality plants more efficiently than [they] had done historically," but instead anticipated production capacity of 40-50% given the extended shutdowns, product scrap, and resulting lost customers. As of the fall of 2024, Perrigo had lost a key customer, Target, due to its failure to consistently and timely fill orders. During the same period, workers at the Vermont facility were continually finding metal fragments in product—instead of stopping to diagnose the root cause of the problem, plant leadership pushed workers to look at the product under a microscope and isolate portions of batches that could be sold, or simply scrapped batches and continued with production to meet quotas.

503. Claims that "[c]ash costs in 2024 to achieve this remediation plan are estimated at $15 to $20 million, of which approximately $17.9 million were incurred during the first three quarters"; "[w]e now project a cash outflow of approximately $25 million in 2024 related to these initiatives, which again, as good news, this outflow is below our original projection of $35 million to $45 million"; "which recovery is excellent and fully in line with expectations at a lower cost than we had first outlooked" were false or, at a minimum, misleading when made because they suggest the costs are known, fixed, and cabined when, in fact, true remediation would require addressing the Unremediated Gateway Problems and Unremediated Vermont problems, both of which would require massive and expensive overhaul of infrastructure and equipment.

504. Analysts responded positively. A Morningstar Equity note issued on November 6, 2024 was titled "Perrigo Earnings: Tepid Performance but Strong Infant Formula Growth Drives Positive Outlook." The shop maintained its fair value estimate and noted that "the infant formula business showed strong improvement this quarter, with sales growing 3% as Perrigo continues to regain market share with its store brand customers. About 85% of volume in key stock-keeping units is back in stock across key customers, and the firm expects a full recovery in those units across the market by the end of 2024. The rebound in infant formula also lifted the bottom line, with adjusted EBIT margin up 160 basis points against last year."

505. A Piper Sandler note that same day was titled "Q3: Confidence Builds Following a Solid Print and Infant Formula Progression." They wrote, "PRGO's solid results and infant formula updates are evidence of the progress this management team is making in cleaning up the business and setting up for stronger future shareholder returns. We do need to be cognizant of the dynamic markets the company plays in and reinvestments to support the growth, but even when conservatively taking down our 2025 estimates, we can still easily get 2025 EPS to just above management's targeted $3."

P. February 28, 2025

506. On February 28, 2025, the Company submitted its annual report for the fiscal year ended December 31, 2024 on a Form 10-K filed with the SEC (the "FY24 10-K"). The FY24 10-K purported to report the factors impacting the Company's infant formula business, as well as the Company's progress with its protocol, process and procedural improvements, and costs associated with its remediation plans, as follows in relevant part:

> *Infant Formula*
>
> As part of its efforts to prevent supply interruptions and risk of *Cronobacter* spp. illnesses associated with powdered infant formula, in March 2023, the FDA released an "Immediate

> National Strategy to Increase the Resiliency of the U.S. Infant Formula Market" and issued a letter to the powdered infant formula industry to share information to assist the industry in improving the microbiologic safety of powdered infant formula. ***In response to those changes, we made considerable investments in all our infant formula manufacturing sites.*** These investments included, among other things, enhancing our cleaning and sanitation protocols, our environmental monitoring programs, and quality oversight, as well as increasing the number of quality and operations personnel at the sites. These changes resulted in higher costs, lower manufacturing output, and lower production yields across our infant formula network.
>
> ***Currently, all our infant formula manufacturing sites are up and running and have returned to reliable, quality-assured production with recent output across our infant formula network near historical levels***. Our focus now lies in continuing to rebuild customer service levels and getting these critical products back on the shelves for consumers who need high-quality, affordable infant formula. ***With production now stabilized***, we're driving strategic investments to strengthen the infant formula operations network to ensure the long-term sustainability of a key component of our CSCA business.

507. The FY24 10-K stated the Company actively monitors and makes the "appropriate adjustments to remain in compliance with" current FDA rules regarding cGMP, quality control procedures, quality factors, notification requirements, and reports and records for the production of infant formulas. Specifically, the FY24 10-K stated the following regarding the Company's compliance with the FDA's cGMP:

> ***We actively monitor this process and make the appropriate adjustments to remain in compliance with current FDA rules regarding cGMP, quality control procedures, quality factors, notification requirements, and reports and records for the production of infant formulas.***

508. The FY24 10-K purported to warn of risks which "could" or "may" impact the Company's results, including the following, in relevant part:

> U.S. and global regulatory agencies regularly inspect our manufacturing facilities and the facilities of our third-party suppliers for good manufacturing practices ("GMP") and other regulatory compliance. ***The failure of one of these facilities to comply with applicable laws and regulations may lead to a breach of representations made to our customers, or to regulatory or government action against us related to the products made in that facility,*** including suspension of or delay in regulatory approvals and product seizure, injunction, recall, suspension of production or distribution of our products, a total or partial shutdown of production in one or more facilities, loss of licenses or other governmental

> penalties, or civil or criminal prosecution, which could result in increased cost, lost revenue, or reputational damage.
>
> * * *
>
> As described in Part II. Item 7, in response to the warning letter from the FDA in August 2023 and additional inspection observations at our Wisconsin infant formula facility, ***we have implemented new protocols and made additional infrastructure investments to address these observations.*** While ***all sites have returned to reliable, quality-assured production,*** we incurred certain extraordinary costs associated with the remediation and enhancement actions and expect higher ongoing operating costs at our infant formula manufacturing sites moving forward. Moreover, if we are unable to address the FDA's past or future observations to the FDA's satisfaction, we could incur additional compliance costs, and our reputation could be adversely affected if we are perceived by consumers to not be in compliance with such framework.

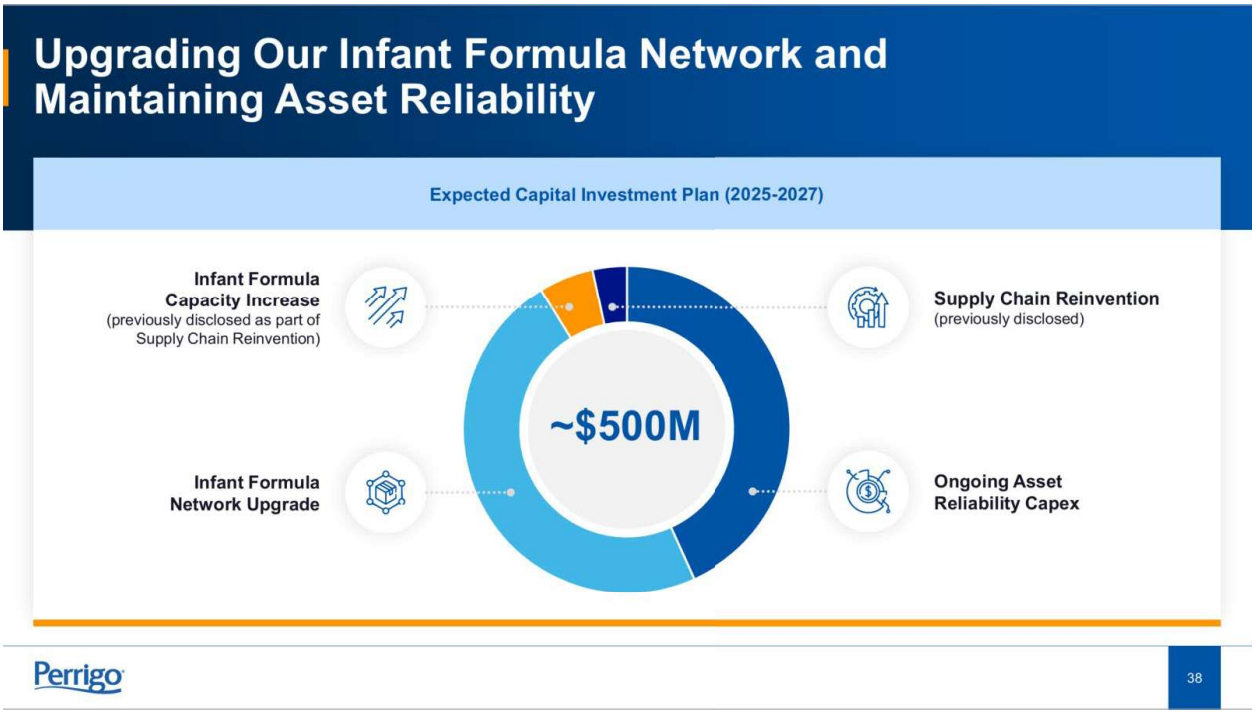
509. The Company highlighted many of these same themes in its Investor Day Conference presentation that same day. Defendant Lockwood-Taylor explained:

> ***[I]nfant formula industry dynamics and regulatory changes created a need for a significant intervention. Importantly, my team and I began to address these right away***. We've made meaningful progress over the past 21 months to adapt quickly to address these challenges and get back to a solid foundation for the future***. We're already seeing positive results. . . . We've achieved the highest standards of quality now in our infant formula business and got to the highest FDA inspection standard of no action indicated in all three of our sites. Furthermore, volume recovery is underway and our store brand share is on track.***

510. The presentation indicated that "important businesses," including infant formula, were "back to winning," and that the only "challenge" facing that business was "regulatory changes."

511. Defendant Bezerra highlighted the Company's financial plans:

We [] plan to reinvest our cash to maintain reliability of our assets, continue our supply chain reinvention program and infant formula capacity increase and upgrade our infant formula network. This last one represents a significant investment of approximately $240 million, and the Nutrition business is expected to generate $100 million or more of annual free cash flow beginning in 2028.



512. Perrigo further emphasized that "***Efforts to stabilize*** OTC store brand and ***infant formula are well underway and working***":

513. In response to an analyst question about what gave the Company "confidence" to make the incremental investment announced that day in infant formula, and what they had been hearing from retailers, Defendant Lockwood-Taylor offered to give the "setup" before inviting Defendant Bezerra along with Schmelter to provide further comment since "***this is a corporate imperative for us.***" Defendant Lockwood-Taylor provided:

> [F]irstly, standing back***, it's a very attractive business.*** We supply hundreds of millions of beading occasions. We play a unique role saving the consumer almost $1,000 a year versus the brand equivalent. So we play an important role. As the significant barriers to entry, you know that this is a very capital-intensive business, okay? And there's only a small number of domestic providers. We like that position.
>
> ***We have been very effective in remediating that busines***s, and a lot of credit to the team on addressing a significant remediation extremely quickly. And ***we are highly quality assured and we're achieving, I think it was about 98% service levels there.*** So outstanding work over the last few months, okay? I say it because I'm very proud of it. A lot was achieved quickly.
>
> To your point around capital expenditure. This is a high-margin business but of a capital-intensive business, okay? We have three plants. We can consolidate that plant configuration, which will allow us to get to even better margins, but it will step change our free cash flow generation from that business by between about 800 and 1,000 basis points. I mean it's very, very significant, and ***we moved from it being a dilutive free cash flow business to actually becoming accretive. We do that relatively quickly.*** And because of that step change in free cash, we pay out that initiative figures within a couple of years.

514. The claims that "we have implemented new protocols and made additional infrastructure investments to address these observations" and "all sites have returned to reliable, quality-assured production"; "[w]e've achieved the highest standards of quality now in our infant formula business"; and "[w]e have been very effective in remediating that business" and "we are highly quality assured and we're achieving, I think it was about 98% service levels there" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest that the work is done and that Perrigo had a functional infant formula manufacturing program that could reliably fill customer orders for

safe, high-quality infant formula. In reality, Perrigo had not addressed the Unremediated Gateway Problems or Unremediated Vermont Problems that had previously caused contamination, product scrap, and production disruptions. Starting at least in January 2025, workers at the Vermont facility began finding metal fragments in product—instead of stopping to diagnose the root cause of the problem, plant leadership pushed workers to look at the product under a microscope and isolate portions of batches that could be sold, or simply scrapped batches and continued with production to meet quotas. The infant formula business was not, in fact, effectively "remediated" – as of the fall of 2024, Perrigo had lost a key customer, Target, due to its failure to consistently and timely fill orders.

515. The claim that the Company was achieving "98% service levels" for its infant formula business was also false or, at a minimum, misleading when made and omitted material facts necessary to make the statement not misleading because it omitted the fact that Perrigo had lost one of its biggest customers during the previous quarter. As a result, reporting service levels (*i.e.*, how consistently the Company met customer demand) without disclosing the loss of a major customer materially misled investors by excluding that customer from the underlying metrics. Similarly, that impression was misleadingly conveyed with Defendants' claims that "Business is Stabilizing After Taking Unprecedented Action to Ensure Quality Assured, Reliable Production" and "Efforts to stabilize . . . formula are well underway and working"; and "[i]n response to those changes, we made considerable investments in all our infant formula manufacturing sites."

516. The claim that "We [] plan to reinvest our cash to maintain reliability of our assets" was materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it suggests the assets (*i.e.*, the formula facilities and their equipment) currently were reliable when, in fact, they were aged, cracked, leaking, poorly

patched, or completely unsuitable for use in the production of infant formula entirely – all contributing to bacterial infection, production pauses, product scrap, and lost customers At this time, there was constant metal in the formula in Vermont, requiring Perrigo to discard massive amounts of product. Vermont was down to using just one of its dryers and had stopped using a sterilizing tank, due to both having issues. By the end of Q1 2025, Vermont was operating at roughly one quarter of its production capacity. Moreover, two weeks before these statements were made, on February 10, 2025, there was a major fire at the Vermont facility stemming from an unaddressed problem with the HVAC system, which had then required a multi-day shutdown to clean the facility and prevent soot contamination.

517. The market reacted positively and credited Defendants' statements and assurances. Analysts at Morningstar noted that despite a "soft finish to 2024, [] [the] path to continued recovery remains intact," in part due to "high-teens growth from infant formula sales, as Perrigo replenished inventories while also gaining share." Morningstar too noted the "positive development" in the change in FDA inspection status for Gateway, thereby "position[ing] the firm for a more stable and efficient trajectory in its infant formula production, ensuring a consistent supply of products to meet growing demand." The report concluded, "Overall, 2024 proved challenging for Perrigo . . . . That being said, we are encouraged by signs of recovery, ***most notably in nutrition***, and the continued resilience from the international segment. Given these factors, we remain optimistic about Perrigo's long-term growth prospects. ***We think investors are also encouraged by the early green shoots of recovery and appreciate the healthy roadmap laid out by the firm.***" Piper Sandler similarly commented on the Company's "solid plan to build toward LT [long-term] recovery," resulting in the analyst's "incrementally more positive" outlook.

Q. March 12, 2025

518. On March 12, 2025, at the UBS Global Consumer & Retail Conference, Perrigo leadership, including Defendants Lockwood-Taylor and Bezerra, presented on the Company's performance. He announced a plan to spend $0.5 billion on capital expenditures, a "significant portion" of would be related to the infant formula business in an effort to "mov[e] into a more optimized network." As a part of that effort, he announced that the Company would "retire one of [their] old sites, [which] is going to give [them] better conversion costs" and "generate $100 million of free cash flow by 2028 with a payback of less than 2 years."

519. Defendants Lockwood-Taylor and Bezerra also fielded an analyst question about what returns were expected from the $240 million investment in the infant formula business. Defendant Lockwood-Taylor responded:

> I'll take the first part and then Eduardo, take the tricky part. So infant formula business, we had to do significant remediation to address the regulatory changes last year. That was a heavy lift. It was an intense effort, credit to the team. ***We have outstanding quality assured reliable manufacturing.*** We're achieving environmental quality thresholds of a new historical level for us, okay, which is outstanding. ***We're getting production throughput, packaging attainment of historical highs, okay? These are extremely well-disciplined well-run plants with GMPs that drive quality production, quality issue production.*** I couldn't be happier with where we ended up.
>
> Speed and effectiveness of it, but yes, it was disruptive, still in recovery. But it was the -- ***it is a very attractive business. It's highly reliable, it's highly predictable. It is significantly margin accretive.*** The opportunity for that business now is to absolutely step change its free cash flow.

520. Defendant Lockwood-Taylor jumped in to add, "I mean, the free cash flow release is so significant, ***we pay the project back in 2 years, I mean that's extraordinary. So absolutely the right thing to do for the business and for shareholders.***"

521. But these statements were materially false and misleading and omitted material facts.

522. Claims that Perrigo has "outstanding quality assured reliable manufacturing" with "extremely well-disciplined well-run plants with GMPs that drive quality production" and that the business is "highly reliable, it's highly predictable" and therefore "is significantly margin accretive" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest a state of affairs that simply did not exist. The Unremediated Gateway Problems and Unremediated Vermont Problems had not been addressed, and therefore both facilities remained out of compliance with cGMPs and FDA rules. Production at the Gateway facility had dropped off substantially in the first quarter of 2025, in the wake of losing Target as a key customer. Similarly, production was operating at 25% capacity in the Vermont facility by the end of the first quarter of 2025, with workers regularly sent home due to the lack of customer demand. Six days before these statements were made, on March 6, 2025, the Company had suddenly announced that it planned to "phase out" the Vermont facility by 2027—shortly thereafter, critical employees began to leave. Moreover, in March 2025, Gateway suffered a positive *Cronobacter* hit, which resulted in a monthlong shutdown and product scrap valued at $10 to 15 million. During this time, the Vermont facility was experiencing constant metal shards found in product, and one dryer and one sterilization tank were broken, and sat unused. Additionally, the Vermont facility had to close for soot decontamination following the February 10, 2025 fire that broke out due to unaddressed issues in the HVAC system.

R. May 7, 2025

523. On May 7, 2025, the Company submitted its report on Form 10-Q for the first quarter of 2025 with the SEC. The quarterly report purported to report the factors impacting the Company's infant formula business, as well as the Company's progress with its protocol, process and procedural improvements, and costs associated with its remediation plans. Specifically, the quarterly report stated as follows in relevant part:

Infant Formula

> As part of its efforts to prevent supply interruptions and risk of *Cronobacter* spp. illnesses associated with powdered infant formula, in March 2023, the FDA released an "Immediate National Strategy to Increase the Resiliency of the U.S. Infant Formula Market" and issued a letter to the powdered infant formula industry to share information to assist the industry in improving the microbiologic safety of powdered infant formula. ***In response to those changes, we made considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs, enhanced quality oversight and increased the number of quality and operations personnel.*** These changes resulted in higher costs and lower manufacturing output and production yields across our infant formula network.

524. The claim that Perrigo has made "considerable investments in all our infant formula manufacturing sites, including enhanced cleaning and sanitation protocols, enhancements to our environmental monitoring programs, enhanced quality oversight and increased the number of quality and operations personnel" was materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it suggests the Company is investing appropriately and making necessary changes to have a safe and reliable manufacturing process. That was materially misleading because it omitted the fact that the Unremediated Gateway Problems and Unremediated Vermont Problems remained unaddressed. As a result, the Vermont facility was regularly experiencing metal shards in the formula and needing to scrap large quantities of product and a dryer and sterilization tank were down indefinitely due to needed maintenance. Moreover, the Vermont facility was losing critical personnel in the wake of the announced phase-out, basic cleaning and sanitation of the Vermont facility, including the bathrooms, was going neglected. Meanwhile, at the Gateway facility, in March 2025 a positive *Cronobacter* hit caused a monthlong production pause and forced Perrigo to scrap $10 to 15 million of formula. Then, in March or April 2025, a massive rainstorm caused leaks into the dryer in the Gateway facility.

525. But once again, the market accepted the Company's reassurances about the state of the infant formula business and their confidence to invest in its expansion, with shares up nearly 7% following the release of the results for the first quarter of 2025. The headline of Morningstar's investor report was "Margin Strength and Infant Formula Recovery Drive Solid Q1 Performance," and Piper Sandler highlighted as a "key point" for the investment thesis that "[i]nfant formula is progressing, and SKUs have been fully restored." The Morningstar report continued, "Infant formula sales rose 19% compared with the prior year, supported by ***improved production metrics across the network and full restoration of key customer stock-keeping units on shelves***." Analysts also accepted the Company's increase in second-half expectations despite increased competition – J.P.Morgan explained that "updates on the infant formula segment were more balanced with 1) increased marketing/promotion from domestic branded players . . . offset by 2) continued volume ramps with the company anticipating 2H sales ahead of our estimates." The report continued that "while this is leading to somewhat tempered expectations on a full-year basis overall, PRGO continues to anticipate a strong recovery in nutritional sales through the year[,] . . . impl[ying] 2H25 sales of ~$315mm, which is ahead of our expected $260mm and offsetting downside vs our estimates in the first half of the year." Finally, analysts at Morningstar parroted the Company's explanations for broader, industry-wide challenges slowing the Company's progress: "the broader category is facing pressure from flat-to-declining US birth rates, increased manufacturing capacity, and rising competition from foreign brands." Jefferies concluded that "[b]enefits from infant formula production and restructuring drove the better flow-through" and that the company was trending in a positive direction based on the "[v]isibility into infant formula recovery" and because "management appears to have good visibility into recovering EPS and lowering leverage in '25."

S. June 10, 2025

526. On June 10, 2025, members of the Perrigo senior leadership team, including Defendants Lockwood-Taylor and Bezerra, attended the virtual Oppenheimer Consumer Growth and E-Growth Conference. Defendant Lockwood-Taylor stated "we're continuing to realize the benefits of our stabilization efforts primarily in infant formula and store brand OTC growth. 2026, we expect the stabilization benefits to continue . . . . Looking out to 2027, we expect a full year of high-growth contribution, a meaningful step up in free cash flow conversion, and net leverage below 3 times as we exit the year."

527. In response to an analyst question about his biggest accomplishments in his two years as CEO, Defendant Lockwood-Taylor pointed to the infant formula business:

> The infant formula business was also deeply troubled. Some of that[sic] external factors in terms of regulatory changes, international competition being opened up. After significant investments and focus in '24, ***we're achieving the highest standards of quality of our infant formula business***. We got to the highest FDA inspection standard of no action indicated for all of our sites. So the turnaround of that business are much more competitively positioned for the future. We went through a lot of work to get clear on our strategy, clear on the operating model, the business model and our portfolio, and that now positions us to really focus on growth, okay, attractive, scalable margin accretive growth.

528. Defendant Lockwood-Taylor also fielded an analyst's request to provide more "color around the recovery of infant formula" and his thoughts on Operation Stork Speed, an initiative from the Department of Health and Human Services, announced on March 18, 2025, with the goal of strengthen the domestic infant formula supply and enhance the safety and nutritional quality of formula on the market. Defendant Lockwood-Taylor explained:

> Yeah, operation store speed is moving at speed and is occupying a lot of our thinking. However, it is a constructive long-term program is my view on it now. Whilst I understand -- how can I say, some of the media highlights recently, this is a responsible program of which we are strongly intertwined, but I'll come to that in a moment.
>
> But firstly, for Perrigo, we had to get to quality-assured manufacturing. That has been an outstanding success for us. ***Our production attainment, packaging attainment, customer service levels are at historical highs. These are more reliable, more efficient, more***

quality assured operations than we've ever had before. And in our view, they're market-leading.

529. But these statements were materially false and misleading and omitted material facts.

530. The claim that "we're continuing to realize the benefits of our stabilization efforts primarily in infant formula"; that Perrigo is achieving the highest standards of quality of our infant formula business" and "[o]ur production attainment, packaging attainment, customer service levels are at historical highs"; "are more reliable, more efficient, more quality assured operations than we've ever had before" and are "market-leading" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because it suggests that Perrigo had a functional program. They did not. The Unremediated Gateway Problems and Unremediated Vermont Problems had not been addressed, and therefore both facilities remained out of compliance with cGMPs and FDA rules, and both continued to suffer from contamination, equipment breakdowns, product scrap, and production delays. Production at the Gateway facility had dropped off substantially in the first quarter of 2025, in the wake of losing Target as a key customer. Similarly, production was operating at 25% capacity in the Vermont facility by the end of the first quarter of 2025, with workers regularly sent home due to the lack of customer demand. In the wake of the Company's sudden announcement that it planned to "phase out" the Vermont facility by 2027, critical employees began to leave. Moreover, in March 2025, Gateway suffered a positive *Cronobacter* hit, which resulted in a monthlong shutdown and product scrap valued at $10 to 15 million. During this time, the Vermont facility was experiencing constant metal shards found in product, and one dryer and one sterilization tank were broken, and sat unused.

T. August 6, 2025

531. The truth once again partially emerged on August 6, 2025, when the Company issued a press release announcing earnings for the second quarter ended June 28, 2025, revealing adjusted gross profit down 6.9%, due in part to "production variability in infant formula, leading to an increase in product scrap in the quarter" and reduced gross margin "due primarily to the same factors."

532. But on the same day, Perrigo hosted an earnings call regarding the Company's financial results for the second quarter ending June 28, 2025 where Bezerra assured investors that "***[r]ecovery in our infant formula business is progressing***."

533. That afternoon, before the market closed, the Company submitted its quarterly report for the second quarter of 2025, on a Form 10-Q filed with the SEC, affirming the previously reported financial results. Specifically, the quarterly report stated as follows in relevant part:

> We have incurred and expect to incur certain extraordinary non-recurring costs associated with the remediation and enhancement actions described above and the evolving U.S. infant formula regulatory landscape, including consulting and legal fees relating to our responses to the FDA and the development and institution of new protocols across our infant formula manufacturing sites, as well as other costs relating to the extended cleaning and sanitization and the pausing and restarting of production. ***Cash costs to date to achieve this remediation plan are approximately $22.6 million.***

534. The claim that ***"[c]ash costs to date to achieve this remediation plan are approximately $22.6 million" suggests costs are known, fixed, and cabined,*** was materially false, or at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because true remediation, which would require addressing the Unremediated Gateway Problems and Unremediated Vermont Problems, would require a massive (and expensive) overhaul of infrastructure and equipment.

535. The claims that "recovery of the infant formula business is progressing" and that the Company had made "considerable investments in all of our infant formula sites" were also

materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest that the Company's work to "reset" the facilities was improving the business and allowing Perrigo to develop a functional program. That was not the case. The Unremediated Gateway Problems and Unremediated Vermont Problems had not been addressed, and therefore both facilities continued to suffer from contamination, equipment breakdowns, product scrap, and production delays. Production at the Gateway facility had dropped off substantially in 2025, in the wake of losing Target as a key customer. Similarly, production was operating at 25% capacity in the Vermont facility by the end of the first quarter of 2025, with workers regularly sent home due to the lack of customer demand. In the wake of the Company's sudden announcement that it planned to "phase out" the Vermont facility by 2027, critical employees had left. Moreover, in March 2025, Gateway suffered a positive *Cronobacter* hit, which resulted in a monthlong shutdown and product scrap valued at $10 to 15 million. During this time, the Vermont facility was experiencing constant metal shards found in product, and one dryer and one sterilization tank were broken, and sat unused. Moreover, over the summer of 2025, the Gateway facility ran another unsuccessful soy production campaign that resulted in half of all formula produced being scrapped due to equipment malfunction.

536. Analysts noted that the second quarter results were "slightly below expectations" and concluded that "[m]argin pressure" due to "infant formula volatility drove the miss" but accepted the Company's statement that poor performance was due to "isolated production variability in infant formula leading to an increase in product scrap" in the quarter. Morningstar was persuaded, stating that while lag in the infant formula business was "due to a one-off production issue, stabilization efforts remain on track." Jefferies noted that "management feels confident in their ability to hit guidance this year." J.P.Morgan announced that the infant formula

business "remain[ed] volatile but well reflected in [the] valuation" and that they were "leaving our margin estimates largely unchanged as we view the scrapped infant formula product as more 1x in nature and with PRGO highlighting that they do not expect the lower absorption of overhead in 2Q to continue."

U. August 12, 2025

537. On August 12, 2025, Defendants Lockwood-Taylor and Bezerra attended the Canaccord Genuity Growth Conference. In his opening remarks, Defendant Lockwood-Taylor stated:

> We operate in a quality-assured environment that gives us confidence in the foundation that we've built in our infant formula business. Our team is aggressively focused on growing household penetration, and ***we are regaining share in the infant formula category. This business is building back. And though we recognize the recovery won't be perfectly linear, we're navigating with a disciplined and long-term view and feel confident in our '25, '26 and '27 assumptions on this business.***

538. When asked where he saw the "biggest opportunity throughout the company," Defendant Lockwood-Taylor pointed to infant formula, characterizing its recovery as a "***revenue builder***."

539. But these claims were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading. Claims that the infant formula business is "regaining share" and "building back" were materially false or, at a minimum, misleading when made and omitted material facts necessary to make the statements not misleading because they suggest the Company was gaining customer and consistently producing infant formula that is safe and meets quality standards. In reality, Perrigo had failed to address the Unremediated Gateway Problems and Unremediated Vermont Problems, thus leaving in place the very conditions and practices that had caused the positive *Cronobacter* hits, production pauses, product scrap, and lost customers. In fact, during the summer of 2025, the Gateway facility once

again ran a soy product campaign that resulted in half of the product being scrapped due to aging equipment. Moreover, throughout 2025, both the Vermont and Gateway facilities were running at much lower capacity due to the loss in customer demand that had not returned. Accordingly, Defendant Lockwood-Taylor's reference to the formula business as a "revenue builder" is also false and misleading.

VIII. INSIDER TRADING ALLEGATIONS

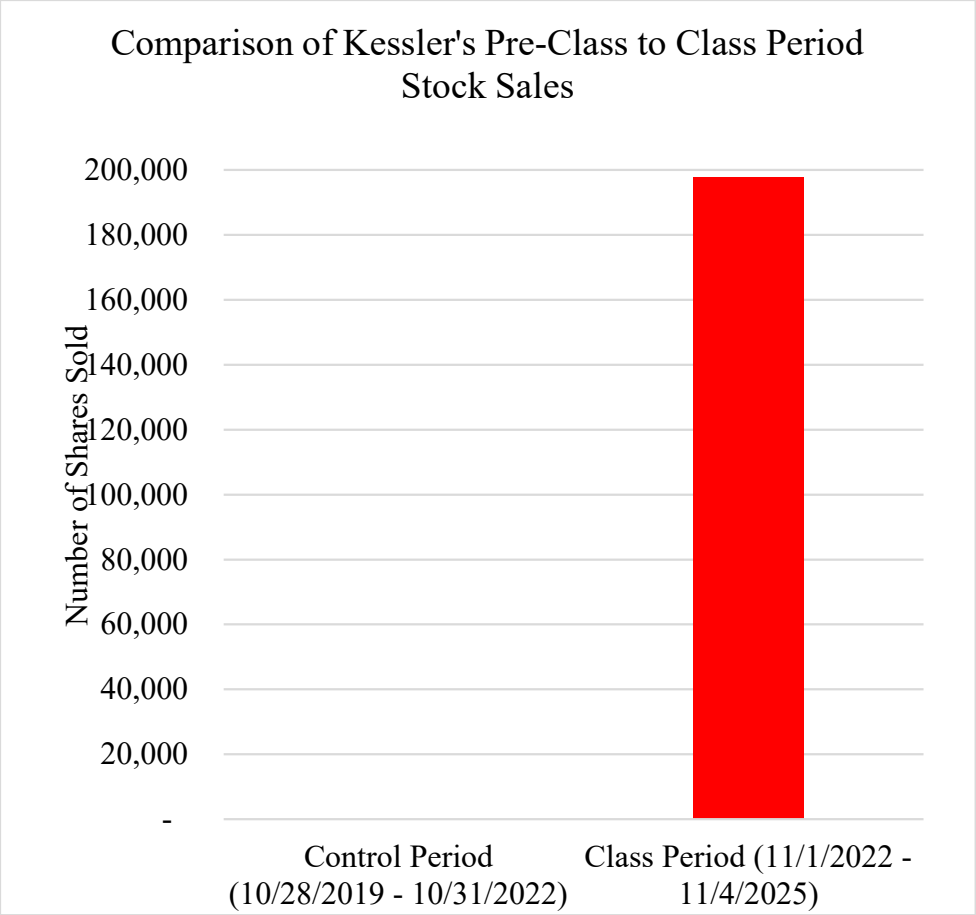
540. At the same time the Defendants touted Perrigo's infant formula business to investors, Defendant Kessler personally enriched himself by selling over $7 million of Perrigo common stock at prices artificially inflated by false and misleading statements and omissions throughout the Class Period. This sale occurred before the full revelation of the truth about Perrigo's infant formula business, and thus before Perrigo's stock price fully declined in response to those revelations.

541. Lead Plaintiff used publicly available trading data reported to the SEC on Form 4 to evaluate Defendant Kessler's trading activity during the Class Period, as well as during a period of equal length immediately prior to the Class Period (the "Control Period").

542. Lead Plaintiff purchased Perrigo common stock contemporaneously with Defendant Kessler's massive $7 million stock sale – just four trading days apart:

Name	**Date**	**Type of Transaction**	**Number of Shares**	**Value of Transaction**
Defendant Kessler	5/11/2023	Sale	197,646	$7,066,358.38
Lead Plaintiff	*5/17/2023*	*Purchase*	*2,550*	*$83,803.16*

543. Defendant Kessler's sale was suspicious in size. During the Control Period, Defendant Kessler made *no* sales of Perrigo common stock. In contrast, during the Class Period, Defendant Kessler sold 197,646 shares of his Perrigo common stock, for proceeds of $7.1 million. That sale was 99% of his Perrigo common stock available to sell:



544. And the timing of Defendant Kessler's sale was highly suspicious. On March 6, 2023, the FDA began a non-public inspection of the Gateway facility. On April 26, 2023, the FDA issued a non-public April 2023 Form 483 to Perrigo, with numerous *Cronobacter* positives and concerning findings.

545. Two weeks later, on May 9, 2023, Defendant Kessler suddenly announced his retirement and two days after that, on May 11, 2023, he made a massive sale of 197,646 shares of Perrigo common stock valued at over $7 million. This sale allowed Defendant Kessler to profit while in possession of material, non-public information.

546. Lead Plaintiff's review of Form 4s indicates that Defendant Kessler's sale was not made pursuant to a 10b5-1 trading plan.

547. But even if the sale had been made pursuant to a 10b5-1 trading plan, that still would not immunize Defendant Kessler. A 10b5-1 plan is a defense to insider trading liability if it is entered into by an insider "[b]efore becoming aware" of material non-public information and was established "in good faith and not as part of a plan or scheme to evade the prohibitions" against insider trading. *See* SEC Rule 10b5-1(c), 17 C.F.R. § 240.10b5- 1 (2022). Beyond violating SEC rules, courts treat adopting or modifying a plan while in possession of material non-public information as highly suspicious of fraud.

548. Moreover, regardless of when the plan is created and whether trades are made pursuant to a 10b5-1 plan, an executive with a 10b5-1 plan could be motivated to make materially false and misleading statements affecting the stock price to their benefit before a scheduled sale or to trigger a sale at a particular price.

IX. ADDITIONAL ALLEGATIONS OF SCIENTER

549. Numerous facts, including those set forth above and summarized below, give rise to a strong inference that Defendants knowingly or recklessly misled investors regarding Perrigo's infant formula business and the Gateway acquisition, as well as the attendant impact on production capacity, sales, earnings per share, and margins.

A. Defendants Knew, Had Access to, or Recklessly Disregarded Information Contradicting their Public Statements.

550. Both before and after Perrigo's acquisition of the Gateway facility and throughout the Class Period, Defendants knew, had access to, or recklessly disregarded information that contradicted their public statements.

1. Pre-Acquisition: Defendants Were Informed of Gateway's Contamination Crisis through the Due Diligence Process and April 2022 Form 483

551. Due diligence is a standard practice for acquisitions of an asset or business of Gateway's magnitude and occurred here, *see infra* ¶¶ 76, 638.

552. Substantial, appropriate due diligence would be expected by investors here: this was a $170 million acquisition of a plant, including rights to Nestlé's Good Start infant formula brand and a major expansion of the factory's production capability. Defendant Kessler himself acknowledged that the Gateway acquisition had been underway for "well over a year."

553. Due diligence enables an acquirer to evaluate the target's business, market position, and future prospects; estimate cost savings and synergies; and plan the target's integration.[50]

554. The basic function of due diligence "is to assess the benefits and liabilities of a proposed acquisition by inquiring into all relevant aspects of the past, present, and predictable future of the business to be purchased" with a "focus on risk"[51] and "red flags" that require further investigation.[52] When a red flag is identified, it should be investigated and assessed so that the risk is well understood and, where possible, quantified and brought to the attention of the acquirer's senior management and/or the Board. "When an investigator encounters a true red flag, it is obligated to investigate further."[53] The management and Board can then discuss the risk identified

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[50] Peter Howson, *Due Diligence: The Critical Stage in Mergers & Acquisitions* 3 (Gower Publ'g 2017) ("[D]ue diligence assesses the deal from a commercial, financial and legal point of view. It is concerned with understanding more about the business being bought, confirming that the buying company is getting what it thinks it is buying . . . ."); Protiviti, *Guide to Mergers and Acquisitions: Frequently Asked Questions* 3 (2016); KPMG LLC, *U.S. Executives on M&A: Full Speed Ahead in 2016*, at 19 (2016) ("Although due diligence may not be seen as the most important factor in deal success, it is obviously an essential part of deal execution. Without it, acquirers may be ill-prepared for what they have in store when they try to integrate their target.").

[51] Alexandra Reed Lajoux & Charles M. Elson, *The Art of M&A Due Diligence: Navigating Critical Steps and Uncovering Crucial Data* 6–7 (McGraw-Hill 2011) ("Lajoux and Elson (2011)").

[52] Jerry Schwartzman, *The Due Diligence Process in M&A Transactions*, *in Mergers and Acquisitions: A Practitioner's Guide to Successful Deals* 45, 46 (Harvey Poniachek ed., World Sci. Publ'g Co. 2019) ("The first purpose of due diligence process is to identify any 'red flags' (deal stoppers or material issues) and to confirm critical facts regarding a business prior to its acquisition.").

[53] Gary M. Lawrence, *Due Diligence: Law, Standard and Practice* 671 (CADDS Scholars Press 2016).

and take informed action such as implementing one or more steps to mitigate the risk, accepting the risk, putting a valuation on the risk, or calling off the potential deal.

555. Limited or poor due diligence increases the risk of failure of an acquisition due to overvaluing the target, unexpected litigation and tax exposure, and poor integration of the acquired company, among other causes.[54] A successful acquisition can increase the value of the acquirer substantially; a poor acquisition can destroy value.[55]

556. Due diligence "typically continues throughout the negotiation phase" of a deal[56] and to be effective, must be substantive and thoughtful, not merely a "box-checking" exercise.[57]

557. In addition to reviewing documents, meeting with the target's management and site visits are "essential component[s] of due diligence, providing a firsthand view of the target's operations."[58]

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[54] Nat'l Ass'n of Corp. Dirs., *Governance Challenges 2016: M&A Oversight* 10 (2016) ("A significant number of deals fall short of achieving their projected returns. This happens for a variety of reasons, including valuation overreach, optimistic projections and assumptions, the lack of a rigorous due diligence process, and the failure to develop a robust post-merger integration plan and monitor the execution of that plan.").

[55] Robert J. Aiello and Michael D. Watkins, *The Fine Art of Friendly Acquisition*, Harv. Bus. Rev., Nov.-Dec. 2000, at 100, 103 ("acquirers have wiped more value off their market capitalization through failures in due diligence than through lapses in any other part of the deal process.")

[56] Donald M. DePamphilis, *Mergers, Acquisitions, and Other Restructuring Activities* 133 (11th ed., Elsevier Academic Press 2022).

[57] Robert F. Bruner, *Applied Mergers and Acquisitions* 227 (John Wiley & Sons, Inc. 2004); Andrew J. Sherman, *Mergers and Acquisitions from A to Z* 68–69 (4th ed., AMACOM 2018) ("Due diligence in M&A requires a deep dive into the history, mission, values, culture and intangible assets of the company, rather than a mere formalistic review of key contracts and corporate housekeeping documents.").

[58] Joshua Rosenbaum & Joshua Pearl, *Investment Banking: Valuation, LBOs, M&A, and IPOs* 314 (3d ed., Wiley 2020). *See also* Lajoux and Elson (2011), at 84 ("Although financial statement analysis forms a large part of due diligence, the most important part of due diligence is conducted 'live' through interviews and on-site visits").

558. Due diligence for an FDA-regulated business like Gateway typically spans topics including cGMP/quality; personnel; engineering; and finance. The cGMP/quality portion typically includes a thorough review of all cGMP/quality systems: people (number and role), process, systems, equipment, plant, materials, and cGMP compliance. The diligence should include a thorough review of written documentation (such as policies, any FDA communications, any deviation reports, SOPs), a tour of the facility to see that it has the cGMP/quality spaces and equipment it purports to have (such as a functional clean room), and conversation with high-level Quality staff of the target company.

559. Categories typically covered in the cGMP/quality portion of due diligence include:

- **Quality Management System:** Establishing, implementing, and following written procedures, including all aspects of quality control and quality assurance. In particular, looking at all the deviations for the last 2 years to identify any serious problems.
- **Facilities and Equipment:** Maintaining clean, sanitized, and properly set up/designed facilities with validated or calibrated and maintained equipment to prevent contamination and cross-contamination.
- **Personnel Qualifications:** Confirming staff are properly qualified and trained, and that this is documented for their tasks.
- **Production and Process Controls:** Having defined manufacturing processes for consistent, reliable, and documented product quality; often includes having a good batch record for each product, and reviewing the batch record.
- **Laboratory Controls:** Conducting testing on raw materials, in-process materials, and finished products, and confirming that all methods are scientifically sound.
- **Records and Reports:** Maintaining complete, accurate, and accessible records of every batch, from raw materials to distribution.
- **Packaging and Labeling:** Controlling all aspects of packing, packaging, and labeling to provide the correct labeling and integrity of the final product.

560. At the conclusion of the due diligence process, a report is typically generated documenting the facility's cGMP compliance, the state of its quality systems, and major issues that require remediation. For example, if there was deferred maintenance, the cGMP/quality diligence team may recommend that an engineer-expert inspect to determine whether replacement or maintenance is needed and associated costs. Or if the plant had design issues that would require

renovation to fix, the cGMP/quality diligence team may recommend an engineering/design team develop a plan and cost estimate.

561. The due diligence process for the Gateway acquisition would have heeded particular attention to quality, sanitation, and compliance with FDA regulations and cGMPs in light of the timing concurrent to the Abbott recall, discussed further in Sections IV(E) and (D), and which occurred over six months before Perrigo's acquisition of the Gateway facility, in February 2022. Abbott's shutdown and recall led to nationwide shortages of infant formula that persisted throughout 2022 and Abbott's business suffered hundreds of millions of dollars in lost sales and profits, as well as costs to remediate the facility. These events were widely reported and known to Defendants, who publicly discussed the Abbott recall and resulting shortage on earnings calls and with analysts.

562. The specific deficiencies that the FDA identified at the Sturgis plant were publicly revealed as early as March 22, 2022, when the FDA released its Form 483s from three inspections of the Sturgis plant, including the most recent inspection from January to March, 2022. The Form 483 for the 2022 inspection documented, among other findings, that (1) *Cronobacter sakazakii* or *Cronobacter* spp. was identified in environmental swabs collected by the FDA and Abbott, including the dryer or dryer area; (2) *Cronobacter* spp. was identified in finished product; (3) evidence of an uncontrolled wet environment and water leaks throughout the facility, including the roof and dry-production areas such as the dryer or dryer area; and (4) internal deterioration of the dryers, including cracks and pits. Based on these observations, the FDA investigators concluded that Abbott "did not establish a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment."

563. On May 16, 2022, the federal government publicly filed a Complaint for Permanent Injunction against Abbott, detailing the same findings from the FDA's 2022 inspection, and explaining that cracks in food-contact surfaces of equipment such as the dryer, uncontrolled water in processing areas, and the presence of *Cronobacter sakazakii,* create an unacceptable risk of bacterial contamination.[59] The federal government alleged that Abbott's unwillingness or inability to take corrective action to address these deficiencies constituted violations of the FDCA.

564. In March 2022—contemporaneously with the public disclosure of the Sturgis findings—the FDA conducted an inspection of the Gateway facility and documented its findings in the April 2022 Form 483. The April 2022 Form 483 identified inadequate manufacturing conditions and practices that closely mirrored those found at Abbott's Sturgis plant, including: (1) *Cronobacter sakazakii* was identified in environmental swabs, including in high hygiene areas such as the dryer or dryer area; (2) *Cronobacter sakazakii* was identified in a batch of finished infant formula product; and (3) water leaks or pooling were observed in the processing environment, including the dryer or dryer area while actively drying infant formula powder. Based on those observations, the FDA investigators concluded that, like Abbott's Sturgis plant, the Gateway facility "had not established a system of process controls covering all stages of processing that was designed to ensure that infant formula does not become adulterated due to the presence of microorganisms in the formula or in the processing environment."

565. The April 2022 Form 483 thus put any acquirer on notice that the Gateway facility suffered from the ***same category of systemic contamination-control failures*** that had forced Abbott to shut down the Sturgis plant, triggered a nationwide infant formula shortage, and exposed Abbott to hundreds of millions of dollars in losses.

[59] Compl. for Permanent Inj. at 11-12, *Abbott Labs.*, ECF No. 1.

566. Following the issuance of the April 2022 Form 483, there was a "regulatory meeting conducted on September 14, 2022"[60] between the FDA and Gateway – right in the midst of the due diligence process, and just a few weeks before Defendant Kessler announced the acquisition.

567. Defendants had actual knowledge of, or at a minimum direct access to, the April 2022 Form 483. According to Defendant Kessler, on the date that Perrigo acquired the Gateway facility on November 1, 2022, Perrigo had "been working on" the acquisition "for well over a year." During that same time, Defendants repeatedly and publicly discussed the Abbott recall and infant formula shortage as a factor driving both revenue and Perrigo's manufacturing capacity needs, demonstrating their keen awareness of the regulatory and safety risks facing infant formula manufacturers.

568. In connection with any acquisition of an FDA-regulated manufacturing facility, as discussed in Section VI, it is standard industry practice for the acquiring company to conduct regulatory and quality due diligence, including review of the facility's compliance with cGMP and regulatory standards, quality control processes, manufacturing conditions and practices, and records pertaining to regulatory inspections or actions such as Form 483s. Perrigo had been in the infant formula business for over a decade prior to the Gateway acquisition, and been through the regular cycle of FDA inspections. In any market environment, failing to review the key record of the primary regulator before acquiring a regulated manufacturing facility would constitute an extreme departure from the standards of ordinary care.

569. And these were not ordinary market conditions. Perrigo acquired the Gateway facility in the immediate wake of the Abbott crisis—a crisis they publicly acknowledged and from

[60] Ex. D, at 5.

which they sought to profit—at a time when the FDA was particularly focused on infant formula manufacturers. Under these circumstances, Defendants had access to the April 2022 Form 483 and either reviewed it and were aware of the Gateway facility's numerous violations of FDA regulations and cGMPs and systemic contamination-control failures that would limit its ability to reliably produce safe, quality formula – or they failed to review the April 2022 Form 483 in an extreme departure from the standards of ordinary care, and under either scenario, they made positive statements contradicted by that information.

2. Post-Acquisition: Defendants Were Informed of Ongoing, Unremediated Problems at the Vermont and Gateway Facilities through Additional Form 483s, FDA Warning Letter, Perrigo's Own Testing, Consultant's Reports, Notifications of Deviations and Positive *Cronobacter* Hits, and More

570. Following the acquisition, Defendants had further actual knowledge or access to information—including FDA Form 483s, an FDA Warning Letter, the results of Perrigo's own environmental and finished-product testing, reports from Perrigo's consultants regarding problems at the formula facilities, reports of deviations, notifications of positive *Cronobacter* hits, and more—that demonstrated Perrigo had not undertaken meaningful corrective action to remediate the numerous violations of FDA regulations and cGMPs and the systemic contamination-control failures at the Gateway and Vermont facilities, and which necessarily limited production capacity and attendant financial metrics.

571. Defendants repeatedly told investors, such as in the FY2022 10-K signed by Defendants Kessler and Bezerra, that they "actively monitor" the FDA compliance process and make "appropriate adjustments to remain in compliance with current FDA rules regarding cGMP, quality control procedures, quality factors, notification requirements, and reports and records for the production of infant formulas." Pursuant to the FDA Investigations Operations Manual, the

Form 483s that were issued should be "sent to the top management of the firm."[61] And according to FE1, FDA Form 483 letters dating back to the Nestlé era for the Gateway facility were maintained in Perrigo's records. The dryer micro-cracks and leaks were also reflected in historical maintenance logs that FE1 reviewed.

572. One day after the November 1, 2022, acquisition announcement that started the Class Period, on November 2, 2022, Perrigo received notification that two finished infant formula products produced at the Gateway facility tested positive for *Cronobacter* species. After discussion with the FDA, Perrigo destroyed all product produced from October 23 to November 2, 2022. Following the November 2, 2022 positive finished-product test, Perrigo also identified *Cronobacter* species in environmental testing of the dryer and other processing locations. These events—occurring on the first full day after the acquisition closed—provided Defendants with actual, contemporaneous knowledge that the violations of FDA regulations and cGMPs and contamination-control deficiencies documented in the April 2022 Form 483 had not been remediated and that the Gateway facility continued to fail to control for contamination from *Cronobacter.*

573. On January 18, 2023, Perrigo received notification of yet another positive test for *Cronobacter* species in finished infant formula powder product, as well as positive environmental swabs from the dryer taken during the same production campaign. Perrigo destroyed the batch of finished infant formula powder product that tested positive but initially released other batches produced during the same production campaign based solely on negative test results. As the FDA

[61] FDA, *Investigations Operations Manual*, ch. 5, § 5.2.3.6 (2025), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual.

would later determine, this decision to release product without a conclusive root cause investigation violated the FDCA.

574. On March 6, 2023, the FDA began another inspection of the Gateway facility.

575. On March 8, 2023, the FDA issued its Letter to Industry, which further notified Perrigo about multiple manufacturing conditions and practices that were essential for controlling contamination from *Cronobacter* and other pathogens, including controlling water in dry production areas, verifying the effectiveness of controls through environmental monitoring, and implementing appropriate corrective actions following identification of a pathogen from environmental or product testing.

576. During the FDA's inspection at Gateway, the FDA investigators found that Perrigo continued to fail to control for contamination from *Cronobacter* – the precise deficient manufacturing conditions and practices highlighted in the FDA's March 8, 2023 Letter to Industry. As documented in the April 2023 Form 483, the FDA investigators found:

a. From November 2, 2022 to April 5, 2023, Perrigo identified *Cronobacter* species multiple batches of finished product as well as from locations in the Gateway facility defined to be areas with "a high potential for product contact."

b. The FDA and Perrigo also collected additional environmental swab samples on March 7 and 8, 2023 from high hygiene areas, including the dryer and dryer area, which tested positive for either *Cronobacter sakazakii* or *Cronobacter* species.

c. FDA investigators observed bubbling and cracking on the floor of the dryer, which had been previously identified as a harborage area for Cronobacter species.

577. On March 17, 2023, following the FDA's evaluation of Perrigo's sanitation records and the Company's further discussions with the agency, Perrigo conducted a voluntary recall of batches of infant formula product that were manufactured during the same January 2023 production campaign as the batch that tested positive for *Cronobacter*. As the FDA later explained in its August 2023 Warning Letter, the recalled batches were deemed adulterated because Perrigo

failed to conduct a root cause investigation that conclusively identified when its production system became contaminated and determined that the released batches were not subject to the insanitary conditions created by the contamination.

578. In connection with the voluntary recall, Perrigo issued a press release that included unqualified statements that the product was "recalled out of an abundance of caution due to the potential presence of *Cronobacter sakazakii,"* that "no distributed product has tested positive for the presence of this bacteria," "no other products manufactured at this facility" were "affected by this recall," that the Company had "numerous regulatory approved procedures throughout the manufacturing process to control for *Cronobacter sakazakii*," that "[e]very batch of infant formula is tested to make certain it meets stringent nutritional, safety, quality, and regulatory requirements, and "[a]s part of our rigorous protocols to protect the safety of families and infants, we are proactively taking this action."

579. At the time of the March 2023 press release and their communications with analysts, Defendants knew facts and had access to information that directly contradicted their public statements had misled analysts about the conditions and practices at the Gateway facility and the reasons for the March 17, 2023 recall, including that:

a. Perrigo's recall was not conducted "out of an abundance of caution due to the potential presence of *Cronobacter sakazakii"* but instead because of actual positive tests of *Cronobacter* species in finished product produced in the same production campaign;

b. Although "no distributed product" had "tested positive for the presence of this bacteria," the distributed product was nonetheless deemed adulterated under the FDCA because Perrigo had not conducted a root cause investigation that conclusively identified when the production system became contaminated and established that the released product was not subjected to the insanitary conditions caused by the contamination;

c. Since the FDA concluded that the Gateway facility did not have established process controls to ensure that infant formula did not become contaminated, Perrigo and FDA continued to identify *Cronobacter* species in finished product

and the processing environment and thus the Gateway facility did not have regulatory approved procedures throughout the manufacturing process that controlled for *Cronobacter sakazakii.*

d. Perrigo's testing could not "make certain" that "[e]very batch of infant formula" met "stringent nutritional, safety, quality, and regulatory requirements," because testing alone without an adequate root cause investigation did not comply with regulatory requirements.

e. Perrigo did not "proactively" conduct the voluntary recall "[a]s part of [the Company's] rigorous protocols to protect the safety of families and infants," but instead did so only after the FDA's evaluation of Perrigo's sanitation records and subsequent discussions with the Agency.

580. Defendants Kessler and Bezerra demonstrated their knowledge of the infant formula business by choosing to speak directly with analysts from Canaccord Genuity about the infant formula shortages and the Company's recall. Documenting the conversations with management in an April 5, 2023 report, the analysts wrote that Defendants told them that the recall would "have a small impact on sales in the quarter but should not have an impact on the year." The analysts were persuaded by management, concluding that the recall was conducted "out of an abundance of caution due to the 'potential' exposure of Cronobacter" and "that no cronobacter was found in the product." Noting that the FDA's inspection of the Sturgis plant "found disrepair of critical equipment, water leaks and standing water, and multiple finished product samples testing positive for cronobacter," the analysts wrote that they believed that "the Abbott issue was isolated to just their company and even the location," and that "Perrigo runs a much tighter ship" and its "facilities do not have the same issue as Abbott's Sturgis facility at all."

581. Defendants also knew and had access to documentation showing that their compliance failures persisted even after Perrigo purported to take corrective action. Following the April 2023 Form 483 and Perrigo's May 2023 letter submitting corrective actions, the FDA issued the August 2023 Warning Letter and the November 2023 Form 483—each of which further

contradicted Defendants' public assurances. Defendant Lockwood-Taylor later acknowledged that he knew the FDA had issued a Warning Letter and Form 483 to the Gateway facility.

582. The August 2023 Warning Letter stated that the agency had determined the findings by FDA investigators during the previous inspections constituted violations of cGMP and the FDCA. The FDA noted, among other things, that for each finished product positive event, Perrigo had not identified a definitive root cause and "assumed that cross-contamination events had occurred between personnel and/or the environment with either food contact surfaces or the product stream within high hygiene zones of the dry production areas."

583. The November 2023 Form 483 documented the findings of FDA investigators, which noted that Perrigo had shut down the Gateway facility from July 18 to August 23, 2023, during which several repair and replacement projects were completed. Despite those projects, the FDA investigators found that (1) from August 23 to November 6, 2023, Perrigo identified *Cronobacter* species on multiple E1 locations in the processing facility; (2) from August 23 to November 17, 2023, Perrigo identified *Cronobacter* species on multiple E2 sites, including areas in or around the dryer; and (3) during the same time period, Perrigo identified ten water leaks in or around the dryer and *Cronobacter* species were found in swabs collected from two of the leak locations. Based on those observations, FDA investigators concluded that the Gateway facility still had not established process controls covering all stages of processing that were designed to ensure infant formula did not become adulterated due to the presence of microorganisms in the formula or in the processing environment.

584. The persistence of these identical deficiencies—through multiple FDA inspections, a Warning Letter, and Perrigo's own purported corrective actions—further supports the inference

that Defendants either knew their positive statements regarding the infant formula business and Gateway acquisition were false or acted with conscious recklessness in making them.

585. Defendant Kessler was focused on infant formula from his start at the Company. In his very first month, at his very first Board meeting, he asked the Board for $250 million for the infant formula business, to build a new facility in Vermont.

586. Defendant Kessler claimed to personally oversee critical quality, stating on an earnings call, "***I added*** 100 people, 30 in quality control and 70 in sanitation" to the Vermont facility to support quality and compliance efforts.

587. Further, Defendant Kessler led and announced the Gateway acquisition.

588. Defendant Lockwood-Taylor was similarly close to the formula business.

589. On an investor call in response to an analyst question about how confident Perrigo was about the remediation and that there would be no backsliding, Defendant Lockwood-Taylor reassured the market that he personally chaired the Steering Committee and was "very close to the remediation work"– a fact he emphasized to investors on an earnings call.

590. He personally went to the Gateway facility to announce it would be shut down for months for cleaning, according to FE4.

591. According to FE4, Defendant Lockwood-Taylor was promptly notified every time there was a positive *Cronobacter* hit in an infant formula facility.

592. As he made clear on the Q4 2023 earnings call, Defendant Lockwood-Taylor personally recruited the consultants brought in to assess Gateway, and according to FE4, Defendant Lockwood-Taylor went to Gateway to announce them. According to FE7, Defendant Lockwood-Taylor, along with other members of the Steering Committee, received regular updates from Perrigo's consultants including included Validant's write-ups of problems with Good

Documentation Practices, Good Manufacturing Practices, food code violations, sanitation issues, and more; its lengthy assessment of problems at Gateway; its 15-page summary with specific recommended changes; and its report on failures of Gateway's environmental monitoring program.[62]

593. According to FE7, Defendant Lockwood-Taylor and the other members of the Steering Committee were notified of every deviation that occurred at Gateway. Validant, the consulting group, had put in place a review process whereby multiple consultants and Gill had to sign off on the deviations and affiliated batch records. Gill plus either Knudtson or Bohl would prepare a report for Defendant Lockwood-Taylor and the Steering Committee.[63] That team also regularly prepared PowerPoint presentations on the deviations to present to Defendant Lockwood-Taylor and the Steering Committee.

594. Defendant Lockwood-Taylor also noted on the Q4 2023 Earnings Call, dated February 27, 2024 that Perrigo would give the FDA monthly updates on Perrigo's progress, reflecting ongoing monitoring and awareness of correspondence with the FDA.

595. He was also directly engaged with Perrigo's regulators. In 2025, Defendant Lockwood-Taylor met directly with the U.S. Secretary of Health and Human Services regarding "areas of focus" for infant formula; he also noted "four to five detailed technical consultations" between Perrigo and the FDA on infant formula issues.

[62] The summary was shared in a Teams folder accessible to Knudtson, Gill, and the internal auditor at Gateway, Jacob Bohl ("Bohl"), Quality Assurance Analyst. FE7 personally reviewed the summary at the end of 2024 or beginning of 2025, when Bohl shared it with her.

[63] According to FE7, Knudtson and Gill, or Bohl stepping in for Knudtson, would put a report together for the Steering Committee based on the deviations data to give leadership a snapshot of the state of the plant. Bohl informed FE7 that they would regularly put a metrics power point presentation based on the deviation data to present to the Steering Committee.

596. On August 8, 2023, in response to an analyst question about 2025 targets, Defendant Lockwood-Taylor made clear that he was directly involved in determining and overseeing the metrics, stating, "I've worked through them as you would hope and expect in detail. I think they're very well considered. I think we have the right action plans and governance in place, but they have to be delivered. And I will stay on top of that governance personally to make sure each of them is on track and how we help the teams to stay on track."

597. As CFO, Defendant Bezerra was responsible for the accounting treatment for the Gateway acquisition and related SEC disclosures. The 10-K for fiscal year 2022 disclosed that the Gateway acquisition was "accounted for as a business combination" with detailed fair value estimates for property, plant and equipment ($61.5M), inventories ($29.8M), and intangible assets ($18.7M).

3. Perrigo Had Extensive Additional Reports and Data Regarding the Problems with the Gateway Acquisition and Infant Formula Business

598. Perrigo was a data-intensive business, and its general reporting and information-sharing processes further support Defendants' knowledge of or access to information contradicting their public statements.

599. Monthly all-hands meetings were held at the facilities where extensive metrics were reviewed – production rates, sales numbers, future objectives, attrition and turnover rates, and more. Updates about receipt of FDA communications, including "yellows" or Warning Letters was also shared at these meetings, according to FE2. According to FE1, infant formula data was tracked in various systems including historical maintenance records tracked via SAP and quality data stored in NeoGen; Perrigo also stored data in Excel spreadsheets, older FDA Form 483 letters dating back to the Nestlé era for the Gateway facility, and document-control files stored in OpenText.

600. Production metrics were carefully tracked. According to FE5, production KPIs were tracked and discussed at daily meetings and weekly meetings, and if those goals were not met, management would discuss corrective actions to take. Weekly meetings where these KPIs were discussed included both experts and supervisors as well as managers from all departments.

601. Production stoppages due to plant issues were also tracked and escalated. For example, according to FE5, senior plant management would have been made aware of the leaks at Gateway because they were a source of microbiological positives, and therefore a reason why production would be paused.

602. Significant problems were communicated up the chain. For example, the leaks in the dryer at Gateway made it impossible for operators to bring their paperwork into the machine to complete it during the cleaning process, as required by the FDA. As a result, operators had to complete their paperwork after the cleaning process ended and at times failed to do so. This problem was escalated to Defendant Lockwood-Taylor, as well as other members of senior leadership.

603. According to FE4, at the Gateway facility, information cascaded upward through a defined daily structure centered around the 8:30 a.m. "Daily Operations Review" meeting. At this meeting, representatives from safety, quality, production, and maintenance reviewed every issue from the prior 24 hours, and any notable problem, such as downtime, quality deviation, or sanitation concerns, was formally documented and elevated to the factory manager. FE4 stated that once Perrigo took over, factory manager Mar-Silva was responsible for escalating any significant issue from these meetings to Thomas, under strict escalation protocols Thomas had imposed. According to FE4, Thomas required immediate notification of major quality events, material production losses, or anything with substantial financial impact. FE4 personally observed

this process during a major *Cronobacter* event, where Mar-Silva contacted Thomas and senior quality leadership immediately – even before all details were known. FE4 also understood that final *Cronobacter* incident reports were sent directly to Perrigo's CEO, reflecting how rapidly serious issues moved up the chain. Twice-weekly broader operations calls with corporate leadership of the Nutrition unit reinforced that executives, including Thomas and others, were routinely briefed on key safety, quality, and reliability problems identified through the daily meeting process.

604. According to FE10, at the Vermont plant, everything was reported up to Perrigo headquarters in Michigan on a daily basis and that there was "total transparency" with headquarters. Reports of everything from a broken electrical socket up to contamination of infant formula were reported up the chain of command through multiple reporting systems.

605. Defendants' pre- and post-acquisition receipt of and access to Form 483s, FDA communications, regular reports, and deep involvement in the infant formula business supports a strong inference of scienter.

B. Defendants Spoke Regularly About the Infant Formula Business, Including In Response to Analyst Questions

606. The infant formula business was a topic of discussion in every earnings call and Investor Day throughout the entire Class Period, with at least one (and often multiple) Defendants addressing infant formula in their prepared remarks.

607. Defendants held themselves out as knowledgeable about all aspects of the business including production capacity, status of remediation, remediation costs, and FDA inspections.

608. Defendants regularly answered analyst questions with positive reassurances about the Gateway acquisition and infant formula business.

609. For example, when an analyst directly asked how "confident" Perrigo was about the remediation and that there would not be "any meaningful setbacks," Defendant Lockwood-Taylor directly reassured him, stating "I've been very close to the remediation work. As you know, I chair the steering committee. ***The remediation work has been executed extremely well across the three sites***. ***All the key performance indicators show that we are fully compliant. I've not seen any backslide in terms of those KPIs [key performance indicators] as we've been through the remediation effort, and we're on the other side of that."***

610. Similarly, when an analyst directly asked if this was "the last iteration we're going to be kind of seeing on nutritionals"? Defendant Lockwood-Taylor responded confidently that at Gateway they had completed a "***very significant intervention with a different level of protocol, corrective actions, preventative actions, quality assurance application and environmental monitoring and cleaning and sanitization***" and "***[t]hat site is up. It's a different level of adherence***."

611. And when an analyst asked what gave the Company the "confidence" to make a $240 million investment in infant formula, and Defendant Lockwood-Taylor responded without qualification that ***"[w]e have been very effective in remediating that business***," "***we are highly quality assured***," and "***we moved from it being a dilutive free cash flow business to actually becoming accretive . . . relatively quickly***."

612. Defendant Lockwood-Taylor's assured responses omitted that Defendants never remedied the specific problems identified to them by consultants, the FDA, and their employees that contributed to ongoing contamination problems, including cracked and aged dryers and leaking roofs, and made Perrigo unable to fill orders, losing major customers.

613. Further, Defendants Kessler and Bezerra personally met with analysts where they discussed the infant formula business and Gateway acquisition, including a meeting with Canaccord Genuity analysts leading them to publish an April 5, 2023, report concluding Perrigo did not suffer from the same problems as Abbott.

614. Defendants' prepared remarks and answers to analyst questions further evidence that they were well-informed about the infant formula business, supporting a strong inference of scienter.

C. Defendants' Fraud Targeted the Core of Perrigo's Business Strategy — The Infant Formula Business

615. The Supply Chain Reinvention Program was Perrigo's key initiative during the Class Period, and the keystone of that program was the Gateway acquisition.

616. The November 1, 2022 press release announcing the Gateway acquisition described it as is the "first major initiative" in the Supply Chain Reinvention program" that would "solidif[y] our long-term manufacturing supply of infant formula in the U.S. . . . and deliver[] value to Perrigo shareholders."

617. Defendant Kessler hailed the Gateway acquisition as "the primary driver" of the $50–70M in incremental operating income that the Supply Chain Reinvention Program was expected to drive.

618. Defendant Lockwood-Taylor described infant formula as a "Strategic Pillar" and "corporate imperative."

619. Defendant Bezerra described executing on infant formula and Project Energize as one of Perrigo's "critical priorities."

620. Infant formula was supposed to be the cash generator that funded Perrigo's investments in branded products, as part of its interdependent business model. As Defendant

Lockwood-Taylor explained: "Perrigo's unique complementary businesses enables each individually to play a specific reinforcing role, where 1) ***store brands and infant formula generate cash for investments into the Company's key higher margin, higher growth or 'High-Grow' brands*** . . ."

621. While infant formula made up less than 10% of total revenue, it had an outsized impact on Perrigo's financial results. In the first quarter of 2024, infant formula drove -6.7% points of organic net sales decline and -520 basis points of adjusted gross margin impact. When the business underperformed in 2024, formula drove $.26 of EPS impact. Infant formula drove three-quarters of the sales decline in certain quarters, and hundreds of basis points of margin compression.

622. The significance of the infant formula business is underscored by the fact that it was a key metric in Defendants' performance evaluations, and was the subject of political advocacy by Perrigo, reported out in its proxy statement.

623. The importance and centrality of the infant formula to Perrigo's business model supports a strong inference of scienter.

D. Defendant Kessler Abruptly Retired Just Two Weeks After the FDA's Damaging Findings at Gateway

624. Scienter is further supported by the suspicious timing of Defendant Kessler's departure from Perrigo. The sudden announcement of his retirement coincided with alarming, non-public FDA findings at Gateway that called into question the very acquisition that Defendant Kessler had led and championed.

625. Unbeknownst to investors until much later, on April 26, 2023, the FDA issued the April 2023 Form 483, detailing results of another lengthy inspection of Gateway that took place between March 6 and April 26, 2023.

626. The FDA's findings were serious. Most notably, the agency identified numerous positive *Cronobacter* hits, including in product (not just the environment), which evidenced Perrigo's "failure to establish a system of process controls . . . designed to ensure that infant formula does not become adulterated . . . ." The April 2023 Form 483 also identified metal fragments in batches – the source of which was the dryer. And significantly, many of the FDA's objections were new since its inspection of Gateway the prior year when the facility was still owned by Nestlé – indicating that new, significant problems had developed under Perrigo's control.

627. Just two weeks later, on May 9, 2023, Defendant Kessler announced plans to retire.

628. The close temporal proximity between the alarming April 2023 Form 483 at Gateway and the sudden departure of the CEO who personally oversaw and publicly touted the Gateway acquisition supports a strong inference of scienter.

E. Defendants Had Powerful Financial Motives to Conceal the Failures of the Gateway Acquisition and Infant Formula Business

1. Defendant Kessler Made a Suspicious Insider Sale of His Perrigo Stock While in Possession of Material Non-Public Information

629. Defendant Kessler's insider sale provides direct evidence of scienter. As described in further detail above, Section VIII, Defendant Kessler personally benefited by disposing of their Perrigo common stock at prices artificially inflated by fraud while in possession of material non-public information about the Gateway acquisition and infant formula business.

630. During the Class Period, Defendant Kessler reaped over $7 million in proceeds from improper insider sales.

631. Defendants Kessler's sale was suspicious in size. He sold far more shares for far greater proceeds during the Class Period than during the Control Period.

632. The sale was suspicious in timing. Defendant Kessler made an enormous $7 million stock sale – 99% of his shares available to sell – just two weeks after the FDA issued the April 2023 Form 483 arising from that investigation, identifying multiple positive *Cronobacter* hits and serious systemic issues at the facility.

633. Defendant Kessler's suspicious insider sale supports a strong inference of scienter.

2. Defendants Lockwood-Taylor and Bezerra's Bonuses Were Directly Tied to the Perceived Success of the Gateway Acquisition and Infant Formula Business They Knew Were Failing

634. Defendants Lockwood-Taylor and Bezerra also had a motivation to deceive because their compensation was directly tied to the perceived success of the infant formula business, creating a powerful incentive to conceal the problems plaguing the Gateway acquisition and infant formula business.

635. Executive compensation at Perrigo is comprised of an annual base salary, an Annual Incentive Plan ("AIP") cash award, and a Long Term Incentive Plan equity award based on overall growth. A "significant portion" of compensation was linked to performance. Executive compensation was reviewed and approved by the Talent & Compensation Committee ("Committee").

636. In 2022 and 2023, AIP was comprised of two components: 80% tied to financial components and success of the company and 20% determined by the Committee's qualitative evaluation of executives' performance on individual strategic objectives and pre-established goals. Each year the Board determined a target AIP for each executive and at the end of the year, the Committee determined the award, which could be anywhere from 0-200% of base salary. In 2024, individual strategic objectives were no longer a separate 20% of the AIP; instead, performance against individual strategic objectives became a modifier on the AIP financial component. The

modifier could adjust the AIP award up by as much as 50% or down by as much as 100% based on the executive's performance.

637. Under either system, an executive's bonus could dramatically change based on success achieving individual strategic objectives. Executives with an infant formula-related strategic objective had a strong incentive to portray that work in a positive light.

638. For fiscal year 2022, as reflected in the Proxy filed on March 24, 2023 with the SEC, Defendant Bezerra's individual strategic objectives and pre-established goals (comprising 20% of his bonus potential) included "Recapture Value and organize Corporate Strategy / Corporate Development areas to deliver on Strategic Plans until 2025." The Committee's evaluation of Bezerra, as reflected in the proxy filed with the SEC, found that Bezerra "[s]uccessfully executed due diligence and negotiation of the Gateway acquisition." The success of acquiring the Gateway facility contributed to Bezerra's 115% payout on individual strategic objectives component of the AIP, resulting in a bonus of 98.21% of target AIP or $549,976.00 bonus for the year.

639. For fiscal year 2023, as reflected in the Proxy filed on March 22, 2024 with the SEC, Defendant Lockwood-Taylor's evaluation against his individual strategic objectives and pre-established goals (comprising 20% of his bonus potential) found that he "[c]ontinued to address new Infant Formula guidelines," That year the Committee capped potential AIP at 75% of base salary to enhance executive accountability for meeting financial targets, but the evaluation against objectives gave Defendant Lockwood-Taylor the maximum possible payout.

640. For fiscal year 2024, as reflected in the Proxy filed on March 21, 2025 with the SEC, the connection between compensation and the infant formula business became even more explicit. The Executive Compensation section of the proxy emphasized that one of Perrigo's goals

was "stabilizing our operations in 2024 as our infant formula business is consistently producing quality assured reliable product," and that the successes were achieved "despite the evolving U.S. regulatory environment within the infant formula industry, which impacted our infant formula business during the year."

641. Defendant Lockwood-Taylor's evaluation of his performance against goals emphasized that he "[o]versaw the intensive remediation efforts to stabilize operations across Infant Formula." And Defendant Bezerra's evaluation of his performance against goals emphasized his success in strategizing and implementing new operational models which would have included infant formula operations. Defendants Lockwood-Taylor and Bezerra both received 63.7% of target AIP payout – above the baseline of 59% – confirming that they received an upward modification based on their performance against individual strategic objectives.

642. Defendants Lockwood-Taylor and Bezerra's compensation was thus deeply connected to a perception of a successful acquisition and stabilized infant formula business, supporting a strong inference of scienter.

F. Individual Defendants' Scienter is Imputed to the Company

643. By virtue of their high-level positions as the most senior officers of the Company, participation in and awareness of Perrigo's day-to-day operations, and control over the issuance of the false or misleading statements alleged above, the knowledge or recklessness of Defendants Kessler, Lockwood-Taylor, and Bezerra's false or misleading statements is imputed to Perrigo. In addition, the knowledge or recklessness of other senior employees and managers, whether or not named herein, concerning the infant formula business, is also imputed to Perrigo. Accordingly, by no later than November 2022, prior to the start of the Class Period, Perrigo knew about or recklessly disregarded its false and misleading statements about the Company's infant formula business.

X. LOSS CAUSATION

644. The fraud alleged herein was the proximate cause of the economic loss suffered by Lead Plaintiff and the Class. There was "a causal connection between the material representation and the loss" (*i.e.*, stock price declines), as described herein. *See, e.g.*, *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 342 (2005); *Carpenters Pension Tr. Fund of St. Louis v. Barclays PLC*, 750 F.3d 227, 235 (2d Cir. 2014).

645. During the Class Period, Defendants made false and misleading statements and material omissions, causing Perrigo's common stock to trade at prices artificially inflated and/or manipulated. Specifically, despite assuring investors that the Gateway acquisition was "immediately accretive" and driving EPS, both the Gateway and Vermont facilities suffered from chronic underinvestment in maintenance and equipment upgrades, causing frequent breakdowns and systemic slowdowns in production. Moreover, both the Gateway and Vermont facilities were in violation of FDA regulations and cGMPs, and the 2024 "resets" touted by management did not address the underlying regulatory and production failures.

646. Relying on the integrity of the market price for Perrigo common stock and public information relating to Perrigo, Lead Plaintiff and other Class members purchased or otherwise acquired Perrigo common stock at prices that incorporated and reflected Defendants' misrepresentations and omissions of material fact alleged herein.

647. Perrigo's common stock price fell precipitously when the truth was partially disclosed to the market on February 27, 2024, May 7, 2024, August 6, 2025, and finally on November 5, 2025.

648. The disclosures that partially corrected the market price of Perrigo's common stock and reduced the artificial inflation caused by Defendants' false and misleading statements and material omissions are summarized as follows:

Date of Corrective Event	Closing Stock Price on Trading Day Prior to Disclosure	Closing Stock Price After Disclosure	Common Stock Price Change	Common Stock % Change	S&P 500 Total Return	Trading Volume	Approx. Market Cap Loss
2/27/2024	$32.17	$27.30	-$4.87	-15.14%	0.17%	10,621,771	-$659,658,616
2/28/2024	$27.30	$26.41	-$0.89	-3.26%	-0.16%	6,364,104	-$120,609,186
5/7/2024	$33.43	$30.15	-$3.28	-9.81%	0.14%	3,898,066	-$420,236,786
8/6/2025	$26.62	$23.61	-$3.01	-11.31%	0.73%	8,456,502	-$413,806,691
8/7/2025	$23.61	$22.83	-$0.78	-3.30%	-0.08%	4,135,987	-$104,823,551
11/5/2025	$20.19	$15.10	-$5.09	-25.21%	0.37%	12,039,686	-$699,674,479

649. As a result of these disclosures, the price of Perrigo common shares crashed from a high of $40.11 on November 1, 2022, the first day of the Class Period, to a closing price of $15.10 on November 5, 2025, the last day of the Class Period, a loss of over $3.4 billion in market capitalization.

650. Until the final disclosure, on November 5, 2025, each of Perrigo's disclosures only partially revealed the relevant truth and Defendants accompanied each with additional false and misleading information that maintained the artificial inflation in Perrigo's common stock price. The full amount of inflation was not removed until after the final disclosure on the last day of the Class Period.

651. As a result of its purchases of Perrigo common stock during the Class Period, Lead Plaintiff and other members of the Class suffered harm.

XI. APPLICABILITY OF PRESUMPTION OF RELIANCE

652. Lead Plaintiff is entitled to a presumption of reliance on Defendants' material representations and omissions pursuant to the fraud-on-the-market doctrine because, during the Class Period:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the Company's securities traded in an efficient market;

(d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of Perrigo's common stock;

(e) Lead Plaintiff and other members of the Class purchased Perrigo common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts;

(f) Perrigo common stock met the requirements for listing and was listed and actively traded on the NYSE, a highly efficient and automated market;

(g) as a regulated issuer, Perrigo filed periodic public reports with the SEC and NYSE;

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

(i) Perrigo was followed by numerous securities analysts employed by major brokerage firms, all of which wrote reports that were distributed to the sales force and certain customers of their respective brokerage firm(s) and that were publicly available and entered the public marketplace.

653. As a result, the market for Perrigo common stock promptly digested current information regarding Perrigo from publicly available sources and reflected such information in the price of Perrigo common stock. Under these circumstances, all persons and entities who or

which purchased or otherwise acquired Perrigo common stock during the Class Period suffered similar injuries through their purchase of Perrigo common stock at artificially inflated prices and thus, the presumption of reliance applies.

654. The material misrepresentations and omissions alleged herein would induce a reasonable investor to misjudge the value of Perrigo common stock.

655. Without knowledge of the misrepresented or omitted material facts alleged herein, Lead Plaintiff and other members of the Class purchased shares of Perrigo common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were fully disclosed.

656. To the extent that Defendants concealed or improperly failed to disclose material information regarding the Gateway acquisition or Perrigo's infant formula business, Lead Plaintiff is entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

XII. NO SAFE HARBOR

657. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the false and misleading statements alleged in this amended complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions.

658. In addition, to the extent certain of the statements alleged to be false and misleading may be characterized by Defendants as forward-looking, those statements were not identified as "forward-looking statements" when made, and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in any purportedly forward-looking statements.

659. Further, to the extent certain of the statements alleged to be false and misleading may be characterized by Defendants as forward-looking, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer who knew that the statement was false when made.

XIII. CLASS ACTION ALLEGATIONS

660. Lead Plaintiff brings this federal securities class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of itself and all persons and entities that purchased or otherwise acquired publicly traded Perrigo Common Stock (NYSE: "PRGO") during the period from November 1, 2022, through November 5, 2025, inclusive, (the "Class Period"), and were damaged thereby, except as excluded below (the "Class").

661. Excluded from the Class are: (a) Defendants; (b) members of the immediate families of any Individual Defendant; (c) the subsidiaries and affiliates of Perrigo; (d) any person who was an officer, director or controlling person of Perrigo during the Class Period; (e) any entity in which any Defendant has a controlling interest or beneficial interest; and (f) the legal representatives, heirs, successors or assigns of any such excluded person or entity, in their capacities as such.

662. The members of the Class are so numerous that joinder of all members is impracticable. While the exact number of Class members is unknown to Lead Plaintiff at this time and can only be ascertained through appropriate discovery, Lead Plaintiff believes that there are thousands of members in the proposed Class. Indeed, Perrigo had hundreds of millions of outstanding shares of Perrigo common stock.

663. Members of the Class may be identified from records maintained by Perrigo or its transfer agent and may be notified of the pendency of this Action by mail, using a form of notice customarily used in securities class actions.

664. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class, including:

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

(b) whether the statements made by Defendants were materially false or misleading, or omitted material facts;

(c) whether Defendants acted knowingly or with deliberate recklessness in making materially false or misleading statements and omitting material facts;

(d) whether the price of Perrigo common stock during the Class Period was artificially inflated and/or artificially maintained because of Defendants' conduct complained of herein;

(e) whether the Individual Defendants were control persons of Perrigo;

(f) whether Defendant Kessler sold Perrigo common stock while in possession of material, non-public information and whether that sale was contemporaneous to Lead Plaintiff's purchase of Perrigo common stock; and

(g) whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

665. Lead Plaintiff's claims are typical of the claims of other members of the Class and Lead Plaintiff sustained damages arising out of Defendants' wrongful conduct akin to the other members of the class in violation of the Exchange Act as alleged in this amended complaint.

666. Lead Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class actions and securities litigation. Lead Plaintiff has no interests antagonistic to, or in conflict with, those of the Class.

667. A class action is superior to other available methods for the fair and efficient adjudication of the controversy since joinder of all members of the Class is impracticable. Furthermore, because the damages suffered by the individual Class members may be relatively small, the expense and burden of individual litigation makes it impractical for the Class members individually to redress the wrongs done to them. There will be no difficulty in the management of this Action as a class action.

668. Lead Plaintiff will rely, at least in part, on the presumption of reliance established by the fraud on the market doctrine. All purchasers of Perrigo common stock during the Class Period suffered similar injuries, including injury through their purchase of Perrigo common stock at artificially inflated prices and/or artificially maintained prices. A presumption of reliance therefore applies.

XIV. COUNTS

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

669. Lead Plaintiff realleges, incorporates, and repeats each allegation above as if fully set forth herein.

670. This Count is brought under § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b) and Rule 10b-5(b) promulgated thereunder by the SEC, 17 C.F.R. § 240.10b5(b), against Defendants Kessler, Lockwood-Taylor, and Bezerra.

671. Defendants made untrue statements of material fact and/or omitted material facts necessary to make the statements made not misleading in violation of § 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder.

672. Defendants acted with scienter in that they knew or recklessly disregarded that the public documents and statements issued or disseminated in the name of or attributable to Perrigo were materially false and misleading due to the omission of material information and were issued or disseminated to the investing public.

673. In ignorance of the false and misleading nature of Defendants' statements and omissions, and relying directly or indirectly on those statements or upon the integrity of the market price for Perrigo common stock, Lead Plaintiff and other members of the Class purchased Perrigo common stock at artificially inflated prices during the Class Period. But for Defendants' fraud, Lead Plaintiff and members of the Class would not have purchased Perrigo common stock at such artificially inflated prices.

674. As set forth herein, when adverse, previously undisclosed facts concerning Perrigo, its infant formula business, and the Gateway acquisition were disclosed and/or when previously concealed risks materialized, the price of Perrigo common stock declined precipitously, and Lead Plaintiff and members of the Class were harmed and damaged as a direct and proximate result of their purchase of shares of Perrigo common stock at artificially inflated prices and the subsequent decline in the price of Perrigo common stock.

675. By virtue of the foregoing, Defendants are liable to Lead Plaintiff and members of the Class for violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5(b) promulgated thereunder.

676. This claim is timely within the applicable statute of limitations and repose.

COUNT II
For Violations of Section 20(a) of the Exchange Act Against Defendants Kessler, Lockwood-Taylor, and Bezerra as Control Persons of Perrigo

677. Lead Plaintiff realleges, incorporates, and repeats each allegation above as if fully set forth herein.

678. This Count is brought under § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), against Defendants Kessler, Lockwood-Taylor, and Bezerra.

679. Defendants Kessler, Lockwood-Taylor, and Bezerra, by reason of their positions as senior executive officers and/or directors of Perrigo, directly, or indirectly controlled the conduct of Perrigo's business and its representations to the public, within the meaning of § 20(a) of the Exchange Act.

680. Defendants Kessler, Lockwood-Taylor, and Bezerra knew or recklessly disregarded the fact that Perrigo's representations to investors were materially false and misleading when made due to the omission of material information. In doing so, Defendants Kessler, Lockwood-Taylor, and Bezerra did not act in good faith.

681. By virtue of their high-level positions and their participation in and awareness of Perrigo's operations and public statements, Defendants Kessler, Lockwood-Taylor, and Bezerra had the power and were able to and did influence and control Perrigo's decision-making, including controlling the content of and causing the dissemination of materially false and misleading statements and omissions of material fact and other deceptive conduct, that Lead Plaintiff and the Class contend artificially inflated and/or artificially maintained the price of Perrigo common stock.

682. Defendants Kessler, Lockwood-Taylor, and Bezerra communicated with investors or the public on behalf of Perrigo during the Class Period. They were provided with, or had access to, copies of the Company's press releases, public filings, and other statements alleged by Lead

Plaintiff to be misleading prior to and/or shortly after their statements were made and had the ability to prevent the issuance of the statements or to cause the statements to be corrected. By virtue of their positions as controlling persons of Perrigo, Defendants Kessler, Lockwood-Taylor, and Bezerra are also liable pursuant to § 20(a) of the Exchange Act. As a direct and proximate result of Defendants Kessler, Lockwood-Taylor, and Bezerra's wrongful conduct, Lead Plaintiff and the Class suffered damages in connection with their purchase of Perrigo common stock during the Class Period.

683. This claim is timely within the applicable statutes of limitation and repose.

COUNT III
For Violation of Section 20A of the Exchange Act Against Defendant Kessler

684. Lead Plaintiff realleges, incorporates, and repeats each allegation above as if fully set forth herein.

685. As detailed herein, Defendant Kessler was in possession of material non-public information concerning Perrigo and took advantage of their possession of material non-public information regarding Perrigo to obtain millions of dollars in insider trading profits during the Class Period.

686. Defendant Kessler's sale of Perrigo common stock for over $7 million in proceeds was made contemporaneously with Lead Plaintiff's purchase of Perrigo common stock (set forth below and in Lead Plaintiff's certification in Exhibit A) during the Class Period:

Defendant Kessler's Sale			**Lead Plaintiff's Contemporaneous Purchase**		
Sale Date	**Number of Shares Sold**	**Value of Transaction**	**Purchase Date**	**Number of Shares Purchased**	**Value of Transaction**
5/11/2023	197,646	$7,066,358.38	5/17/2023	2,550	$83,803.16

687. Lead Plaintiff and members of the Class who purchased shares of Perrigo common stock contemporaneously with Defendant Kessler's sale suffered damages because (1) in reliance on the integrity of the market, they paid artificially inflated prices as a result of the violations of §§ 10(b) and 20(a) of the Exchange Act as alleged herein; and (2) they would not have purchased the securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by the materially false and misleading statements and omissions alleged herein.

688. Lead Plaintiff and members of the Class who purchased shares of Perrigo common stock contemporaneously with sales by Defendant Kessler suffered damages because (1) in reliance on the integrity of the market, they paid artificially inflated prices as a result of the violations of §§ 10(b) and 20(a) of the Exchange Act as alleged herein; and (2) they would not have purchased the securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially inflated by the materially false and misleading statements and omissions alleged herein.

689. This claim is timely within the applicable statutes of limitation and repose. This action was brought within five years of the date of the last transaction that is the subject of Defendant Kessler's violation of Section 20A, and with respect to the underlying violations of Section 10(b) alleged in this Count and Counts I and II above, was brought within five years after the date of the last transaction that violated Section 20A of the Exchange Act by Defendant Kessler.

XV. PRAYER FOR RELIEF

WHEREFORE, LEAD PLAINTIFF, individually and on behalf of the proposed Class, respectfully prays for relief and judgment against Defendants as follows:

- Determining that this action is a proper class action, certifying Lead Plaintiff as the class

representative under Rule 23 of the Federal Rules of Civil Procedure and Lead Plaintiff's counsel as Class Counsel;

- Awarding Lead Plaintiff and the Class compensatory damages against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, together with pre-judgment interest thereon;
- Awarding Lead Plaintiff and the Class their reasonable costs and expenses incurred in this action, including, but not limited to, attorneys' fees and costs incurred by consulting and testifying expert witnesses; and
- Granting such other, further, and/or different relief as the Court deems just and proper.

XVI. DEMAND FOR JURY TRIAL

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

Dated: May 13, 2026

Respectfully submitted,

By: /s/ *Carol V. Gilden*

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