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

PEMBROKE PINES FIREFIGHTERS & POLICE OFFICERS PENSION FUND, individually and on behalf of all others similarly situated,	)	
Plaintiffs,	)	Case No. 22-cv-4661
v.	)	Hon. Steven C. Seeger
ABBOTT LABORATORIES, *et al.*,	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

In 2022, Abbott Laboratories announced a recall of powdered infant formula produced at its plant in Sturgis, Michigan. Abbott temporarily shuttered the facility. And the federal government upped the ante by announcing an investigation.

Abbott's recall followed reports of *Cronobacter* infections in infants who had consumed formula from Sturgis. That nasty-sounding bacteria isn't a big deal for the average adult. But for infants, it can be deadly.

Abbott is one of a handful of infant formula makers in the United States, and Sturgis is a massive facility. So, the recall was a big deal. It exacerbated a nationwide formula shortage.

Unsurprisingly, the recall generated a lot of bad press and government attention for Abbott. At first, investment analysts didn't think that the recall would cause much of a dent in Abbott's financial picture. That prediction didn't age well.

When it was all said and done, Abbott's shares took a big hit. The company's sales went down because of the shutdown. And Abbott spent a lot of money cleaning up the regulatory

mess. Plaintiffs – who had invested in Abbott stock – believe that they were misled, kept in the dark, and left holding the bag.

So Plaintiffs filed this putative class action lawsuit under the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b). They allege that Abbott and four executives made fraudulent statements, and engaged in fraudulent conduct, about the nature and severity of the problem. They claim that the company lied to them about its commitment to quality and product safety, too.

The complaint spans over 200 pages, and covers a lot of territory. That's a lot, but in the end, it wasn't enough. Plaintiffs fail to offer the factual goods to get their claims off the ground. The complaint says too much, and too little.

For the reasons stated below, Defendants' motion to dismiss the amended complaint is granted.

Background

At the motion-to-dismiss stage, the Court must accept as true the complaint's well-pleaded allegations. *See Lett v. City of Chicago*, 946 F.3d 398, 399 (7th Cir. 2020). The Court "offer[s] no opinion on the ultimate merits because further development of the record may cast the facts in a light different from the complaint." *Savory v. Cannon*, 947 F.3d 409, 412 (7th Cir. 2020).

Before diving in, the Court offers the reader a disclaimer. The operative complaint weighs in at 217 pages (plus 20 pages of appendices), and stretches across 486 paragraphs. *See generally* Am. Cplt. (Dckt. No. 35). If placed end to end, the pages of the complaint would nearly match the longest field goal in NFL history.

In support of their motion to dismiss, Defendants added 25 exhibits to the pile, including multiple regulatory filings clocking in at over 90 pages (each). *See* Defs.' Decl. (Dckt. No. 42). And when they responded to the motion to dismiss, Plaintiffs plopped seven more exhibits on top of the factual mountain. *See* Ormsbee Dec. (Dckt. No. 44).

The parties' briefs provided about 130 pages of additional reading. *See* Defs.' Mem. in Support of Mtn. to Dismiss (Dckt. No. 41) (50 pages); Pls.' Resp. (Dckt. No. 43) (50 pages); Defs.' Reply (Dckt. No. 45) (26 pages). And because the arguments for dismissal are so voluminous, Defendants provided the Court with a 19-page, eight-column spreadsheet listing each alleged misstatement and the basis for dismissal. *See* Defs.' App'x (Dckt. No. 41-1).

This Court did its level-best to condense the supersized payload of allegations into a digestible bite. This Opinion aims to fly like a crow, not a butterfly, but there's a lot of ground to cover.

So buckle up, and consider yourself forewarned that you've got a long journey ahead of you. The ride is not for the faint of heart. The facts of this Opinion alone take up a considerable amount of real estate.

Here is a Cliffs Notes version of the facts: This securities fraud case is about allegedly false and misleading statements and conduct related to a recall of infant formula manufactured at Abbott's facility in Sturgis, Michigan.

Abbott's Business

The Court begins by offering a bit of background about Abbott Laboratories. Abbott is a publicly traded health care products company. *See* Am. Cplt., at ¶ 37 (Dckt. No. 35).

The company is a behemoth. It employs more than 100,000 people across 160 countries. *See* Abbott 2022 Form 10-K, at 4 (Dckt. No. 42-1, at 7 of 92). Abbott operates across four

reportable segments: Established Pharmaceutical Products, Diagnostic Products, Nutritional Products, and Medical Devices. *See* Am. Cplt., at ¶ 37 (Dckt. No. 35). It has nearly 90 manufacturing facilities across the globe. *See* Abbott 2022 Form 10-K, at 15 (Dckt. No. 42-1, at 18 of 92).

This case focuses on a specific segment of Abbott's business: Nutrition. *See* Am. Cplt., at ¶ 38 (Dckt. No. 35). The Nutrition division has a trio of product lines: (1) infant formula, (2) adult and other pediatric nutritional products, and (3) tube-fed products for use in healthcare facilities. *Id.*

In 2020, Nutrition accounted for 22 percent of Abbott's total sales. *Id.* Across all sectors, the company's 2021 sales topped $43 billion internationally, and $16.6 billion in the United States. *See* Abbott 2021 Form 10-K, at 50 (Dckt. No. 42-2, at 52 of 95). Abbott's pediatric nutritional product sales totaled $4.3 billion internationally in 2021, according to its Form 10-K. *See* Am. Cplt., at ¶ 39 (Dckt. No. 35); *see also* Abbott 2021 Form 10-K, at 29 (31 of 95). Stateside, Abbott's sales of pediatric nutritional products saw a 10 percent increase year-on-year, climbing from $1.98 billion for 2020 to $2.19 billion for 2021. *See* Am. Cplt., at ¶ 38. Infant formula accounted for a slice of the pediatric nutritional products pie, and products from the Sturgis facility accounted for a smaller piece still.

Abbott is a dominant player in the infant formula market. In 2020, it controlled 40 percent of the U.S. market (valued at $3.9 billion). *Id.* at ¶ 41. One of Abbott's "crown jewels" is Similac, an infant formula with a nearly 90-year history. *Id.* at ¶ 40. Defendant Robert Ford, the president and CEO of Abbott, has touted Similac as a "market-leading infant formula brand." *Id.* at ¶ 41.

The U.S. infant formula market is highly concentrated. *Id.* at ¶ 42. Four companies – Abbott, Reckitt Benckiser Group's Mead Johnson & Company, Nestle Group's Gerber Products Company, and Perrigo Nutritionals – control 90 percent of the market. *Id.* The U.S. produces almost all formula consumed domestically (98 percent). *Id.* And strict regulations – set by the U.S. Food and Drug Administration – dissuade would-be competitors from entering the market. *Id.*

Abbott produces 40 percent of the nation's infant formula from just a handful of plants. *Id.* The company also has plants in Ohio and Arizona, but its facility in Sturgis, Michigan takes center stage in this litigation. *Id.*

Sturgis is a huge facility. The plant spans 787,000 square feet and sits on 94 acres. *Id.* at ¶ 162. To put that in perspective, Sturgis is the size of more than thirteen football fields. *Id.* Put thirteen Soldier Fields together, and you get Sturgis.

Sturgis makes nearly half of Abbott's U.S. formula. *Id.* at ¶ 42. In 2021, one in five formula-fed infants in the U.S. drank Sturgis-produced formula. *Id.* at ¶ 43.

Many infants consume Abbott formula through the Department of Agriculture's Special Supplemental Nutrition Program for Women, Infants, and Children ("WIC"). *Id.* at ¶ 44. WIC is a federally funded nutrition program for low-income families.

Nearly half (47 percent) of the 1.2 million babies who get formula through WIC are entitled *only* to Abbott's formula. *Id.* Abbott also promotes the use of its products at hospitals by making its products readily accessible to new parents. *Id.* at ¶ 45.

Infant Formula Regulations

As you might guess, the production of infant formula is heavily regulated, given how important formula is to the health of little people. The Food, Drug, and Cosmetic Act of 1983

(the "FDCA") protects consumers against food "prepared, packed or held under insanitary conditions . . . whereby it may have been rendered injurious to health." *See* 21 U.S.C. § 342(a).

The Food and Drug Administration supplements the FDCA with Current Good Manufacturing Practices ("CGMP"). *See* Am. Cplt., at ¶¶ 50–55 (Dckt. No. 35). The FDA has overarching CGMP regulations for food manufacturing, which are aimed at preventing contamination. *Id.* at ¶ 54.

The FDA has also promulgated infant formula-specific CGMP regulations. *Id.* at ¶ 50. Those CGMP regulations set forth "the minimum current good manufacturing practices that are to be used in, and the facilities or controls that are to be used for, the manufacture, processing, packing, or holding of an infant formula." *See* 21 C.F.R. § 106.5(a). The CGMP regulations lay out multiple processes that infant formula manufacturers must follow to prevent contamination.

For example, facilities "shall be maintained in a clean and sanitary condition." *See* 21 C.F.R. § 106.20(a). Employees "shall practice good personal hygiene to protect the infant formula against contamination," including by "[w]earing clean outer garments and, as necessary, protective apparel such as head, face, hand, and arm coverings." *See* 21 C.F.R. § 106.10(b)(1).

The FDA has promulgated recordkeeping requirements for infant formula manufacturers, too. *See* Am. Cplt., at ¶ 53 (Dckt. No. 35). After receiving a complaint showing a possible health hazard, a manufacturer must investigate. *Id.* And if manufacturers know (or have reason to know) about adulteration or misbranding of their infant formula, they must "promptly notify" the FDA. *Id.* at ¶ 56 (citing 21 C.F.R. § 106.150(a)).

Relevant to this case, the CGMP regulations include specific controls about preventing the adulteration of infant formula from bacteria – specifically, *Cronobacter* and *Salmonella*. *See id.* at ¶ 50.

Most people are probably familiar with *Salmonella*. That little fella is why some people frown when you want to eat raw (delicious) cookie dough. But *Cronobacter*, the bacteria at the heart of the recall here, may not ring a bell.

Cronobacter sounds like an ancient strain of a bacteria unearthed and awoken by accident from the primordial soup in an arctic ice block in a science-fiction movie. *Cronobacter* is a naturally occurring bacteria. *Id.* at ¶ 59. It can survive on almost any surface – *e.g.*, formula bottles or countertops – but it thrives in dry foods. *Id.*

Cronobacter infections are rare. *Id.* For most adults, *Cronobacter* is harmless. *Id.* But not for infants. *Id.*

Cronobacter infections can be deadly for babies. *Id.* Infants face a heightened risk if they are less than two months old, premature, immunocompromised, or low birthweight. *Id.* *Cronobacter* can lead to sepsis (a blood infection) or meningitis (swelling of the linings surrounding the brain and spinal cord). *Id.* The mortality rate for *Cronobacter*-induced illness is between 40 percent to 80 percent. *Id.* at ¶ 65. Survivors of *Cronobacter*-induced meningitis suffer lifelong mental and physical developmental delays. *Id.* at ¶ 64.

Powdered infant formula can become contaminated with *Cronobacter* in the home or in a processing facility. *See* CDC Webpage on *Cronobacter* (Dckt. No. 42-7, at 2 of 5). In the home, *Cronobacter* can live on surfaces such as kitchen counters or sinks, and in water. *Id.* If the formula touches a contaminated surface – *e.g.*, if a formula scoop is placed on an infected counter, and then touches formula – the formula can become infected. *Id.*

Cronobacter can enter factories on employees' hands or on the soles of their shoes. *See* Am. Cplt., at ¶ 62 (Dckt. No. 35). Formula powder can become contaminated if it touches an infected surface, or if the manufacturer uses compromised ingredients. *Id.* Because liquid

formulas receive certain processing treatments that powdered formulas do not, the risk of *Cronobacter* infection is higher for powdered infant formulas than for liquid ones. *Id.*

In 2014, the FDA promulgated CGMP regulations with testing requirements for *Cronobacter* and *Salmonella*. *Id.* at ¶ 63. Under the regulations, formula makers must test thirty or more samples in each lot or batch for *Cronobacter*. *Id.*

The FDCA provides a mechanism to enforce the CGMP regulations. *Id.* at ¶ 57. If manufacturers fail to comply with CGMP regulations, their formula will be considered adulterated under the FDCA. *Id.* (citing 21 U.S.C. §§ 350a(a)(3), 350a(b)(2); 21 C.F.R. §§ 106.1(a), 106.5(b)).

To ensure compliance with its regulations, the FDA periodically inspects infant formula manufacturing facilities. *Id.* at ¶ 68. The FDA memorializes any significant deviations from the relevant statutes in something called a "Form 483," which it shares with the inspected company's management. *Id.* at ¶¶ 69–70.

A Form 483 identifies any conditions that could violate the FDCA and related statutes. *Id.* at ¶ 69. The FDA does not typically publicize a Form 483. *Id.* at ¶ 71. But it requires the recipient to "respond to the FDA's observations within fifteen business days with a root cause analysis, impact assessment, and a set of corrective and preventative actions." *Id.*

If the FDA finds the response inadequate, it can issue a warning letter. *Id.* at ¶ 72.[1] For serious violations, such as intentional misconduct, data-integrity-related CGMP violations, and repeated, historical issues, the FDA will take serious action. *Id.* at ¶¶ 72–74. A company could

[1] While Form 483 reports are typically not disclosed publicly, the FDA makes warning letters available on its website. *See Warning Letters*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters (last visited July 20, 2026).

be forced to shutter its operations (in part or entirely) because of regulatory noncompliance. *Id.* at ¶ 74.

Failure to comply with federal regulations could spell the end to a company's participation in government programs like WIC, too. *Id.* at ¶ 79. To participate in WIC, infant formula manufacturers must comply with the FDCA. *Id.* (citing 42 U.S.C. § 1786(f)(15)).

FDA Advisory & Formula Recall

The scandal quickly grew, like *Cronobacter* itself.

The FDA turned up the temperature on Abbott in February 2022. On February 17, 2022, the FDA issued a release "advising consumers not to use Similac, Alimentum, or EleCare powdered infant formulas" originating from Abbott's Sturgis, Michigan plant. *Id.* at ¶ 184.

The FDA explained that it was "investigating consumer complaints" about *Cronobacter* and *Salmonella* contamination of formula produced at Sturgis. *Id.* According to the FDA, "[a]ll four cases related to these complaints were hospitalized and *Cronobacter* may have contributed to a death in one case." *Id.* The FDA added that it had launched an ongoing investigation, "along with the U.S. Centers for Disease Control and Prevention and state and local partners." *Id.*

The FDA revealed that it had inspected the Sturgis facility and uncovered several positive *Cronobacter* samples. *Id.* at ¶ 186. The agency stated that a "review of [Abbott's] internal records also indicate environmental contamination with *Cronobacter sakazakii* and the firm's destruction of product due to the presence of *Cronobacter*." *Id.*

The same day as the FDA advisory, Abbott announced a recall of its powdered infant formula. *Id.* at ¶ 360. In a press release, the company described the recall as "proactive" and

"voluntary." *Id.* Plaintiffs think that those descriptors are inaccurate – in reality, they say, Abbott only recalled the formula after "days of pressure from the FDA." *Id.* at ¶ 188.

The company's press release stated that Abbott had found *Cronobacter* "in non-product contact areas" but did not find evidence of *Salmonella*. *Id.* at ¶ 190. Abbott's press release did not mention that the FDA was conducting an onsite investigation at the Sturgis facility. *Id.* at ¶ 189. It also did not reveal what had prompted the FDA's investigation – namely, reported *Cronobacter* hospitalizations and a whistleblower complaint. *Id.*

After the recall, Abbott temporarily halted production at the Sturgis plant. *Id.* at ¶ 12. The closure contributed to a nationwide formula shortage, which had started because of supply chain issues related to COVID-19. *Id.*

The recall sent shockwaves through the market, and Abbott's stock prices took a tumble. *Id.* at ¶ 200. When the market closed on February 17, 2022 – hours before the FDA advisory and formula recall – Abbott's common stock was valued at $120.58 per share. *Id.* On February 18, Abbott's common stock closed at $117.79 per share. *Id.* It fell $3.79 per share. *Id.*

Also on February 18, Abbott issued a Form 8-K (*i.e.*, a regulatory filing about major events) confirming the recall. *Id.* at ¶¶ 195, 369. Abbott downplayed the impact of the recall in the filing. *Id.* at ¶ 195.

The Form 8-K stated that "Abbott will incur a one-time specified item in the first quarter 2022 for recall related expenses, including inventory destruction and other recall expenses." *Id.* The company added that it "d[id] not expect that these expenses will have a material impact on Abbott's consolidated financial statements." *Id.* The Form 8-K was signed by Defendant Robert Funck, the Chief Financial Officer of Abbott. *Id.* at ¶ 369.

In its Form 10-K (*i.e.*, the annual report) issued that same day, Abbott did not mention the recall or its impact on the company. *Id.* at ¶ 195. It also announced the issuance of quarterly dividends. *Id.*

Initially, analysts agreed with Abbott that the impact from the recall would be short-lived. *Id.* at ¶ 198. Analysts from Evercome ISI estimated that the recall impact would be "resolved in 3 months." *Id.* Analysts from RBC Capital similarly predicted that the impact would "likely [] be immaterial at the total company level." *Id.* The analysts credited Abbott's statements that it had only found *Cronobacter* in non-product contact areas and its assurance that the recall was "proactive" and "voluntary." *Id.* at ¶ 199.

As February marched on, the recall put Abbott under the microscope of the media and regulators. *Id.* at ¶ 196. On February 18, 2022, *Politico* reported that Abbott had received an initial complaint about *Cronobacter* in September 2021, meaning five months before the recall. *Id.* at ¶ 201.

On February 26, U.S. Senators Patty Murray and Bob Casey sent a letter to Abbott CEO Robert Ford, demanding that the company "hand over information and documents related to the company's sweeping infant formula recall last week." *Id.*

On February 28, the FDA provided a recall update. The FDA revealed that another infant had suffered a *Cronobacter* infection after exposure to powdered formula produced at the Sturgis facility. *Id.* at ¶ 202.

On March 22, 2022, Abbott issued an update on its website about the recall, explaining that no *Cronobacter* was found in the testing of its products distributed to consumers. *Id.* at ¶ 372. The update stated that *Cronobacter* was found only in non-product contact areas and did not match *Cronobacter* found from the reported cases. *Id.*

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

Abbott also touted that it had "already begun implementing corrective actions and enhancements" at Sturgis, such as beefing up finished product testing. *Id.* at ¶ 371. "Our actions include . . . [i]ncreasing our finished product testing, which already meets or exceeds regulatory requirements." *Id.*

Release of Form 483 Reports

The FDA completed its onsite inspection of the Sturgis plant in March 2022. Then, it released previously non-public Form 483 reports from its 2019, 2021, and 2022 Sturgis visits. *Id.* at ¶ 209.

As a reminder, after the FDA completes an inspection, the FDA issues a Form 483 report to give company management a heads-up about possible regulatory violations. *Id.* at ¶ 208.

In 2022, the FDA issued a Form 483 that noted a host of problems at the Sturgis facility. *Id.* at ¶ 209. During its 2022 visit, the FDA saw *Cronobacter* contamination in several infant formula production areas at Sturgis. *Id.* at ¶ 210. Its report stated that a "scoop hopper" – which "feed[s] scoops" that directly touch infant formula containers – tested positive for *Cronobacter*. *Id.* at ¶ 211.

According to the 2022 Form 483, Abbott's internal records showed that, between September 2019 and February 2022, the company had found *Cronobacter* in medium or high

care areas of formula production on eight occasions. *Id.* at ¶ 212. Abbott's records also showed that its packaged powdered infant formula tested positive for *Cronobacter* at least twice between 2019 and 2020. *Id.* at ¶ 213. Abbott destroyed formula after the *Cronobacter* contamination. *Id.* at ¶ 406. But it did not shut down Sturgis or determine the cause of the contamination. *Id.*

Further, the 2021 and 2022 Form 483 reports revealed that the FDA had observed water in the Sturgis facility. *Id.* at ¶ 214. Water is a problem because it allows *Cronobacter* to thrive. *Id.* The 2021 report detailed other safety lapses too, such as an improperly used forklift and ingredient pallets stored in improper places. *Id.* at ¶ 219. In total, it listed five "objectionable observations." *Id.* at ¶ 405.

The 2022 Form 483 stated that the FDA had observed employees handling formula, raw materials, packaging, and equipment without wearing "necessary protective apparel." *Id.* at ¶ 218. It also noted design and maintenance deficiencies with the dryers used in formula production. *Id.* at ¶ 216. And the 2022 report revealed that Abbott did not test retained samples from a lot of Similac formula after it received a consumer complaint about *Cronobacter* related to that batch. *Id.* at ¶ 217. This failure to test violated Abbott's internal policy. *Id.*

An earlier Form 483, from 2019, revealed that Abbott hadn't tested the minimally required representative sample of powdered infant formula at the final product stage and before production. *Id.* at ¶ 405.

The Form 483s were new to the public in March 2022. But within Abbott, executives already knew about the reports. The 2019 report was issued to "Patrick A. Cooper, Site Director." *See* 2019 Form 483 (Dckt. No. 42-14, at 2 of 3). The 2021 report was issued to "TJ Hathaway, Site Director." *See* 2021 Form 483 (Dckt. No. 42-16, at 2–4 of 5).

The complaint asserts that Defendant Lori Randall (a non-officer Abbott Nutrition executive) helped devise Abbott's response to the reports. *See* Am. Cplt., at ¶ 407 (Dckt. No. 35). Randall allegedly visited the Sturgis facility "frequently." *Id.* at ¶ 411. Corporate employees from Nutrition trekked from Columbus, Ohio to Sturgis about once a month. *Id.*

Likewise, Abbott had an internal audit team that visited plants about once a year. *Id.* at ¶ 413. The audit team tracked its visits – and any quality issues that it uncovered – through an internal system. *Id.*

The complaint alleges that senior management at Abbott would have known about the Form 483 reports and discussed Abbott's response. *Id.* at ¶ 408. Specifically, CEO Ford and CFO Funck would have received briefings about the "reputational risk" posed by the Form 483 reports. *Id.* at ¶ 409.

The Form 483s were old news to Abbott, but they were a revelation to the public in March 2022. The publicity caused Abbott's stock price to drop. *Id.* at ¶ 221. Abbott's price per share fell by $4.97 (or 4 percent) on the day of the release. *Id.* It slid from $121.89 per share at the close of trading on March 22 to $116.92 at close on March 23. *Id.*

Abbott kept up a positive front in light of the Form 483 reports. The day the reports went public, the company issued a statement noting that the "unique genetic makeup" of the *Cronobacter* found at the "non-product contact areas" of the Sturgis facility "did not match" the *Cronobacter* microbes in the reported cases. *Id.* at ¶ 223.

Abbott noted that no *Cronobacter* "was found in any of our testing of products distributed to consumers." *Id.* And it emphasized its commitment to upholding the "highest standards for manufacturing of all nutrition products." *Id.*

Analysts were unfazed by the Form 483 reports. In an April 2022 report, Cowen analysts estimated that Abbott would still deliver upon its full-year guidance, despite the downward tick in Nutrition sales. *Id.* at ¶ 224.

Days later, Abbott held its first-quarter earnings call. *Id.* at ¶ 226. CEO Ford assured investors that "testing of retained samples related to this recall action . . . have all come back negative" for *Cronobacter*. *Id.* Ford reiterated that there was "no genetic match between the strains of the bacteria identified in non-product contact areas of our facility and available samples obtained from customer complaints." *Id.*

The earnings call seemed to placate analysts, who looked favorably upon Abbott's outlook. *Id.* at ¶ 228. But things got worse for investors, not better.

Publication of October 2021 Whistleblower Complaint

On April 28, 2022, Congresswoman Rosa DeLauro publicized an October 2021 whistleblower complaint revealing unsanitary conditions at Sturgis. *Id.* at ¶ 229.

Congresswoman DeLauro stated that the report laid out "a damning list of allegations of wrongdoing at the factory." *Id.* News outlets – including *Politico* and *Food Safety News* – echoed Congresswoman DeLauro's concerns. *Id.* at ¶ 233.

In the report, the whistleblower alleged multiple violations of the FDCA and the infant formula CGMP regulations. *Id.* at ¶ 393. The whistleblower also sounded the alarm on violations of Abbott's own policies. *Id.* The alleged misconduct included: (1) releasing untested infant formula despite a significant risk of bacterial contamination, (2) concealing information about possible contamination from FDA inspectors in 2019, (3) falsifying records about testing, cleaning, and maintenance, (4) using lax cleaning procedures that allowed water

and mold to enter the formula production environment, and (5) failing to replace or repair damaged machinery. *Id.*

The whistleblower also alleged that Abbott knew about the alleged violations but hadn't tried to correct them. *Id.* at ¶ 396. According to the whistleblower, Abbott executives were concerned about sniffing out the rat, not about addressing the purported misconduct. *Id.* at ¶¶ 396, 402.

Specifically, the whistleblower stated that Abbott senior management – including the Individual Defendants in this lawsuit – knew about the allegations but did not take corrective action. *Id.* at ¶ 397. The whistleblower asserted that the company's "inaction is directly at odds with the mandate of Sarbanes-Oxley mandating adequate internal controls and the Department of Justice's policy mandating effective compliance program." *Id.*

Abbott responded to the release by stating that the whistleblower – a former employee – was "dismissed due to serious violations of Abbott's food safety policies." *Id.* at ¶ 234. The company followed that statement with an April 29 press release, which reiterated that *Cronobacter* was found in "non-product contact areas." *Id.* at ¶ 236.

Abbott's stock price fell by $4.51 per share (3.8 percent) after the report became public. *Id.* at ¶ 235. After closing at $118.01 per share on April 28, the stock price closed at $113.50 per share on April 29. *Id.*

White House Voices Concerns

The nationwide formula shortage became an issue of national concern, and the Biden administration entered the fray. *Id.* at ¶ 239.

The White House issued a statement on May 12, 2022, noting that various executive agencies "ha[d] worked diligently over the last few months to address the shortfall in infant

formula production while the Sturgis plant remains offline." *Id.* In a press conference the following day, the White House Press Secretary stated that the Sturgis recall had caused the shortage and that Abbott's "tainted formula" had "killed two babies." *Id.* at ¶ 240.

Abbott responded to the Press Secretary's comments with a flurry of tweets. *Id.* at ¶ 241. The tweets stated that the investigation "found no evidence that our formulas caused infant illnesses." *Id.* The company added that the *Cronobacter* "found in environmental testing during the investigation was in non-product contact areas of the facility and has not been linked to any known infant illness." *Id.*

Abbott ended the tweet storm with an emphatic conclusion: "formula from [Sturgis] did not cause these infant illnesses." *Id.*

On May 16, the FDA confirmed that the *Cronobacter* genotypes from the cases were "not necessarily matching what was in the plant," but stated that it was too early to know whether there was a causal connection. *Id.* at ¶ 244. The FDA also suggested that Abbott was overemphasizing the negative tests. In its view, "an overreliance on end product testing is not really the best way to assure food safety. It's really about process control." *Id.* at ¶ 246.

Department of Justice Consent Decree

On May 16, 2022 – the same day as the FDA statements – the U.S. Department of Justice filed a complaint against Abbott with a proposed consent decree. *Id.* at ¶ 248.

The DOJ wanted Abbott to take certain measures to increase safety and ensure compliance with FDA regulations. *Id.* at ¶¶ 248–49. It alleged that Abbott had violated the CGMP regulations for food manufacturing generally, along with the infant formula-specific regulations. *Id.* at ¶ 251.

The DOJ also alleged that Randall (again, a senior leader within the Nutrition division) had violated the FDCA. *Id.* at ¶ 414. In support of its request for injunctive relief, the DOJ pointed out that Abbott had not made "sustained corrections" after the 2021 and 2022 inspections. *Id.* at ¶ 252; *see also id.* at ¶¶ 417–18.

Abbott agreed to resolve the DOJ complaint through the consent decree. *Id.* at ¶ 253. The consent decree requires Abbott to notify the FDA of contamination and to store *Cronobacter* samples for three years. *Id.* Abbott also agreed to retain an outside expert to ensure that the Sturgis facility complies with FDA regulations. *Id.* The consent decree required the company to implement environmental monitoring and safety plans, as well as employee training programs. *Id.*

Abbott issued a press release on May 16 about the consent decree. *Id.* at ¶ 254. The company stated that it had already taken steps to address the FDA's concerns. *Id.* The release included a quote from CEO Ford, which read in part: "Our safety and quality processes meet even the toughest scrutiny and we're committed to continuously improving our processes and protocols." *Id.* at ¶ 255.

Abbott repeated its now-familiar line that the *Cronobacter* was located "in non-product contact areas of the facility and has not been linked to any known infant illness." *Id.* at ¶ 256. The press release also stated that the company did not expect the recall to impact its full-year guidance. *Id.* at ¶ 257.

The market responded favorably to the consent decree, because it provided a roadmap on how Abbott could restart production at Sturgis. *Id.* at ¶ 258.

A few days after entering into the consent decree, Ford (the CEO) wrote a *Washington Post* piece titled: "Abbott CEO: We're sorry about the formula shortage. Here's what we're

doing to fix it." *Id.* at ¶ 259. Ford repeated Abbott's refrain about the four sick children: "The data collected during the investigation, genetic sequencing, retained product samples and available product from the four complaints did not find any connection between our products and the four reported illnesses in children." *Id.*

Ford downplayed the regulatory aspect to the recall, referring to it as a "voluntary recall" that was "the right thing to do." *Id.*

Congressional Investigation into Abbott

On May 18, 2022, the Senate Finance Committee opened an investigation into Abbott. *Id.* at ¶ 433. Senator Ron Wyden, the chairman of the committee, wrote a letter to Ford. *Id.* Senator Wyden asked Ford a pointed question: whether Abbott had used billions of dollars in tax cuts to buy back shares, rather than to update and upgrade the Sturgis facility. *Id.*

In a congressional subcommittee public hearing on May 25, the FDA Commissioner explained that, during its inspection, the FDA had "contacted Abbott to ask the company to issue a voluntary recall." *Id.* at ¶ 263. The FDA Commissioner also stated that, although the FDA could not confirm that the "egregiously unsanitary conditions" at Sturgis caused the reported illnesses, the FDA could not "rule it out either." *Id.* at ¶ 262; *see also id.* at ¶ 267.

The Commissioner explained that "getting the Sturgis facility up and running safely was a top priority." *Id.* at ¶ 264. But the FDA "had no confidence in the integrity of the Abbott Quality Program at this facility." *Id.* Therefore, the FDA had initiated the consent decree proceedings. *Id.*

Defendant Christopher Calamari – president of Nutrition North America and senior vice president of U.S. Nutrition – also testified at the congressional hearing. *Id.* at ¶ 268. Calamari repeated Abbott's line that the "swabs that tested positive were from areas that do not come into

direct contact with production." *Id.* at ¶ 269. He said that Abbott "prioritizes compliance" and that the company spends "tens of millions of dollars on quality and maintenance." *Id.* at ¶ 436.

Calamari addressed the October 2021 whistleblower report, too. Calamari said that Abbott "became aware of the whistleblower complaint in the end of April [2022] when it was made public by Congress." *Id.* at ¶ 270; *see also id.* at ¶¶ 374–76. He added that Abbott "encourages employees to speak up" and has a "zero tolerance policy for retaliation." *Id.* at ¶ 436; *see also id.* at ¶ 374.

Still, Calamari apologized on behalf of Abbott, expressing the company's "extraordinary disappointment" about the shortage. *Id.* at ¶ 446.

Publication of February 2021 Whistleblower Complaint

In June 2022, investors caught wind that Abbott had received another whistleblower complaint. Worse yet, it showed that Abbott had known about the potential problems much earlier than previously believed.

Abbott received the other whistleblower complaint in February 2021. *Id.* at ¶ 273. The whistleblower made a complaint to OSHA in February 2021, and OSHA forwarded the complaint to Abbott and the FDA that month. *Id.* Abbott submitted a formal response two months later. *Id.*

The revelation of a whistleblower complaint from February 2021 pushed back the chronology of when Abbott first received notice of a potential problem. Abbott knew about potential problems as early as February 2021.

Putting that date in perspective, Congresswoman Rosa DeLauro publicized the October 2021 whistleblower complaint on April 28, 2022. *Id.* at ¶ 229. But in June 2022, investors learned that Abbott had learned about potential problems as early as February 2021.

According to Plaintiffs, the whistleblower report from February 2021 was old news to Abbott, but was a revelation to everyone else (except regulators). Abbott received the whistleblower report from OSHA in February 2021, and responded by April 2021. *Id.* at ¶ 392. But investors heard nothing about it until June 2022. *Id.*

The whistleblower complaint documented the whistleblower's firsthand observations about how Abbott's "practices violated laws, regulations, and other guidelines administered and enforced by the [FDA]." *Id.* at ¶ 393. The whistleblower also stated that he had "raised concerns" about the alleged violations. *Id.* The whistleblower provided a map and index to the allegedly unsafe conditions at Sturgis, too. *Id.* at ¶ 402. He also named individuals at Abbott who allegedly knew about the violations. *Id.* at ¶ 394.

Plaintiffs attempt to show that senior leadership at Abbott knew about the whistleblower complaint. To get there, Plaintiffs rely on a confidential source.

Taking a step back, the complaint relies on information from five confidential sources, who Plaintiffs call "FE1," "FE2," and so on (meaning Former Employee #1 and Former Employee #2). *See* Am. Cplt., App. C, Former Employee Key (Dckt. No. 235, at 237 of 237). Plaintiffs rely on those anonymous witnesses throughout the complaint. *See, e.g.*, *id.* at ¶¶ 66, 121, 131, 135, 136, 139, 140, 141, 142, 143, 144, 145, 146, 148, 152, 157, 162, 163, 209, 214, 216, 234, 314, 315, 318, 321, 323, 326, 330, 333, 342, 348, 352, 358, 363, 412, 413, 431, 437, 440, 441 (relying on FE1); *see also id.* at ¶¶ 108, 171, 400, 401, 402, 407, 408, 409 (relying on FE2).

By and large, Former Employee #1 described the conditions at the Sturgis plant, and Former Employee #2 described what senior leadership would have known. The other three former employees offered information about problems at Sturgis, too.

Plaintiffs rely on one of those unidentified former employees to establish that top brass at Abbott knew about the whistleblower complaint. The anonymous source opined that the whistleblower complaint likely would have made its way to the top at Abbott, including CEO Robert Ford. *Id.* at ¶ 400. The former executive stated that Christopher Calamari and Lori Randall (who have top roles within the Nutrition division) would have known about Abbott's strategy for responding to the complaint. *Id.* at ¶ 401. While Ford likely wouldn't have helped formulate the substantive response, he would have known about the nature of the allegations and Abbott's response. *Id.*

Abbott responded to the publication of the February 2021 whistleblower complaint by releasing a statement. Abbott said that it "believe[d] this to be a former employee who was dismissed due to serious violations of Abbott's food safety policies." *Id.* at ¶ 275.

ABC News pointed out that Calamari had not mentioned the February 2021 report at the May 2022 congressional hearing. *Id.* at ¶ 277. Congresswoman DeLauro again expressed her outrage. *Id.*

On the same day as the publicization of the February 2021 whistleblower complaint (meaning June 8, 2022), *Food Safety News* reported that the FDA had received consumer complaints about seven additional deaths of babies who consumed Sturgis-made formula. *Id.* at ¶ 278.

Once again, Abbott stock prices fell. *Id.* at ¶ 280. Common stock prices slid by $4.17 per share (*i.e.*, by 3.6 percent). *Id.* Prices slipped from $116.88 at close on June 7 to $112.71 at close on June 9. *Id.*

On June 10, 2022, another infant death was reported. *Id.* at ¶ 281. On June 22, the FDA announced that it was investigating the death. *Id.* The agency issued a press release reporting

that it had investigated a total of 129 complaints about Abbott formula products – 119 of which were reported post-recall. *Id.*

The Wall Street Journal ran stories about the status of the investigation. On June 23, 2022, the newspaper reported that, according to a report, *Cronobacter* had caused the death of one of the infants. *Id.* at ¶ 282.

The newspaper described the financial hit that Abbott had taken from the recall. Abbott's formula sales had taken a massive blow. The company's market share fell from 48% right before the recall to 28% by the week ending May 21, 2022. *Id.*

New York Times Report

In September 2022, the *New York Times* unleashed an investigative report with the headline: "How Abbott Kept Sick Babies From Becoming a Scandal." *Id.* at ¶ 283. The article explained that other babies had become sick or died after consuming Abbott's powdered infant formula in the past. *Id.* But Abbott had batted down bad press by taking a "scorched earth" approach to litigation. *Id.*

The journalist behind the article had spent months investigating Abbott. *Id.* at ¶ 285. He had asked an Abbott spokesman, Scott Stoffel, for comment in January 2022. *Id.* Stoffel provided a statement that Abbott's "products undergo rigorous quality . . . checks to ensure that they meet both the nutritional and safety needs of infants and children." *Id.*

The *New York Times* report caught the eye of Senator Elizabeth Warren. *Id.* at ¶ 287. She sent Abbott CEO Ford a letter asking for information about litigation and settlements involving Abbott Nutrition, dating back to 2003. *Id.* Senator Warren specifically asked for information on settlements about alleged *Cronobacter* infections from powdered infant formulas.

Id. at ¶ 288. Senator Warren criticized Abbott for "cut[ting] corners and operat[ing] under lax safety measures." *Id.*

Abbott Sales Slump & Leadership Shakeup

Remember, despite the negative attention, Abbott had not adjusted its outlook. But its third-quarter 2022 results saw a bigger-than-expected drop. *Id.* at ¶ 289.

Specifically, the company reported a 39.1 percent decline in total U.S. pediatric sales on an organic basis (or a 24.8 percent decrease on a reported basis). *Id.* Nutrition division sales fell 10.3 percent on an organic basis. *Id.* And Abbott's net earnings dropped 31.7 percent, sliding to $1.44 billion compared with $2.1 billion a year earlier. *Id.*

On Abbott's earnings call, Robert Funck (the CFO) confirmed that the shutdown of the Sturgis facility had "negatively impacted" organic sales growth. *Id.* at ¶ 290.

CEO Robert Ford revealed "leadership changes both at our Sturgis site and in our quality organization." *Id.* at ¶ 291. Ford did not provide specifics about the leadership shakeup. *Id.* But the complaint asserts that Abbott replaced the site director at Sturgis. *Id.* at ¶ 431.

Analysts responded negatively to Abbott's earnings report. *Id.* at ¶ 292. Wolfe Research and Goldman Sachs rated Abbott's stock poorly. *Id.* And Abbott's stock price took a tumble, sliding $6.87 per share (*i.e.*, a decline of 6.54 percent). *Id.* at ¶ 293.

The fourth quarter of 2022 did not see an uptick for Abbott. In its 2022 Form 10-K, the company reported $1.562 billion in domestic pediatric nutritional revenues for the 2022 fiscal year, compared with $2.192 billion the previous year (*i.e.*, a 28.7 percent drop). *Id.* at ¶ 302.

Abbott pinned the blame on the recall. The downslide "reflect[ed] the impact of the voluntary recall and production stoppage of certain infant powder formula products

manufactured at Abbott's facility in Sturgis, Michigan, partially offset by increased demand for Abbott's Pedialyte products." *Id.*

Abbott reported that operating earnings for its Nutrition division had slumped 60 percent. *Id.* It attributed the drop to "the impact of the voluntary infant product recall and manufacturing stoppage." *Id.* And the company reported $176 million of charges related to the voluntary recall in 2022, bringing the costs of the recall to nearly $900 million for the year. *Id.*

Abbott's Allegedly Misleading Statements

During the putative class period – meaning from February 19, 2021 to October 19, 2022 – Abbott made a number of public statements on its website. Plaintiffs allege that the statements were materially false or misleading. *Id.* at p.1 & ¶¶ 3, 19, 129.

Abbott posted a brochure on its website about its commitment to quality. The company stated that it was "dedicated to improving healthcare by providing high-quality, safe and effective products," which it "achieved through a commitment to quality and the continuing effectiveness of our quality management system to meet customer expectations and regulatory requirements." *Id.* at ¶ 313. The brochure also stated that Abbott "maintain[s] compliance with all laws, rules and regulations in every country in which we operate." *Id.*

Similarly, Abbott's website featured an infographic titled "The Abbott Quality Promise." *Id.* at ¶ 317. The Quality Promise included a number of statements that Plaintiffs view as false and misleading.

For starters, the Quality Promise stated: "Good nutrition is the foundation of a happy and healthy life. So, from our ingredients to our packaging, our employees are committed to bringing you safe, superior-quality products you can trust." *Id.* The Quality Promise also touted

Abbott's "high tech quality processes," which Abbott claimed "ensure safety and quality throughout every stage of the manufacturing process." *Id.* at ¶ 319.

Under a "Clean Facilities" header, the Quality Promise stated: "Our facilities are designed and maintained to the highest Good Manufacturing Practice standards, which are recognized globally. All employees follow strict hygiene measures, such as wearing specialized uniforms, facemasks and sanitized gloves." *Id.* at ¶ 322.

Under a header reading "Quality Checks," the Quality Promise stated: "Before releasing products for sale, we extensively test each batch to ensure it meets our quality standards, which are among the highest in the world. And, we ensure that our products comply with all global and local regulations." *Id.* at ¶ 325.

Abbott's website also includes a "Policy" section, which featured a description of its "Comprehensive Ethics and Compliance Program" during the class period. *Id.* at ¶ 327. Abbott claimed to have "established systems and processes for employees to ask questions and report suspected or actual violations of our Code, policies and procedures." *Id.* Under a header titled "Other Disclosures," Abbott asserted that it was "fully committed to delivering products with the highest standards of quality, safety, and performance." *Id.* at ¶ 329.

In addition to statements on its website, Plaintiffs allege that Abbott made false or misleading statements in its public filings with the SEC. *Id.* at ¶ 331.

One of the statements addressed the suitability of its manufacturing facilities. The company's annual reports in 2020 and 2021 stated that its "facilities are deemed suitable." *Id.* at ¶¶ 332, 362.

The Form 10-Ks also addressed the costs of regulation and the uncertainty of future compliance. "Abbott is subject to numerous governmental regulations and it can be costly to

comply with these regulations and to develop compliant products and processes. . . . [N]o assurance can be given that Abbott will remain in compliance with applicable FDA and other regulatory requirements once approval or marketing authorization has been obtained for a product." *Id.* at ¶¶ 334, 364.

CEO Ford and CFO Funck signed certifications attached to the 2020 and 2021 Form 10-Ks. *Id.* at ¶¶ 336, 366. They certified that the reports "d[id] not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made . . . not misleading." *Id.* According to Plaintiffs, Defendants filed similar certifications accompanying multiple Form 10-Qs throughout the class period. *Id.* at ¶¶ 338, 368.

Plaintiffs believe that the disclosures in Abbott's Form 10-Ks and Form 10-Qs during the class period "were materially false or misleading." *Id.* at ¶ 380. In their view, "Defendants failed to disclose material uncertainties and trends associated with Abbott's systemic quality control deficiencies in the production and manufacturing of its powdered infant formula then known to management that were reasonably likely to result in lawsuits and regulatory actions that would have a material effect on the Company's future operating results." *Id.* Plaintiffs also assert that Abbott failed to disclose its then-existing failure to comply with governmental regulations, in violation of SEC requirements. *Id.* at ¶¶ 382–83.

Plaintiffs take issue with Abbott's 2020 Global Sustainability Report, too. *Id.* at ¶ 339.[2] In that document, released on July 16, 2021, Ford wrote that Abbott's "purpose" was "helping people live healthier, fuller lives. We pursue this mission very deliberately through our business strategies and processes." *Id.*

[2] The Global Sustainability Report is an annual report about the company's environmental, social, and governance ("ESG") impacts. *See* Am. Cplt., at ¶ 339 (Dckt. No. 35). The report allows a company "to be more transparent about the risks and opportunities it faces." *Id.* at ¶ 339 n.12.

The report also addressed Abbott's Nutrition division: "Abbott's nutrition business ensures food safety through a tightly controlled manufacturing process that encompasses all steps from accepting materials from suppliers through to final product distribution. We monitor and verify microbiology, packaging integrity, and nutrient and lot control. We complete extensive finished product testing before releasing it for commercial distribution." *Id.* at ¶¶ 341, 345.

According to the Global Sustainability Report, "[e]very Abbott nutrition manufacturing operation is certified to local and globally recognized GMP and food safety standards." *Id.* at ¶ 345. The report touted Abbott's "well-established systems for ensuring that conduct at every level of the business conforms to our Global Infant Formula Marketing Policy, as well as the laws of the countries in which we operate." *Id.* at ¶ 347.

The Global Sustainability Report added that Abbott's operating businesses "perform[] internal quality audits in line with local regulatory requirements," and that the company "develop[s] correction plans to address any compliance issues" identified in the audits. *Id.* at ¶ 343. The report addressed Abbott's "Process for Reporting Concerns," including its goal of creating a retaliation-free environment. *Id.* at ¶ 349. "Abbott does not tolerate illegal or unethical behavior in any aspect of our business." *Id.*

Abbott released a second document with a similar-sounding name, the "2020 Sustainability Report Summary," in November 2021. *Id.* at ¶ 353. That report made representations about the safety of Abbott's manufacturing process for infant formula, echoing the representations in the earlier Global Sustainability Report. *Id.*

Abbott also posted its Code of Business Conduct on its website throughout the class period. *Id.* at ¶ 351. The Code included a subsection on "Product Quality." *Id.* "We produce and deliver safe, effective products that people trust. . . . We are committed to timely identifying,

evaluating, and addressing product safety issues. We . . . communicate with regulatory or public health agencies in the event of potential safety concerns." *Id.*

The complaint also alleges that Ford (the CEO) and Randall (the Division Vice President of Nutrition Quality Assurance) made other false or misleading statements.

In January 2022, Ford touted Abbott's "best in-class performance" at a JPMorgan event. *Id.* at ¶ 357. Ford stated that the company was in "great shape" across various sectors, including Nutrition. *Id.*

Randall made statements in a December 2021 article published in the magazine Quality Assurance and Food Safety. *Id.* at ¶ 355. Randall referred to Abbott's "best practices" for food manufacturing. *Id.* She stated that the company wants "everyone to be an advocate for food safety," emphasizing the importance of employees having "confidence in knowing that it's okay to speak up and say something." *Id.*

Post-Class Period Government Investigations

In January 2023, news broke that the DOJ's consumer protection arm was conducting a criminal investigation of Abbott related to the Sturgis shutdown. *Id.* at ¶ 295. An Abbott spokesperson stated that the company was "cooperating fully." *Id.* In its Form 10-K for the 2022 fiscal year, Abbott revealed that it had learned about the DOJ investigation in November 2022. *Id.*

The risks associated with the criminal investigation were nothing to sneeze at. Misdemeanor violations of the FDCA can result in fines of $100,000 per violation for an individual, and fines of $200,000 per violation for a corporation. *Id.* at ¶ 297. And if the DOJ found evidence of felony violations at Sturgis, Abbott could face fines of up to $500,000 per offense. *Id.* Individuals could go to prison, too.

Abbott's 2022 Form 10-K also revealed that an SEC investigation was underway. *Id.* at ¶ 299. Specifically, the annual report stated that it had received a subpoena from the SEC's Enforcement Division "requesting information relating to Abbott's powder infant formula business and related public disclosures" in December 2022. *Id.*

What's more, Abbott's 2022 annual report revealed an investigation by the Federal Trade Commission. *Id.* at ¶ 300. It stated that the company had received in January 2023 a "civil investigative demand from the United States Federal Trade Commission seeking information in connection with its investigation of companies who participate in bids for Women, Infants, and Children infant formula contracts." *Id.*

This Lawsuit

Plaintiffs, investors in Abbott, filed this putative class action against Abbott and four of its executives – Chief Executive Officer Robert Ford, Chief Financial Officer Robert Funck, Senior Vice President, U.S. Nutrition Christopher Calamari, and Division Vice President of Nutrition Quality Assurance Lori Randall. *See* Cplt. (Dckt. No. 1). The Court will refer to the four executives as the Individual Defendants.[3]

The amended complaint alleges securities fraud, so the Private Securities Litigation Reform Act ("PSLRA") governs. *See* 10/6/22 Order (Dckt. No. 8). The PSLRA requires publication of notice to putative class members before the appointment of a lead plaintiff. *See* 15 U.S.C. § 78u-4(a)(3). In line with the statutory requirements, Plaintiffs' counsel published a

[3] The Court noticed that the case caption includes a fifth individual on the second half of the "v.": Joseph Manning, Abbott Executive Vice President of Nutritional Products. *See, e.g.*, Am. Cplt., at 1 (Dckt. No. 35). The complaint includes one statement from Manning, a statement that "framed the recall as a proactive step to protect consumers." *Id.* at ¶ 194. But Manning is not listed as a Defendant within the amended complaint. There is no mention of Manning in the list of parties, and his name doesn't appear within the definition of the "Individual Defendants," either. *Id.* at ¶ 35 ("Defendants Ford, Funck, Calamari, and Randall are collectively referred to herein as 'the Individual Defendants.'"). The docket does not reflect service of process on Manning, either. So Manning isn't a party.

press release about the lawsuit on Business Wire. *See* Notice of Publication (Dckt. No. 9). They also notified members of the purported class about the deadline to file a motion to serve as lead plaintiff. *Id.*

KBC Asset Management NV and Quoniam Asset Management GmbH filed a motion for approval as Lead Plaintiffs. *See* Pls.' Mtn. for Approval (Dckt. No. 13). No one filed an opposition to the appointment, despite timely notice. So, the Court appointed KBC and Quoniam as Lead Plaintiffs. *Id.* It appointed Motley Rice LLC and Bernstein Litowitz Berger & Grossman LLP as Lead Counsel.

After the appointment, Plaintiffs filed an amended complaint. *See* Am. Cplt. (Dckt. No. 35). The punchline is that the complaint alleges securities fraud.

Plaintiffs claim that Defendants made false or misleading statements and omissions about material facts to keep the market in the dark about the gravity of the situation. *Id.* at ¶ 448. Plaintiffs allege fraudulent conduct, too. The complaint alleges that, when the truth finally came to light, Abbott's stock price dropped significantly, causing investors to suffer losses. *Id.*

The complaint includes three claims. The first claim is about Abbott's statements. The second claim is about Abbott's conduct. And the third claim is about vicarious liability.

The first claim falls under section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b), and Rule 10b-5(b), 17 C.F.R. § 204.10b-5(b). *Id.* at ¶¶ 462–69. Plaintiffs bring that claim against Abbott and all four Individual Defendants.

Count I alleges that Abbott and the executives "made various untrue and/or misleading statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading." *Id.* at ¶ 465. The complaint alleges that Defendants "deceive[d] the investing public" about

"Abbott's commitment and adherence to regulatory safety protocols in the production of infant formula, its compliance with CGMPs, and the unsanitary conditions at Sturgis." *Id.*

The second claim falls under section 10(b) of the Securities Exchange Act, too. *Id.* at ¶¶ 470–79. But it invokes two other subparts of Rule 10b-5. The second claim alleges fraudulent conduct in violation of Rule 10b-5(a) and Rule 10b-5(c). That's different than the first claim, which alleges fraudulent statements in violation of Rule 10b-5(b).

Count II alleges that Abbott and the four Individual Defendants "employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct that operated as a fraud and deceit upon Plaintiffs." *Id.* at ¶ 473. Once again, the complaint alleges that Defendants "deceive[d] the investing public" about "Abbott's commitment and adherence to regulatory safety protocols in the production of infant formula, its compliance with CGMPs, and the unsanitary conditions at Sturgis." *Id.*

Count II offers a long list of actions that Abbott allegedly took as part of its scheme to defraud investors. *Id.* at ¶ 474. By and large, the list describes how Abbott mishandled the Sturgis facility. Abbott allegedly kept false maintenance records, failed to maintain machinery, failed to plug water leaks, and so on. *Id.*

The third claim is only against the Individual Defendants only. *See* Am. Cplt., at ¶¶ 480–86 (Dckt. No. 35). Plaintiffs seek to hold the executives accountable through vicarious liability.

Count III alleges that the Individual Defendants violated section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), by using "their positions of control and authority as officers and/or directors of Abbott . . . to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of." *Id.* at ¶ 482.

Plaintiffs bring their claims on behalf of themselves and a proposed class consisting of "all those who purchased or otherwise acquired Abbott common stock between February 19, 2021 and October 19, 2022, inclusive, and who were damaged thereby." *Id.* at ¶ 455. The class definition excludes "Defendants, the officers and directors of Abbott at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which Defendants have or had a controlling interest." *Id.*

Abbott's stock took a beating during the proposed class period. On February 17, 2022 (hours before Abbott publicly announced the recall), Abbott's common stock closed at $120.58 per share. *Id.* at ¶ 449. On October 19, 2022 (the day after Abbott announced leadership changes at Sturgis and its worse-than-expected third-quarter earnings), Abbott's common stock closed at $98.11. *Id.* That's a fall of 18.6 percent. *Id.*

When it was all said and done, Abbott suffered a market capitalization loss of roughly $40 billion. *Id.*

Defendants moved to dismiss.

Legal Standard

A motion to dismiss under Rule 12(b)(6) challenges the sufficiency of the complaint, not its merits. *See* Fed. R. Civ. P. 12(b)(6); *Gibson v. City of Chicago*, 910 F.2d 1510, 1520 (7th Cir. 1990). In considering a Rule 12(b)(6) motion to dismiss, the Court accepts as true all well-pleaded facts in the complaint and draws all reasonable inferences from those facts in the plaintiff's favor. *See AnchorBank, FSB v. Hofer*, 649 F.3d 610, 614 (7th Cir. 2011). To survive a Rule 12(b)(6) motion, the complaint must provide the defendant with fair notice of the basis for the claim, and it must be facially plausible. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009); *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "A claim has facial plausibility when the

plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

Plaintiffs in securities fraud cases must overcome the heightened pleading standard of Rule 9(b). *See Cornielsen v. Infinium Cap. Mgmt., LLC*, 916 F.3d 589, 598 (7th Cir. 2019). Under Rule 9(b), a plaintiff must "state with particularity the circumstances constituting fraud." *See* Fed. R. Civ. P. 9(b). A plaintiff must allege the "who, what, when, where, and how" of the circumstances surrounding the fraud. *See Borsellino v. Goldman Sachs Grp., Inc.*, 477 F.3d 502, 507 (7th Cir. 2007) (citation omitted); *see also United States ex rel. Lusby v. Rolls-Royce Corp.*, 570 F.3d 849, 853 (7th Cir. 2009).

The purpose of this particularity requirement is "to discourage a 'sue first, ask questions later' philosophy." *See Pirelli Armstrong Tire Corp. Retiree Med. Benefits Trust v. Walgreen Co.*, 631 F.3d 436, 441 (7th Cir. 2011). "Greater precomplaint investigation is warranted in fraud cases," and for good reason. *See Ackerman v. Northwestern Mut. Life Ins. Co.*, 172 F.3d 467, 469 (7th Cir. 1999).

Accusing someone of fraud "can do great harm to the reputation of a business firm or other enterprise (or individual)." *Id.* What's more, "fraud is frequently charged irresponsibly by people who have suffered a loss and want to find someone to blame for it." *Id.*

A securities fraud claim also must clear the hurdle of the heightened pleading standard in the Private Securities Litigation Reform Act. For allegedly fraudulent statements, "the complaint shall specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." *See* 15 U.S.C. § 78u-4(b); *see also Smykla v. Molinaroli*, 85 F.4th 1228, 1235 (7th Cir.

2023). Under the PSLRA, "a suit must be dismissed unless the complaint shows that the forbidden intent is at least as likely as its absence." *Barry v. Cboe Glob. Markets, Inc.*, 42 F.4th 619, 622 (7th Cir. 2022).

The PSLRA raised the bar for scienter, too. "*Scienter* pleadings in securities fraud class actions must satisfy a heightened standard of plausibility." *Pension Tr. Fund for Operating Engineers v. Kohl's Corp.*, 895 F.3d 933, 936 (7th Cir. 2018) (emphasis in original). The PSLRA requires plaintiffs to "state *with particularity* facts giving rise to a *strong inference* that the defendant acted with the required state of mind." *See* 15 U.S.C. § 78u-4(b)(2)(A) (emphasis added).

Discussion

The motion to dismiss requires the Court to consider the alleged misrepresentations, omissions, and fraudulent conduct at a granular level. And there is a lot of ground to cover. The complaint spans hundreds of pages, and Defendants point to more than thirty statements that, in their view, cannot give rise to a claim. *See generally* Defs.' App'x (Dckt. No. 41-1).

That's a tall order. So, before embarking on the journey and getting into the specifics, the Court will begin with a general overview of the claims, the allegations, and the arguments.

As a reminder, the first two claims allege violations of section 10(b) of the Securities Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5, 17 C.F.R. § 240.10b-5. *See* Am. Cplt., at ¶¶ 462–79 (Dckt. No. 35). The third claim alleges control person liability under section 20(a) of the statute.

Section 10(b) makes it illegal to "use or employ, in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, or any securities-based swap agreement any manipulative or deceptive device or contrivance in

contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." *See* 15 U.S.C. § 78j(b).

The SEC fleshed out the meaning of section 10(b) when it adopted Rule 10b-5, and gave it teeth. The Rule has several subparts, and the different subparts cover different (but overlapping) types of fraudulent behavior.

Rule 10b-5(b) deals with false *statements*. Rule 10b-5(b) makes it unlawful to "make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading[.]" *See* 17 C.F.R. § 240.10b-5(b).

Rule 10b-5(a) and Rule 10b-5(c) deal with fraudulent *conduct*. *See* 17 C.F.R. § 240.10b-5(a), (c). Rule 10b-5(a) makes it illegal to "employ any device, scheme, or artifice to defraud." *See* 17 C.F.R. § 240.10b-5(a). And Rule 10b-5(c) prohibits "engag[ing] in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person." *See* 17 C.F.R. § 240.10b-5(c).

To bring a claim about a statement under Rule 10b-5(b), a plaintiff must allege (1) a material misrepresentation or omission (meaning a half-truth); (2) scienter (*i.e.*, a wrongful state of mind); (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation.[4] *See Stoneridge Inv. Partners, LLC v. Sci.-Atlanta*, 552 U.S. 148, 157

[4] As an aside, courts often refer to a misrepresentation or "omission" when describing the first element. *See, e.g.*, *Halliburton Co. v. Erica P. John Fund, Inc.*, 573 U.S. 258, 267 (2014) ("To recover damages for violations of section 10(b) and Rule 10b-5, a plaintiff must prove '(1) a material misrepresentation or omission by the defendant . . . .'"). That phraseology leaves a little something to be desired, because a pure omission can't give rise to a claim under Rule 10b-5. *See Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 260 (2024). Maybe courts could tighten the phraseology and refer to a misrepresentation or a "half-truth."

(2008); *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341 (2005); *In re Allstate Corp. Sec. Litig.*, 966 F.3d 595, 604 (7th Cir. 2020).

The same elements apply to claims about conduct under Rule 10b-5(a) and Rule 10b-5(c), with one caveat. Instead of a misstatement, a plaintiff must allege "acts that created a false appearance of fact in furtherance of the scheme, including making false statements." *See SEC v. Winemaster*, 529 F. Supp. 3d 880, 917 (N.D. Ill. 2021). Unlawful conduct under Rule 10b-5(a) and Rule 10b-5(c) can include "disseminating false or misleading information to prospective investors with the intent to defraud." *See Lorenzo v. SEC*, 587 U.S. 71, 79 (2019).

Viewed together, the subparts of Rule 10b-5 have a big footprint and cover a lot of terrain. The footprints overlap because Congress wanted to stomp out securities fraud. *See Lorenzo*, 587 U.S. at 79 ("These provisions capture a wide range of conduct. . . . [T]his Court and the Commission have long recognized considerable overlap among the subsections of the Rule and related provisions of the securities laws.").

The Exchange Act also creates vicarious liability for people who hold the reins of a company that violates the securities laws. "Section 20(a) creates vicarious liability for a person who actually or potentially controlled the primary violator's acts." *Foss v. Bear, Stearns & Co.*, 394 F.3d 540, 543 (7th Cir. 2005).

The statute provides that "[e]very person who, directly or indirectly, controls any person liable under any provision of this title or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person[.]" *See* 15 U.S.C. § 78t(a). It's called – as you might guess – control person liability.

Section 20(a) involves secondary liability, meaning that it needs to piggyback on a claim that establishes primary liability. A violation of section 10(b) and Rule 10b-5 "is necessary to

support a violation of section 20(a)." *See Pension Tr. Fund for Operating Engineers v. Kohl's Corp.*, 895 F.3d 933, 936 (7th Cir. 2018); *see also Pugh v. Trib. Co.*, 521 F.3d 686, 693 (7th Cir. 2008). No underlying violation, no vicarious liability.

Plaintiffs bring three claims. The first claim is about statements. The second claim is about conduct. And the third claim is about vicarious liability.

Specifically, Count I alleges that Defendants made false or misleading statements in violation of Rule 10b-5(b). Count II alleges that Defendants engaged in fraudulent conduct in violation of Rule 10b-5(a) and Rule 10b-5(c). Count III alleges that the Individual Defendants violated section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a).

Defendants argue that Count I fails to state a claim because the complaint does not allege misrepresentations of material fact. *See* Defs.' Mem. (Dckt. No. 41). That is, they challenge both the materiality and the falsity of the statements in question. Defendants also contend that some of the statements were opinions that cannot give rise to a claim.

Next, Defendants contend that Count II does not state a claim about fraudulent conduct. As they see things, the complaint alleges that the company mismanaged the Sturgis facility, which is not securities fraud.

To top it off, Defendants argue that the complaint fails to allege a strong inference of scienter as required by the PSLRA. *Id.* That argument applies to each of the first two claims, both of which fall under section 10(b) and Rule 10b-5.

Turning to the third claim, Defendants argue that there is no control person liability under section 20(a) because the complaint does not state a claim under section 10(b). *See* Defs.' Mem., at 10 n.4 (Dckt. No. 41). Put differently, Count III rises or falls with the other claims. Count III

can't stand on its own – it needs another leg to stand on. Count III survives if either Count I *or* Count II survives.

The Court will begin with the claim about the statements (Count I). The question is whether the complaint adequately alleges that Defendants made a false statement or omission (meaning a half-truth) about a material fact. That question includes a few subparts, such as whether the complaint alleges materiality and falsity.

Next, the Court will address the claim about the conduct (Count II). At that point, the Court will address the issue of scienter, which applies to each of the first two claims under Rule 10b-5. The last stop on the tour through the complaint will be the third claim, which alleges control person liability.

I. The Statements.

Defendants open with the argument that the complaint fails to state a claim about misrepresentations or half-truths about material facts. *See* Am. Cplt., Count I (Dckt. No. 35).

Defendants offer a number of reasons why, in their view, the allegations do not state a claim. First, Defendants believe that many of the statements are immaterial as a matter of law. Second, they argue that some of the statements were not false or misleading. Third, they contend that some of the statements were statements of opinion, not fact. And finally, Defendants argue that their SEC filings under Regulation S-K do not give rise to a claim. *See* Defs.' Mem., at 10, 23 (Dckt. No. 41).

The Court will consider each topic – meaning materiality, falsity, opinions, and Regulation S-K – in that order.

A. Materiality

The first issue is materiality. Basically, the question is whether the statements would be important to a reasonable investor. Defendants believe that many of the statements are immaterial as a matter of law.

"To prevail on a § 10(b) claim, a plaintiff must show that the defendant made a statement that was '*misleading* as to a *material* fact.'" *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 38 (2011) (quoting *Basic Inc. v. Levinson*, 485 U.S. 224, 238 (1988)) (emphasis in original). "[T]his materiality requirement is satisfied when there is a substantial likelihood that the disclosure of the omitted fact would have been viewed by the reasonable investor as having significantly altered the 'total mix' of information made available." *Id.* (cleaned up).

"An omission or misstatement is material if a substantial likelihood exists that a reasonable investor would find the omitted or misstated fact significant in deciding whether to buy or sell a security, and on what terms to buy or sell." *SEC v. Kameli*, 276 F. Supp. 3d 852, 862 (N.D. Ill. 2017) (quoting *Rowe v. Maremont Corp.*, 850 F.2d 1226, 1233 (7th Cir. 1988)); *see also Lowry v. RTI Surgical Holdings, Inc.*, 532 F. Supp. 3d 652, 660 (N.D. Ill. 2021) ("A misrepresentation is material if a reasonable investor would view it as significantly altering the total mix of information available and important to deciding whether to buy or sell a security.") (cleaned up).

The Supreme Court was "'careful not to set too low a standard of materiality' for fear that management would 'bury the shareholders in an avalanche of trivial information.'" *See Matrixx Initiatives*, 563 U.S. at 38 (quoting *Basic*, 485 U.S. at 231). Dumping an "overabundance of information" on investors would make "informed decisionmaking" harder, not easier. *See Basic*, 485 U.S. at 231.

Materiality is a "fact-specific inquiry" that "depends on the significance the reasonable investor would place on the withheld or misrepresented information." *See Basic*, 485 U.S. at 240. "This determination 'requires delicate assessments of the inferences a "reasonable shareholder" would draw from a given set of facts and the significance of those inferences to him, and these assessments are peculiarly ones for the trier of fact."' *SEC v. Bauer*, 723 F.3d 758, 772 (7th Cir. 2013) (quoting *TSC Indus., Inc. v. Northway, Inc.*, 426 U.S. 438, 450 (1976)).

Materiality depends on the facts, so "a materiality determination is rarely appropriate at the summary judgment stage, let alone on a motion to dismiss." *See Marks v. CDW Computer Centers, Inc.*, 122 F.3d 363, 370 (7th Cir. 1997); *Hedick v. Kraft Heinz Co.*, 2021 WL 3566602, at *7 (N.D. Ill. 2021) (Dow, J.) (opining that a securities fraud claim cannot be dismissed for lack of materiality unless the alleged misstatements or omissions are "so obviously unimportant to a reasonable investor that reasonable minds could not differ on the question of their importance") (citation omitted); *City of Sterling Heights v. Hospira, Inc.*, 2013 WL 566805, at *23 (N.D. Ill. 2013) (St. Eve, J.) ("Materiality is typically an issue to be resolved by the finder of fact.") (cleaned up).

But not always. Courts "can and have decided materiality as a matter of law when the facts allow." *See Silverman v. Motorola, Inc.*, 2008 WL 4360648, at *8 (N.D. Ill. 2008); *see also In re Midway Games Inc. Sec. Litig.*, 332 F. Supp. 2d 1152, 1164 (N.D. Ill. 2004) (collecting cases). It depends on the content of the statements themselves.

"While materiality is normally a question of fact reserved for the trier of fact . . . [a court] can resolve materiality as a matter of law when the information at issue is so obviously unimportant that reasonable minds could not differ." *See Smykla v. Molinaroli*, 85 F.4th 1228, 1236 (7th Cir. 2023); *Kuebler v. Vectren Corp.*, 13 F.4th 631, 638 (7th Cir. 2021); *TSC Indus.*,

426 U.S. at 450 (stating that a district court can decide materiality as a matter of law only if "reasonable minds cannot differ on the question of materiality").

Puffery is a classic example. A statement that amounts to "vague aspiration or unspecified puffery" is not material. *See Chandler v. Ulta Beauty, Inc.*, 2022 WL 952441, at *7 (N.D. Ill. 2022). Puffery can include "(1) indefinite predictions of growth; (2) optimistic rhetoric and hype; (3) subjective statements; and (4) vague statements." *See Van Noppen v. InnerWorkings, Inc.*, 136 F. Supp. 3d 922, 940 (N.D. Ill. 2015).

"Puffing is '[t]he expression of an exaggerated opinion – as opposed to a factual misrepresentation – with the intent to sell a good or service.'" *United States v. Burns*, 843 F.3d 679, 684 (7th Cir. 2016) (quoting *Black's Law Dictionary* 1269 (8th ed. 2004)). Puffery "involves ambiguous and vague promises," and it "is nonactionable because no reasonable investor would rely on such empty superlatives." *Id*. (internal quotation omitted).

Fraud is about blowing smoke. Puffery is about blowing rainbows, sunshine, and hot air.

"Expressions of puffery and corporate optimism do not give rise to securities violations. Up to a point, companies must be permitted to operate with a hopeful outlook." *In re Synchrony Fin. Sec. Litig.*, 988 F.3d 157, 170 (2d Cir. 2021) (internal quotation omitted); *see also Boca Raton Firefighters & Police Pension Fund v. Bahash*, 506 F. App'x 32, 37 (2d Cir. 2012) ("The puffery designation, however, stems from the generic, indefinite nature of the statements at issue, not their scope. Otherwise, we would bring within the sweep of federal securities laws many routine representations made by investment institutions.") (cleaned up).

"Courts have held immaterial as a matter of law 'loosely optimistic statements that are so vague, so lacking in specificity, or so clearly constituting the opinions of the speaker, that no reasonable investor could find them important to the total mix of information available.'" *See In*

re Midway Games, Inc. Sec. Litig., 332 F. Supp. 2d 1152, 1164 (N.D. Ill. 2004) (citation omitted).

Hopes, dreams, goals, aspirations, visions, values, and principles rarely provide material information to reasonable investors. All too often, they hover at a high level of generality, without providing anything concrete or measurable. It's a lot of fluff, and not a lot of meat.

The complaint at hand includes allegations about dozens of statements. Defendants organize the statements by placing them into three buckets. The statements address: (1) product quality and safety; (2) regulatory compliance and broader company values; and (3) Abbott's manufacturing facilities and processes. *See* Defs.' Mem., at 11–17 (Dckt. No. 41).

At long last, the Court will dive in. The Court will reach into each bucket, one at a time.

1. Statements About Product Quality & Safety

Defendants begin with the statements about product quality and safety. Defendants believe that the statements are immaterial as a matter of law because they amounted to nothing more than "marketing rhetoric." *Id.* at 11. The statements in question come from Abbott's website, its Global Sustainability Report, and its Code of Business Conduct.

Language on Abbott's Website

To start, Defendants challenge allegations about the content of Abbott's website, which described the company's policies and priorities. *Id.*

The company stated: "At Abbott, we are dedicated to improving healthcare by providing high-quality, safe and effective products." *See* Am. Cplt., at ¶ 313 (Dckt. No. 35). Abbott added: "So, from our ingredients to our packaging, our employees are committed to bringing you safe, superior-quality products you can trust." *Id.* at ¶ 317. And then: "We produce and

deliver safe, effective products that people trust. We endeavor to maintain the highest level of quality throughout our business . . . ." *Id.* at ¶ 351.

That's a lot of squish. "[S]tatements describing a product in terms of 'quality' . . . are too squishy, too untethered to anything measurable, to communicate anything that a reasonable person would deem important to a securities investment decision." *City of Monroe v. Bridgestone Corp.*, 399 F.3d 651, 671 (6th Cir. 2005); *see also Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019) ("General statements about reputation, integrity, and compliance with ethical norms are inactionable 'puffery,' meaning that they are too general to cause a reasonable investor to rely upon them.") (citation omitted).

"[V]ague affirmations of safety . . . are immaterial puffery and opinion, nonactionable as a matter of law." *In re Boeing Co. Aircraft Sec. Litig.*, 2022 WL 3595058, at *9 (N.D. Ill. 2022). Investors are unlikely to get out their checkbooks and buy stock just because a company says that it makes safe products.

Critically, Abbott's statements on its website, such as those in its "Quality Promise," were not specific to Sturgis. The statements didn't mention infant formula, either. *See* Am. Cplt., at ¶¶ 313, 317, 319, 322, 329 (Dckt. No. 35) (not mentioning the Sturgis facility or infant formula).

Abbott made generalized statements about product quality and product safety that applied across *all* sectors of its business. And it's a humungous, global company. Lofty statements about the quality and safety of the company's products in general are not enough to give rise to a claim.

Abbott's Global Sustainability Report & Code of Business Conduct

The same goes for Abbott's statements about safety in its Global Sustainability Reports in 2020 and 2021, and in its Code of Business Conduct. *See* Am. Cplt., at ¶¶ 339, 343, 351 (Dckt. No. 35). Materiality is about meat, but the statements were cotton candy.

The 2020 Global Sustainability Report said that Abbott's "purpose" was "helping people live healthier, fuller lives." *Id.* at ¶ 339. Not a lot of people would run to their stockbroker after reading a sentence like that.

The 2021 Global Sustainability Report bonged the same empty drum. Abbott stated that "[o]ur purpose of enabling fuller lives through the power of health depends on trust, and trust in Abbott depends on our ability to consistently deliver safe, effective and high-quality products." *Id.* at ¶ 343 (emphasis removed). Abbott has models that "assess relevant quality and compliance risks," and the company "take[s] action when required." *Id.* (emphasis removed). That's not much of a news bulletin.

The Code of Business Conduct included fluffy puffy language, too. Abbott said that it "produce[s] and deliver[s] safe, effective products that people trust. We endeavor to maintain the highest level of quality throughout our business. . . . [D]elivering high quality is imperative every step of the way." *Id.* at ¶ 351 (emphasis removed). Abbott added: "our commitment to the health and safety of the people who use our products is always at the forefront of everything we do." *Id.* (emphasis removed).

Courts widely dismiss statements on materiality grounds if the statements merely convey aspirational goals for safety and compliance. *See, e.g.*, *Ong v. Chipotle Mexican Grill, Inc.*, 294 F. Supp. 3d 199, 232 (S.D.N.Y. 2018) (concluding that the statements that "Chipotle is 'committed to serving safe, high quality food to its customers' and that its 'food safety programs

are also designed to ensure that the Company complies with applicable federal, state and local food safety regulations'" were "inactionable puffery") (cleaned up); *Howard v. Arconic Inc.*, 395 F. Supp. 3d 516, 549 (W.D. Pa. 2019) ("Arconic's product-safety-specific statements in its 'EHS Principles' that 'we supply and use safe and reliable products and services' and 'we comply with all laws and set higher standards for ourselves and our suppliers where unacceptable risks are identified,' when read in context, are plainly aspirational goals for Environmental Health and Safety.") (cleaned up); *In re Lyft Inc. Sec. Litig.*, 484 F. Supp. 3d 758, 770–71 (N.D. Cal. 2020) (concluding that "generalized assertions about Lyft's commitment to safety, its safety measures, and the role safety plays in their rideshare market" were "aspirational, indicative of corporate optimism, and not actionable as material misstatements"); *Hall v. Johnson & Johnson*, 2019 WL 7207491, at *15 (D.N.J. 2019) (concluding that "general value-oriented statements regarding . . . commitment to customer safety" were mere puffery).

No reasonable investor would think that those generalized, squishier-than-Charmin sentences added anything of substance. General assurances of safety and product quality do not contribute anything of value to a reasonable investor when making investment decisions. *See Lowry*, 532 F. Supp. 3d at 660. Public relations fluff-puff about a commitment to product quality and safety does not move the needle on the market. *See In re Ford Motor Co. Sec. Litig.*, *Class Action*, 381 F.3d 563, 570 (6th Cir. 2004) ("All public companies praise their products and their objectives," so "a reasonable investor would not view [such praise] as significantly changing the general gist of available information[.]").

If you asked Corporate America for a show of hands, and asked CEOs whether they make safe and high-quality products, not a lot of executives would sit still. People would jump out of

their chairs, and wave their arms as if attempting to take flight. Everyone says that they make quality products, so a generic statement along those lines doesn't mean anything to anybody.

But some of Abbott's statements could give rise to a claim. Abbott's Global Sustainability Report, and the corresponding summary, touted the company's internal audit procedures at a more granular level. *See* Am. Cplt., at ¶¶ 343, 353 (Dckt. No. 35).

In relevant part, the Global Sustainability Report dated July 16, 2021, stated as follows: "Our audits assess internal processes, such as design, production processes, supply chain, data integrity, corrective and preventive actions (CAPA), and complaint handling. Each of our operating businesses also performs internal quality audits in line with local regulatory requirements and then highlights any findings in management reviews. We develop correction plans to address any compliance issues our audits identify." *Id.* at ¶ 343. The 2020 Sustainability Report Summary dated November 15, 2021, said basically the same thing. *Id.* at ¶ 353.

A reasonable investor could have taken Abbott's detailed statements about its internal auditing procedures into account. Abbott claimed to have a comprehensive internal procedure for weeding out regulatory noncompliance. An investor could consider that process when weighing the severity of the problem at Sturgis, even if the statement was not specific to the Sturgis facility per se. *See, e.g.*, *In re: Bofi Holding, Inc. Sec. Litig.*, 2016 WL 5390533, at *11 (S.D. Cal. 2016) (concluding that statements about internal controls were material); *City of Brockton Ret. Sys. v. Avon Prod., Inc.*, 2014 WL 4832321, at *16 (S.D.N.Y. 2014) (finding that statements about internal auditing procedures were not immaterial as a matter of law).

Defendant Randall's Statements in a Magazine Interview

Defendants also assert that statements by Lori Randall in a December 2021 magazine interview are immaterial as a matter of law. *See* Defs.' Mem., at 11 (Dckt. No. 41).

In that interview, Randall (a non-officer Nutrition executive) touted Abbott as "customer centric." *See* Am. Cplt., at ¶ 355 (Dckt. No. 35). She stated that the company "put[s] the customer first and see[s] the face of the customer when [] thinking about food safety." *Id.* Randall also emphasized Abbott's "best practices" and its "goal to have everyone be an advocate for food safety." *Id.*

Randall did not refer to Sturgis specifically. *Id.* (not mentioning "Sturgis" or "infant formula"). She used aspirational language about her hopes for Abbott's business.

Hearing that a company cares about its customers isn't exactly a lightning bolt of new information. It's more akin to rainbows and sunshine. It doesn't tell anyone anything. For that reason, general statements about focusing on the customer are mere puffery. *See, e.g.*, *Anastasio v. Internap Network Servs. Corp.*, 2010 WL 11459838, at *11 (N.D. Ga. 2010) (opining that the statement "Internap has always been a customer-centric company" was "[t]ypical of those statements that may be corporate optimism or puffery").

A reasonable investor would not have assigned any value to that broad language. No investor learns anything by hearing that a company cares about its customers and puts them first. Everyone says that, so no one says anything material.

In sum, Defendants' nonspecific statements about product quality and safety are immaterial and not actionable. Randall's aspirational language is immaterial as a matter of law, too. But Abbott's more detailed statements about its internal auditing procedures do have enough granularity to support a possible claim.

2. Statements About Regulatory Compliance & Broader Company Values

Next, Defendants take aim at statements about regulatory compliance, and other statements in Abbott's Code of Business Conduct. *See* Defs.' Mem., at 12–15 (Dckt. No. 41). The arguments about regulatory compliance and the code of conduct overlap. But they aren't the same. So, the Court will discuss them separately, in that order.

Regulatory Compliance

Defendants think that Plaintiffs have pointed to "immaterial statements concern[ing] compliance with ethics, policies, rules, or regulations." *See* Defs.' Mem., at 12 (Dckt. No. 41).

For instance, Abbott's website stated: "Before releasing products for sale, we extensively test each batch to ensure it meets our quality standards, which are among the highest in the world. And, we ensure that our products comply with all global and local regulations." *See* Am. Cplt., at ¶ 325 (Dckt. No. 35).

A brochure on the website highlighted the company's "dedicat[ion] to improving healthcare by providing high-quality, safe and effective products." *Id.* at ¶ 313. Abbott's Global Sustainability Report touted its "well-established systems for ensuring that conduct at every level of the business conforms to our Global Infant Formula Marketing Policy, as well as the laws of the countries in which we operate." *Id.* at ¶ 347.

"'General declarations about the importance of acting lawfully and with integrity' are inactionable puffery, especially when expressed in aspirational terms." *Plumber & Steamfitters Loc. 773 Pension Fund v. Danske Bank A/S*, 11 F.4th 90, 103 (2d Cir. 2021) (quoting *Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019)); *see also Boeing*, 2022 WL 3595058, at *19 ("[S]tatements about Boeing's 'core values' and similar affirmations of safety are just that kind of rosy affirmation that reasonable investors know are meaningless to the total mix of

information."). Statements using words such as "robust," "strong," "rigorous," and "effective" do not contain discernable standards and therefore are inactionable puffery. *See Lord Abbett Affiliated Fund, Inc. v. Navient Corp.*, 363 F. Supp. 3d 476, 487 (D. Del. 2019); *see also Phila. Fin. Mgmt. of S.F., LLC v. DJSP Enters., Inc.*, 572 F. App'x 713, 716 (11th Cir. 2014); *W. Palm Beach Firefighters' Pension Fund v. Conagra Brands, Inc.*, 495 F. Supp. 3d 622, 649 (N.D. Ill. 2020).

By contrast, statements could contribute something of value to an investor if they "specifically refer[] to present condition[s]" (depending on the statement). *See City of Sterling Heights*, 2013 WL 566805, at *23; *see also Silverman v. Motorola, Inc.*, 2008 WL 4360648, at *10 (N.D. Ill. 2008) (opining that "specific statements of present fact [] could be considered material").

One of the statements about regulatory compliance does clear the materiality bar (at least, at the pleading stage). Abbott's Global Sustainability report included a statement that Abbott had "well-established systems for ensuring that conduct at every level of the business conforms to our Global Infant Formula Marketing Policy, as well as the laws of countries in which we operate." *See* Am. Cplt., at ¶ 347 (Dckt. No. 35).

That statement was tied to infant formula, and it referred to the existence of systems for ensuring regulatory compliance. A reasonable investor could have relied on that statement when assessing the seriousness of the Sturgis problem. *See, e.g.*, *Ross v. Career Educ. Corp.*, 2012 WL 5363431, at *7–8 (N.D. Ill. 2012) (opining that statements "made in a context relating directly to regulatory compliance" could be materially misleading given the company's "poor compliance track record"); *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 251 (2d Cir. 2014) (explaining that "descriptions of pollution-preventing equipment and 24-hour monitoring teams

gave comfort to investors that reasonably effectively steps were being taken to comply" with applicable regulations). By referring to the Global Infant Formula Marketing Policy, the statement suggests compliance with infant formula-specific regulations.

Abbott's other statements fall into the category of aspirations. *See Plumber & Steamfitters*, 11 F.4th at 103. For example, Abbott stated that it "does not tolerate illegal or unethical behavior in any aspect of our business and . . . employees are required to ask questions and/or report any concerns." *See* Am. Cplt., at ¶ 349 (Dckt. No. 35); *see also id.* at ¶¶ 313, 325, 327, 349, 351.[5]

A reasonable investor would not have relied on the company's broad statements about complying with regulations and living up to ethical standards. It's not a revelation to anybody that a company does not tolerate illegal or unethical behavior. No one gets off the couch and buys securities on that basis.

General statements about doing a little good in the world and playing by the rules can't support a claim. They're too general, too vague, and too vapid to mean anything. *See, e.g.*, *In re Fifth Third Bancorp Derivative Litig.*, 2023 WL 2429009, at *21 (N.D. Ill. 2023) ("Statements about oversight programs designed to mitigate risks are general and aspirational, and therefore not actionable."); *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1321 (11th Cir. 2019) (Newsom, J.) ("Ocwen's . . . boasts that it was taking a 'leading role' and making 'progress' toward compliance are precisely the sorts of statements that our sister circuits have – we think correctly – deemed puffery and found immaterial as a matter of law."); *Veal v. LendingClub Corp.*, 423 F. Supp. 3d 785, 804 (N.D. Cal. 2019) ("[S]tatements touting LendingClub's focus on

[5] Defendants argue that some statements are immaterial as a matter of law both because they generally refer to product safety and because they're about regulatory compliance. *See* Defs.' Mem., at 11–12 (Dckt. No. 41). The Court declines to find that paragraphs 343 and 353 are immaterial as a matter of law under either category.

compliance, building trust with various stakeholders, and transparency are examples of corporate optimism and puffery."); *In re Braskem S.A. Sec. Litig.*, 246 F. Supp. 3d 731, 755 (S.D.N.Y. 2017) (concluding that statements about "integrity," "compliance with the laws," and commitment to "transparency and good corporate governance practices" were mere puffery).

Plaintiffs do not contend that the market reacted to these general statements, either. *Cf. City of Sterling Heights*, 2013 WL 566805, at *24 (concluding that a statement was not immaterial as a matter of law in part because the market reacted positively to it); *Van Noppen v. InnerWorkings, Inc.*, 136 F. Supp. 3d 922, 942 (N.D. Ill. 2015) (holding that statements were immaterial in part because the "[p]laintiff ha[d] not shown that the market reacted" to them); *Lowry v. RTI Surgical Holdings, Inc.*, 532 F. Supp. 3d 652, 660 (N.D. Ill. 2021) (observing that "reaction from the market may indicate materiality").

To sum up, the statement mentioning infant formula policy and regulations might be material. *See* Am. Cplt., at ¶ 347 (Dckt. No. 35). A reasonable investor might have considered that statement when making decisions about Abbott stock amidst the recall. But broader statements about the company's commitment to regulatory compliance in general are immaterial as a matter of law.

Broader Company Values

Defendants also challenge the materiality of statements that announced broader company values and ethical standards. Many of the statements appeared in Abbott's Code of Business Conduct.

A statement of values, without more, is not a guarantee or a representation of compliance. "[A] company's adoption and publication of a code of ethics does not imply that all of its

directors and officers are in compliance with that code." *Desai v. Gen. Growth Properties, Inc.*, 654 F. Supp. 2d 836, 859 (N.D. Ill. 2009).

Codes of conduct are "nonactionable when they are inherently aspirational or do not imply compliance." *See Flynn v. Exelon Corp.*, 2021 WL 1561712, at *9 (N.D. Ill. 2021). Put differently, "general prohibitions on employee behavior" do not constitute actionable statements. *See Heavy & Gen. Laborers v. Fifth Third Bancorp*, 2022 WL 1642221, at *18 (N.D. Ill. 2022).

However, "unqualified statements regarding [a] [c]ompany's conduct" are "out of the realm of nonactionable aspirational statements and in[] the realm of statements regarding the [c]ompany's conduct and impl[ying] compliance." *See Flynn*, 2021 WL 1561712, at *9; *see also Holwill v. AbbVie Inc.*, 2020 WL 5235005, at *4 (N.D. Ill. 2020).

Abbott's Code of Business Conduct begins with a note from its CEO, Robert Ford, that underscores the aspirational nature of the document. "Our Code lays out our values and our principles, so every Abbott person around the world understands the expectations and requirements that guide the actions we take on Abbott's behalf." *See* Code of Business Conduct, at 2 (Dckt. No. 42-19). Ford stated the importance of Abbott employees "hold[ing] [themselves] to the highest standards, to live up to our best ideals, and to operate our business with the utmost integrity at all times." *Id.*

A deeper dive into Abbott's Code of Business Conduct reveals general statements about safety and health. For instance: "We produce and deliver safe, effective products that people trust." *See* Am. Cplt., at ¶ 351 (Dckt. No. 35). And: "Our commitment to the health and safety of the people who use our products is always at the forefront of everything we do." *Id.* And: "We are committed to timely identifying, evaluating, and addressing product safety issues." *Id.*

Courts routinely dismiss claims based on general statements about compliance with ethical norms. *See, e.g.*, *Chandler*, 2022 WL 952441, at *8 (concluding that code of conduct statements – such as "[t]he [c]ompany is committed to dealing with customers fairly, honestly and with integrity" – were inactionable as a matter of law); *Heavy & Gen. Laborers*, 2022 WL 1642221, at *18 (concluding that code of conduct statements expressing "zero tolerance for internal fraud" and requiring employees to report fraud to the defendant company were immaterial as a matter of law); *accord Singh v. Cigna Corp.*, 918 F.3d 57, 63 (2d Cir. 2019); *Retail Wholesale & Dep't Store Union v. Hewlett-Packard Co.*, 845 F.3d 1268, 1276 (9th Cir. 2017).

As Plaintiffs rightly note, a statement isn't out of bounds in a securities-fraud case simply because it appears in a code of conduct. *See* Pls.' Resp., at 17–18 (Dckt. No. 43). A code of conduct isn't a safety zone when it comes to potential fraud claims.

Sometimes statements in a code of conduct can give rise to a claim. But most of the time, statements in a code of conduct are too general and too aspirational to support a claim. Cases that allow claims to survive typically involve statements with unqualified, categorical language (like "never" and "always"). *See, e.g.*, *Flynn*, 2021 WL 1561712, at *9 ("We *never* request, offer or accept any form of payment or incentive intended to improperly influence a decision.") (emphasis added); *Holwill*, 2020 WL 5235005, at *4 ("We *never* offer or provide anything of value to healthcare professionals or other individuals to inappropriately influence their medical judgment or purchasing or prescribing practices in favor of an AbbVie product.") (emphasis added); *In re Signet Jewelers Ltd. Sec. Litig.*, 2018 WL 6167889, at *17 (S.D.N.Y. 2018) (concluding that statements in a code of conduct that the company "bases . . . decisions *solely*" on merit were potentially actionable) (emphasis added).

Aspirational statements about complying with the law and delivering safe products are not material. Abbott's Code of Business Conduct is purely aspirational, and no reasonable investor would rely on those statements when making investment decisions. So the statements in question cannot give rise to a claim.

3. Statements About Manufacturing Facilities & Processes

Next, Defendants challenge the statements about Abbott's manufacturing facilities and processes. *See* Defs.' Mem., at 15 (Dckt. No. 41). Once again, Defendants contend that the statements are immaterial.

Defendants subdivide these statements into three categories: (1) manufacturing processes; (2) clean facilities; and (3) product testing. *Id.* at 15–16.

Manufacturing Processes

Defendants point to several allegations about manufacturing processes that they view as immaterial. *Id.* at 15 (citing Am. Cplt., at ¶¶ 319, 341, 343 (Dckt. No. 35)).

The Court has already addressed paragraphs 319 (immaterial as a matter of law) and 343 (arguably material).

Moving on, paragraph 341 contains a statement from Abbott's Global Sustainability Report about the Nutrition business. *Id.* at ¶ 341. The statement highlights how Abbott "ensures food safety through a tightly controlled manufacturing process." *Id.* It touts how Abbott "monitor[s] and verif[ies] microbiology, packaging integrity, and nutrient and lot control." *Id.* The statement explains that Abbott "complete[s] extensive finished product testing before releasing it for commercial distribution." *Id.*

The part of Abbott's statement about the "tightly controlled manufacturing process" is not "specific, measurable, or concrete." *See W. Palm Beach Firefighters' Pension Fund*,

495 F. Supp. 3d at 654. But things get more granular. Abbott refers to specific processes used in its manufacturing, such as "finished product testing." *See* Am. Cplt., at ¶ 341 (Dckt. No. 35).

At the pleading stage, the Court cannot conclude that these granular statements about manufacturing processes are immaterial as a matter of law. *See, e.g.*, *Johnson & Johnson*, 2019 WL 7207491, at *16 (concluding that statements "ostensibly meant to preclude investors and the public from second-guessing [the defendant's] approach to quality assurance and research" were arguably material); *Theodore v. Purecycle Techs., Inc.*, 2022 WL 20157415, at *10 (M.D. Fla. 2022) (opining that certain statements about testing and validation processes were not puffery).

In sum, Abbott's statement in paragraph 341 is arguably material to the extent that it refers to specific processes for product testing in the Nutrition business.

Clean Facilities

The next statements are about cleanliness.

Plaintiffs point to a slide on Abbott's website, entitled "The Abbott Quality Promise." *See* Am. Cplt., at ¶¶ 86–87 (Dckt. No. 35). The slide covered topics such as "Ingredients," "Manufacturing," and "Packaging and Distribution," with an assortment of bullet points appearing underneath.

It's a snazzy promo with plenty of cartoons adorning the slide. A cornucopia of fresh vegetables sits atop the "Ingredients" header. A pleasing-looking, tree-surrounded building with a slanted roof appears above the "Manufacturing" header. The "Packaging and Distribution" header appears below all sorts of eager, active-looking objects, like a truck, a forklift, a clock, and maybe a clipboard with a checklist.

Hovering above it all, a graceful field in the country appears at the top of the page, creating a placid rural aura. A sturdy farmhouse sits by a windmill and an oak tree, standing guard over the flowing fields of wheat or maybe soybeans. A glistening sun spreads sunshine and good cheer over the entire image, creating an all-American, down-home feel.

Abbott's "Quality Promise" begins with health and happiness. "Good nutrition is the foundation of a happy and healthy life." *Id.* at ¶ 86. Another platitude soon appeared. The company is "committed to bringing you safe, superior-quality products you can trust." *Id.*

Plaintiffs take issue with one of the bullets under the "Manufacturing" header. The slide included a subheading, "Clean Facilities." *Id.* And then, Abbott stated that its "facilities are designed and maintained to the highest Good Manufacturing Practice standards, which are recognized globally." *Id.* at ¶ 322. "All employees follow strict hygiene measures, such as wearing specialized uniforms, facemasks and sanitized gloves." *Id.*

In Defendants' view, no reasonable investor would interpret those statements to guarantee compliance given their context, meaning their appearance in a "consumer-marketing" Quality Promise.[6] *See* Defs.' Reply, at 5–6 (Dckt. No. 45). Defendants also point out that Abbott had experienced well-publicized regulatory issues in the past. Given that public

[6] Some courts have decided that statements were immaterial as a matter of law because the statements were promotional and appeared in consumer-facing documents and websites. *See, e.g.*, *In re Mylan Sec. Litig.*, 2023 WL 3539371, at *9 (W.D. Pa. 2023) (concluding that the fact that "alleged misstatements appeared on Mylan's general website, not its investor-relations page . . . suggest[ed] that investors visiting Mylan's website would view the information contained on the separate investor-relations page to have more value to them"); *In re Medtronic Inc., Sec. Litig.*, 618 F. Supp. 2d 1016, 1030 (D. Minn. 2009) ("No reasonable investor would rely upon these promotional phrases [on the company's website] in making investment decisions."). This Court is a bit skeptical of that distinction. After all, many consumers are investors. Plus, the Exchange Act doesn't categorically exempt consumer-facing documents from its reach. A consumer-facing document is not automatically in the safety zone. That said, Defendants are onto something when they point out the cartoonish-looking nature of the slide. A slide with cartoons isn't likely to inspire a lot of stock purchases.

knowledge, Abbott argues that "no reasonable investor would have understood Abbott's statement to say that such issues would never arise." *See* Defs.' Mem., at 16 (Dckt. No. 41).

By and large, the Court agrees with Defendants for a few reasons. A reasonable investor wouldn't have relied on the snippets on this slide when making investment decisions.

For starters, the statements in question were highly general. They weren't specific to the Sturgis facility. They didn't mention infant formula, or any product in particular. And they weren't describing a manufacturing process, either. The statements involved high-level affirmations that the company had clean facilities. No reasonable investor would read those statements and think that Abbott didn't have any issues at any of its plants.

In addition, investors knew that there was *some* risk that Abbott would face regulatory issues in the future. After all, Abbott had faced regulatory issues in the past. When regulatory issues are public knowledge, a statement about a company's "core values" – like a commitment to ensuring compliance – is not "relevant to the total mix of information." *See Boeing*, 2022 WL 3595058, at *19.

Investors knew that Abbott had faced regulatory challenges before, and so they knew that Abbott could face such issues again. A reasonable investor would not read the statements in question as some type of guarantee that Abbott would face no issues in perpetuity.

At bottom, the statements were little more than general quality assurances. The promotional statements "are just that kind of rosy affirmation that reasonable investors know are meaningless to the total mix of information." *Id.*; *see also City of Monroe Emp.'s Ret. Sys. v. Bridgestone Corp.*, 399 F.3d 651, 669–70 (6th Cir. 2005) ("Thus, federal courts everywhere have demonstrated a willingness to find immaterial as a matter of law certain kinds of rosy affirmation heard from corporate managers and numbingly familiar to the marketplace – loosely optimistic

statements that are so vague, and so lacking in specificity, that no reasonable investor could find them important to the total mix of information available.") (cleaned up); *Singh v. Cigna Corporation*, 918 F.3d 57, 63 (2d Cir. 2019) (holding that statements in a company's code of ethics are puffery because they are "too general to cause a reasonable investor to rely upon them"); *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 575 U.S. 175, 190 (2015) ("[A]n investor reads each statement within such a document, whether of fact or of opinion, in light of its surrounding text, including hedges, disclaimers, and apparently conflicting information.").

What's more, the statements on Abbott's website were not unqualified. In its Form 10-Ks, Abbott warned investors that "no assurance can be given that Abbott will remain in compliance with applicable FDA and other regulatory requirements . . . ." *See* Am. Cplt., at ¶¶ 334, 364 (Dckt. No. 35). "[A]n investor reads each statement . . . in light of its surrounding text, including hedges, disclaimers, and apparently conflicting information." *See Omnicare*, 575 U.S. at 190. So a reasonable investor wouldn't have relied on the general assurances about clean facilities in this glossy slide on Abbott's website. At the very least, a reasonable investor would have known that the statements were qualified by other statements in Abbott's SEC filings.

In sum, Abbott's statements about its clean facilities from the Abbott Quality Promise are immaterial as a matter of law.

Product Testing

Defendants believe that three paragraphs about product testing are immaterial. *See* Defs.' Mem., at 16–17 (Dckt. No. 41) (citing Am. Cplt., at ¶¶ 325, 341, 345 (Dckt. No. 35)). The Court has already addressed two of the paragraphs, meaning paragraphs 325 and 341.

The other one is paragraph 345. It contains an excerpt from Abbott's Global Sustainability Report. *See* Am. Cplt., at ¶ 345 (Dckt. No. 35). It states that "[e]very Abbott nutrition manufacturing operation is certified to local and globally recognized GMP and food safety standards." *Id.*

Paragraph 345 contains a specific, ascertainable assertion about Abbott's Nutrition business. It represented that Abbott had one or more certifications about food safety. That's a knowable fact, and potentially material. *See, e.g.*, *Johnson & Johnson*, 2019 WL 7207491, at *16.

* * *

This Court has poured through a number of statements and addressed whether they could alter the total mix of information for a reasonable investor. Materiality is one thing. Falsity is another. And that's the next issue.

B. Falsity

The next question is whether the complaint adequately alleges that the statements were false or misleading.

Defendants argue that the complaint has failed "to allege with particularity facts showing that any statement of fact was false or misleading." *See* Defs.' Mem., at 17 (Dckt. No. 41).

"In determining whether a statement is misleading, the Court considers the context in which the statement was made and must determine whether the facts alleged are sufficient to support a reasonable belief as to the misleading nature of the statement or omission." *See Hedick*, 2021 WL 3566602, at *4 (cleaned up); *see also Constr. Workers Pension Fund-Lake Cnty. & Vicinity v. Navistar Int'l Corp.*, 114 F. Supp. 3d 633, 651 (N.D. Ill. 2015) ("[C]ontext is the key to determining whether a statement was misleading.").

"[T]here is no 'fraud by hindsight.'" *Water Island Event-Driven Fund, LLC v. Trib. Media Co.*, 39 F.4th 402, 408 (7th Cir. 2022) (quoting *Denny v. Barber*, 576 F.2d 465, 470 (2d Cir. 1978) (Friendly, J.)). "The securities laws approach matters from an ex ante perspective[.] [A] statement true when made does not become fraudulent because things unexpectedly go wrong . . . ." *Pommer v. Medtest Corp.*, 961 F.2d 620, 623 (7th Cir. 1992).

"Even statements that are literally true can still be actionable under § 10(b) as misleading if they are susceptible to another interpretation by a reasonable investor." *Navistar*, 114 F. Supp. 3d at 651; *see also Arbitrage Event-Driven Fund v. Trib. Media Co.*, 2020 WL 60186, at *7 (N.D. Ill. 2020) (explaining that some statements can be misleading in context, even though they are "literally accurate"); *Kham & Nate's Shoes No. 2, Inc. v. First Bank of Whiting*, 908 F.2d 1351, 1357 (7th Cir. 1990) ("Few people pass out of childhood without learning fables about genies, whose wickedly literal interpretation of their 'masters'' wishes always leads to calamity.").

Put differently, "[t]he federal securities laws cover half-truths (and half-falsities). It is the difference between failing to tell your clerks that there is a tiger in the office, and telling your clerks that there is a cat in the office (which, it turns out, happens to be a tiger)." *Burke v. Nationstar Mortg., LLC*, 2022 WL 888811, at *19 (N.D. Ill. 2022).

In everyday life, a pure omission can be misleading. But "[section] 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011); *see also Gallagher v. Abbott Lab'ys*, 269 F.3d 806, 808 (7th Cir. 2001) ("[F]irms are entitled to keep silent (about good news as well as bad news) unless positive law creates a duty to disclose.").

"An omission is actionable only if disclosure of the omitted information was necessary to make statements made, in the light of the circumstances under which they were made, not misleading." *Goucher v. Iterum Therapeutics plc*, 648 F. Supp. 3d 962, 972 (N.D. Ill. 2022) (cleaned up); *see also Matrixx*, 563 U.S. at 44.

Defendants sort the statements into five buckets. *See* Defs.' Mem., at 18–21 (Dckt. No. 41). The Court will pour through each one, and will address whether the complaint alleges falsity.

Proactive, Voluntary Recall

The first batch of statements is about the recall. Plaintiffs allege that Abbott made false and misleading statements by characterizing the recall as "proactive" and "voluntary." *See* Am. Cplt., at ¶¶ 360, 369, 370 (Dckt. No. 35). Defendants believe that those statements were truthful. *See* Defs.' Mem., at 18 (Dckt. No. 41).

On February 18, 2022, Abbott issued an 8-K and announced a "proactive, voluntary recall of Similac-brand powder infant formulas manufactured in Sturgis, Michigan." *See* Am. Cplt., at ¶ 369 (Dckt. No. 35); *see also id.* at ¶ 360 (summarizing the press release dated February 17, 2022). Two months later, Ford characterized that action as a "voluntary recall" during an earnings call. *Id.* at ¶ 226. He doubled down in May 2022, calling it a "voluntary recall" in an op-ed in the Washington Post. *Id.* at ¶ 259.

But Abbott wasn't the only one who characterized the recall as voluntary, as the complaint itself concedes. On May 12, 2022, the White House released a statement describing Abbott's "*voluntary* recall of several lines of powdered formula." *Id.* at ¶ 239 (emphasis added).

Even the FDA characterized the company's decision as a voluntary act. During congressional testimony on May 25, 2022, the FDA Commissioner noted that the agency had

"contacted Abbott to *ask* the company to issue a *voluntary recall*." *Id.* at ¶ 188 (emphasis added); *see also id.* at ¶ 263.

It's hard to quibble with the statements that the recall was voluntary when even the White House and the FDA characterized the recall as voluntary. The federal government didn't think that those statements were false – after all, they said the exact same thing.

The complaint gives little reason to think that Abbott's statements were false. If anything, the complaint supports the notion that Abbott's statements were true.

In the alternative, Plaintiffs argue that the statements were misleading because the recall wasn't *proactive*, because the FDA had demanded the recall. *See* Pls.' Resp., at 21 (Dckt. No. 43).

In response, Defendants point out that the FDA's role wasn't a secret. Far from it. In fact, the FDA issued a press release about an "ongoing investigation" on February 17, 2022, the same day that Abbott announced the recall. *See* Am. Cplt., at ¶ 184 (Dckt. No. 35); *see also* Defs.' Mem., at 18 (Dckt. No. 41). So investors knew that the FDA was on the case.

As a starting point, Plaintiffs cannot bring a claim based on a pure omission, meaning a failure to disclose the existence of the FDA's investigation. Rule 10b-5(b) does not apply to pure omissions. *See Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257, 260 (2024).

There is no special exception for inspections. Abbott didn't have a duty to disclose preliminary investigations, non-final agency determinations, or inspections. *See City of Austin Police Ret. Sys. v. ITT Educ. Servs., Inc.*, 388 F. Supp. 2d 932, 947 (S.D. Ind. 2005); *see also Schaeffer v. Nabriva Therapeutics plc*, 2020 WL 7701463, at *9 (S.D.N.Y. 2020) ("Because a Form 483 is interim FDA feedback, there is no standalone duty to disclose its existence.");

McClain v. Iradimed Corp., 111 F. Supp. 3d 1293, 1304–05 (S.D. Fla. 2015) (describing a Form 483 identifying eight potential violations as "an inspector's observations during a routine inspection," and that defendants "were not required to prematurely disclose that the FDA might take action"); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015) ("Analogously, courts have held that there is no duty to disclose the results of FDA inspections that do not reflect final agency determinations.") (collecting cases); *FDA Form 483 Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions, (published Jan. 9, 2020) (explaining that "[t]he FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the [Food, Drug, and Cosmetic] Act or any of its relevant regulations").

Rule 10b-5(b) does apply to half-truths, meaning omissions that render statements false or misleading. *Id.* But it's hard to see how characterizing a recall as "proactive" was a half-truth. Abbott didn't suggest that the FDA wasn't involved. And Abbott didn't suggest that the FDA didn't play a role in Abbott's decision to recall the formula.

The word "proactive" doesn't mean "pressure-free." "Proactive" does not imply the non-involvement of the FDA.

If anything, it would be surprising if a food recall *didn't* involve the FDA someway, somehow. One would hope that the FDA is involved in a food recall.

Plus, investors weren't exactly kept in the dark about the FDA's involvement. On February 17, 2022, the same day that Abbott announced the recall, the FDA issued a press release about its ongoing investigation. *See* Am. Cplt., at ¶¶ 184–86 (Dckt. No. 35) (citing the FDA's press release).

The FDA used the blowhorn of a press release to announce its presence. And the market hears horns blown by regulators. Maybe Abbott's press release didn't mention the FDA. But the FDA made its involvement known, loud and clear.

"A plaintiff cannot credibly claim to be misled by a company's attempt to hide negative information when that same information is publicly available via alternate channels." *Chu v. Sabratek Corp.*, 100 F. Supp. 2d 827, 834 (N.D. Ill. 2000); *see also In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 540 (S.D.N.Y. 2015) ("Given this publicly available information, a reasonable investor had reason to know that the design of the Lemtrada clinical trials fell short of the FDA's gold standard."); *Goucher*, 648 F. Supp. 3d at 974 ("So, even if that the [New Drug Application] fell short of the FDA's gold standard, a reasonable investor had reason to know as much given Defendants' disclosures and the publicly available information set forth in the FDA guidelines.") (cleaned up); *Kleinman v. Elan Corp.*, 706 F.3d 145, 147–156 (2d Cir. 2013) (holding that a press release describing clinical trial results of an Alzheimer's disease drug as "encouraging" was not false or misleading despite the study's unreliable methods because "it is understood that those results are less significant and should therefore have less impact on investors" because the methodology conflicted with publicly available FDA guidance); *Garvey v. Arkoosh*, 354 F. Supp. 2d 73, 82 (D. Mass. 2005) ("[T]he presumption that the market price has internalized all publicly available information cuts both ways.") (quoting *Raab v. Gen. Physics Corp.*, 4 F.3d 286, 289 (4th Cir. 1993)).

In sum, Abbott's statement about a "proactive, voluntary recall" cannot give rise to a claim.

Non-Product Contact Areas

The next statements addressed where Abbott found *Cronobacter* at the Sturgis plant.

On February 17, 2022, Abbott issued a press release and announced the recall of the infant formula. Abbott represented that it had found *Cronobacter* "in non-product contact areas" of the facility. *See* Am. Cplt., at ¶ 360 (Dckt. No. 35). That phrasing suggests that the bacteria did not touch the formula.

One month later, on March 22, 2022, Abbott gave an update on its website. Abbott reiterated that it had found *Cronobacter* in "non-product contact areas at the Sturgis facility." *Id.* at ¶ 372.

In their motion to dismiss, Defendants point out that Abbott found *Cronobacter* on a non-contact part of a "scoop hopper." *See* Defs.' Mem., at 19 (Dckt. No. 41). So, in their view, the statements were not false or misleading.

In response, Plaintiffs do not take issue with where Abbott found *Cronobacter*. That is, they do not deny the literal truth of Abbott's statements. But they believe that the statements were false or misleading because they suggested that "Sturgis posed no real danger of contaminating the product." *See* Pls.' Resp., at 22 (Dckt. No. 43).

A positive *Cronobacter* sample came from a scoop hopper. *See* Am. Cplt., at ¶ 361 (Dckt. No. 35). A scoop hopper holds formula scoops. And the scoops go in formula cans.

The Form 483 states that the "clear cover of the scoop hopper" tested positive. *See* 2022 Form 483 (Dckt. No. 42-21, at 2 of 11). The cover does not make direct contact with the scoops. *Id.* But the scoops are inside the hopper. And the scoops directly touch formula.

To be sure, the Form 483 does not state that Abbott uncovered *Cronobacter* in a product contact area. So, Abbott's statements do not appear to be literally false.

Still, it is hard to say in the abstract that Abbott's statements were not misleading. The phrase "non-product contact areas" doesn't give a lot of information about how close the bacteria

was to the formula. It's possible to read that statement to suggest that the bacteria was not close to the food.

Investors could have found the statements misleading. At least one investor read Abbott's statement to suggest that the bacteria wasn't near the formula. Analysts from various firms emphasized Abbott's "assurance that there was no *Cronobacter* found near the finished infant formula." *See* Am. Cplt., at ¶ 199 (Dckt. No. 35).

Based on Abbott's statement, investors may have believed that the risk of *Cronobacter* contamination was lower than it really was. *Cf. W. Virginia Pipe Trades Health & Welfare Fund v. Medtronic, Inc.*, 57 F. Supp. 3d 950, 981 (D. Minn. 2014) (understating risks to inflate investor confidence could be misleading).

Proximity matters. There is a big difference between finding a cockroach in your basement, and finding a cockroach in your kitchen.

Imagine if you spotted a cockroach sitting on top of an open bag of Doritos on your kitchen counter during a barbecue. And then, imagine if you told the dinner guests that you spotted a cockroach, but didn't see it touching the food. A dinner guest might be nonplussed if you later revealed – as the guest munched away on the Doritos – that the cockroach was sitting on top of the bag. It's hard to swallow that type of news.

If a barista poured milk out of a jug that had *E. coli* on the outside of the jug, you probably wouldn't drink the latte. And you wouldn't hand a glass of milk to your kid, either.

Based on the complaint, it's difficult to sort out whether Abbott's statement was false or misleading. It would help to know more about the machinery, including the spatial proximity. More facts would help. So, at this early stage, this Court concludes that the complaint alleges a false or misleading statement about the scoop hopper.

Test Results

The next batch of statements involves Abbott's testing. The complaint alleges that Abbott misled the public about whether *Cronobacter* at the Sturgis plant caused the sickness in the children. *See* Defs.' Mem., at 19 (Dckt. No. 41).

When it announced the recall in February 2022, Abbott emphasized that "no distributed product ha[d] tested positive" for *Cronobacter*. *See* Am. Cplt., at ¶ 360 (Dckt. No. 35). The company stated that retained samples had tested negative, and that "Abbott's testing of finished product detected no pathogens." *Id.*

In March 2022, Abbott released a statement on its website that emphasized that the *Cronobacter* found at Sturgis "did not match" the *Cronobacter* from the reported cases. *Id.* at ¶ 372.

In May 2022, Abbott posted a series of tweets about the FDA investigation and the illnesses. *Id.* at ¶ 241. The company represented that a "comprehensive investigation by Abbott, FDA and CDC found no evidence that our formulas caused infant illnesses." *Id.* (emphasis removed). Abbott added: "Specifically CDC concluded its investigation with no findings of a link between our formulas and infant illnesses." *Id.*

Abbott then went a step further. Abbott affirmatively represented that the "formula from this plant did not cause these infant illnesses." *Id.* (emphasis removed).

The complaint fails to allege that Abbott's statements about the tests were false or misleading.

For starters, Plaintiffs do not seem to take issue with Abbott's early statements. That is, in February 2022, Abbott announced the recall and represented that it had not found *Cronobacter*

in the formula. Plaintiffs don't allege that Abbott actually *did* find *Cronobacter* in the formula, and thus lied to investors.

In a similar vein, in March 2022, Abbott represented that the *Cronobacter* at Sturgis did not match the bacteria in the cases with the sick children. Once again, Plaintiffs do not allege that the bacteria *did* match.

Instead, Plaintiffs point to Abbott's statements about the government's lack of evidence and lack of findings. Abbott represented that the FDA and the CDA had found no evidence of a connection between the *Cronobacter* at the plant and the illnesses of the children.

Abbott made a representation about a lack of evidence. So, to allege falsity, the complaint would need to come forward with facts suggesting that the FDA and the CDC *did* have evidence of a connection between Abbott's infant formula and the illnesses.

That is, a statement that the FDA and the CDC *didn't* have evidence could be false and misleading if those agencies *did* have evidence of a connection at the time. The existence of evidence could undermine a representation about a lack of evidence.

But that allegation isn't in the complaint. The complaint doesn't allege that the federal government found a connection at the time. Without it, the complaint does not plausibly allege that Abbott made a false or misleading statement about the lack of evidence.

Another statement is a closer call. On May 13, 2022, Abbott tweeted that the "formula from this plant did not cause these infant illnesses." *Id.* at ¶ 241 (emphasis removed).

In that statement, Abbott didn't simply say that the government had found no connection between the *Cronobacter* at the Sturgis plant and the infant illnesses. Instead, Abbott affirmatively represented that the formula didn't make the children sick.

The complaint doesn't allege falsity. Instead, it alleges that Abbott was more sure of a lack of a connection than the FDA. According to the complaint, the FDA had its doubts, and was unwilling to rule anything out.

Several allegations in the complaint addressed the uncertainty of regulators about whether the Sturgis plant had a connection to the sick children. For example, when asked about Abbott's statement that the plant didn't the cause the illnesses, the FDA Commissioner said that the FDA was yet not in a position to make any "definitive statements," given the "ongoing investigation." *Id.* at ¶ 244.

Dr. Susan Mayne, Director of the Center for Food and Applied Nutrition at the FDA, chimed in too. She commented that the FDA lacked "the evidence to demonstrate [] causality." *Id.* "[T]here are many factors involved in this investigation and we're just not in a position yet to make any definitive statements." *Id.* "So we simply don't have the evidence to demonstrate that causality, but again the data are so limited with sequencing available only for two out of the four cases." *Id.*

The FDA Deputy Commissioner also cautioned the public against reading too much into negative test results. *Id.* at ¶ 246.

Overall, Plaintiffs think that Defendants got ahead of themselves and over their skis by representing that the Sturgis plant didn't cause the illnesses.

Abbott didn't simply say that its formula didn't cause the illnesses, and leave it at that. Abbott provided a basis for its conclusion that the Sturgis facility wasn't to blame. Abbott tweeted that investigators had found *Cronobacter* in non-product contact areas of the facility. That is, they did find bacteria, but they didn't find bacteria in a part of the plant that came in contact with food.

Abbott made a statement about causation, and offered a basis for its assertion. An interpretation that is otherwise reasonable does not become false and misleading simply because parties dispute how to interpret data. *See Kleinman v. Elan Corp.*, 706 F.3d 145, 154 (2d Cir. 2013) ("[W]here a defendant's competing analysis or interpretation of data is itself reasonable, there is no false statement."); *see also In Re Philip Morris Int'l Inc. Sec. Litig.*, 89 F.4th 408, 424 (2d Cir. 2023).

Abbott offered its view on whether the company caused the illnesses, and it gave a reason for its position. Maybe the FDA and the CDC were unwilling to give Abbott a clean bill of health. But uncertainty by government regulators isn't enough to render Abbott's statement false and misleading. The complaint needed something more, but the complaint contains nothing else.

Congressional Testimony

The next batch of statements involves the congressional testimony by Calamari (a Nutrition executive) about the whistleblower complaint from October 2021.

Before diving in, here's a quick refresher on the two whistleblower complaints. There were two whistleblower complaints – the first from February 2021, and the second from October 2021. Each time, the whistleblower complained to the government, not to Abbott itself.

Abbott learned about the February 2021 complaint that month, and responded in April 2021. *See* Am. Cplt., at ¶¶ 99, 101 (Dckt. No. 35). Abbott learned about the October 2021 complaint in April 2022. *Id.* at ¶¶ 104, 229, 270, 375.

At a subcommittee hearing on May 25, 2022, a member of Congress asked Calamari about the October 2021 whistleblower complaint. *Id.* at ¶¶ 374–75. Representative Rice seemed to ask why no one used Abbott's internal process to blow the whistle, instead of going to the government.

Representative Rice asked: "[I]f you have what you're describing as a specific program to allow employees to go directly to someone within the company to register an issue with something that's going on in any one of your facilities, why didn't that happen here?" *Id.* at ¶ 374.

The complaint applies a heavy coat of gloss on that question. The representative seemed to ask why the whistleblower did not use Abbott's internal process to raise an issue. But the complaint characterizes the question as asking whether Abbott had knowledge of any whistleblower complaints before October 2021. Plaintiffs portray the question as asking about timing, meaning when Abbott first learned about the problem.

Calamari responded to the question by stating that the company didn't learn of the October 2021 whistleblower complaint until April 2022. He testified: "Abbott did not find out about it until . . . it [the whistleblower complaint] was made public [at] the end of April. And it was the – the particular individual who raised the complaint, it was their choice to use that mechanism to raise the complaint." *Id.* at ¶ 375 (brackets in the complaint).

In that answer, Calamari didn't say anything about the whistleblower complaint from February 2021. And he didn't reveal that the company knew about that first whistleblower complaint in April 2021, months before the whistleblower complaint in October 2021.

But again, Rule 10b-5(b) does not create a freestanding duty to disclose. *See Macquarie*, 601 U.S. at 260. It does prohibit half-truths.

Even so, it is a stretch to characterize Calamari's response as a half-truth. The representative did not squarely ask when Abbott first learned of a potential issue. She didn't ask if anyone came forward before October 2021, or anything along those lines.

Calamari testified that "Abbott did not find out about it" until April 2022. *Id.* at ¶¶ 374–75. The use of the word "it" leaves something to be desired. Based on the other statements, it appears that Calamari testified about the October 2021 whistleblower complaint, not Abbott's awareness of potential problems more generally. It requires too much interpretative gloss to read that statement as a representation that Abbott had no knowledge of any problems at the Sturgis facility or any whistleblower complaints until April 2022.

Overall, the question and answer are too muddled to give rise to a claim under Rule 10b-5(b). No reasonable investor would read that statement as a representation that Abbott first learned of problems in 2022.

Certification of SEC Filings

The next collection of representations came from Abbott's annual reports.

Ford (the CEO) and Funck (the CFO) submitted certifications with Abbott's Form 10-Ks in 2020 and 2021. They certified that, to the best of their knowledge, the filings did not "contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report." *See* Am. Cplt., at ¶¶ 336, 366, 388 (Dckt. No. 35).

According to Defendants, the complaint fails to allege facts showing that these representations were false. *See* Defs.' Mem., at 21 (Dckt. No. 41).

Taking a step back, in assessing the veracity of the certifications, what matters is what they knew at the time. That is, Ford and Funck's statements were misstatements only if they were aware of material misrepresentations in the Form 10-K filings at the time. *See Chandler*, 2022 WL 952441, at *22 (concluding that "even if [the defendant company's] filings did contain

material misrepresentations, it was not false for [the executives] to represent that they were unaware of any material misrepresentations"); *see also City of Roseville v. Horizon Lines, Inc.*, 686 F. Supp. 2d 404, 420 (D. Del. 2009) ("Officers . . . must certify that they *personally* have no knowledge of such misleading statements or omissions. Of course, this is not a license for executives to simply bury their heads in the sand, but it does mean they can only certify the truthfulness of their reports based on the information they know, or of which they should reasonably have been aware, at the time.") (emphasis in original); *New England Carpenters Guaranteed Annuity & Pension Funds v. DeCarlo*, 80 F.4th 158, 176 (2d Cir. 2023).

Turning to the underlying assertions within the 10-K filings, Plaintiffs point to one assertion that they think was false. They take issue with the representation that Abbott's manufacturing facilities were "deemed suitable" for their intended purposes. *See* Pls.' Resp., at 25 (Dckt. No. 43); *see also* Am. Cplt., at ¶¶ 366–67 (Dckt. No. 35).

Plaintiffs state that Ford and Funck knew that the Sturgis facility was not "deemed suitable." *See* Pls.' Resp., at 25 (Dckt. No. 43). But Plaintiffs have not pleaded facts suggesting that Ford and Funck viewed the facility as not suitable. *Cf.* Am. Cplt., at ¶¶ 336–37, 366–68 (Dckt. No. 35). So, the allegations are insufficient because they do not allege knowledge of a falsehood. *See, e.g.*, *Das v. Rio Tinto PLC*, 332 F. Supp. 3d 786, 812 (S.D.N.Y. 2018) (concluding that statements about certifications were not actionable when the plaintiff failed to show that the defendants had actual knowledge of the alleged falsehood).

To be sure, Ford and Funck knew about issues at Sturgis at the time of the 2021 Form 10-K report, which was filed the day after the announcement of the Sturgis recall. *See* Am. Cplt., at ¶ 366 (Dckt. No. 35). But the statements could not have misled investors, who already

knew about the recall and the FDA's involvement. *Id.* at ¶ 198; *see also Boeing*, 2022 WL 3595058, at *19.

In sum, the Court concludes that the certifications by Ford and Funck cannot give rise to a claim.

C. Statements of Opinion

The next group of statements involves opinions.

Again, Rule 10b-5(b) covers an untrue "statement of a material fact" and a half-truth about a "material fact" (meaning an omission that renders a statement misleading). *See* 17 C.F.R. § 240.10b-5(b). For present purposes, the key takeaway is that the rule covers facts.

"[A] sincere statement of pure opinion is not an 'untrue statement of material fact,' regardless of whether an investor can ultimately prove the belief wrong." *Societe Generale Sec. Servs., GbmH v. Caterpillar, Inc.*, 2018 WL 4616356, at *5 (N.D. Ill. 2018) (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 186 (2015)).

In *Omnicare*, the Supreme Court explained the difference between a fact and an opinion. "A fact is 'a thing done or existing' or 'an actual happening.' An opinion is 'a belief, a view,' or a 'sentiment which the mind forms of persons or things.' Most important, a statement of fact ('the coffee is hot') expresses certainty about a thing, whereas a statement of opinion ('I think the coffee is hot') does not." *See Omnicare*, 575 U.S. at 183 (cleaned up).

Under *Omnicare*, "an opinion statement can be actionable as misleading in three ways: (1) the speaker did not hold the belief professed; (2) the opinion statement contained supporting facts which were untrue; or (3) the statement omits material facts about the company's inquiry into or knowledge regarding a statement of opinion when 'those facts conflict with what a

reasonable investor would take from the statement itself[.]'" *Fryman v. Atlas Fin. Holdings, Inc.*, 2022 WL 1136577, at *14 (N.D. Ill. 2022) (citing *Omnicare*, 575 U.S. at 185, 189).

In short, opinions can give rise to a claim under Rule 10b-5(b), in limited circumstances. The question is whether any of the opinions at hand can thread the needle.

Ford's Statements at the JP Morgan Conference

Defendants challenge the allegations about the statements made by Ford at a JPMorgan healthcare conference. In their view, Ford offered opinions that cannot give rise to a claim. *See* Defs.' Mem., at 22 (Dckt. No. 41).

Ford made forward-looking statements and backward-looking statements. Looking forward, he swooned with optimism about the company's future prospects: "I think we are in a great shape with the businesses that we have." *See* Am. Cplt., at ¶ 357 (Dckt. No. 35). Looking back, Ford boasted about the company's "best-in-class performance" and growth in 2021. *Id.*

That cheerleading doesn't come close to providing the basis for a claim. At best, Ford offered lofty, jargony, shiny-happy-people business-speak.

The complaint contains no facts suggesting that Ford didn't believe those statements (such as they are). *Id.* at ¶¶ 357–58. The complaint doesn't allege that the opinions contained untrue statements, either.

Forward-looking, predictive statements aren't misleading simply because they prove to be wrong, either. CEOs and other corporate officers often express optimism about their companies' futures, but they don't have a crystal ball.

Executives don't violate the securities law by making incorrect predictions, unless they know that the predictions won't pan out. *See Water Island Event-Driven Fund*, 39 F.4th at 406 ("Securities law requires honest disclosures but not prescience or mind reading."); *Arazie v.*

Mullane, 2 F.3d 1456, 1468 (7th Cir. 1993) (opining that "predictions of future performance are inevitably inaccurate because things almost never go exactly as planned"). But "courts in this district have concluded that a plaintiff sufficiently alleges a forward-looking claim when defendants disclose goals that they know are not attainable." *Washtenaw Cnty. Employees' Ret. Sys. v. Walgreen Co.*, 2019 WL 4597518, at *4 (N.D. Ill. 2019).

Plaintiffs do not plausibly allege that Ford offered fake optimism, as opposed to misjudging the impact of the Sturgis problems on the company's bottom line.

The complaint also does not plausibly allege that Ford's backward-looking statements were false, either. That is, Plaintiffs do not contend that Abbott did not grow its market share in 2021. The complaint doesn't allege that Ford lied when he said that he was happy with the company's performance. In fact, the complaint suggests that Abbott's business performed well in 2021. *See* Am. Cplt., at ¶ 38 (Dckt. No. 35).

In short, Ford's musings at the JPMorgan conference cannot give rise to a claim.

Suitability of Facilities

The next statement is about suitability. Abbott's annual reports represented that "Abbott's facilities are deemed suitable and provide adequate productive capacity." *Id.* at ¶¶ 332, 362.

The parties disagree about whether statements about the "suitability" of Abbott's manufacturing facilities constitute facts or opinions. *See* Pls.' Resp., at 24–25 (Dckt. No. 43); Defs.' Reply, at 10 (Dckt. No. 45).

At this stage in the litigation, the Court cannot say, as a matter of law, that statements that Abbott's manufacturing facilities were "deemed suitable" are mere opinions. One wonders if suitability is a term of art, too. The complaint cites a regulation that uses that term, so maybe it

has a specialized meaning. *See* Am. Cplt., at ¶ 54 (Dckt. No. 54). "Appropriate quality control operations must be employed to ensure that food is *suitable* for human consumption and that food-packaging materials are safe and *suitable*." *See* 21 C.F.R. § 117.80(a)(2) (emphasis added).

Such statements could be opinions. *See, e.g.*, *Mylan*, 2023 WL 3539371, at *12–13 (concluding that a statement about the suitability of facilities was an inactionable "opinion about the physical characteristics of its manufacturing facilities"). Or maybe not.

However, as Plaintiffs point out, the language about the facilities was not couched in prefatory language putting it squarely into Opinion-Land. *Cf. Omnicare*, 575 U.S. at 183; *Stein v. U.S. Xpress Enterprises, Inc.*, 2020 WL 3584800, at *13 (E.D. Tenn. 2020).

At this early stage, the Court cannot conclude that the statement about suitability were inactionable opinions.

D. Regulation S-K

The next set of allegations is about Abbott's filings with the SEC.

Plaintiffs contend that Abbott failed to disclose information required by Regulation S-K when it filed its annual and quarterly reports. Specifically, Plaintiffs allege that Abbott didn't divulge information covered by Items 303, 105, and 307. *See* Am. Cplt., at ¶¶ 377–89 (Dckt. No. 35).[7] As Plaintiffs see things, Abbott's failure to disclose gives rise to a claim under Rule 10b-5(b).

Before digging in, this Court will briefly touch on Regulation S-K, and then will stroll through recent developments in the case law. Then, the Court will explore Plaintiffs' allegations about Items 303, 105, and 307, one at a time.

[7] The complaint references Item 503, not Item 105. *See* Am. Cplt., at ¶ 382 (Dckt. No. 35). The parties agree that the allegations relate to Item 105, which was previously numbered at Item 503. *See* Defs.' Mem., at 23 n.9 (Dckt. No. 41); Pls.' Resp., at 36 (Dckt. No. 43).

At a high level, Regulation S-K imposes reporting requirements for SEC filings by public companies. *See* 17 C.F.R. § 229 *et seq.*; *In re HEXO Corp. Sec. Litig.*, 524 F. Supp. 3d 283, 302 (S.D.N.Y. 2021) ("Regulation S-K is a set of rules that sets forth reporting requirements applicable to various filings under the Securities Act. . . ."); *see also In re CarLotz, Inc. Sec. Litig.*, 2024 WL 1348749, at *12 (S.D.N.Y. 2024) ("Regulation S-K imposes disclosure requirements on companies filing SEC-mandated reports, including registration statements.") (cleaned up); Thomas Lee Hazen, 2 LAW SEC. REG. § 9.40 (2023) ("As the basic disclosure guide, Regulation S-K must be consulted whenever filing documents with the SEC. Regulations [sic] S-K provides the explanations and guidelines that are necessary to complete the line-item disclosures on the various SEC forms required for public companies to file."). Basically, Regulation S-K tells companies what they must tell the public.

Public companies must make all sorts of public disclosures – after all, that's one of the reasons why they're called public companies. And Regulation S-K governs the type of information that companies must disclose.

Regulation S-K organizes the requirements into so-called "Items," which correspond with subsections of the regulation. So, for example, Item 105 governs risk factors, and appears at section 229.105 of the regulation. *See* 17 C.F.R. § 229.105. Item 303 applies to management's discussion of the company's financial condition and results (17 C.F.R. § 229.303), and Item 307 covers the company's disclosure controls and procedures (17 C.F.R. § 229.307). The term "Item" is simply a shorthand way to refer to a particular subsection of the regulation.

Regulation S-K comes into play as soon as a company registers securities with the SEC. From that moment forward, Regulation S-K's Items impose disclosure requirements on

registrants to include in their annual and quarterly filings (Forms 10-K and 10-Q, respectively). It covers other events, too, such as tender offers and notices of big events under Form 8-K.

Regulation S-K creates a duty to disclose, and thus a duty to speak. And that's where a potential claim under section 10(b) and Rule 10b-5(b) comes into play.

Until recently, there was a circuit split about whether a violation of Regulation S-K could give rise to a claim under section 10(b). Decades ago, then-Judge Alito explained for the Third Circuit that a violation of Item 303's "reporting requirements does not *automatically* give rise to a material omission under Rule 10b-5." *See Oran v. Stafford*, 226 F.3d 275, 288 (3d Cir. 2000) (Alito, J.) (emphasis added). Rather, Judge Alito wrote that an Item 303 violation cannot provide a basis for liability absent a separate showing of an "actionable misrepresentation or omission." *Id.* The Ninth Circuit and Eleventh Circuit adopted the Third Circuit's approach. *See In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1054 (9th Cir. 2014); *see also Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1331 (11th Cir. 2019).

The Second Circuit came out the other way. It concluded that "Item 303's affirmative duty to disclose in Form 10-Qs can serve as the basis for a securities fraud claim under Section 10(b)." *See Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 101 (2d Cir. 2015).

In 2024, the Supreme Court settled the split. It held that a failure to disclose information under Regulation S-K does not, in and of itself, state a claim under section 10(b). *See Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 601 U.S. 257 (2024). "Pure omissions are not actionable under Rule 10b-5(b)." *Id.* at 260.

In *Macquarie*, an investor sued a chemical company for not disclosing that its subsidiary's largest product (high-sulfur fuel oil) faced a worldwide ban. The complaint alleged that the company had an affirmative duty to disclose this risk to investors under Item 303 of

Regulation S-K. And the plaintiff claimed that the failure to disclose a risk as required by Item 303 was enough to state a claim under Rule 10b-5(b). *Id.* at 261–62.

The Supreme Court disagreed, holding that a failure to comply with Regulation S-K does not, in and of itself, give rise to a section 10(b) claim. The Supreme Court "confirm[ed] that the failure to disclose information required by Item 303 can support a Rule 10b-5(b) claim only if the omission renders affirmative statements made misleading." *Id.* at 265.

The Supreme Court fastened its ruling to the text of the rule. Rule 10b-5(b) makes it unlawful to "make any untrue *statement* of a material fact or to omit to state a material fact necessary in order to make the *statements* made, in the light of the circumstances under which they were made, not misleading." *See* 17 C.F.R. § 240.10b-5(b) (emphasis added).

The first half of the sentence refers to a "statement," and the second half of the sentence refers to an omission tied to "statements." *Id.* So the existence of a statement is a *sine qua non* of a claim under Rule 10b-5(b).

Rule 10b-5(b) "accomplishes two things." *See Macquarie*, 601 U.S. at 263. By covering untrue statements, Rule 10b-5(b) prohibits "false statements or lies." *Id.* And by covering omissions necessary to make a statement not misleading, Rule 10b-5(b) covers "half-truths." *Id.* That is, by prohibiting omissions tied to statements, Rule 10b-5(b) "requires disclosure of information necessary to ensure that statements already made are clear and complete." *Id.* at 264.

But "Rule 10b-5(b) does not proscribe pure omissions." *Id.* It doesn't create liability for saying nothing at all.

A pure omission isn't the same thing as a half-truth. "[T]he difference between a pure omission and a half-truth is the difference between a child not telling his parents he ate a whole cake and telling them he had dessert." *Id.*

"It once again bears emphasis that § 10(b) and Rule 10b-5(b) do not create an affirmative duty to disclose any and all material information. Disclosure is required under these provisions only when necessary to make statements made, in the light of the circumstances under which they were made, not misleading." *Id.* (cleaned up).

Silence, standing alone, is not actionable under Rule 10b-5(b). The fact that Regulation S-K might require disclosure does not mean that a pure omission is a violation of Rule 10b-5(b). "Even a duty to disclose, however, does not automatically render silence misleading under Rule 10b-5(b)." *Id.* at 265.

No statement, no claim. The "Sound of Silence" is an all-time-great song, but it cannot give rise to a claim under Rule 10b-5(b).

Regulation S-K creates a duty to disclose and thus a duty to speak. But a violation of Regulation S-K, standing alone, does not necessarily give rise to a claim under Rule 10b-5(b). It depends on whether the violation was a misstatement, an omission tied to a statement, or a pure omission.

A false statement in a filing can give rise to a claim. By the same token, "private parties remain free to bring claims based on [Regulation S-K] violations that create misleading half-truths." *Id.* at 266. But if the violation of Regulation S-K is a pure omission, it's not actionable under Rule 10b-5(b).

Macquarie provides the backdrop for the claims at issue here. Plaintiffs allege that Defendants failed to comply with Items 303, 105, and 307 under Regulation S-K. This Court will give each one a close look, with the benefit of the light shed by *Macquarie*.

Again, the question is not whether Defendants failed to disclose something required by Items 303, 105, and 307. The question is whether the would-be violations could give rise to a claim under Rule 10b-5(b). That is, the question is whether Defendants made a false statement or said half-truths in their filings required by Regulation S-K. Omitting something in a filing might be a problem, but it's not a *Rule 10b-5(b)* problem.

As an aside, Plaintiffs didn't make it easy to follow the thread about the alleged non-compliance with these Items. The complaint blends and blurs dates and events, and doesn't signpost for the reader. The complaint is 217 pages, and it's easy for a reader to lose the forest for the trees, even with a compass in hand.

Relevant allegations are sprawled across hundreds of paragraphs. To understand the story, a reader must wander here and there on a marathon march through 217 pages, and 486 paragraphs, in hopes of following the trail without losing the thread.

With that background in mind, it's time to look at Abbott's statements in response to Items 303, 105, and 307. Item 303 is about trends and uncertainties. Item 105 is about risks. And Item 307 is about internal processes for disclosures.

Item 303

Item 303 requires the disclosure of "known trends or uncertainties that have had or that are reasonably likely to have a material favorable or unfavorable impact on net sales or revenues or income from continuing operations." *See* 17 C.F.R. § 229.303(b)(2)(ii).

Plaintiffs allege that Abbott violated Item 303 by failing to disclose certain "trends and uncertainties" in its annual and quarterly filings (10-K and 10-Q forms, respectively). *See* Am. Cplt., at ¶ 380 (Dckt. No. 35). Plaintiffs say that Abbott knew about "systemic quality control deficiencies in the production and manufacturing of its powdered infant formula," but didn't say anything to anyone at any time. *Id.* at ¶¶ 380–81.

Plaintiffs don't allege that Abbott lied, or said something that was half-right and half-wrong. Instead, Plaintiffs claim that Abbott didn't disclose quality control issues in the first place.

That theory is going nowhere fast. In *Macquarie*, the Supreme Court "confirm[ed] that the failure to disclose information required by Item 303 can support a Rule 10b-5(b) claim only if the omission renders affirmative statements made misleading." *See Macquarie*, 601 U.S. at 265. "Pure omissions are not actionable under Rule 10b-5(b)." *Id.* at 266.

Plaintiffs bring a claim based on Abbott's silence, but Abbott's silence cannot give rise to a claim under Rule 10b-5(b). So Plaintiffs have no claim about Item 303 of Regulation S-K.

Item 105

The next Item is about risks. Item 105 requires the disclosure of "the material factors that make an investment in the registrant . . . speculative or risky." *See* 17 C.F.R. § 229.105(a).

At a high level, Plaintiffs allege that Abbott's 10-K filings "deceptively referred to ***potential risks*** . . . when, in fact, such risks were ***then existing*** due to Abbott's failure to comply with good manufacturing practices." *See* Am. Cplt., at ¶ 383 (Dckt. No. 35) (emphasis in original). According to Plaintiffs, Abbott knew about existing health and safety issues at the Sturgis facility, but only referred to "potential" risks in its disclosures. As Plaintiffs see things,

Abbott told half-truths by alluding to potential risks without disclosing the risks that already existed.

A statement about risks can give rise to a claim under Rule 10b-5(b). But it depends on what the statement says. It's one thing to say that a cabin in a parched area in the western United States faces a risk of fire. It's another thing to say that the cabin faces a risk when the cabin is already surrounded by a burning ring of fire.

Plaintiffs seem to rest their claim on the history of problematic inspections. And in particular, they point to the fact that the FDA had issued Form 483s.

Taking a step back, the FDA prepares a report called a Form 483 after it conducts inspections. "At the end of [an] inspection, the FDA issues a Form 483, which sets forth the observations of any conditions an FDA investigator believes constitute violations of laws or regulations." *Africano v. Atrium Med. Corp.*, 2021 WL 4940974, at *1 (N.D. Ill. 2021) (internal citation omitted); *see also* Am. Cplt., at ¶¶ 69–70 (Dckt. No. 35).

The FDA inspected the Sturgis facility several times, including an inspection in September 2019. After that inspection, the FDA prepared a Form 483 report that noted that Abbott had failed to ensure that the Sturgis facility met certain safety standards. *Id.* at ¶ 2. The FDA believed that Abbott had "deficiencies" in its infant formula safety testing process. *Id.* at ¶ 311.

The FDA inspected the Sturgis facility again in 2021, and yet again in 2022. After each visit, the FDA prepared another Form 483 report. The 2022 report contained particularly troubling observations. The FDA observed *Cronobacter* contamination in several infant formula production areas at Sturgis. *Id.* at ¶¶ 209–10. The FDA reported that a "scoop hopper" – a

device that "feed[s] scoops" that directly touch infant formula containers – tested positive for *Cronobacter*. *Id.* at ¶ 211.

According to the 2022 report, Abbott's internal records showed that, between September 2019 and February 2022, the company had found *Cronobacter* in medium or high care areas of formula production on eight occasions. *Id.* at ¶ 212. Abbott's records also showed that its packaged powdered infant formula tested positive for *Cronobacter* at least twice between 2019 and 2020. *Id.* at ¶ 213. And in September 2019 and June 2020, Abbott destroyed powdered infant formula made at Sturgis due to *Cronobacter* contamination. *Id.* at ¶ 2.

Meanwhile, Abbott filed 10-K disclosure forms in February 2021 and February 2022. *Id.* at ¶¶ 332, 362. Two statements jump out.

First, Abbott said that it "is subject to numerous governmental regulations and it can be costly to comply with these regulations and to develop compliant products and processes." *Id.* at ¶¶ 332, 362, 383 (emphasis removed from original).

That's true. Abbott is heavily regulated, and regulation is costly.

Second, and more importantly, Abbott said that "no assurance could be given that Abbott will remain in compliance with applicable FDA and other regulatory requirements once approval or marketing authorization has been obtained for a product. These requirements include, among other things, regulations regarding manufacturing practices . . . ." *Id.* at ¶¶ 332, 362, 383 (emphasis removed from original).

According to Plaintiffs, "Defendants were already aware that the Sturgis facility suffered from extensive manufacturing and quality control deficiencies" when Abbott made these disclosures. *See* Pls.' Resp., at 27 (Dckt. No. 43). Plaintiffs contend that Defendants'

"boilerplate" language was insufficient given that Abbott had already received a Form 483 that identified safety risks, and given that Abbott had already destroyed contaminated formula. *Id*.

In Plaintiffs' view, Abbott's disclosures contained half-truths. Abbott said that it could provide "no assurance" that it "will remain in compliance" with FDA standards. *See* Am. Cplt., at ¶¶ 332, 362, 383 (Dckt. No. 35). But Plaintiffs argue that Abbott was *already* not in compliance when it filed its disclosures. *Id.* at ¶ 335.

Plaintiffs hang their hat on the fact that the FDA prepared a Form 483 on a few occasions. And Plaintiffs rely on the fact that the bacteria made its way into the factory. By the sound of things, Plaintiffs equate the issuance of a Form 483 with a regulatory violation.

That's a bridge too far. Plaintiffs' theory overstates the importance of a Form 483. A Form 483 is not a finding by the agency that a company is out of compliance. It's not a declaration of a violation. A Form 483 report is not a final agency determination.

"In industry jargon, a '483' is an observation by an inspector, providing information about 'significant objectionable conditions' (not serious enough to merit a warning or any formal action by the agency) that the inspector believes will be useful to the company. The shorthand '483' derives from the fact that these observations are recorded on the FDA's Form 483." *See Plumbers and Pipefitters Local Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 679 F.3d 952, 956 (7th Cir. 2012).

The FDA's own website explains that "[t]he FDA Form 483 does not constitute a final Agency determination of whether any condition is in violation of the [Food, Drug, and Cosmetic] Act or any of its relevant regulations." *See FDA Form 483 Frequently Asked Questions*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/inspections-compliance-enforcement-and-criminal-

investigations/inspection-references/fda-form-483-frequently-asked-questions, (published Jan. 9, 2020). A Form 483 is more akin to a question mark than an exclamation point.

Abbott had no obligation to disclose that the FDA had issued Form 483 reports. "Because a Form 483 is interim FDA feedback, there is no standalone duty to disclose its existence." *Schaeffer v. Nabriva Therapeutics plc*, 2020 WL 7701463, at *9 (S.D.N.Y. 2020); *see also McClain v. Iradimed Corp.*, 111 F. Supp. 3d 1293, 1304–05 (S.D. Fla. 2015) (describing a Form 483 identifying eight potential violations as "an inspector's observations during a routine inspection," and that defendants "were not required to prematurely disclose that the FDA might take action"); *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 542 (S.D.N.Y. 2015) ("Analogously, courts have held that there is no duty to disclose the results of FDA inspections that do not reflect final agency determinations.") (collecting cases); *Anderson v. Abbott Lab'ys*, 140 F. Supp. 2d 894, 902 (N.D. Ill.), *aff'd sub nom. Gallagher v. Abbott Lab'ys*, 269 F.3d 806 (7th Cir. 2001).

Hypothetically speaking, a failure to disclose a Form 483 might give rise to a claim in limited circumstances. For example, if a company told investors that it was "substantially in compliance" with regulations, then a failure to disclose a recent Form 483 might give rise to a claim. *See Schaeffer*, 2020 WL 7701463, at *11 ("For example, failing to disclose a recent Form 483 that lists numerous potential cGMP violations could render misleading a company's statements that it is presently substantially in compliance with cGMP regulations."). "Similarly, if the FDA issued a Form 483 listing various concerns regarding a manufacturing facility, describing that as a 'good inspection' would probably mislead reasonable investors even if the concerns were ultimately remediable." *Id.*

That's not what happened here. Abbott did not tell investors that it was "substantially" in compliance with FDA regulations. And Abbott did not describe recent FDA inspections as "good." Abbott didn't say that the FDA had given it a clean bill of health.

Instead, Abbott merely told investors that it faced a potential risk of falling out of compliance in the future. Since the FDA had not concluded that Abbott was out of compliance at the time of the statements, Abbott did "not have a duty 'to disclose uncharged, unadjudicated wrongdoing."' *See City of Pontiac Policemen's & Firemen's Ret. Sys. v. UBS AG*, 752 F.3d 173, 184 (2d Cir. 2014) (quoting *Ciresi v. Citicorp*, 782 F. Supp. 819, 823 (S.D.N.Y. 1991), *aff'd without opinion*, 956 F.2d 1161 (2d Cir. 1992)).

Basically, the FDA raised concerns about Abbott's compliance, but that's it. The FDA did not make any findings about a violation, let alone take any final agency action.

There were clouds over the Sturgis facility, but not rain, and certainly not thunder.

Abbott did not guarantee that, at the time of the filing, the company fully complied with FDA regulations. Instead, Abbott explicitly warned investors that it faced a risk of non-compliance in the future.

Future-looking statements about possible risks typically do not give rise to a claim, so long as they do not deny the existence of past or present problems. *See Wochos v. Tesla, Inc.*, 985 F.3d 1180, 1195–96 (9th Cir. 2021) ("Plaintiffs contend that, by failing to disclose that some of these types of risks had *already* been experienced, Tesla's statements constituted misleading omissions about current or past challenges. But unlike the affirmative statements about 'backlog' figures at issue in the case on which Plaintiffs rely . . . these challenged statements contain no explicit or implicit representation that Tesla had *not* already experienced such issues.") (citation omitted; emphasis in original); *Bondali v. Yum! Brands, Inc.*, 620 F. App'x

483, 491 (6th Cir. 2015); *Kolominsky v. Root, Inc.*, 100 F.4th 675, 688–89 (6th Cir. 2024), *cert. dismissed sub nom. Plumbers Loc. 290 Pension Tr. v. Root, Inc.*, 145 S. Ct. 838 (2024); *Coll. Ret. Equities Fund v. Boeing Co.*, 2026 WL 891657, at *14 (N.D. Ill. 2026); *In re FBR Inc. Sec. Litig.*, 544 F. Supp. 2d 346, 362 (S.D.N.Y. 2008).

"Risk disclosures like the ones accompanying 10–Qs and other SEC filings are inherently *prospective* in nature. They warn an investor of what *may* come to their investment. They are not meant to educate investors on what harms are currently affecting the company. . . . For these reasons, a reasonable investor would be unlikely to infer anything regarding the current state of a corporation's compliance, safety, or other operations from a statement intended to educate the investor on *future* harms." *Bondali*, 620 F. App'x at 491 (emphases in original); *see also In re FBR Inc. Sec. Litig.*, 544 F. Supp. 2d at 362 (concluding that "cautionary statements are not actionable to the extent plaintiffs contend defendants should have disclosed risk facts 'are' affecting financial results than 'may' affect financial results.") (cleaned up); *Coll. Ret. Equities Fund*, 2026 WL 891657, at *14 ("Risk disclosure statements in SEC filings are inherently forward-looking. These statements are not actionable to the extent plaintiffs contend defendants should have disclosed risk factors 'are' affecting financial results rather than 'may' affect financial results.") (cleaned up).

Abbott did not make an "explicit or implicit representation" that it was not encountering risks at the time of the statement. *See Wochos*, 985 F.3d at 1195–96. Abbott did not say that it had no quality control issues at Sturgis. Abbott didn't represent that everything was A-OK.

Instead, the company simply represented that it could not guarantee future compliance with regulations. That's not enough to give rise to a claim under Rule 10b-5(b).

Item 307

One other Item remains on the table. Item 307 requires the disclosure of "the conclusions of the registrant's principal executive and principal financial officers, or persons performing similar functions, regarding the effectiveness of the registrant's disclosure controls and procedures." *See* 17 C.F.R. § 229.307.

Plaintiffs allege that CEO Robert Ford, CFO Robert Funck, and Abbott violated Item 307 by lying or misrepresenting that the company had effective disclosure controls. *See* Am. Cplt., at ¶¶ 385–86 (Dckt. No. 35); *see also* 17 C.F.R. § 240.13a–15(e). In several SEC filings, Ford and Funck each certified that they had "evaluated the effectiveness of Abbott Laboratories' disclosure controls and procedures" and that its "procedures were effective." *See* Am. Cplt., at ¶¶ 387–88 (Dckt. No. 35).

As Plaintiffs see things, Abbott did not have proper disclosure protocols because the company didn't disclose the issues with the Sturgis facility. *Id.* at ¶ 389. In their view, Ford and Funck couldn't have truthfully certified that the disclosure protocols were effective because they knew about those issues. *Id.* at ¶¶ 389, 397, 407–08.

Those allegations are too conclusory to support a claim. The complaint simply asserts that the controls "were poorly designed and 'ineffective' in assessing the risk of material misstatements." *Id.* at ¶ 387. But Plaintiffs do not offer any specifics about how the controls worked or why they were ineffective.

The Seventh Circuit has explained that a plaintiff cannot simply argue that "controls *must* have been weak *because* a fraud actually occurred." *See Pugh v. Trib. Co.*, 521 F.3d 686, 694 (7th Cir. 2008) (emphasis in original). Instead, plaintiffs must "stat[e] allegations about the existing or missing controls." *Id.*; *see also Hawaii Structural Ironworkers Pension Tr. Fund v.*

AMC Ent. Holdings, Inc., 422 F. Supp. 3d 821, 853 (S.D.N.Y. 2019) (rejecting plaintiffs' arguments about Item 307's "general requirement regarding review of disclosure requirements" because plaintiffs failed to connect the arguments to "actual knowledge of the specific facts relevant" to omissions); *Arora v. HDFC Bank Ltd.*, 671 F. Supp. 3d 305, 314 (E.D.N.Y. 2023) ("Conclusory allegations that a company made false or misleading statements that its controls were effective because a later-revealed instance of impropriety indicates otherwise – absent specific allegations about how or why those controls were ineffective – do not state a claim for securities fraud."). It is not enough to allege that something bad happened, so the controls must have been lax.

What's more, Plaintiffs failed to meet their pleading burden under Rule 9(b) by failing to plead *how* the controls were ineffective. *See Pirelli Armstrong Tire Corp. Retiree Med. Benefits Tr. v. Walgreen Co.*, 631 F.3d 436, 441 (7th Cir. 2011) (explaining that Rule 9(b) requires plaintiffs to plead the "who, what, when, where, and how" of fraud, or "the first paragraph of a newspaper story") (citation omitted).

To sum it all up, the complaint fails to state a claim under Rule 10b-5(b) based on Abbott's disclosures under Items 303, 105, or 307 of Regulation S-K.

* * *

At this juncture, this Court will offer a backward-looking statement and a forward-looking statement of its own. At long last, this Court has completed its journey through a tangle of statements by Abbott. This Court has addressed whether they can give rise to a claim under Rule 10b-5(b). That's Count I.

The next task is to walk through the allegations about the conduct, and consider whether they can support a claim under Rule 10b-5(a) and Rule 10b-5(c). So it is time to turn to Count II.

II. The Conduct

The second claim is about Defendants' conduct.

Plaintiffs allege that Abbott deceived investors through its actions, above and beyond its public statements. *See* Am. Cplt., Count II (Dckt. No. 35). As they see things, the conduct is an independent basis for liability under Rule 10b-5(a) and Rule 10b-5(c).

At this stage, the intrepid reader might appreciate a bit of a refresher (if not an intermission). Again, Rule 10b-5(a) and Rule 10b-5(c) deal with fraudulent *conduct*. *See* 17 C.F.R. § 240.10b-5. Rule 10b-5(a) makes it illegal to "employ any device, scheme, or artifice to defraud." *See* 17 C.F.R. § 240.10b-5(a). And Rule 10b-5(c) prohibits "engag[ing] in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person." *See* 17 C.F.R. § 240.10b-5(c).

The complaint alleges that Defendants engaged in a scheme to deceive investors about "Abbott's commitment and adherence to regulatory safety protocols in the production of infant formula, its compliance with CGMPs, and the unsanitary conditions at Sturgis." *See* Am. Cplt., at ¶ 473 (Dckt. No. 35). Plaintiffs point to several "deceptive activities." *Id.* at ¶ 474.

The complaint gives a laundry list of ways that Abbott and the Individual Defendants allegedly committed fraud. Some of the acts involve Abbott's dealings with the FDA. And some of the acts involve how Abbott operated the Sturgis facility.

Specifically, the basket of bad acts includes (1) refusing to destroy potentially contaminated formula; (2) deceiving FDA investigators; (3) falsifying records about testing, cleaning, and maintenance; (4) failing to upkeep machinery; (5) failing to address water leaks;

(6) fostering a culture of fear about retaliation for speaking up; (7) failing to staff the facility; (8) failing to modernize the plant; (9) failing to have procedures to ensure traceability of infant formula; (10) concealing the poor conditions at the plant; and (11) destroying evidence before the FDA's 2022 inspection. *Id.* at ¶ 474.

Basically, Plaintiffs allege that Abbott deceived the FDA and others by running Sturgis poorly and not telling anyone about it. As a result, news about Sturgis didn't come to light sooner, and investors were left in the dark. As Plaintiffs see things, the deceptive acts inflated the price of Abbott's stock, because the price would have fallen if investors had known the truth about the Sturgis facility. *Id.* at ¶¶ 475–77.

Count II fails for a few reasons.

First, the complaint does not allege fraudulent conduct in connection with the purchase or sale of a security. Second, Plaintiffs' theory of reliance is too remote to support liability. Third, Plaintiffs do not allege facts with particularity as required by Rule 9(b).

A. The "In Connection With" Requirement

The first problem is the lack of a connection to the purchase or sale of a security. The complaint describes deceptive conduct that has nothing to do with buying or selling securities. So it doesn't allege securities fraud.

The Securities Exchange Act is about – you guessed it – securities. The statute does not impose an all-encompassing prohibition on fraudulent behavior in every corner of the economy. Instead, the statute prohibits fraud in connection with the buying and selling of a security.

The statutory text makes this point crystal clear. In fact, the need for a connection to a security is one of the very first things mentioned in the statutory text. Congress had barely gotten warmed up before it penciled in the need for a connection to securities.

Section 10(b) makes it illegal to "use or employ, *in connection with the purchase or sale of any security* registered on a national securities exchange or any security not so registered, or any securities-based swap agreement any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." *See* 15 U.S.C. § 78j(b) (emphasis added).

The SEC reinforced the point in Rule 10b-5. The SEC made it unlawful "(a) [t]o employ any device, scheme, or artifice to defraud, (b) [t]o make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or (c) [t]o engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, *in connection with the purchase or sale of any security*." *See* 17 C.F.R. § 240.10b-5 (emphasis added).

Viewed together, the "in connection with" requirement is a pair of bookends. Section 10(b) of the Exchange Act starts with it, and Rule 10b-5 ends with it. From beginning to end, the point is clear: without a connection to a security, it's not securities fraud.

One could be forgiven for thinking that everything is securities fraud. *Read frequently* Matt Levine, *Money Stuff*, BLOOMBERG (2026). But it isn't. The Supreme Court made that point decades ago.

"Congress, in enacting the securities laws, did not intend to provide a broad federal remedy for all fraud." *Marine Bank v. Weaver*, 455 U.S. 551, 556 (1982). Instead, a section 10(b) claim requires a connection to the purchase or sale of securities. *See SEC v. Zandford*, 535 U.S. 813, 819–22 (2002).

The "in connection with" requirement is a relatively unexplored corner of securities law. "The requirement . . . that the prohibited conduct be 'in connection with the purchase or sale of any security' is not the least difficult aspect of the Rule 10b-5 complex to tie down." *See* Loss, Seligman, and Paredes, SECURITIES REGULATION, Ch. 9.B.7 (8th ed. 2025). Oftentimes, the connection is obvious, so the issue doesn't come up.

The leading case involved theft by a stockbroker. In *Zandford*, a stockbroker sold his customers' securities and used the proceeds for his own benefit without the customers' knowledge or consent. *See Zandford*, 535 U.S. at 815–16. The sale of the stock, in and of itself, wasn't unlawful. But the stockbroker misappropriated the proceeds for himself.

The Fourth Circuit held that the conduct was not "in connection with" the purchase or sale of a security. But the Supreme Court saw things differently, and reversed.

As a starting point, the Supreme Court acknowledged that "the SEC has consistently adopted a broad reading of the phrase 'in connection with the purchase or sale of any security.'" *Id.* at 820. The broad interpretation reflects the expansiveness of the text.

The statute has a long reach, but it doesn't touch everything. "[T]he statute must not be construed so broadly as to convert every common-law fraud that happens to involve securities into a violation of § 10(b)." *Id.*

Even so, the Supreme Court held that the stockbroker's conduct fell comfortably within the scope of the statute. The sale of the stock was not ancillary to the fraud. The sale of the stock was central to the fraud itself.

"The securities sales and respondent's fraudulent practices were not independent events. This is not a case in which, after a lawful transaction had been consummated, a broker decided to steal the proceeds and did so. Nor is it a case in which a thief simply invested the proceeds of a

routine conversion in the stock market. Rather, respondent's fraud coincided with the sales themselves." *Id.*

The stockbroker sold the stock for the purpose of stealing the proceeds. So "each sale was made to further [the stockbroker's] fraudulent scheme." *Id.*

The Supreme Court also highlighted that the stockbroker abused his position of trust as a fiduciary. He executed trades that were "neither authorized by, nor disclosed to," his clients. *Id.* at 821. The abuse of power posed a "threat to investor confidence in the securities industry." *Id.* at 822.

Overall, the sale of the stock – and the abuse of the position as a stockbroker – were more than enough to satisfy the statutory requirement of fraud "in connection with" the purchase or sale of a security.

In a later case, the Supreme Court explained that "it is enough that the fraud alleged 'coincide' with a securities transaction – whether by the plaintiff or by someone else." *See Merrill Lynch, Pierce, Fenner & Smith Inc. v. Dabit*, 547 U.S. 71, 85 (2006). "The requisite showing, in other words, is deception 'in connection with the purchase or sale of any security,' not deception of an identifiable purchaser or seller." *Id.* (cleaned up).

As the Seventh Circuit has explained, "[t]he Supreme Court . . . has treated the in-connection-with requirement as merely requiring a misrepresentation 'coinciding' with or 'touching' a securities transaction." *See United States v. Durham*, 766 F.3d 672, 682 (7th Cir. 2014).

"[T]here must be a *significant* connection between the fraud and a purchase or sale of securities." *See* Thomas Lee Hazen, 3 LAW. SEC. REG. § 12:20 (2026) (emphasis added). "In order to survive a motion to dismiss [a] plaintiff must allege facts sufficient to support a

conclusion the fraud, misstatement, or omission was in connection with a purchase or sale of security." *Id.*

In short, not all fraud is securities fraud. Rule 10b-5 doesn't reach any and all fraudulent behavior. The phrase "in connection with the purchase or sale of any security" does not cover anything and everything that might affect a company's bottom line or have an impact on its stock price.

The complaint at hand falls far short of satisfying the "in connection with" requirement. Plaintiffs allege a grab bag of deceptive conduct by Abbott. They point out that Abbott bungled the Sturgis plant in various ways, and neglected to run it properly. And they allege that Abbott concealed information from the FDA.

Noticeably missing from the laundry list of deceptive acts is any connection to the purchase or sale of a security. The acts have nothing to do with providing misinformation to investors, or misleading the SEC, or manipulating financial data, or anything along those lines. *See, e.g.*, *In re The Rsrv. Fund Sec. & Derivative Litig.*, 2012 WL 12356743, at *6 (S.D.N.Y. 2012) (concluding that plaintiffs satisfied the "in connection with" requirement by alleging that defendants "publicly disseminated" statements to investors, correlating "with substantial trading activity"); *SEC v. Winemaster*, 529 F. Supp. 3d 880, 922 (N.D. Ill. 2021) (holding that the "in connection with" requirement was met when defendants "misstated revenue numbers [that] would eventually reach investors").

Maybe Abbott didn't manage the Sturgis plant as it should have. But mismanagement of a manufacturing plant is not securities fraud. Concealing information from the FDA is not securities fraud, either. Neglecting water leaks is bad, but it doesn't violate the Exchange Act.

The statute and Rule 10b-5 require a nexus to securities, but the connection is noticeably absent here. The bad acts did not "coincide" with or "touch" the buying or selling of securities. *See Zandford*, 535 U.S. at 820–22; *Durham*, 766 F.3d at 682.

If anything, courts have dismissed claims with arguably stronger connections to securities than the allegations at hand. *See, e.g.*, *Levitin v. PaineWebber, Inc.*, 933 F. Supp. 325, 328 (S.D.N.Y. 1996) ("To satisfy this ['in connection with the purchase or sale'] requirement, the misrepresentation or omission must pertain to the securities themselves; allegations of fraud merely involving securities are not sufficient."); *Vekaria v. Mthree Corp. Consulting, Ltd.*, 2023 WL 6387275, at *7 (S.D.N.Y. 2023) (concluding that "claims predicated on allegations of fraud related only to the defendant's refusal to transfer promised shares" are "excluded from the ambit of Section 10(b)" because they fail to satisfy the "in connection with" requirement); *In re The Rsrv. Fund Sec. & Derivative Litig.*, 2012 WL 12356743, at *5 ("It is likewise clear, however, that under Section 10(b) 'the requirement of fraud in connection with the purchase or sale of a security is not satisfied by an allegation that plaintiffs were induced fraudulently not to sell their securities.'").

Admittedly, some courts have held that a scheme to defraud the FDA by falsifying data could give rise to liability under section 10(b). *See, e.g.*, *In re Able Lab'ys Sec. Litig.*, 2008 WL 1967509, at *21 (D.N.J. 2008) (falsifying test results and forging data to conceal noncompliance with FDA standards constitutes actionable conduct under section 10(b)); *Klein v. Altria Grp., Inc.*, 525 F. Supp. 3d 638, 665 (E.D. Va. 2021) (concluding that the plaintiffs adequately pled liability by alleging that the defendants submitted falsified data and studies to deceive the FDA); *In re Dentsply Sirona, Inc. Sec. Litig.*, 816 F. Supp. 3d 449, 487 (S.D.N.Y. 2026) ("Here, defendants' efforts to conceal thousands of injuries visible through the internal Trackwise system

from the FDA constituted a fraudulent scheme."). But none of those cases discussed the "in connection with" requirement in any level of detail.[8]

Plaintiffs make no attempt to connect the conduct to the purchase or sale of securities, except boilerplate. The complaint alleges that "[t]hese deceptive acts were part of a course of conduct that operated as a fraud and deceit upon Plaintiffs and others similarly situated in connection with their purchases of Abbott common stock during the Class Period in an effort to maintain artificially high market prices for Abbott common stock." *Id.* at ¶ 475.

By the look of things, Plaintiffs allege that Abbott's actions affected its stock price, and kept it at an artificially high level. Maybe so. But that's not enough to satisfy the "in connection with" requirement.

If any bad behavior that affects a company's bottom line is securities fraud, then everything is securities fraud. But not everything is securities fraud.

True, Rule 10b-5 should not be construed "technically and restrictively." *See Zandford*, 535 U.S. at 819. But the Rule shouldn't be read atextually, either. It's not a technicality to say that mismanaging a manufacturing plant doesn't violate the Exchange Act.

At best, the complaint alleges that Abbott mishandled the Sturgis facility and the FDA's inspection. Mismanaging a plant that makes infant formula is bad. But it's not securities fraud.

[8] At least one of those cases came closer to satisfying the "in connection with" requirement than the case at hand. In *Dentsply Sirona*, a defendant illegally hid from the FDA that nearly 7,000 patients were seriously injured by its medical device. *See Dentsply Sirona*, 816 F. Supp. 3d at 465. Various statutes, regulations, and internal policies required that the defendant report those injuries to the FDA. *Id.* at 464–65. The defendant "represented in public filings and other communications" that it *did* comply with those requirements. *Id.* at 465. So, the district court found a nexus between the bad acts and the statements to investors.

B. Reliance

The second claim fails for a second, related reason. The complaint does not adequately allege reliance.

On this issue, *Stoneridge* takes center stage. *See Stoneridge Inv. Partners, LLC v. Sci.-Atlanta*, 552 U.S. 148, 160–61 (2008). The parties argue over the meaning of *Stoneridge* when addressing the claim about conduct under Rule 10b-5(a) and Rule 10b-5(c).[9] *See* Defs.' Mem., at 27–29 (Dckt. No. 41); Pls.' Resp., at 28–29 (Dckt. No. 43); Defs.' Reply, at 12 (Dckt. No. 45).

In *Stoneridge*, investors brought a class action against a cable television company (Charter), its executives, and the company's vendors, among others. *See Stoneridge*, 552 U.S. at 153–55. The cable company had entered into sham transactions with its vendors, which inflated the company's operating revenues and cash flow, and eventually, raised its stock price. *Id.*

More specifically, the vendors overcharged the cable company for their cable boxes, and the vendors used the overpayment to purchase advertising from the cable company at above-market rates. *Id.* at 154–55. As a result, the cable company fooled its auditor into approving financial statements that said it met projected revenue and cash flow numbers. And the fraudulent financial statement led to an artificially inflated stock price. *Id.* at 154.

The investors sued the cable company, and sued the vendors, too. Aiding and abetting liability wasn't an option after the Supreme Court's decision in *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N. A.*, 511 U.S. 164 (1994). But the investors sought to hold the vendors liable as secondary actors.

As an aside, "secondary actors" are "parties who are not employed by the issuing firm whose securities are the subject of the allegations of fraud." *See Pac. Inv. Mgmt. Co. v. Mayer*

[9] Despite the girth of the filings, the briefs about Count II are relatively sparse. The parties devoted only a few pages to the second claim.

Brown LLP, 603 F.3d 144, 148 n.1 (2d Cir. 2010). Simply put, a secondary actor is a party other than the company that issued the securities (meaning the securities owned by the investor-plaintiffs), or that company's employees. Lawyers, accountants, banks, and consultants are common examples.

Turning back to *Stoneridge*, the Supreme Court addressed whether the complaint stated a claim against the vendors for deceptive conduct. The plaintiffs alleged scheme liability. *Id.* at 159–60. The complaint claimed that the defendants had engaged in "deceptive acts" in violation of Rule 10b-5(a) and Rule 10b-(c).

The case involved *primary* liability for secondary actors, not aiding and abetting liability. The Supreme Court addressed whether the complaint stated a claim against the secondary actors in their own right. "The § 10(b) implied private right of action does not extend to aiders and abettors. The conduct of a secondary actor must satisfy each of the elements or preconditions for liability; and we consider whether the allegations here are sufficient to do so." *See Stoneridge*, 552 U.S. at 158.

The vendors' conduct was deceptive, and it helped the cable company mislead investors. But the Supreme Court held that the vendors weren't liable to the plaintiffs.

The Supreme Court rested its ruling on a lack of reliance. In a nutshell, the plaintiffs didn't know about the deceptive conduct. And the case didn't involve a rebuttable presumption of reliance (based on a duty to disclose, or a fraud-on-the-market theory), either.

The vendors' "deceptive acts were not communicated to the public. No member of the investing public had knowledge, either actual or presumed, of the deceptive acts during the relevant times." *Id.* at 159.

The plaintiffs tried to establish reliance by pointing to the inevitable impact on the company's financial statements. In their view, the conduct had the "purpose and effect" of misrepresenting the company's revenue. *Id.* at 160.

"The argument is that the financial statement Charter released to the public was a natural and expected consequence of respondents' deceptive acts; had respondents not assisted Charter [*i.e.*, the issuing company], Charter's auditor would not have been fooled, and the financial statement would have been a more accurate reflection of Charter's financial condition." *Id.*

The Supreme Court rejected the attempt to establish reliance through an "indirect chain," concluding that it was "too remote for liability." *Id.* at 159. "In all events we conclude respondents' deceptive acts, which were not disclosed to the investing public, are too remote to satisfy the requirement of reliance." *Id.* at 161.

The Supreme Court reaffirmed the longstanding principle that not every fraudulent act is securities fraud, even if it affects a stock price. "Were this concept of reliance to be adopted, the implied cause of action would reach the whole marketplace in which the issuing company does business; and there is no authority for this rule." *Id.*

The fact that the scheme affected the price of securities, in a downstream way, did not mean that the fraud constituted securities fraud. "Though § 10(b) is not limited to preserving the integrity of the securities markets, it does not reach all commercial transactions that are fraudulent and affect the price of a security in some attenuated way." *Id.* at 162 (cleaned up); *see also id.* at 161 ("Were the implied cause of action to be extended to the practices described here, however, there would be a risk that the federal power would be used to invite litigation beyond the immediate sphere of securities litigation and in areas already governed by functioning and effective state-law guarantees. Our precedents counsel against this extension.").

The lack of reliance sunk the claims because "liability cannot be imposed" based on "acts or statements [that] were not relied upon by the investors."[10] *Id.* at 159.

Along the way, the Supreme Court also acknowledged the close relationship between reliance, causation, and the "in connection with" requirement. The concepts are often blended and blurred because they are interrelated.

"[R]eliance is tied to causation, leading to the inquiry whether respondents' acts were immediate or remote to the injury. In considering petitioner's arguments, we note § 10(b) provides that the deceptive act must be 'in connection with the purchase or sale of any security.' Though this phrase in part defines the statute's coverage rather than causation (and so we do not evaluate the 'in connection with' requirement of § 10(b) in this case), the emphasis on

[10] *Stoneridge* involved a claim brought by private investors, not the SEC. The posture of the case would have been completely different if the SEC had filed the complaint. The SEC sits in a different place, for at least two reasons. First, the SEC can bring claims about aiding and abetting liability. "Congress amended the securities laws to provide for limited coverage of aiders and abettors. Aiding and abetting liability is authorized in actions brought by the SEC but not by private parties." *Id.* "Since the SEC can pursue defendants either as primary violators or as aiders and abettors, the distinction [between primary and secondary actors] is not as crucial in SEC litigation as it is in private suits." *See* Hazen, 4 LAW SEC. REG. § 12:210. Second, unlike private parties, the SEC doesn't need to prove or allege reliance, causation, or damages under Section 10(b) of the Exchange Act, Rule 10b-5, or Section 17(a) of the Securities Act. *See SEC v. Grybniak*, 2024 WL 4287222, at *24 (E.D.N.Y. 2024) ("The Second Circuit has repeatedly held that the SEC does not need to prove investor reliance, loss causation, or damages in an action under Section 10(b) of the Exchange Act, Rule 10b–5, or Section 17(a) of the Securities Act.") (cleaned up) (collecting cases); *SEC v. Jarkesy*, 603 U.S. 109, 118 (2024) ("And the SEC may levy these penalties even when no investor has actually suffered financial loss."); *Lorenzo v. SEC*, 587 U.S. 71, 84 (2019) ("[T]he Commission, unlike private parties, need not show reliance in its enforcement actions."); *SEC v. Kelly*, 765 F. Supp. 2d 301, 319 (S.D.N.Y. 2011) ("[U]nlike a private plaintiff, the SEC need not allege or prove reliance, causation, or damages in an action under Section 10(b) or Rule 10b-5."); *SEC v. Ferrone*, 2014 WL 5152367, at *3 (N.D. Ill. 2014) ("Unlike private plaintiffs, the SEC is not required to establish reliance, damages, or loss causation in a civil enforcement action."); *McCann v. Hy–Vee, Inc.*, 663 F.3d 926, 931 (7th Cir. 2011) ("[T]he SEC can bring an enforcement action for a violation of federal securities law without anyone having suffered harm, which is to say without anyone having relied on a misrepresentation or misleading omission to his detriment."); *SEC v. Genovese*, 553 F. Supp. 3d 24, 44 (S.D.N.Y. 2021) ("The SEC is not required to demonstrate reliance when bringing the enforcement claims at issue here, unlike plaintiffs in private causes of action.") (collecting cases); *SEC v. Lek Sec. Corp.*, 276 F. Supp. 3d 49, 59 (S.D.N.Y. 2017) ("Unlike private plaintiffs, the SEC is not required to prove investor reliance, loss causation, or damages.") (collecting cases).

a purchase or sale of securities does provide some insight into the deceptive acts that concerned the enacting Congress." *Id.* at 160 (citation omitted).

At one level, *Stoneridge* seems different than the case at hand. After all, *Stoneridge* involved claims against secondary actors. The Supreme Court did not expressly address the liability of the cable company, meaning the company that issued the shares. But this case involves claims against the issuing company. Plaintiffs are investors in Abbott, and they sued Abbott.

But that's a distinction without a difference. The Supreme Court in *Stoneridge* addressed the primary liability of secondary actors. But the Supreme Court didn't say that a claim against secondary actors is held to a different standard than a claim against the issuing company.

If anything, the Supreme Court said the opposite. "The § 10(b) implied private right of action does not extend to aiders and abettors. The conduct of a secondary actor must satisfy each of the elements or preconditions for liability." *Id.* at 158.

The Supreme Court spoke broadly about what it takes to establish reliance. The Supreme Court didn't suggest that a claim against an issuing company is held to a lower standard when it comes to reliance. If a theory of reliance doesn't work for secondary actors, then that theory of reliance doesn't work for an issuing company, either.

After *Stoneridge*, the term "secondary actor" no longer carries much meaning, at least when it comes to primary liability. A secondary actor is held to the same standard of primary liability as the issuing company. The same elements apply for primary liability, regardless of whether the defendant is the issuing company or a secondary actor. *See, e.g.*, *Forsberg v. Always Consulting, Inc.*, 2008 WL 5449003, at *13 (S.D.N.Y. 2008) ("Under *Stoneridge* and *Central Bank*, therefore, a plaintiff can only maintain a claim for relief under section 10(b) and Rule

10b–5 against a secondary actor when the plaintiff can establish that the secondary actor would himself or herself be liable as a primary actor under these provisions."); *Burnett v. Rowzee*, 561 F. Supp. 2d 1120, 126 (C.D. Cal. 2008) ("Accordingly, Halstead may only be liable as a primary actor; that is, he must have committed a deceptive act in furtherance of the scheme upon which Plaintiff relied. As the Supreme Court warned in *Stoneridge*, this Court must take care to avoid resurrecting aiding and abetting liability under the guise of primary liability for a fraudulent scheme."); *Saltz v. First Frontier, LP*, 782 F. Supp. 2d 61, 73 (S.D.N.Y. 2010) ("Secondary actors, such as accountants, lawyers, and consultants, may be held liable as primary violators of 10b–5 if all the requirements for primary liability are met, including a material misstatement (or omission) on which a purchaser or seller of securities relies.'") (cleaned up), *aff'd sub nom. Saltz v. First Frontier, L.P.*, 485 F. App'x 461 (2d Cir. 2012).

If an indirect theory of reliance doesn't work against secondary actors, as the Supreme Court explained in *Stoneridge*, then an indirect theory of reliance doesn't work when the claim is against the issuing company, either. The issuing company and secondary actors are held to the same standard when it comes to primary liability.

The Seventh Circuit later fleshed out the meaning of *Stoneridge*. *See Pugh v. Trib. Co.*, 521 F.3d 686, 697 (7th Cir. 2008). In *Pugh*, an individual participated in a criminally fraudulent advertising scheme. *Id.* at 696. The scheme had the effect of artificially inflating the revenue of the Tribune Company, the issuing company.

The Seventh Circuit concluded that the individual's conduct did not give rise to liability under section 10(b) because he "had no role in preparing or disseminating Tribune's financial statements or press releases." *Id.* at 697.

The Seventh Circuit recognized that it was foreseeable that the fraudulent advertising scheme would lead to inflated profits, and eventually affect the company's revenues. *Id.* Even so, "*Stoneridge* indicates that an indirect chain to the contents of false public statements is too remote to establish primary liability." *Id.*

The Seventh Circuit needed "allegations establishing the requisite proximate relation between" defendants' fraud and "investors' harm." *Id.* And since the plaintiffs failed to make those necessary allegations, the Seventh Circuit concluded that it "cannot uphold the complaint." *Id.*

The holdings about reliance from the Supreme Court and the Seventh Circuit extend beyond the sphere of "secondary actors." And those observations apply forcefully in this case.

Plaintiffs allege the same sort of indirect, daisy-chain theory of reliance that the Supreme Court rejected in *Stoneridge*. Plaintiffs give a long list of deceptive acts by Abbott and its executives. They allege that the company refused to destroy potentially contaminated formula, and deceived FDA investigators, and falsified records about testing, cleaning, and maintenance, and so on.

Plaintiffs don't allege that they knew about any of those bad acts. In fact, Plaintiffs did the opposite. Plaintiffs admit that they did not know about Abbott's deceptive practices when running the Sturgis plant. *See, e.g.*, Am. Cplt., at ¶ 477 (Dckt. No. 35) ("Plaintiffs and the Class would not have purchased Abbott common stock at the prices they paid, or at all, *had they been aware* that the market prices for Abbott common stock had been artificially inflated by Defendant Abbott and the Individual Defendants' fraudulent course of conduct.").

Plaintiffs cannot adequately plead reliance without knowledge of Defendants' conduct. *See Stoneridge*, 552 U.S. at 159; *see also Pac. Inv. Mgmt. Co.*, 603 F.3d at 160 (noting that

Stoneridge "was primarily focused on whether investors were aware of, and relied on, the defendants' own conduct"); Hazen, 4 LAW SEC. REG. § 12:210 ("In determining primary liability, the issue is not the closeness or remoteness of the defendant from the core of the violation but rather whether the deceptive conduct 'has been publicly disclosed and attributed to the actor."').

Plaintiffs had no idea about the alleged mismanagement of the Sturgis facility. At best, the complaint alleges that the bad acts had a downstream effect on the company's financials. But the Supreme Court rejected that theory of reliance in *Stoneridge*. *See Stoneridge*, 552 U.S. at 160 (rejecting a theory that "in an efficient market investors rely not only upon the public statements relating to a security but also upon the transactions those statements reflect").

If anything, the theory of reliance in this case is even more attenuated than the theories in *Stoneridge* and *Pugh*. Both of those cases involved cooking the books of the company. The vendors in *Stoneridge* helped the company inflate its revenue and cash flow numbers. In a similar vein, the individual in *Pugh* helped the Tribune artificially increase the company's revenue.

But here, Plaintiffs allege that Abbott mismanaged a manufacturing plant. None of the bad acts directly involved the company's financial statements.

Stoneridge and *Pugh* involved manipulating a company's financials. But this case involves the mishandling of a factory, which later affected the company's financials. That's one step removed (or more) – and the theories in *Stoneridge* and *Pugh* were already a bridge too far.

Plaintiffs hang their hat on the Supreme Court's later decision in *Lorenzo v. SEC*, 587 U.S. 71 (2019). That case addressed whether a person can be liable under Rule 10b-5(a) and Rule 10b-5(c) for disseminating a false statement, even though that person was not a "maker" of

the statement (within the meaning of *Janus Capital Group, Inc. v. First Derivative Traders*, 564 U.S. 135 (2011)).

Along the way, the Supreme Court highlighted the breadth of the anti-fraud provisions of the Exchange Act and the Securities Act. A "wide range of conduct" can form the basis for a Rule 10b-5(a) or (c) violation. *See Lorenzo*, 587 U.S. at 79. Given the breadth of the language, "[i]t would seem obvious that the words in these provisions are, as ordinarily used, sufficiently broad to include within their scope the dissemination of false or misleading information with the intent to defraud." *Id.* at 78.

Lorenzo addressed a different issue than the one at hand. The Supreme Court addressed whether a defendant could have scheme liability under Rule 10b-5(a) and Rule 10b-5(c), even if the defendant was not a "maker" of a statement within the meaning of *Janus*. It did not dilute, let alone wash away, the need for reliance.

Maybe Abbott mismanaged the Sturgis facility. But that doesn't mean that the mismanagement was *securities* fraud. Section 10(b) "does not reach all commercial transactions that are fraudulent and affect the price of a security in some attenuated way." *See Stoneridge*, 552 U.S. at 162.

In sum, the complaint does not allege reliance on Defendants' deceptive acts, so the second claim cannot survive.

C. Rule 9(b)

There is one final roadblock. Under Rule 9(b)'s heightened pleading standard, "[t]he complaint must describe the who, what, when, where, and how of the fraud to survive a motion to dismiss." *See United States v. Molina Healthcare of Illinois, Inc.*, 17 F.4th 732, 739 (7th Cir. 2021). "To satisfy Rule 9(b)'s particularity standard, a complaint must state the identity of the

person who made the misrepresentation, the time, place and content of the misrepresentation, and the method by which the misrepresentation was communicated to the plaintiff." *See Cornielsen v. Infinium Cap. Mgmt., LLC*, 916 F.3d 589, 599 (7th Cir. 2019) (cleaned up).

"A complaint that attributes misrepresentations to all defendants, lumped together for pleading purposes, generally is insufficient." *Sears v. Likens*, 912 F.2d 889, 893 (7th Cir. 1990) (cleaned up); *see also Flynn v. Exelon Corp.*, 2021 WL 1561712, at *4 (N.D. Ill. 2021) (stating the same). "Without an explanation as to who played what role in the alleged scheme," a claim will fail "to meet the pleading requirements." *See Desai v. General Growth Props., Inc.*, 654 F. Supp. 2d 836, 862 (N.D. Ill. 2009) (Shadur, J.).

To state a claim, Plaintiffs needed to plead, with particularity, which defendants played what role in the alleged deceptive scheme. It is a high standard, and Plaintiffs don't come close to clearing it.

Plaintiffs pled that misconduct occurred at the Sturgis facility. *See* Am. Cplt., at ¶¶ 470–79 (Dckt. No. 35). But Plaintiffs do not make specific allegations about *any* Individual Defendant. Instead, they say that "the Individual Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices to defraud." *Id.* at ¶ 473.

The allegations about the Individual Defendants are vague, non-descript, and conclusory. Plaintiffs needed to plead more. For instance, they needed to plead that a specific defendant, like CEO Ford, personally directed subordinates to destroy evidence before an FDA inspection. Or they needed to allege that Randall (in Nutrition) personally saw the Sturgis facility's decrepit machinery and water leaks, and then told the public that the facility was in terrific condition. Or something along those lines.

The complaint doesn't allege that any Individual Defendant directed staff at Sturgis to mislead the FDA, destroy evidence, allow the facility to fall into a state of disrepair, and so on. *Id.* at ¶ 474 (describing the bad acts, without pointing to anyone in particular).

Put another way, the *who* and the *how* are missing in the complaint. The complaint doesn't reveal *who* was responsible for the alleged misconduct at Sturgis, let alone *how* that person was responsible. So, it doesn't pass muster under Rule 9(b).

In sum, the complaint does not allege a fraudulent scheme, so Count II is dismissed.

* * *

This Court has walked through the claim about the statements (Count I), and the claim about the conduct (Count II). Another issue lurks in the background. And it's a big issue. Each claim requires a showing of scienter. And that's the next stop on the tour.

III. Scienter

The next issue is scienter. Defendants believe that the complaint fails to allege facts supporting a strong inference of scienter, meaning a culpable state of mind. *See* Defs.' Mem., at 30 (Dckt. No. 41).

Scienter is an essential element of a securities fraud claim under Rule 10b-5. *See Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 27 (2011). All three subparts of Rule 10b-5 require a showing of scienter. So Plaintiffs must allege scienter to state a claim about Abbott's statements under Rule 10b-5(b), and to state a claim about Abbott's conduct under Rule 10b-5(a) and Rule 10b-5(c).

Scienter means acting with an "intent to deceive, demonstrated by knowledge of the statement's falsity or reckless disregard of a substantial risk that the statement is false." *See Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 756 (7th Cir. 2007); *see also Appvion, Inc.*

Retirement Savings and Employee Stock Ownership Plan by and through Lyon v. Buth, 99 F.4th 928, 951 (7th Cir. 2024); *Ernst & Ernst v. Hochfelder*, 425 U.S. 185, 193 (1976) (referring to scienter as "intent to deceive, manipulate, or defraud").

A "reckless" state of mind means "an extreme departure from the standards of ordinary care . . . to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it." *See City of Livonia v. Boeing Co.*, 711 F.3d 754, 756 (7th Cir. 2013) (citations omitted). "When the facts known to a person place him on notice of a risk, he cannot ignore the facts and plead ignorance of the risk." *Makor Issues & Rts., Ltd. v. Tellabs Inc.*, 513 F.3d 702, 704 (7th Cir. 2008).

That's a high standard, but Congress later raised the bar in the Private Securities Litigation Reform Act of 1995. Congress elevated the pleading standards in the PSLRA to protect defendants from abusive securities-fraud lawsuits. *See Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 323 (2007) ("Private securities fraud actions, however, if not adequately contained, can be employed abusively to impose substantial costs on companies and individuals whose conduct conforms to the law. As a check against abusive litigation by private parties, Congress enacted the Private Securities Litigation Reform Act of 1995 (PSLRA)."); *Amgen Inc. v. Connecticut Retirement Plans and Trust Funds*, 568 U.S. 455, 475 (2013) ("Congress recognized that although private securities-fraud litigation furthers important public-policy interests, prime among them, deterring wrongdoing and providing restitution to defrauded investors, such lawsuits have also been subject to abuse, including the extract[ion] of extortionate settlements of frivolous claims.") (cleaned up; brackets in original).

Under the PSLRA, a complaint must "state with particularity facts giving rise to a *strong inference* that the defendant acted with the required state of mind." *See* 15 U.S.C. § 78(u)-4(b)(2)(A) (emphasis added).

A plausible inference will not do the trick. "Congress required plaintiffs to plead with particularity facts that give rise to a 'strong' – *i.e.,* a powerful or cogent – inference." *See Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 323 (2007). To satisfy the PSLRA's "strong inference" requirement, "an inference of scienter must be more than merely plausible or reasonable – it must be cogent and at least as compelling as any opposing inference of nonfraudulent intent." *Id.* at 314.

"[C]ourts must consider the complaint in its entirety, as well as other sources courts ordinarily examine when ruling on Rule 12(b)(6) motions to dismiss, in particular, documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Id.* at 322. Courts must consider "plausible opposing inferences," too. *Id.* at 323.

"The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts? To determine whether the plaintiff has alleged facts that give rise to the requisite 'strong inference' of scienter, a court must consider plausible, nonculpable explanations for the defendant's conduct, as well as inferences favoring the plaintiff." *Id.* at 323–24.

"In the end, the Court must determine whether all the facts set forth in the amended complaint and other sources that it may consider on a motion to dismiss, accepted as true and taken collectively, give rise to a strong inference of scienter." *In re Baxter Int'l Inc. Sec. Litig.*, 2021 WL 100457, at *11 (N.D. Ill. 2021) (citation omitted).

The complaint at hand includes quite a few allegations about scienter. After marching through 389 paragraphs in 174 pages, the complaint offers a summary of the allegations about scienter. The summary is lengthy in its own right, spanning more than 50 paragraphs. *See* Am. Cplt., at ¶¶ 390–446 (Dckt. No. 35).

The complaint organizes the allegations of scienter by topic, not by defendant. For example, the first subheading is about the whistleblower complaint from February 2021. *Id.* at ¶¶ 392–404. The second subheading is about the Form 483s in 2019 and 2021. *Id.* at ¶¶ 405–410. And so on.

Defendants believe that the allegations about scienter aren't enough, despite their girth. As they see things, the complaint does not include enough facts to give rise to a strong inference of scienter.

This Court will address the allegations about the Individual Defendants, before turning to the allegations about the company.

A. The Individual Defendants

The first question is whether the complaint alleges facts that give rise to a strong inference of scienter for each Individual Defendant.

Plaintiffs don't get very far before they run into trouble. By and large, Plaintiffs lump all of the Individual Defendants into one big stew pot. Instead of focusing on whether each Individual Defendant intended to deceive, Plaintiffs focus on the Individual Defendants as a group.

That approach is difficult to square with the text of the statute. The PSLRA requires a complaint to "state with particularity facts giving rise to a strong inference that *the defendant* acted with the required state of mind." *See* 15 U.S.C. § 78u-4(b)(2)(A) (emphasis

added). As the text reveals, the proper focus is on each individual defendant, not defendants as a whole.

The Seventh Circuit has beat that drum a few times. A complaint must "create a strong inference of scienter with respect to *each individual defendant*." *See Pugh*, 521 F.3d at 693 (emphasis added). Put differently, a complaint must plead scienter with particularity "as to each Individual Defendant." *See Cornielsen v. Infinium Cap. Mgmt., LLC*, 916 F.3d 589, 602 (7th Cir. 2019); *see also Twin Master Fund, Ltd. v. Akorn, Inc.*, 2020 WL 564222, at *13 (N.D. Ill. 2020) ("Pleading 'collective scienter' for a group of defendants does not meet the PSLRA's particularity standard, and a plaintiff must plead a defendant's scienter as to each statement or omission underlying a section 10(b) claim.").

The question at hand is not whether the "Individual Defendants" collectively intended to deceive. Instead, the question is whether each individual person – viewed separately – intended to deceive. Scienter is a defendant-by-defendant, person-by-person exercise. *See Pugh*, 521 F.3d at 693 ("We have rejected the 'group pleading doctrine,' a judicial presumption that statements in group-published documents are attributable to officers who have daily involvement in company operations; thus, the plaintiffs must create a strong inference of scienter with respect to each individual defendant.").

Some cases involve complaints with allegations that equally apply to each of the individuals, so they all rise or fall together. But in the complaint at hand, the allegations aren't exactly the same. Oftentimes, the allegations are substantially similar for Ford (the CEO) and Funck (the CFO). But that's less true for the other two individuals, meaning Calimari (the Senior Vice President, U.S. Nutrition) and Randall (Division Vice President of Nutrition Quality Assurance).

Plaintiffs discuss the allegations of scienter by topic, not by person. That's problematic when the proper focus is the individual. It leads to blending and blurring. Even so, the Court will follow suit.

February 2021 Whistleblower Complaint

Plaintiffs believe that the February 2021 whistleblower complaint supports a strong inference of scienter. *See* Am. Cplt., at ¶¶ 392–404 (Dckt. No. 35).

According to the complaint, a confidential witness confirmed that the Individual Defendants "*would have been* made aware" of the whistleblower's complaint. *Id.* at ¶ 400 (emphasis added). That unidentified person is a former senior public relations executive at Abbott, but his or her identity is otherwise shrouded in mystery.

The confidential witness reported that Randall and Calamari (again, executives in Nutrition) "*would have been* informed" of the complaint and Abbott's "general strategy for responding." *Id.* at ¶ 401 (emphasis added). And Ford (the CEO) "*would have been* informed" about the complaint and "the nature of its allegations," and Abbott's response. *Id.* (emphasis added).

The allegations based on the confidential witness face a couple of hurdles.

For starters, allegations from confidential witnesses receive a "heavy discount." *City of Livonia v. Boeing Co.*, 711 F.3d 754, 759 (7th Cir. 2013); *see also Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 757 (7th Cir. 2007) ("Usually that discount will be steep."). "The sources may be ill-informed, may be acting from spite rather than knowledge, may be misrepresented, may even be nonexistent – a gimmick for obtaining discovery costly to the defendants and maybe forcing settlement or inducing more favorable settlement terms." *See City of Livonia*, 495 F.3d at 759.

Anonymous witnesses don't count for much, but they don't automatically count for nothing, either. "[T]he absence of proper names does not invalidate the drawing of a strong inference from informants' assertions." *Makor*, 513 F.3d at 712. Other facts could lend credence to the statements of an unidentified source. For instance, the job description of the anonymous person might strengthen the inference of personal knowledge. *Id.* The number of anonymous sources might lend a hand. *Id.* Specificity matters, too.

Here, Plaintiffs rely on an unidentified media person. The confidential witness "oversaw Abbott's top tier business media relations across all businesses, including Nutrition, and prepped Defendant Ford for media interviews." *See* Am. Cplt., at ¶ 400 (Dckt. No. 35). The complaint doesn't shed light on what role, if any, that former executive played in responding to whistleblower complaints. The complaint does not allege that the source knew about problems at Sturgis, either.

The fact that the former executive worked directly with Ford is not enough. Plaintiffs do not explain how a media relations executive would have gotten involved in resolving a whistleblower complaint at that early stage of the story. After all, there were no media interviews with the CEO at the time (the purported basis for the whistleblower's knowledge), because the issues with Sturgis hadn't come to light yet.

The infant formula situation became a scandal later, but Plaintiffs give no reason to think that a media person would have played a role so early in the process. *See Selbst v. McDonald's Corp.*, 432 F. Supp. 2d 777, 787 (N.D. Ill. 2006) (concluding that the allegations did not support an inference of scienter where the confidential witness failed to allege facts about how the confidential witness knew that the defendants ever saw certain reports); *In re Tupperware Brands Corp. Sec. Litig.*, 2023 WL 5091802, at *6 (11th Cir. 2023) (opining that allegations

from anonymous former employees did not support a strong inference of scienter when the complaint lacked particularized facts showing how the employees would have known about the company's financial reporting).

What's more, the non-descript information from the confidential source doesn't inspire confidence that the informant had personal knowledge. The witness didn't describe what that person knew. The witness described what "would have been." *See, e.g.*, Am. Cplt., at ¶¶ 400–01 (Dckt. No. 35). It sounds closer to speculation and guesswork than personal knowledge.

"Would've, could've, should've" is not enough to meet the heightened pleading requirement of the PSLRA and Rule 9(b). "[C]ourts in this district have declined to allow plaintiffs to use a 'must have known' theory as 'an end-run around the requirement that plaintiffs set forth particularized facts to suggest that defendants acted knowingly or recklessly.'" *See W. Palm Beach Firefighters' Pension Fund*, 495 F. Supp. 3d at 659 (citation omitted); *see also Chew v. Moneygram Int'l, Inc.*, 2024 WL 4346522, at *18 (N.D. Ill. 2024) (same); *In re Fifth Third Bancorp Deriv. Litig.*, 2023 WL 2429009, at *20 (N.D. Ill. 2023) (same); *Pension Tr. Fund for Operating Engineers v. DeVry Educ. Grp., Inc.*, 2017 WL 6039926, at *13 (N.D. Ill. 2017) (explaining that the inference of scienter based on allegations that confidential witnesses "believed" the defendants "were aware of certain data" was "weak at best"); *In re Bally Total Fitness Sec. Litig.*, 2006 WL 3714708, at *9 (N.D. Ill. 2006) ("Plaintiffs cannot rely on a 'must have known' theory."); *Hunter v. Elanco Animal Health Inc.*, 2023 WL 62954487, at *18 (S.D. Ind. 2023) ("These statements amount to the 'epitome' of what the PSLRA categorizes as inactionable: to wit, that Defendants 'must have known' about underlying fraud that Plaintiffs still fail to plead adequately."); *Sjunde AP-Fonden v. Gen. Elec. Co.*, 2021 WL 311003, at *8 (S.D.N.Y. 2021) ("This is the language of supposition (albeit confident supposition), not

personal knowledge, and does not suffice to establish that [the former employee] had any contact with the Individual Defendants or would have knowledge of what they knew.") (citation omitted).

At the very least, a complaint would need to offer more support to create an inference based on what a person "would have known." For example, imagine if a confidential source said that the quarterback of the Chicago Bears "would have" warmed up before taking the field and throwing a touchdown pass against the Green Bay Packers. The confidential source would need to give a firm factual basis for that assertion – say, establishing personal knowledge that it's the longstanding practice of all NFL quarterbacks to warm up before taking the field. The source would need to offer some other piece of information to bridge the gap and solidify the inference.

That's not what happened here. The confidential source didn't say that the CEO of Abbott received every letter from a disgruntled employee, or anything along those lines.

Pushing back, Plaintiffs argue that senior executives are likely to know about pervasive compliance issues at their own companies. *See* Pls.' Resp., at 31 (Dckt. No. 43).

Defendants respond that Abbott is a behemoth, with over 100,000 employees and dozens of manufacturing facilities. *See* Defs.' Reply, at 14 (Dckt. No. 45). So, in their view, the strongest inference is that top-level executives at Abbott did not know about issues at Sturgis.

The size of the company matters when it comes to inferring knowledge about problems. *See, e.g.*, *Oklahoma Firefighters Pension & Ret. Sys. v. Six Flags Ent. Corp.*, 58 F.4th 195, 219 (5th Cir. 2023). For smaller companies, "it might be 'absurd' to think that the CEO and CFO . . . would be unaware of the alleged substandard, non-compliant conditions pervading their company's manufacturing and quality control divisions." *See Mulligan v. Impax Lab'ys, Inc.*, 36 F. Supp. 3d 942, 970 (N.D. Cal. 2014).

But Abbott is a colossus, not a mom-and-pop shop. One can only imagine how many inspections a company like Abbott must undergo each year. After all, Abbott has dozens of plants spread around the globe, and over 100,000 employees.

Given its size, it is not a sure thing that a potential regulatory issue will percolate all the way to the top of the company. *See Six Flags*, 58 F.4th at 219 (stating that the fact that "Six Flags is undoubtedly a large company" undermined the inference of scienter); *Oklahoma Police Pension Fund & Ret. Sys. v. Teligent, Inc.*, 2020 WL 3268531, at *19 (S.D.N.Y. 2020) (explaining that allegations that a CEO would have been aware of regulatory failures supported an inference of scienter because the company was small).

The complaint does not include enough facts to give rise to an inference that the 2021 whistleblower complaint went all the way to the top, especially early on. The fact that an employee complained about serious problems isn't enough to infer that it hit the desks of senior executives.

Calling an employee a "whistleblower" might give that person undue stature, too, especially in hindsight. There is a fine line between a whistleblower and a disgruntled employee, and it can take some time to figure out if there is any merit to the employee's complaint. Not every complaint by an employee goes right to the top, even for big issues. Some issues eventually get there, but they can take awhile to bubble up.

Basically, Plaintiffs rely on a confidential source's "would have beens," without showing that the source had firsthand knowledge, and without showing that senior executives knew about the whistleblower's complaint. Those allegations are insufficient to support a strong inference of scienter, particularly given the size of Abbott.

More importantly, knowledge of a potential problem is one thing. But knowledge of *falsity* is another. A defendant doesn't act with scienter simply because that defendant knows that a problem exists.

Again, scienter is an intent to *deceive*. It's a mental state that exists when a defendant knew that a statement was false, or showed reckless disregard for the substantial risk of falsity. *See Appvion*, 99 F.4th at 951.

At best, the confidential source addressed what senior executives would have known about the existence of problems at Sturgis. The confidential source did not offer facts creating a strong inference that the executives intended to *deceive*.

The allegations about the letter to Abbott's General Counsel (a non-defendant) cannot save the day, either. The complaint alleges that the General Counsel knew the content of the whistleblower's complaints because the whistleblower's counsel contacted the General Counsel, and "request[ed] that Abbott preserve records associated with the Whistleblower . . . ." *See* Am. Cplt., at ¶ 399 (Dckt. No. 35).

Plaintiffs believe that the letter "put the General Counsel on notice that a complaint was forthcoming." *See* Pls.' Resp., at 31 (Dckt. No. 43). In their view, the letter supports an inference that the General Counsel shared the information from the whistleblower with Ford.

That inference requires a logical hop, skip, and jump over a bridge too far.

For starters, the letter to the General Counsel didn't raise any issues with the regulatory complaints at the Sturgis facility. The letter said nothing about infant formula, or *Cronobacter*, or contamination, or the cleanliness of the facility, or anything along those lines. Potential contamination didn't come up. *See* Pls.' Resp., at 31 (Dckt. No. 43).

Instead, the letter asked Abbott to preserve records about the whistleblower, and to send along copies of his personnel file. *See* Ex. 9 (Dckt. No. 42-9). That request wouldn't send shock waves through any company, let alone a corporate behemoth.

True, the letter did say that Abbott "should also know that a complaint has been filed with Michigan and federal authorities." *Id.* But the letter didn't reveal anything about the subject matter of the complaint. For all Abbott knew, the complaint could have involved race discrimination, or worker safety, or the Fair Labor Standards Act, or antitrust, or any other possible topic under the sun.

Even then, sending a letter to the General Counsel doesn't mean that the General Counsel read it. The response suggests otherwise. Abbott's response came from someone else, a lower-level member of its legal team. *See* Ex. 10 (Dckt. No. 42-10). Abbott's counsel's response also stated that the company did not know about the "substantive nature" of the whistleblower's claims. *Id.*

Also, even if the General Counsel knew about the preservation letter, it's hard to imagine that the General Counsel would have elevated the complaint to Ford. One can only imagine the look on the face of the CEO if the General Counsel had picked up the phone, called the CEO, and divulged the breaking news that an employee had asked for his personnel file.

In sum, the allegations about the whistleblower complaint from February 2021 fall far short of the goal line. They do not support any meaningful inference of scienter, let alone a strong one.

Form 483 Reports

Next, Plaintiffs argue that Abbott's "receipt of multiple Forms 483 regarding Sturgis provides further evidence of scienter." *See* Pls.' Resp., at 33 (Dckt. No. 43); *see also* Am. Cplt., at ¶¶ 405–10 (Dckt. No. 35).

The complaint alleges that Randall was copied on the Form 483 reports, and played a role in the company's response. *See* Am. Cplt., at ¶¶ 171, 176, 407–08 (Dckt. No. 35). But the complaint doesn't reveal whether the other Individual Defendants received the Form 483s, too. So the Court will start with the other three people (Ford, Funck, and Calamari), before addressing Randall.

The complaint doesn't say that Ford, Funck, and Calamari knew about the Form 483s. Instead, the complaint says that they "would have" known about them. And even then, the complaint doesn't offer much to go on.

According to the anonymous source, Ford, Funck, and Calamari "*would have* been informed of the 483 Reports and Abbott's response." *Id.* at ¶ 408 (emphasis added). Ford, Funck, and Calamari "*would have* participated in conversations regarding how to respond." *Id.* (emphasis added).

The anonymous source added that Ford and Funck "*would have* received updates regarding the risk posted by the 483 Report as well as Abbott's response." *Id.* at ¶ 409 (emphasis added). The unidentified witness also believed that any Form 483 reports showing positive *Cronobacter* results "*would have* been escalated" to Ford in "less than a month." *Id.* (emphasis added).

Once again, the confidential source offers "would haves," which don't satisfy the heightened pleading standards. *See, e.g.*, *DeVry Educ. Grp.*, 2017 WL 6039926, at *13. The

confidential source didn't offer much of a reason for inferring knowledge, apart from his or her say-so.

If Plaintiffs had facts to support a finding of scienter, they *would have* put it in the complaint.

It isn't clear how the confidential witness would have known about the response to Form 483 reports, either. *See Tupperware Brands*, 2023 WL 5091802, at *6. It's not obvious that a public relations executive would have played a role in responding to a non-public regulatory issue. Plaintiffs do not plead facts suggesting that this employee was involved in the response to the FDA, especially at the early stages. The complaint does not allege that the confidential witness played a role in any internal debates about potential public disclosures, either.

Plaintiffs resort to musings about "best practices." The complaint alleges that "best practices following a Form 483 letter dictate that the response to a Form 483 'include a commitment/statement from senior leadership.'" *See* Am. Cplt., at ¶ 171 (Dckt. No. 35). Plaintiffs claim in conclusory fashion that "Abbott Nutrition followed this principle." *Id.* But they do not plead facts supporting that conclusion.

Plaintiffs also point out that the Individual Defendants could access the Form 483 reports through "TrackWise." *Id.* at ¶ 413.

Access to information isn't enough. As the Seventh Circuit has cautioned, "a complaint fails to satisfy the PSLRA's particularity requirements by making conclusory allegations of scienter derived from a defendant's mere access to information." *See Cornielsen*, 916 F.3d at 602.

The fact that the Individual Defendants *could* look at the reports does not say much about whether they *did* look at the reports. Plaintiffs needed to plead the latter. And on that front, they fell short.

Plaintiffs focus special attention on Randall, the Nutrition executive who decided to do the recall of infant formula. *See* Am. Cplt., at ¶ 34 (Dckt. No. 35). Plaintiffs point out that Randall knew the content of the Form 483s, and played a role in the company's response. *Id.* at ¶¶ 407–08.

Maybe so. But Randall's knowledge of the Form 483s matters only if that knowledge means that Randall said something or did something that was false or misleading. Knowledge of a potential regulatory problem isn't scienter in its own right. The key is that the person must say or do something *inconsistent with the knowledge*.

The complaint is long in pages, but short on statements from Randall. The complaint does include a number of generic quotes from a magazine interview about the importance of focusing on the customer (as previously discussed). *Id.* at ¶ 96. But Randall didn't say anything in that interview that was inconsistent with knowledge of the Form 483s. So knowledge of the Form 483s can't give rise to an inference of scienter, let alone a strong one.

In sum, the complaint fails to allege facts about the Form 483s that could give rise to a strong inference of scienter for any of the Individual Defendants.

Core Operations

Next, Plaintiffs argue that a "strong inference of Defendants' scienter is further evidenced by the critical nature of the sale of safe, uncontaminated infant formula within the U.S. to Abbott." *See* Am. Cplt., at ¶ 422 (Dckt. No. 35). Basically, Plaintiffs argue that, because infant formula is heavily regulated, and because infant formula mattered to Abbott's bottom line, the

"key officers knew or were at least reckless in not knowing" about the violations. *Id.* at ¶¶ 422–26.

Under the so-called "core operations" theory, officers of a company "can be assumed to know of facts critical to a business's core operations . . . that would affect a company's performance." *Jones v. Corus Bankshares, Inc.*, 701 F. Supp. 2d 1014, 1028 (N.D. Ill. 2010) (citation omitted). Typically, the doctrine applies "only where the operation in question constitutes nearly all of a company's business." *Fifth Third Bancorp*, 2023 WL 2429009, at *19 (cleaned up); *see also Makor*, 513 F.3d at 709 (concluding that it was "exceedingly unlikely" that senior management did not know about issues with their employer's "most important products").

"In a typical case, senior positions within a company do not suggest scienter without additional support from internal documents or communications. When courts deviate from this approach, the subjects of the statements or omissions are typically of great importance to the company." *W. Palm Beach Firefighters' Pension Fund*, 495 F. Supp. 3d at 661–62 (cleaned up).

The core operations theory is a way of inferring knowledge about a problem by the higher ups at a company. Senior executives presumably know about major issues affecting important parts of the business.

Even so, there is a difference between knowing about a problem, and knowing that a statement is *false or misleading*. *See Higginbotham*, 495 F.3d at 758 ("[There is a big difference between knowing about the reports . . . . and knowing that the reports are false.").

Again, scienter is about intent to deceive. Knowledge of a potential regulatory problem isn't the same thing as an intent to deceive.

A person does not speak or act with intent to deceive simply because that person is aware that the company faces headwinds. Knowledge of a potential problem is relevant to scienter only if that knowledge renders a statement or action false or misleading.

Knowing that "X" is true is relevant to scienter if the speaker said "not-X." That is, knowledge of the truth becomes important to showing an intent to deceive, if that knowledge means that the speaker knew that a statement was false or misleading. But knowledge of a potential problem, standing alone, does not create an inference of scienter (let alone a strong one).

Knowing about a problem can inform whether a speaker had scienter, depending on the statement. For example, if a CEO denies that the company had any regulatory issues, when the CEO knew that the company was loaded with regulatory issues, then the CEO's knowledge could have a bearing on the issue of scienter. But in that situation, knowledge of a problem plays a role only because the CEO denied the existence of any problems.

Here, Plaintiffs try to establish scienter based on the nature, scope, and importance of the problem, including its potential impact on the company's bottom line. Plaintiffs pleaded that infant formula sales were "highly material" to Abbott's financial results because Abbott controlled 40 percent of the national market. *See* Am. Cplt., at ¶ 424 (Dckt. No. 35).

The complaint alleges that the Sturgis facility manufactured 40 percent of Abbott's formula. *Id.* at ¶ 424. And the shutdown of Sturgis had consequences for the broader market: it caused a nationwide market shortage and disruption. *Id.* at ¶ 425. The shutdown had significant financial repercussions for Abbott, too. According to the complaint, Abbott suffered a loss of over $1 billion in 2022 because of the recall and stoppage. *Id.* at ¶ 424.

Still, as Defendants point out, infant formula is a relatively small piece of the overall Abbott pie. Abbott's international sales for 2021 topped $43 billion internationally. *See* Abbott 2021 Form 10-K, at 50 (Dckt. No. 42-2, at 52 of 95). Its pediatric nutrition sales internationally totaled $4.3 billion. *Id.* at 29 (31 of 95). And Sturgis itself accounted for significantly less than 5 percent of Abbott's revenue. *See* Defs.' Reply, at 19 (Dckt. No. 45).

Financials are just one piece, though. Some courts have recognized that products carrying an outsized *reputational* risk can constitute "core operations" even when the products have a lessened financial impact. *See, e.g.*, *Industriens Pensionsforsikring A/S v. Becton, Dickinson & Co.*, 620 F. Supp. 3d 167, 196 (D.N.J. 2022) ("A product need not have an outsized impact on a company's financial performance to constitute a 'core operation'; products that present substantial reputational risk may suffice as well."); *In re Toyota Motor Corp. Sec. Litig.*, 2011 WL 2675395, at *4 (C.D. Cal. 2011) (explaining that the core operations inference applied in part because "Toyota's carefully cultivated reputation for quality and safety and its market credibility were clearly at risk").

Failing to adhere to infant formula regulations can also have significant non-monetary consequences. For instance, failure to adhere to formula regulations can "cause illness and death, and instill panic and fear in parents and caregivers." *See* Am. Cplt., at ¶ 423 (Dckt. No. 35).

Harming infants is bad for business. Not all press is good press. Shining a spotlight on a company's regulatory shortcomings – and the negative impact on babies – is bad press.

Even so, none of the allegations create an inference of scienter, let alone a strong one. Knowledge of potential problems at the Sturgis facility isn't the same thing as knowledge of the falsity of statements about the Sturgis facility. To link it up, the complaint would need to

establish that the Individual Defendants said or did something deceptive, when they knew the truth. And Plaintiffs never get there.

Site Visits to Sturgis

Plaintiffs claim that Abbott senior management "had actual knowledge because they visited the plant and saw first-hand the plant's flagrant violations." *See* Am. Cplt., at ¶ 411 (Dckt. No. 35).

Specifically, the complaint alleges that Randall "visit[ed] Sturgis frequently." *Id.* at ¶ 412. The complaint fails to mention whether the other Individual Defendants visited Sturgis. *Id.* at ¶¶ 411–12 (mentioning only Randall and two non-Defendant Abbott executives).

In Plaintiffs' view, the Sturgis facility "was in markedly poor condition, and any corporate visitor would or should have noticed." *See* Pls.' Resp., at 38 (Dckt. No. 43). Plaintiffs also claim that senior management – including Randall – "dangled funding for improvements out like a carrot that employees had to earn." *See* Am. Cplt., at ¶ 139 (Dckt. No. 35). For example, senior management dangled a "badly-needed new dryer to replace a decades old dryer that was always breaking down." *Id.* Plaintiffs plead with particularity that Randall knew about issues with Sturgis's dryers. *Id.*

But the fact that *Randall* visited Sturgis does not say much about whether the other Individual Defendants knew about the problems there. Plaintiffs need to support a strong inference of scienter for each Defendant, individually. *See Pugh*, 521 F.3d at 693.

On that front, Plaintiffs fall short. They don't claim that the other Defendants visited Sturgis. They don't allege that Randall informed the other Individual Defendants about issues at Sturgis. They don't plead facts suggesting that information about problems observed during visits made its way up the chain.

Again, Abbott is a massive company. The fact that some executives knew about problems at Sturgis does not create a strong inference that the folks at the top of the organizational chart knew, too.

The allegations aren't enough for Randall, either. Again, knowledge of potential problems at the plant isn't enough. That knowledge can give rise to an inference of scienter only if the complaint creates a nexus to a false statement or deceptive conduct. The complaint must establish knowledge of falsity, not knowledge of a problem. And once again, the complaint falls short.

Information Access

Plaintiffs claim that "Abbott's own audit and tracking systems provided access to all the information concerning the violations." *See* Am. Cplt., at ¶ 413 (Dckt. No. 35); *see also id.* at ¶ 411. According to an anonymous former Abbott employee, users could view all food safety problems reported at Abbott facilities, "as well as corrective actions that should have been taken." *Id.* at ¶ 413.

Again, "mere access to information" does not satisfy the PSLRA's scienter requirements. *See Cornielsen*, 916 F.3d at 602; *see also Chandler*, 2022 WL 952441, at *27 ("Mere access to sources of information – without any allegations regarding if, when, and how defendants actually accessed this information – is not enough to contribute to a strong inference of scienter.") (citation omitted).

Plaintiffs fail to offer facts suggesting that the Individual Defendants actually looked at those audit and tracking systems. Therefore, the Court does not infer scienter from the ability to access information.

Government Investigations

Plaintiffs assert that criminal investigations into Abbott by the DOJ and the SEC "contribute to a strong inference of Defendants' scienter." *See* Am. Cplt., at ¶ 430 (Dckt. No. 35); *see also id.* at ¶¶ 427–29.

In Defendants' view, the fact that a government investigation occurred after the recall doesn't say much about whether specific corporate officers knew of problems beforehand. *See* Defs.' Mem., at 37 (Dckt. No. 41).

Some courts have placed weight on the existence of DOJ and SEC investigations, finding that they can "provide[] additional support for finding that scienter has been adequately pleaded." *In re Akorn, Inc. Sec. Litig.*, 240 F. Supp. 3d 802, 820 (N.D. Ill. 2017); *see also Washtenaw Cnty. Emps. Ret. Sys. v. Avid Tech., Inc.*, 28 F. Supp. 3d 93, 114 (D. Mass. 2014) (explaining that a government investigation – while "insufficient in and of itself" to show scienter – "can be seen as one more piece of the puzzle" creating an inference of scienter).

There is something un-American about the notion that, if the government investigates you, you must have done something wrong. Knowledge of a government investigation isn't the same thing as knowledge of wrongdoing, let alone knowledge of falsity.

One can envision a scenario where the existence of an investigation might render a statement false or misleading. For example, imagine if the EPA performed an inspection and raised questions about why a chemical company was dumping green toxic sludge into the Mississippi River. And imagine if the CEO knew about the potential regulatory issues, but later declared that the EPA had given the company a gold star, and had signed off on the company's emissions without raising any issues. In that scenario, the existence of the EPA's investigation could speak to scienter.

But that's not this case. Abbott didn't declare that the FDA had not raised any questions or issued any Form 483s. Abbott didn't declare that the FDA had found no violations when the FDA *had* found violations, or anything similar.

The existence of a government investigation, without more, does not give rise to an inference of scienter. The fact that the government is investigating a company is not enough to establish an intent to deceive, unless the statement mischaracterizes the existence or the findings of the investigation itself (or something along those lines).

Knowledge of government investigations isn't enough, because knowledge of the investigations did not render any statement false or misleading. That knowledge doesn't create any inference at all, let alone a strong one.

Post-Recall Apologies

Plaintiffs contend that post-recall apologies by Ford and Calamari support an inference of scienter. *See* Pls.' Resp., at 39 (Dckt. No. 43).

Specifically, Ford stated that "[w]e're sorry to every family we've let down since our voluntary recall exacerbated our nation's baby formula shortage." *See* Am. Cplt., at ¶ 446 (Dckt. No. 35). Ford added that Abbott needed to "earn[] back" the public's trust. *Id.*

Calamari "express[ed] [Abbott's] extraordinary disappointment about the shortage." *Id.* Calamari explained that the company was "deeply, deeply sorry." *Id.*

Plaintiffs frame these apologies as acknowledgements of Defendants' "fault and responsibility for the egregious sanitary violations at Sturgis." *Id.* In Defendants' view, "an apology after the fact does not imply prior knowledge, much less fraudulent intent." *See* Defs.' Mem., at 36 (Dckt. No. 41).

To be sure, some courts have inferred scienter from admissions of wrongdoing. *See In re Zoom Secs. Litig.*, 2022 U.S. Dist. LEXIS 28265, at *10 (N.D. Cal. 2022) (concluding that the defendant's apology for the company's "incorrect" use of a term amounted to an admission that he "knew it all along"); *Thomas v. Magnachip Semiconductor Corp.*, 167 F. Supp. 3d 1029, 1043 (N.D. Cal. 2016) ("[A]n admission of fault by 'management' as a whole may be enough for a court to infer scienter even if the company was unwilling – or unable at the time – to disclose specifically who was responsible.").

Here, Ford and Calamari made broad apologies about the *shortage*. Ford admitted that the recall had contributed to the nationwide formula shortage. But Ford's apology didn't address whether Abbott *knew* about issues before the recall. The same goes for Calamari's apology.

And more importantly, an apology about a shortage isn't the same thing as apologizing for telling lies. The issue is knowledge about the falsity of the statements, not knowledge about potential regulatory issues. Saying you're sorry for a lack of baby formula isn't the same thing as saying you're sorry for misleading everyone about contamination at the plant.

Ford and Calamari did not apologize for misleading the public, or providing misinformation, or anything along those lines. They apologized for supply problems with infant formula. That apology is a far cry from scienter.

Post-Recall Leadership Changes

Finally, Plaintiffs point out that Abbott made leadership changes at Sturgis in the wake of the recall. *See* Am. Cplt., at ¶ 431 (Dckt. No. 35).

Specifically, during Abbott's quarterly earnings call on October 19, 2022, Ford announced that the company had "made leadership changes, both at [the] Sturgis site and in [its]

quality organization." *Id.* Ford declined to share details about the "leadership changes," but a former Abbott employee reported that the Sturgis site director was replaced. *Id.*

In Plaintiffs' view, these "remedial measures" support a strong inference of scienter because "this type of 'house-cleaning' does not typically follow innocent instances of mismanagement." *Id.*

As an initial matter, inferring fraud from *ex post* improvements seems like an uneasy fit with Rule 407 of the Federal Rules of Evidence. *See Higginbotham*, 495 F.3d at 760; *Pugh*, 521 F.3d at 695 ("[D]rawing an inference from such facts does not comport with Federal Rule of Evidence 407, which provides that subsequent remedial measures may not be used as evidence of liability.").

Under Rule 407, "evidence of subsequent measures" that "would have made an earlier injury or harm less likely to occur" is inadmissible to prove "culpable conduct." *See* Fed. R. Evid. 407. If cleaning house isn't admissible at trial, then it's hard to see how an allegation about cleaning house could get a complaint over the hump at the pleading stage.

In any event, a change in leadership does not contribute much, if anything, when it comes to intent to deceive. Remedial measures are "at most an acknowledgment that the company identified a better way of doing things moving forward, not an indicator that fraudulent intent existed at the time the alleged omissions occurred." *See In re Zagg, Inc. Sec. Litig.*, 797 F.3d 1194, 1205 (10th Cir. 2015); *see also Pugh*, 521 F.3d at 686 (rejecting the plaintiffs' argument that "controls *must* have been weak *because* a fraud actually occurred" and explaining that "by definition, *all* frauds demonstrate the 'inadequacy' of existing controls") (emphasis in original).

True, some courts have opined that "house-cleaning and reforms do not follow innocent mistakes." *In re Am. Serv. Grp., Inc.*, 2009 WL 1348163, at *58 (M.D. Tenn. Mar. 31, 2009)

(quoting *In re Sipex Corp. Sec. Litig.*, 2005 WL 3096178, at *1 (N.D. Cal. 2005)); *see also In re Firstenergy Corp.*, 2022 WL 681320, at *21 (S.D. Ohio 2022) (concluding that executive firings – which were related to a criminal complaint and ensuing investigation – supported an inference of scienter).

That's a bridge too far. People get fired for lots of reasons – like negligence or ineptitude – that have nothing to do with dishonesty. The same goes for leadership changes. Companies change leadership for all sorts of reasons that have nothing to do with fraud.

Cleaning house does not create an inference of scienter, because cleaning house doesn't shed much light on whether the executives who were shown the door did something dishonest. To get over the hump, Plaintiffs needed to connect the house-cleaning to the allegations of fraud. *See In re Hertz Glob. Holdings Inc.*, 905 F.3d 106, 118 (3d Cir. 2018) ("[F]or corporate departures to strengthen an inference of scienter, there must be particularized allegations connecting the departures to the alleged fraud."); *see also Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1002 (9th Cir. 2009).

Again, there is no fraud by hindsight. *See, e.g.*, *Higginbotham*, 495 F.3d at 760. In hindsight, things obviously went awry at Sturgis. But Plaintiffs fail to connect the clean-up effort to *fraud*.

Indeed, the complaint does not suggest that the fired individuals made fraudulent statements. If anything, the fact that other employees were cleared out – while the folks at the top kept their spots – tends to suggest that any misfeasance occurred further down the chain. After all, people with unclean hands do not usually survive a house-cleaning.

In sum, the post-recall leadership changes do not support a strong inference of scienter.

* * *

At long last, this Court has picked through the allegations about scienter one by one. But it recognizes that it must look at the complaint as a whole.

Sometimes, one allegation, viewed in isolation, may not look like much. But stringing together a bunch of facts sometimes can create an inference worth more than the sum of its parts. Like a mosaic, little pieces that seem inconsequential on their own can add up to something bigger.

But not always. Sometimes adding one allegation on top of the next doesn't do much. A laundry list of facts that individually add little weight might add up to a light load. A weak inference and a weak inference and a weak inference, considered together, might just lead to a weak inference.

Unfortunately for Plaintiffs, considering all the inferences together does not lead to a strong inference of scienter here. The allegations are heavy in volume, but light in weight. Viewing the allegations in a light favorable to Plaintiffs, the allegations of the complaint fall far short of creating a strong inference that any of the Individual Defendants acted with scienter.

B. The Company

The next question is whether the complaint includes allegations that create a strong inference of scienter by Abbott (meaning the company itself).

Corporations are not sentient beings. So, a corporation's state of mind depends on the state of mind of its employees.

That said, courts do not construct scienter by taking bits and pieces of information from different people, and cobbling it all together into one collective mass. Instead, the state of mind of an individual corporate officer is attributable to the company.

"[T]he corporate scienter inquiry must focus on the state of mind of the individual corporate official or officials who make or issue the statement (or order or approve it or its making or issuance, or who furnish information or language for inclusion therein, or the like) rather than generally to the collective knowledge of all the corporation's officers and employees acquired in the course of their employment." *Pugh*, 521 F.3d at 697 (internal quotation marks and citation omitted); *see also Makor*, 513 F.3d at 708 (same).

"To prove liability against a corporation, of course, a plaintiff must prove that an agent of the corporation committed a culpable act with the requisite scienter, and that the act (and accompanying mental state) are attributable to the corporation." *Teamsters Loc. 445 Freight Div. Pension Fund v. Dynex Cap. Inc.*, 531 F.3d 190, 195 (2d Cir. 2008) (citing *Makor*, 513 F.3d at 708).

"When the defendant is a corporate entity, this means that the pleaded facts must create a strong inference that someone whose intent could be imputed to the corporation acted with the requisite scienter." *Id.*

Generally, "[c]orporate scienter cannot be established in the absence of any individual corporate official's scienter." *See Chow v. Archer-Daniels-Midland Co.*, 2025 WL 790854, at *3 (N.D. Ill. 2025) (citing *Makor*, 513 F.3d at 708); *see also Plumbers & Pipefitters Loc. Union 719 Pension Fund v. Zimmer Holdings, Inc.*, 2011 WL 338865, at *18 n.9 (S.D. Ind. 2011) ("Having failed to establish the requisite strong inference of scienter on the part of either individual Defendant, we further find that Plaintiff has failed to establish Zimmer's corporate scienter."), *aff'd,* 679 F.3d 952 (7th Cir. 2012); *Smith v. PureCycle Techs., Inc.*, 2024 WL 5186586, at *15 (S.D.N.Y. 2024) ("But because the [complaint] fails to plead scienter plausibly against any individual defendant, and the plaintiff has failed to 'create a strong inference that someone [else]

whose intent could be imputed to [the defendant] acted with requisite scienter,' the [complaint] also fails to plead corporate scienter.") (quoting *Teamsters Loc. 445*, 531 F.3d at 195) (second alteration in original).

A corporation is only liable for statements by an employee who has apparent authority to make them. *See Makor*, 513 F.3d at 708. A corporation will be liable for "deliberate wrongs by an employee" only if they are both "within the scope of his employment" and "in attempted furtherance of the employer's goals." *Id.*

"The most straightforward way to raise [an inference of scienter] for a corporate defendant will be to plead it for an individual defendant." *See Teamsters Loc. 445*, 531 F.3d at 195. But in rare cases, a court can "draw a strong inference of corporate scienter" even if the complaint fails to "name the individuals who concocted and disseminated the fraud." *See Makor*, 513 F.3d at 710.

The *Makor* opinion offered a helpful example. If "General Motors announced that it had sold one million SUVs in 2006, and the actual number was zero," that announcement would create a "strong inference of corporate scienter, since so dramatic an announcement would have been approved by corporate officials sufficiently knowledgeable about the company to know that the announcement was false." *Id.*

As explained before, Plaintiffs failed to adequately plead scienter for the Individual Defendants. So, Plaintiffs cannot plead corporate scienter in the "most straightforward way." *See Teamsters Loc. 445*, 531 F.3d at 195.

Plaintiffs cannot create a strong inference of corporate scienter by other means, either. This isn't a case involving a dramatic statement by the company, with uncertainty about which

human drafted the statement. And except for the Individual Defendants, Plaintiffs haven't suggested that some other individual's scienter can be imputed to Abbott.

In sum, the complaint doesn't get over the scienter hump for the Individual Defendants. So it doesn't get over the hump for the company, either.

* * *

The punchline is that the complaint fails to allege facts that give rise to a strong inference of scienter, as required by the PSLRA. The complaint says a lot about knowledge of problems at the Sturgis facility. But it doesn't come close to satisfying the heightened pleading standards when it comes to intent to deceive.

The failure to allege scienter is an independent basis for dismissal of the first two claims under section 10(b) and Rule 10-b(5), meaning the claims about the statements and the conduct. The lack of scienter is a reason for dismissal, above and beyond all of the deficiencies that this Court has already addressed.

This Court previously rejected many of the allegations about misstatements (for lack of materiality, etc.), but did allow a few to survive. But scienter is a freestanding hurdle. And none of the claims got over the hump.

IV. Control Person Liability

The last remaining claim falls under section 20(a). Again, the statute creates vicarious liability for control persons. *See* 15 U.S.C. § 78t(a).

A violation of section 10(b) and Rule 10b-5 "is necessary to support a violation of section 20(a)." *See Pension Tr. Fund for Operating Engineers v. Kohl's Corp.*, 895 F.3d 933, 936 (7th Cir. 2018); *see also Pugh v. Trib. Co.*, 521 F.3d 686, 693 (7th Cir. 2008); *Foss v. Bear, Stearns*

& Co., 394 F.3d 540, 543 (7th Cir. 2005). So the dismissal of the first two claims means that the third claim fails, too.

V. Leave to Amend

This Court has completed its march through 486 paragraphs of a 217-page complaint. Despite its girth, the complaint fails to state a claim against Abbott or any of the Individual Defendants.

In their response brief, Plaintiffs asked for leave to file an amended complaint if this Court grants the motion to dismiss. Rule 15(a)(2) provides that a district court "should freely give leave when justice so requires." *See* Fed. R. Civ. P. 15(a)(2).

Even so, an opportunity to amend a complaint is not a sure thing. One could be forgiven for thinking that the case law places too much emphasis on the phrase "should freely give leave," and too little emphasis on the phrase "when justice so requires." *Id.*

Futility is a classic example of when amending a complaint makes little sense. *See, e.g.*, *Hongbo Han v. United Cont'l Holdings, Inc.*, 762 F.3d 598, 603 (7th Cir. 2014). After all, amending a complaint creates costs for the parties, and consumes judicial resources too. There is no point in another squeeze if the claims have no juice.

The complaint at hand is over 200 pages long. One has to think that Plaintiffs put it all on the table, and left it all on the floor. It's hard to imagine that Plaintiffs withheld anything that could change the outcome.

Even so, this Court will hear Plaintiffs out, if they want to make such a request. Any motion for leave to file a second amended complaint is due within three weeks of entry of this order. The Court reminds counsel to attach a proposed second amended complaint with a redline, as stated in this Court's Standing Order.

Conclusion

For the reasons explained above, the motion to dismiss the amended complaint is granted. Any motion for leave to file a second amended complaint is due within three weeks.

Date: July 24, 2026

Steven C. Seeger
United States District Judge