UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

THE TRUSTEES OF THE WELFARE AND PENSION FUNDS OF LOCAL 464A – PENSION FUND, et al., *Individually and on Behalf of All Others Similarly Situated*,	Case No. 22-cv-2197 (LMP/LIB)
Plaintiffs,	**ORDER GRANTING MOTION TO DISMISS FIRST AMENDED CONSOLIDATED COMPLAINT**
v.	
MEDTRONIC PLC, GEOFFREY S. MARTHA, KAREN L. PARKHILL, SEAN SALMON, and HOOMAN HAKAMI,	
Defendants.	

June Pineda Hoidal and Charles R. Toomajian, III, **Zimmerman Reed LLP, Minneapolis, MN**; Darryl J. Alvarado, Ashley M. Price, Erika L. Oliver, Jack Abbey Gephart, **Robins Geller Rudman & Dowd, San Diego, CA**, for Plaintiffs Phoenix Insurance Company Ltd. and Phoenix Provident Pension Fund Ltd.

Kristin K. Zinsmaster and Benjamin L. Ellison, **Jones Day, Minneapolis, MN**; Amanda M. MacDonald, Aden MacMillan, and Jamie Wolfe, **Williams & Connolly LLP, Washington, D.C.**, for Defendants Medtronic PLC, Geoffrey S. Martha, Karen L. Parkhill, Sean Salmon, and Hooman Hakami.

On March 28, 2024, the Honorable Katherine M. Menendez, United States District Judge for the District of Minnesota, dismissed the consolidated securities class action complaint brought by lead plaintiffs Phoenix Insurance Company Ltd. and Phoenix Provident Pension Fund Ltd. (collectively "Phoenix"). *See generally Trs. of Welfare & Pension Funds of Local 464A — Pension Fund v. Medtronic PLC*, 726 F. Supp. 3d 938 (D. Minn. 2024). With leave of court, ECF No. 97, Phoenix filed a first amended consolidated

complaint ("FACC"), ECF No. 99. Defendants Medtronic PLC, Geoffrey S. Martha, Karen L. Parkhill, Sean Salmon, and Hooman Hakami (collectively "Medtronic") move to dismiss.[1] ECF No. 108. Because the FACC suffers from the same deficiencies as those identified by Judge Menendez, the Court grants Medtronic's motion to dismiss and dismisses the FACC with prejudice.

BACKGROUND[2]

Phoenix represents a putative class of investors who purchased Medtronic common stock between May 23, 2019, and May 26, 2022 (the "Class Period"). ECF No. 99 ¶ 22. Phoenix alleges that during the Class Period, Medtronic engaged in two separate "schemes" intended to prevent internal issues from becoming public. *See id.* ¶ 1. The schemes, generally, can be separated into the time periods before and after the Food and Drug Administration ("FDA") investigated one of Medtronic's manufacturing facilities that produced products to help manage diabetes. That investigation began on June 7, 2021, and the FDA issued a Warning Letter as a result of the investigation on December 15, 2021. *Id.* ¶¶ 57–58.

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[1] During the relevant time period, Martha was Medtronic's President and is now Medtronic's Chief Executive Officer; Parkhill was Medtronic's Executive Vice President and Chief Financial Officer; and Hakami was the President of Medtronic's Diabetes Group until October 2019, when he was replaced by Salmon. ECF No. 99 ¶¶ 28–31.

[2] For purposes of assessing Defendant's motion to dismiss, the Court must accept the factual allegations in Phoenix's complaint as true. *L.H. v. Indep. Sch. Dist.*, 111 F.4th 886, 892 (8th Cir. 2024). As such, the Factual Background here is drawn largely from the FACC. ECF No. 99.

Phoenix alleges that prior to the FDA investigation, Medtronic and Defendants Hakami and Salmon "engaged in deceptive conduct for the purpose of covering up severe product quality issues" at the facility, "causing the price of Medtronic stock to trade at artificially inflated levels." *Id.* ¶ 7. Phoenix calls these actions the "scheme," and the Court will do the same. *Id.*

Phoenix also alleges that after the FDA launched its investigation, Medtronic made a series of misrepresentations intended to cover up the extent of the FDA investigation and, more importantly, the effect that it would have on the FDA's approval of a new Medtronic product. *See id.* ¶¶ 15–21. Phoenix alleges that between "August 2021 and December 2021," Medtronic issued "misleading statements concerning their interactions with the FDA, approval of the [product], regulatory compliance, and facility quality and investigations." *Id.* ¶ 15. Phoenix calls these actions the "misrepresentations," and again the Court will do the same.

The scheme and the misrepresentations were committed, according to Phoenix, to: (1) deceive Medtronic's investors; (2) artificially inflate and maintain Medtronic's stock price; and (3) cause Phoenix and members of the putative class it represents to acquire Medtronic stock at artificially inflated prices. *Id.* ¶ 207. Phoenix alleges the scheme and misrepresentations violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"), as amended by the Private Securities Litigation Reform Act of 1995 ("PSLRA"). *Id.* ¶ 22.

I. Medtronic and the Diabetes Group

Medtronic is a global healthcare company divided into four groups: (1) Cardiac and Vascular, (2) Minimally Invasive Therapies, (3) Restorative Therapies, and (4) Diabetes. *Id.* ¶¶ 36–37. The Diabetes Group contributes billions of dollars in revenue to Medtronic and was Medtronic's fastest growing group in 2018. *Id.* ¶ 38.

Diabetes is a disease that interferes with the body's ability to regulate the amount of glucose in the bloodstream. *Id.* ¶ 32. There are two types. *Id.* In Type 1 diabetes, the body mistakenly destroys pancreatic cells responsible for producing insulin, a hormone that helps blood cells receive glucose. *Id.* This leaves the body with insufficient insulin, and cells accordingly do not receive sufficient glucose. *Id.* at 18. Individuals with Type 2 diabetes produce enough insulin, but the body's cells have stopped responding to it, likewise leaving the cells with insufficient glucose. *Id.* For individuals with Type 1 diabetes, strict efforts must be made to keep the body's blood glucose concentrations between 80–120 milligrams per deciliter. *Id.* ¶ 33. When the concentration strays above or below that level, an individual is susceptible to severe medical complications, including death. *Id.*

Modern medicine has enabled the development of insulin pumps, which connect to the body and operate alongside an insulin cartridge to "allow a constant drip of miniscule, calibrated amounts of insulin" and "increas[e] the amount of time a diabetic can spend . . . within the target range." *Id.* ¶ 34. Modern pumps connect with a continuous glucose monitor, a separate device worn on the body which constantly reads an individual's glucose level and informs the pump how much insulin to deliver and when. *Id.* ¶ 35. These

systems are known as "hybrid closed loop systems." *Id.* But hybrid closed loop systems cannot determine when to deliver a "bolus," a one-time additional delivery of insulin necessary at mealtimes to control a corresponding glucose spike. *Id.* More advanced pumps, however, are capable of determining when to deliver such boluses, and they result in the closest replication of a healthy pancreas by providing the right amount of insulin with little to no human intervention. *Id.* These systems are known as "advanced hybrid closed loop systems." *Id.*

In 2009, Medtronic accounted for 58% of the insulin pump global market share, which grew to 70% by 2017. *Id.* ¶ 38. This was, in part, because of Medtronic's MiniMed line of insulin pumps. *Id.* ¶ 39. Prior to 2017, Medtronic had released several models of the MiniMed pump: the 620G, 630G, and 640G. *Id.* The entire MiniMed 600 Series is designed and manufactured in Medtronic's facility in Northridge, California (the "MiniMed Facility"). *Id.* ¶ 46. None of these original models—and, in fact, no model in the world at the time—operated as a "hybrid closed loop system." *Id.* That changed when Medtronic introduced the 670G model in 2017, which helped Medtronic maintain its dominance in the insulin pump market." *Id.* ¶¶ 39–40. By the end of 2019, however, Medtronic had lost ground in the market and the Diabetes Group's performance was stagnating, in part, because competitors had introduced products with "advanced hybrid closed-loop capabilities." *Id.* ¶ 45. As a result, on June 8, 2019, Medtronic announced a "pivotal trial" of its first advanced hybrid closed-loop product, the 780G. *Id.* ¶¶ 46, 47. The 780G was designed and manufactured in the MiniMed Facility and contained the same overall pump design as the 670G. *Id.* ¶ 46. Medtronic believed the 780G was superior to

its competitors' products in various ways and would help restore Medtronic's place as the global market leader. *Id.* ¶¶ 46–48.

Around the same time, in October 2019, Medtronic announced the departure of the head of its Diabetes Group. *Id.* ¶ 49. Hakami was replaced by Salmon. *Id.* ¶ 30. Medtronic also announced a new CEO, Geoffrey Martha, who acknowledged it was his priority to reinvigorate the Diabetes Group. *Id.* ¶¶ 28, 50.

II. Medtronic's Alleged Cover-up Scheme Successfully Minimizes Quality Issues for Years

Phoenix alleges that between May 23, 2019, and December 15, 2021, Medtronic, Hakami, and Salmon engaged in a scheme to fraudulently conceal significant quality issues with the MiniMed devices that they had known about since 2016. *Id.* ¶¶ 65–66, 68.

A. Medtronic Becomes Aware of, and Internally Minimizes, Retainer Ring Issues

In June 2016, Medtronic learned of manufacturing defects in the "clear retainer ring" of the 600 Series. *Id.* ¶ 68. This ring is "meant to lock together the pump and insulin cartridge." *Id.* ¶ 8. A faulty retainer ring could lead to "the over- or under-delivery of insulin resulting in serious, life-threatening conditions up to and including death." *Id.* Between June 2016 and November 2019, Medtronic received 74,000 complaints related to retainer rings. *Id.* ¶ 70.

Medtronic launched a series of internal studies to investigate the complaints. *Id.* ¶¶ 68, 74. But the studies, Phoenix alleges, were intentionally flawed and "inappropriately and consistently underestimated the likelihood that those pumps would harm patients." *Id.*¶ 69. Indeed, the FDA later concluded that "Medtronic understated the risk posed by

this defect and failed to warn customers of the potential for hazardous failure of the pumps." *Id.* ¶ 68. Phoenix alleges that these flawed studies, as a result, allowed Medtronic to "stay silent," at least for a time. *Id.* ¶ 71.

The complaints continued, and in March 2021, Medtronic commissioned another study with a new risk formula. *Id.* ¶ 75. According to Phoenix, this study was also intentionally flawed because it overestimated the number of units in use and increased the risk parameters. *Id.* Those flaws, in combination, allowed Medtronic to "manufacture an estimated probability of harm that was low enough to justify its refusal to recall" the pumps. *Id.* ¶ 76. The FDA later concluded that the study initially led to Medtronic "fail[ing] to adequately remove the pumps containing the older, less robust ring from the market." *Id.*

Phoenix also alleges that Medtronic publicly downplayed the risk posed by the MiniMed products. For instance, rather than acknowledging the internally identified issues regarding the flaw in the ring, Medtronic released several studies highlighting the pump's positive health benefits. *Id.* ¶¶ 81–84.

B. Medtronic Downplays Cybersecurity Issues

Separately, in 2018, Medtronic became aware of a software vulnerability which allowed unauthorized individuals to gain access to the remote controllers of the pumps in ways that might "result in catastrophic harm to patients." *Id.* ¶ 77. Medtronic once again commissioned an internal study, which led to the destruction of any non-shipped products and the recall of any vulnerable remotes shipped between 2014 and 2018, even though the vulnerability was present in all of Medtronic's remotes made since 1999. *Id.* ¶ 78. Because Medtronic's recall was limited only to some of the affected remotes, the FDA later found

the recall violated federal regulations and did not "notify all customers of this safety issue." *Id.* In doing so, Phoenix alleges that Medtronic "perpetuated the appearance that their diabetes products were safe and effective by keeping crucial information about potential cybersecurity vulnerabilities from customers." *Id.* ¶ 80.

C. Medtronic Issues a Recall

In August 2019, Medtronic began acting publicly to address the problems it had internally identified in 2016. *Id.* ¶ 86. It first quietly updated products released after August 2019 to include a "supposedly more robust black retainer ring." *Id.* Medtronic did not, however, address ring problems with earlier-released pumps until November 21, 2019. *Id.* ¶ 87. On that date, Medtronic issued a "Field Safety Notification," which formally and publicly acknowledged the product defects. *Id.* The notification directed users of the 630G and 670G models to "examine the pumps' retainer rings and notify [Medtronic] if the ring appeared damaged or missing." *Id.*

Although Medtronic did not consider its notification to be a "recall," on February 7, 2020, the FDA concluded that the Field Safety Notification constituted a Class I recall of not only the 630G and 670G models but also of the 620G and 640G models. *Id.* ¶¶ 89–90. According to the FDA, a Class I recall indicates "a reasonable probability that the use of or exposure to [the] violative product will cause serious adverse health consequences or death." *Id.* Initially—even after the recall—Medtronic encouraged users to continue to use the MiniMed pumps unless the retainer ring was not working properly. *Id.* ¶ 92. Eventually, the recall would expand to any MiniMed 600 Series product with a clear

retainer ring, even those with no visible damage and that appeared to be functioning properly. *Id.* ¶ 94.

D. The FDA Investigates and Criticizes Medtronic for Its Response to Years of Product Issues

When the FDA learns of a Class I recall, federal regulations allow the FDA to initiate an investigation into the recall's causes. *Id.* ¶ 95. Accordingly, from June 7 to July 7, 2021, the FDA inspected the MiniMed Facility. *Id.* Upon conclusion of the inspection, the FDA issued a Form 483. *Id.* ¶ 96. In general, a Form 483 is issued by the FDA to notify a company's "top management in writing of significant objectionable conditions, relating to products and/or processes . . . which were observed during the inspection." FDA Investigations Operations Manual, Ch. 5, § 5.5.10 (2025)); *see also Pub. Pension Fund Grp. v. KV Pharm. Co.*, 679 F.3d 972, 976 (8th Cir. 2012) (explaining the purpose of a Form 483). It is "presented and discussed with the company's senior management," and "[c]ompanies are encouraged to respond to the FDA Form 483 in writing with their corrective action plan and then implement that corrective action plan expeditiously."[3] The Form 483, though, "does not constitute a final Agency determination of whether any condition is in violation" but "is considered, along with a written report . . . , all evidence or documentation collected on-site, and any responses made by the company" to "determine[] what further action, if any, is appropriate." *Id.*

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[3] *FDA Form 483 Frequently Asked Questions*, U.S. Food & Drug Admin. (Jan. 9, 2020), https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/fda-form-483-frequently-asked-questions [https://perma.cc/3NQY-AHDB].

Here, the Form 483 informed Medtronic that the FDA found "multiple, systemic deficiencies" that "went well beyond the already significant manufacturing defects plaguing the MiniMed retainer rings." ECF No. 99 ¶ 96. For instance, the Form 483 stated that Medtronic: (1) failed to establish adequate "procedures for corrective and preventive action," referring to Medtronic's inappropriate risk analysis procedures; (2) failed to investigate "[c]omplaints involving the possible failure of a device to meet any of its specifications"; and (3) failed to implement written Medical Device Report (MDR) procedures. *Id.*; *see also id.* ¶ 166.

As noted, the issuance of a Form 483 is the first in a series of potential actions the FDA may take. *Id.* ¶ 124. Relevant here, after the initial inspection and issuance of a Form 483, the FDA engages in dialogue with the company and decides whether to issue a formal "warning letter." *Id.* "A Warning Letter is the agency's principal means of achieving prompt voluntary compliance," and they are "based on the expectation that most individuals and firms will voluntarily comply with the law." FDA Regulatory Procedures Manual, Ch. 4 § 4-1-1. Although a warning letter is significant and one of the FDA's final steps before bringing an enforcement action, "the letters [do not] represent a decision determining rights or obligations, or one from which legal consequences flow." *Holistic Candlers & Consumers Ass'n v. Food & Drug Admin.*, 664 F.3d 940, 944 (D.C. Cir. 2012).

On December 9, 2021, the FDA issued Medtronic a Warning Letter. *Id.* ¶ 98. The Warning Letter noted that:

> Medtronic utilized an incorrect risk threshold when evaluating the danger posed by the 600 Series pumps; failed to adequately review and investigate complaints regarding failed retainer rings; failed to

> adequately review and investigate new complaints regarding the supposedly fixed replacement retainer rings; failed to timely notify the FDA of a reportable serious injury potentially caused by one of Medtronic's defective pumps; and failed to timely notify the FDA of reports that its devices may be malfunctioning in a manner likely to cause or contribute to death or serious injury if the malfunction was to recur.

Id. (internal quotation marks omitted).

Specifically, regarding Medtronic's "procedures for corrective and preventive action," the FDA explained that "there was a reasonable probability that the use of, or exposure to, the pumps manufactured with the clear retainer ring would cause serious adverse health consequences." *Id.* ¶ 100. Yet according to the Warning Letter, Medtronic "failed to adequately analyze all sources of quality data, failed to identify actions needed to correct nonconforming product, and . . . did not appropriately verify or validate the change to [the] device to ensure corrective and preventive actions taken were effective and did not adversely affect the finished device." *Id.* Regarding Medtronic's complaint evaluation process, the Warning Letter noted "multiple instances where the Diabetes Group received complaints of defective pumps and adverse health results" but "failed to report those complaints, as required by applicable regulations." *Id.* ¶ 101. And regarding Medtronic's failure to notify the FDA of the complaints it received, the Warning Letter "detailed multiple instances where the Diabetes Group failed to submit required MDRs" or "where the Diabetes Group submitted MDRs beyond the required due dates." *Id.* ¶ 102.

E. Hakami and Salmon Were Aware of, But Downplayed, the Product Issues

Phoenix finally alleges that Hakami and Salmon intentionally downplayed the issues because they were under pressure to reinvigorate the Diabetes Group. For instance, Phoenix alleges that Hakami and Salmon were responsible for the "oversight of quality problems and corrective actions concerning the MiniMed 600 Series" due to their positions as leaders of the Diabetes Group. *Id.* ¶ 110. Consequently, they would have had knowledge of the issues plaguing the production of the pumps. *Id.* Indeed, a confidential witness explained that Salmon attended monthly "product review" meetings and that "all developments in the Diabetes units were reported up the chain of command to the CEO." *Id.* ¶ 63. Despite their knowledge, Hakami and Salmon repeatedly misled the public about the status of the Diabetes Group, expressing that the Group was strong and that future product innovations were imminent. *See, e.g., id.* ¶ 107. They did so, allegedly, because they were under pressure to revitalize the Diabetes Group, and because that revitalization was directly conditioned on getting approval of the 780G from the FDA. *Id.* ¶¶ 112–13.

III. Medtronic's Alleged Misrepresentation Successfully Delays the Disclosure of the FDA Investigation and Its Effect on the 780G's Approval

Separate from the scheme, Phoenix also alleges that Medtronic engaged in public misrepresentations concerning the status of the 780G, intentionally downplaying the FDA's investigation and the effect it would have on the 780G's approval.

The first major step towards the 780G's introduction came on February 22, 2021, when Medtronic submitted the 780G for approval to the FDA. *Id.* ¶ 51. The next day, Martha told investors that Medtronic was "gaining momentum with the successful

launch[]" of the 780G. *Id.* ¶ 53. In May 2021, Martha reiterated his stance, stating that the 780G was "under active review with the FDA." *Id.* ¶ 54. As a result, some stock market analysts anticipated that the 780G would receive approval by April 2022 and projected growth for Medtronic. *Id.* ¶¶ 54–55. April 2022 marked the end of Medtronic's 2021 fiscal year. *See id.* ¶ 54; *see also id.* ¶ 36 n.2 ("Medtronic's fiscal year . . . ends on the last Friday in April of each calendar year and begins immediately thereafter.").

But Phoenix alleges that the approval of the 780G was put in jeopardy by the FDA's July 2021 investigation. *Id.* ¶ 123. Phoenix alleges that the Form 483 identified such fundamental issues that Medtronic was aware, by July 7, 2021, that the FDA would not approve the 780G for at least a year and that this fact became increasingly apparent to Medtronic as it attempted to remediate its MiniMed Facility. *Id.*

A. Medtronic's Private Response to the Form 483

On July 7, 2021, the FDA and senior managers from Medtronic discussed the Form 483 and two additional "management discussion topics." *Id.* ¶ 126. At that meeting, the FDA also set out corrective action that Medtronic would need to take to return the MiniMed Facility to compliance. *Id.* ¶ 127. Phoenix alleges that the deficiencies, and the identified defects, were "fundamental" and would take a "year or longer" to remediate. *Id.* ¶ 123.

In the following months, Medtronic sent a series of letters to the FDA in an effort to stave off a warning letter. First, it sent a letter on July 28, 2021, in which Salmon acknowledged that Medtronic would need to take "broad, systemic actions" to address the deficiencies identified by the FDA and that Medtronic would provide its first "periodic

update[] on the progress" of its remediation efforts by September 3, 2021. *Id.* ¶ 129. The letter also included 68 pages of "action items" that Medtronic believed were necessary for the remediation and anticipated that these initial measures would not be complete until January 31, 2022. *Id.*

On September 3, 2021, Medtronic sent another letter detailing its initial remediation actions. *Id.* ¶ 141. The letter also identified unexecuted remediation actions and again estimated that those would be completed by January 31, 2022. *Id.* Nevertheless, Phoenix alleges that even if the deficiencies were fixed by January 31, 2022, it would take several months *after* the completion of remediation efforts for the FDA to review Medtronic's efforts. *Id.*

On October 5, 2021, Medtronic updated its previously announced limited recall to include not just damaged products but "any 600 series" pumps with a clear retainer ring. *Id.* ¶ 142. On October 8, 2021, Salmon sent a third letter to the FDA, again explaining that Medtronic had undertaken some remediation actions but that many remained outstanding. *Id.* ¶ 144. On November 5, 2021, Salmon updated the status of Medtronic's efforts, explained that any outstanding remediation efforts would not be complete until June 24, 2022, and acknowledged that other planned corrective actions did not have an estimated completion date. *Id.* ¶ 147. Finally, on December 3, 2021, Salmon again identified planned but incomplete remediation efforts and estimated that these would not be completed until January 14, 2023. *Id.* ¶ 152.

The FDA, apparently, was dissatisfied with Medtronic's initial responses to the Form 483 and issued a Warning Letter on December 9, 2021. *Id.* ¶ 153. The Warning

Letter explained that Medtronic's responses to the Form 483 were "not adequate" and that the FDA would not grant approval of "Class III devices to which the Quality System regulation deficiencies are reasonably related . . . until the deficiencies have been corrected." *Id.*

B. Public-Facing Optimism and Analyst Anticipation

Phoenix alleges that despite Medtronic's knowledge of the Form 483, Medtronic made a series of public misrepresentations aimed at hiding the FDA investigation and overstating the likelihood that the 780G would receive FDA approval by April 2022.

First, on August 24, 2021, Medtronic issued its Quarter 1 Form 8-K[4] touting the growth of the 780G in international markets and emphasizing Medtronic's expectation that revenue would continue to grow. *Id.* ¶ 130. Martha and Salmon thereafter held an earnings call, during which Martha represented that the 780G was under review with the FDA, and in which Salmon noted that Medtronic's discussions with the FDA were "really good," that "it's hard to handicap exactly when" the 780G would be approved, but that "things are on track as far as we can tell." *Id.* ¶¶ 132–33. Martha also gave a televised interview in which he stated that Medtronic's conversations with the FDA were "very positive" and attributed any delay in the 780G approval process to the FDA's focus on its COVID-19 response. *Id.* ¶ 134.

[4] According to the SEC's website, a Form 8-K "is the 'current report' companies must file with the SEC to announce major events that shareholders should know about." *Form 8-K,* U.S. Sec. & Exch. Comm'n (Aug. 10, 2012), https://www.sec.gov/answers/form8k.htm [https://perma.cc/24DH-D4M3].

The same day, market analysts projected optimism about the 780G's approval by the end of April 2022, and variously stated that "approval could come before the end of this calendar year"; that "FDA approval [is] likely in FY'22"; that Medtronic continued to hope that approval would come in 2021; that approval was likely in the "next couple quarters"; and that "management does view approval prior to year-end 2021 as realistic." *Id.* ¶ 137. Nevertheless, analysts also acknowledged that the FDA was overwhelmed with its COVID-19 response and that "[m]ost diabetes FDA submissions have faced delays this year." *Id.* ¶ 138.

A week later, on September 1, 2021, Martha reiterated that Medtronic was in "active dialogue" with the FDA "on these approvals." *Id.* ¶ 139. Nevertheless, he acknowledged that the FDA was "pretty busy with" COVID-19 and that it was therefore difficult to determine when to expect the 780G's approval *Id.* The next day, Medtronic released its Quarter 1 financial results for fiscal year ("FY") 2022 on a Form 10-Q.[5] *Id.* ¶ 155. In that Form 10-Q, Medtronic acknowledged, generally, that the FDA had the power to inspect any of its facilities, issue a Form 483 or warning letter, and deny product approval applications if the FDA determined that it was "not in compliance with applicable laws or

[5] The Form 10-Q "includes unaudited financial statements and provides a continuing view of the company's financial position during the year." *Form 10-Q*, U.S. Sec. & Exch. Comm'n, https://www.investor.gov/introduction-investing/investing-basics/glossary/form-10-q [https://perma.cc/SM24-59FN].

regulations." *Id.* Medtronic, however, did not acknowledge explicitly that the FDA had already taken some of these steps.[6] *Id.* ¶ 157.

On October 12, 2021, Medtronic issued an Integrated Performance Report ("IPR"). *Id.* ¶ 145. In the IPR, Medtronic stated, "We adhere to regulatory requirements, . . . and we update our procedures in line with emerging regulations and standards." *Id.* The IPR also stated that Medtronic had improved its facility quality and compliance. *Id.* ¶ 146.

Finally, on November 23, 2021, Medtronic issued its Quarter 2 FY22 Form 8-K, highlighting "[s]trong pump sales." *Id.* ¶ 149. Martha later stated that the 780G was "under active review with the FDA" and that "our diabetes turnaround is coming." *Id.* Salmon also reiterated that nothing had changed with the 780G approval process since Quarter 1 and that Medtronic had "very good interactive conversations with the FDA" and was "making excellent progress there." *Id.* Once again, market analysts projected 780G approval in early 2022. *Id.* ¶ 151.

According to Phoenix, all of these public statements were misrepresentations because Medtronic knew by no later than July 7, 2021, that the 780G would not be approved until Medtronic remediated all of the issues identified by the FDA in the Form 483, and Medtronic knew that it could not fully remediate the issues in less than a year. *See generally id.* ¶ 154.

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[6] Medtronic issued the same statement in its Quarter 2 FY22 10-Q, issued on December 2, 2021. ECF No. 99 ¶ 156.

C. The FDA Issues Come to Light, the Market Reacts, and Medtronic Does Damage Control

On December 9, 2021, the FDA issued its Warning Letter, *id.* ¶ 98, which Medtronic made public through a press release on December 15, 2021, *id.* ¶ 188. The press release acknowledged for the first time that the FDA inspected the MiniMed Facility in 2021 and explained that the Warning Letter "focuses on the inadequacy of specific medical device quality system requirements at the [MiniMed Facility] in the areas of risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events." *Id.* On the same day, Medtronic announced that the Warning Letter created uncertainty about FDA approval of its diabetes products and that, as a result, it was lowering its previous expectations for the Diabetes Group's 2022 revenue. *Id.*

On January 10, 2022, Martha publicly acknowledged that the MiniMed Facility required "extensive remediation," *id.* ¶ 59, and later stated that the Diabetes Group's first priority was "to work the warning letter issues," which Medtronic had "been working on . . . for 2 years now, even before the warning letter was issued," *id.* ¶ 158. Another executive noted that Medtronic had "a lot of work to do" to solve the issues identified by the FDA. *Id.* ¶ 59.

On May 26, 2022, Medtronic announced the Diabetes Group's 2022 fiscal year financial results and 2023 outlook: revenue was down 3% in 2022 and was expected to decrease another 6 to 7% in 2023. *Id.* ¶ 189. Medtronic admitted that it did not believe that the 780G would receive approval during its 2023 fiscal year, meaning that it would not be approved before April 2023, because, as Salmon acknowledged, Medtronic needed to

improve its quality systems to meet the FDA's demands. *Id.* As a result, Medtronic stock fell 5.8%. *Id.*

Medtronic announced on April 21, 2023, that the FDA had approved the 780G and on April 25, 2023, announced that the FDA had lifted the Warning Letter. *Id.* ¶ 190.

IV. Confidential Witnesses

To support the FACC, Phoenix obtained information from two individuals, Confidential Witnesses 1 and 2 ("CW-1" and "CW-2"). *Id.* ¶¶ 61–63.

CW-1 was a Diabetes Management Consultant and a Senior Territory Manager from June 2006 through April 2018, and a Principal Territory Manager from April 2018 to January 2022. CW-1 also sold MiniMed pumps. *Id.* ¶ 62. CW-1 explained that Medtronic faced four problems with the MiniMed pumps: "a retainer ring issue, a blood glucose loop issue, a reservoir clogging issue, and an alarm sounding issue." *Id.* CW-1 believes that these issues arose when Hakami instituted cost cutting measures within the Diabetes Group. *Id.*

CW-2 was a Senior Director at Medtronic from October 2020 to August 2022 and managed a group responsible for obtaining FDA approval of the 780G. *Id.* ¶ 63. CW-2 states that executive management at Medtronic knew that the 780G would not be approved by the FDA even before the Warning Letter was issued but that Medtronic nevertheless "continued to communicate misinformation to the public." *Id.* CW-2 also estimated that it would take one or two years to address the problems identified by the FDA in the Form 483 and that management did not share the 780G's approval progress, or lack thereof, with the public. *Id.* In fact, CW-2 informed executive management that the 780G would

not be timely approved but was told that such information should not be made public. *Id.* Finally, CW-2 said that "problems with FDA approval of the MiniMed 780G system became clear" in November 2021 because the FDA stalled a different Medtronic product, and Medtronic understood that to be a "a hint that a warning letter was coming." *Id.*

V. Procedural Background

A. The First Consolidated Complaint

Phoenix initiated this action on September 8, 2022, ECF No. 1, and filed its first consolidated complaint ("FCC") on February 14, 2023, ECF No. 58. Like the present complaint, the FCC alleged, generally, that Defendants, through a scheme and misrepresentations, (1) violated Section 10(b) of the Exchange Act and 17 C.F.R. § 240.10b-5, a rule implemented pursuant to the Exchange Act; and (2) violated Section 20(a) of the Exchange Act. ECF No. 58 ¶¶ 270–286; *see also Medtronic,* 726 F. Supp. 3d at 950–59 (detailing the FCC's factual background).

Although the FCC alleged the same scheme conduct as the present FACC,[7] the FCC alleged a much broader series of misrepresentations. For instance, whereas the FACC alleges eight misrepresentations made between August 24 and December 2, 2021, *see*

[7] The FCC's scheme liability claims were based on: (1) allegedly erroneous 2016 and 2021 internal studies commissioned by Medtronic but withheld from the public, ECF No. 58 ¶¶ 47–56; (2) Medtronic's alleged disregard of cybersecurity issues, *id.* ¶¶ 57–60; (3) 2018 and 2019 publicly released studies purportedly highlighting the safety of the MiniMed products, *id.* ¶¶ 61–64; and (4) Medtronic's actions in downplaying the retainer ring issues prior to the FDA's full recall, *id.* ¶¶ 65–76. The FACC's scheme claim presents the same four categories. *See* ECF No. 99 ¶¶ 67–76 (erroneous internal studies), ¶¶ 77–80 (disregard of known cybersecurity issues), ¶¶ 81–84 (2018 and 2019 misleading public studies), ¶¶ 85–94 (downplaying retainer ring issues until full recall).

generally ECF No. 99 ¶¶ 15–19, the FCC alleged dozens of misrepresentations made by Medtronic between June 9, 2019 and March 3, 2022, ECF No. 58 ¶¶ 117–89. Judge Menendez grouped the alleged misrepresentations into four categories: (1) statements about the MiniMed 600 Series pumps; (2) statements concerning the FDA approval process for the 780G made both before and after the Form 483 was issued; (3) misleading statements in Medtronic's Form 10-K and Form 10-Q filings with the SEC; and (4) omissions from SEC filings that violated Item 303 of SEC Regulation S-K.[8] *Medtronic,* 726 F. Supp. 3d at 962–64.

Medtronic moved to dismiss the FCC, ECF No. 63, and on March 28, 2024, Judge Menendez granted the motion. *See generally Medtronic,* 726 F. Supp. 3d at 993. Judge Menendez determined that Phoenix had not identified any actionable misstatements made by any Defendant and that Phoenix had not adequately pleaded that any Defendant acted with scienter—that is, with "intention to deceive, manipulate, or defraud," or otherwise with "severe recklessness"—as is required for both of Phoenix's claims, *see Medtronic,* 726 F. Supp. 3d at 965–91.

[8] Item 303(a)(3) "requires disclosure of, among other things, 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." *Medtronic,* 726 F. Supp. 3d at 957.

VI. The First Amended Consolidated Complaint

On April 29, 2024, Phoenix filed a motion for leave to file an amended complaint, ECF No. 82, which Judge Menendez granted, ECF No. 97.[9]

In Count I of the FACC, Phoenix generally alleges the same two types of liability under Section 10(b) of the Exchange Act as in the FCC: (1) misrepresentation liability based on Rule 10b-5(a), and (2) scheme liability based on Rule 10b-5(a). ECF No. 99 ¶¶ 64, 122, 206. In Count II, Phoenix alleges Section 20(a) controlling-person claims against the individual defendants. ECF No. 99 ¶¶ 221–22. Section 20(a) claims are entirely derivative of Section 10(b) claims. *See Lustgraaf v. Behrens*, 619 F.3d 867, 874 (8th Cir. 2010).

As Judge Menendez noted, the FACC makes significant changes, at least as to Phoenix's misrepresentation theory in Count I.[10] Most importantly, the FACC significantly narrows the number of alleged misrepresentations. Gone are any misrepresentations related to the 600 Series pumps; statements concerning the likelihood of the 780G's approval made *before* the FDA began its investigation on June 7, 2021; and any Item 303 omissions. *See* ECF No. 115 at 26–27. In place of those misrepresentations, Phoenix now limits its claim to eight alleged misrepresentations, all made *after* the FDA concluded its investigation on July 7, 2021 and provided Medtronic with the Form 483. The statements

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[9] The case was reassigned to the undersigned on October 28, 2024. ECF No. 100.

[10] Phoenix's scheme liability claim is largely unchanged, premised again on actions taken by Medtronic between May 23, 2019, and December 15, 2021, to conceal problems with the Diabetes Group and the MiniMed Facility. ECF No. 99 ¶¶ 64–66.

fall into three broad categories: (1) statements concerning the FDA approval process of the 780G made after the FDA investigation started; (2) statements regarding Medtronic's compliance with FDA regulations; and (3) statements about the status of risks faced by Medtronic.

i. Statements on the FDA's Approval Process of the 780G

Phoenix first asserts that four public statements made by Salmon and Martha regarding the status of the approval process of the 780G were materially misleading. Those statements are:

(1) Salmon's August 24, 2021 statement that:

> The combination of 780G with the sensor that doesn't require confirmation, call it non-adjunctive, has been filed in the United States and *we're seeing really good interactive back and forth review so that's really good*. But that Europe launch right in the second quarter where you have a no finger stick sensor mixed with an infusion set and 780G. It's really a nice combination. Of course, we'd love to bring that to the U.S. as soon as possible. *But things are on track as far as we can tell. As you may know, that division of FDA has been very busy with COVID*, so it's hard to handicap exactly when time lines happen. *But we do think we're making good progress in the review.*

ECF No. 99 ¶ 133 (emphasis in original).

(2) Martha's August 24, 2021 statement that:

> [W]e have a very rich pipeline of new pumps, new sensors, new continuous glucose monitoring sensors, new infusion sets that are used to deliver the insulin from you know into the body and even new form factors. We've got a new smart pen. So we've got a great pipeline of products actually on the market in Europe and growing very well and taking share. *And we just got to get those products from Europe approved here in the United States. And the FDA has been very busy with COVID and a few other things. But the*

> *conversations we're having with them have been very positive on Diabetes approvals.*

Id. ¶ 134 (emphasis in original).

(3) Martha's September 1, 2021 comment that:

> *The FDA that handles that approval's been pretty busy with COVID* and it's hard to handicap and approve it, *but we're [in] active dialogue with them on these approvals with our pump* and new sensor and various other things.

Id. ¶ 139 (emphasis in original).

(6) Salmon's November 23, 2021 statement that:

> Yes, Larry, *so nothing different than what we've been talking about all along*. We've got really strong uptake of 780G and Guardians 4 Sensor outside the United States. In the U.S., we have just – we're waiting for that approval to come through, and *we've had very good interactive conversations with FDA*. I think *we're making excellent progress there*.

Id. ¶ 149 (emphasis in original).[11]

Of these, statements numbers one and six were also included in Phoenix's FCC. *See* ECF No. 58 ¶¶ 165, 169. Judge Menendez determined they were inactionable because they constituted "statements of optimism or puffery" or "inactionable opinions." *Medtronic*, 726 F. Supp. 3d at 969–70 ("The Court finds that statements in which Defendants characterized their conversations with the FDA as "good" or "interactive" are inherently subjective statements of optimism, not objective statements of fact that reasonable investors would rely on in making investment decisions.").

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[11] Phoenix numbers the misstatements according to the date they were made, whereas the Court here lists them by category. To avoid confusion, the Court will continue to refer to Phoenix's assigned numbers.

ii. Statements about Medtronic's FDA Compliance

Next, Phoenix alleges that statements made in Medtronic's October 12, 2021 IPR were misleading. First, Phoenix takes issue with Medtronic's statement that "[w]e adhere to regulatory requirements, such as those set by the U.S. FDA, and we update our procedures in line with emerging regulations and standards." ECF No. 99 ¶ 145. Second, Phoenix challenges a statement in the same report that "[i]n FY21, we received an average of . . . 0.02 findings per U.S. Food and Drug Administration (FDA) inspection—continuing to demonstrate year-on-year improvements." *Id.* ¶ 146. Neither of these statements were included in the FCC considered by Judge Menendez.

iii. Statements About the Status of Risks

Finally, Phoenix alleges that Medtronic misled its investors in its September and December 2021 Form 10-Qs. ECF No. 99 ¶¶ 155–56. In those documents, Medtronic identified "risk factors" by stating as follows:

> Both before and after a product is commercially released, *we have ongoing responsibilities under the U.S. FDA* and other applicable non-U.S. government agency regulations. For instance, *many of our facilities and procedures and those of our suppliers are also subject to periodic inspections by the U.S. FDA to determine compliance with applicable regulations. The results of these inspections can include inspectional observations on the U.S. FDA's Form 483,* warning letters, or other forms of enforcement. *If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations*, or that any of our medical products are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such medical products, detain or seize adulterated or misbranded medical products, order a recall, repair, replacement, or refund of such products, *refuse to grant pending pre-market approval applications or require certificates of non-U.S. governments for exports*, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health.

ECF No. 99 ¶¶ 155–56 (emphasis in original).

Both of these alleged misrepresentations were included in the FCC. ECF No. 58 ¶ 176(b). Judge Menendez held that they were either not false or constituted inactionable forward-looking statements. "Plaintiffs have not plausibly alleged that at the times Defendants made the forward-looking statements, they knew that the potential risk of FDA delay or regulatory denial about which they cautioned had already been realized." *Medtronic*, 726 F. Supp. 3d at 974.

Medtronic moves to dismiss the FACC, arguing that the misrepresentation theory is inadequate for the same reasons it was rejected by Judge Menendez: it "hinges on the hindsight driven view that, absent any communication from the FDA, [Medtronic] should have assumed the FDA would delay 780G approval because of its observations in the Form 483." ECF No. 108 at 26, 30. As for scheme liability, Medtronic argues that Phoenix again fails to plead a "scheme," or that any Defendant acted with scienter. *Id.* at 45–50; *see* ECF No. 99 ¶¶ 64–66.

ANALYSIS

I. Standard of Review and Applicable Law

Section 10(b) of the Exchange Act, codified at 15 U.S.C. § 78j(b), prohibits "the use of any manipulative or deceptive device or contrivance in connection with the purchase or sale of a security." *In re K-tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 888 (8th Cir. 2002) (citation omitted) (internal quotation marks omitted). Rule 10b-5, implemented pursuant to the Exchange Act, specifically makes it unlawful for any person, by or through interstate commerce, mail, or any national securities exchange facility:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) 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, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person.

17 C.F.R. § 240.10b-5. Together, Section 10(b) and Rule 10b-5 impose liability under two theories: (1) "false statement liability" under 17 C.F.R. § 240.10b–5(b); and (2) "scheme liability" under 17 C.F.R. § 240.10b–5(a) and (c). *W. Va. Pipe Trades Health & Welfare Fund v. Medtronic, Inc*. (*W. Va. Pipe Trades II*), 845 F.3d 384, 389 (8th Cir. 2016).

To prevail on a misrepresentation—that is, "false statement"—theory, a plaintiff must show: (1) a material misrepresentation or omission by the defendant, (2) scienter, (3) a connection between the misrepresentation or omission and the purchase or sale of a security, (4) reliance upon the misrepresentation or omission, (5) economic loss, and (6) loss causation. *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37–38 (2011).

To prevail on a scheme theory, a plaintiff must show: (1) that the defendant committed a deceptive act, (2) with scienter, (3) that the act affected the market for securities or was otherwise in connection with their purchase or sale, and (4) that defendant's actions caused the plaintiff's injuries. *W. Va. Pipe Trades II*, 845 F.3d at 389 (quoting *In re Parmalat Sec. Litig*., 414 F. Supp. 2d 428, 432 (S.D.N.Y. 2006)).

In addition, Section 20(a) of the Exchange Act, codified at 15 U.S.C. § 78t(a), provides that a "person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly

and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable." 15 U.S.C. § 78t(a). So-called "controlling person" claims must show that: (1) a primary violator violated the federal securities laws; (2) the alleged control person actually exercised control over the general operations of the primary violator; and (3) the alleged control person possessed—but did not necessarily exercise—the power to determine the specific acts or omissions upon which the underlying violation is predicated. *Lustgraaf*, 619 F.3d at 873. Nevertheless, controlling-person claims are derivative of misrepresentation and scheme liability violations, so if a misrepresentation or scheme claim fails, the derivative controlling-person claim fails as well. *See id.* at 874.

Both misrepresentation and scheme liability claims are subject to a heightened pleading standard. *See id.* For a misrepresentation claim, the PSLRA requires that a complaint "'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 must 'state with particularity all facts on which that belief is formed.'" *City of Plantation Police Officers Pension Fund v. Meredith Corp.*, 16 F.4th 553, 556 (8th Cir. 2021) (quoting 15 U.S.C. § 78u-4(b)(1)). This means that the "circumstances of the fraud must be stated with particularity, including such matters as the time, place and contents of false representations," the "identity of the person" who made the representations, and "what was obtained or given up" in reliance on the representations—in other words, "the who, what, when, where, and how." *In re K-tel Int'l*, 300 F.3d at 890 (citation omitted) (internal quotation marks omitted). Scheme liability claims are not subject to the PSLRA's heightened standard but nevertheless must meet the

heightened pleading standard under Federal Rule of Civil Procedure 9(b). This means that the complaint must state, with particularity, "what manipulative acts were performed, which defendants performed them, when the manipulative acts were performed and what effect the scheme had on the securities at issue." *KV Pharm.*, 679 F.3d at 986 (citation omitted). To adequately plead the scienter element required for both misrepresentation and scheme claims, the complaint also must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." *Lustgraaf*, 619 F.3d at 873 (quoting 15 U.S.C. § 78u-4(b)(2)).

As is the case with any motion to dismiss, the Court must "accept as true" Phoenix's factual allegations and "grant all reasonable inferences" in Phoenix's favor. *Minneapolis Firefighters Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1027 (8th Cir. 2011).

II. Misrepresentation Liability

Medtronic argues that Phoenix fails to identify any actionable misrepresentations and to show that Medtronic acted with scienter.[12] ECF No. 110 at 30–45. The Court agrees

[12] Medtronic does not contest the remaining four elements: connection between the misrepresentation or omission and the purchase of a security; reliance upon the misrepresentation or omission; economic loss; and causation. *Matrixx Initiatives*, 563 U.S. at 37–38.

that none of the alleged misrepresentations by Medtronic are actionable and, as a result, need not discuss whether Phoenix adequately alleged scienter.[13]

In general, the Exchange Act prohibits making a statement *or* omission that is "*misleading* as to a *material* fact." *Matrixx Initiatives*, 563 U.S. at 38 (citation omitted). A statement or omission is misleading "if it would give a reasonable investor the 'impression of a state of affairs that differs in a material way from the one that actually exists.'" *Retail Wholesale & Dep't Store Union Local 338 Ret. Fund v. Hewlett-Packard Co.*, 845 F.3d 1268, 1275 (9th Cir. 2017) (citation omitted). A statement or omission is *material* only if 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." *KV Pharm.*, 679 F.3d at 981 (citation omitted).

Accordingly, "[n]ot all inaccurate statements constitute material misrepresentations." *City of Plantation*, 16 F.4th at 556. Indeed, Congress and the courts have identified several categorically inactionable statements such as statements of puffery or corporate optimism, statements of opinion, and forward-looking statements.

"Puffery," statements are "vague" and "obvious hyperbole," and they are immaterial and therefore not actionable because "no reasonable investor would rely upon" them. *In re Stratasys Ltd. S'holder Sec. Litig.*, 864 F.3d 879, 882 (8th Cir. 2017) (citation omitted). "Examples of corporate puffery include forecasts of 'significant growth,' claims that a

[13] Judge Menendez found that Phoenix had not adequately alleged scienter. *Medtronic*, 726 F. Supp. 3d at 977–91. Most of the allegations surrounding scienter in the FACC are identical to those already discussed and rejected by Judge Menendez. *Compare* ECF No. 58 ¶¶ 193–250 *with* ECF No. 99 ¶¶ 158–82.

company is 'recession-resistant,' and boasts that a company is 'leading the race.'" *City of Plantation*, 16 F.4th at 557 (citations omitted).

Statements of corporate opinion are generally inactionable because they are not misleading. *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 186 (2015) ("[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."). An opinion is a "belief," a "view," or a "sentiment which the mind forms of persons or things" that, unlike a "statement of fact," does not "express[] certainty about a thing." *Id.* at 183 (citation omitted). To be sure, there are circumstances in which a statement of opinion might be actionable, such as where: "(1) the speaker did not hold the stated belief; (2) the statements 'contain embedded statements of fact'; or (3) the statement 'omits material facts about the issuer's inquiry into or knowledge concerning a statement of opinion, and if those facts conflict with what a reasonable investor would take from the statement itself.'" *In re 3M Co. Sec. Litig.*, No. 20-cv-2488 (NEB/KMM), 2021 WL 4482987, at *14 (D. Minn. Sept. 30, 2021) (quoting *Omnicare*, 575 U.S. at 184–89). Even then, however, a statement of opinion is "not necessarily misleading" simply because "an issuer knows, but fails to disclose, some fact cutting the other way" because "[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts." *Omnicare*, 575 U.S. at 189–90. Therefore, to show that an opinion misleadingly omitted material information, "[t]he investor must identify particular (and material) facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context." *Id.* at 194.

Forward-looking statements are also generally inactionable if they are "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement." *City of Plantation*, 16 F.4th at 556 (quoting 15 U.S.C. § 78u-5(c)(1)(A)(i)). A "statement is forward-looking if and only if its truth or falsity is discernible only after it is made." *Id.* (citation omitted) (internal quotation marks omitted). But a forward-looking statement may be actionable if it was "made with actual knowledge by that person that the statement was false or misleading." 15 U.S.C. § 78u-5(c)(1)(B)(i).

Finally, for a materially misleading statement or omission to be actionable, it must have been known to be false or misleading at the time it was made. That is because courts may not assume that "simply because the alleged misrepresentation conflicts with the current state of facts, the charged statement must have been false." *In re K-tel Int'l*, 300 F.3d at 891 (citation omitted). A plaintiff must therefore "allege 'facts or further particularities that, if true, demonstrate that the defendants had access to, or knowledge of, information contradicting their public statements when they were made.'" *Id.* (quoting *In re Navarre Corp. Sec. Litig.*, 299 F.3d 735, 742 (8th Cir. 2002)).

A. None of the Alleged Statements by Medtronic are Actionable Misrepresentations

As noted, Phoenix's misrepresentation claims are based on statements made by various Medtronic officials after June 7, 2021, and the Court groups Phoenix's eight alleged misrepresentations into three general categories: (1) Medtronic's statements on the status of the FDA's approval process of the 780G; (2) Medtronic's statements about its

compliance with FDA regulations; and (3) Medtronic's omissions about potential risk factors.

i. Statements on the FDA's Approval Process of the 780G

Phoenix first asserts that four public statements (statements 1, 2, 3, and 6) made by Salmon and Martha regarding the status of the approval process of the 780G were materially misleading. These statements are Salmon's August 24, 2021 statement, ECF No. 99 ¶ 133; Martha's August 24, 2021 statement, *id.* ¶ 134; Martha's September 1, 2021 statement, *id.* ¶ 139; and Salmon's November 23, 2021 statement, *id.* ¶ 149. Phoenix argues that these statements were misleading because Salmon and Martha either: (1) "misrepresented their dealings with the FDA" on the back and forth regarding the 780G approval process,[14] ECF No. 115 at 45–50; or (2) misrepresented the status and timing of the 780G's approval because the statements did not accurately account for an imperiled approval process, *id.* at 50–55.

a) Dealings with the FDA

Phoenix's first category—statements that "misrepresented [Medtronic's] dealings with the FDA" on the 780G—is premised on a portion of Salmon's August 24, 2021 statement in which he said that "we're seeing really good interactive back and forth review

[14] To the extent that Phoenix argues that the statements in this first category relate to Medtronic's general dealings with the FDA, even those outside the 780G context, the Court rejects such a characterization. In context, each of the four statements related exclusively to the FDA's approval process of the 780G and Medtronic's back-and-forth dialogue with the FDA on that specific product. *Silver v. H&R Block, Inc.*, 105 F.3d 394, 396 (8th Cir. 1997) (explaining that alleged misrepresentations must be considered "together and in context"). Indeed, each of these statements was made in response to a specific question about the status of the 780G. *See* ECF No. 112-1 at 11–12; ECF No. 112-4 at 9.

so that's really good"; Martha's statement on the same day that "the conversations we're having with them have been very positive on Diabetes approvals"; and Salmon's November 23, 2021 statement that "we've had very good interactive conversations with FDA." ECF No. 115 at 45–46.

Judge Menendez held that these statements were inactionable primarily because they are "inherently subjective statements of optimism, not objective statements of fact that reasonable investors would rely on in making investment decisions." *Medtronic*, 726 F. Supp. 3d at 970. In the FACC and subsequent briefing before this Court, Phoenix does not squarely address Judge Menendez's holding but instead argues that the optimistic opinions are actionable because Medtronic could not have held such opinions at the same time that Medtronic was actively attempting to remediate deficiencies identified in the Form 483, as evidenced by the letters Medtronic sent to the FDA between July and December 2021. ECF No. 115 at 45–46.

But missing from the FACC is any actual showing that the opinions were false. Because all three statements, when read in context, essentially say nothing more than that Medtronic was engaged in "good" dialogue with the FDA about the 780G, to be untrue there would need to be some showing that the dialogue was not "good."[15] But there are simply no concrete allegations that the back-and-forth dialogue between Medtronic and the

[15] This assumes that generic optimistic statements such as "good" or "positive" can *ever* be actionable in the first place. The Court is not so sure. *See, e.g.*, *Tongue v. Sanofi*, 816 F.3d 199, 213 (2d Cir. 2016) (quoting *Omnicare*, 575 U.S. at 188) (questioning whether the defendants' statements that "they were feeling 'relaxed' or 'satisfied'" were actionable because "[s]uch a generalized statement of subjective optimism arguably does not even 'convey facts about how the speaker has formed the opinion'").

FDA regarding the 780G itself was anything but positive. Instead, Phoenix asks the Court to presume that those conversations were going poorly because Medtronic had received the Form 483 and subsequently sent several letters to the FDA detailing remediation attempts at the MiniMed Facility. Yet the Form 483 itself—and Medtronic's letters to the FDA in response to the Form 483—made no mention about the 780G but, instead, identified unrelated issues with the MiniMed Facility. Consequently, the Form 483's relevance to the executives' opinion statements about the dialogue on the 780G approval process is tenuous, at best, and Phoenix's argument that the 780G process was stalled due to Medtronic's remediation efforts on other unrelated issues is entirely speculative. Indeed, counsel for Phoenix acknowledged at the hearing on Defendants' motion to dismiss that Phoenix "[does not] know" whether the 780G approval process stalled between July and December 2021, and that there is "no allegation that the FDA told the defendants everything is paused." ECF No. 124 at 39:7–39:14.

All things considered, short of some demonstrated connection between the Form 483 and the 780G approval process, or some other indication from the FDA that the 780G process had stalled, Phoenix's assertion that the conversations about the 780G could not have been positive is nothing more than speculation.[16] But it is Phoenix's burden to

[16] Even if the FDA had expressed some uncertainty about the 780G approval, the statements that dialogue was "good" or "positive" would *still* likely constitute inactionable opinions because "sophisticated investors . . . would fully expect that Defendants and the FDA were engaged in a dialogue . . . about the sufficiency" of Medtronic's remediation efforts "and that *inherent in the nature of a dialogue are differing views*." *Tongue*, 816 F.3d at 211 (emphasis added); *see also Omnicare*, 575 U.S. at 189–90 (explaining that "[a]n opinion statement . . . is not necessarily misleading" simply because "an issuer knows, but

"identify particular (and material) facts going to the basis for the issuer's opinion . . . whose omission makes the opinion statement at issue misleading." *Omnicare*, 575 U.S. at 194. It has not met that burden in the FACC.

Phoenix asserts that *West Virginia Pipe Trades Health & Welfare Fund v. Medtronic, Inc*. ("*W. Va. Pipe Trades I*"), 57 F. Supp. 3d 950 (D. Minn. 2014), is instructive. ECF No. 115 at 47–48. The Court agrees that it is instructive, though not in the way Phoenix intends. There, Medtronic was seeking the approval from the FDA of AMPLIFY, a bone graft product. *W. Va. Pipe Trades I*, 57 F. Supp. 3d at 956–57. A Medtronic executive, asked during a conference call "whether the FDA might delay its approval of AMPLIFY," responded that Medtronic was "continuing to work with the FDA to figure out kind of where they are on this." *Id.* at 958. But the plaintiffs alleged that the FDA had already sent a letter to Medtronic informing it that "AMPLIFY would not be approved," *id.* at 959, and the plaintiffs argued that the executive, "having chosen to comment on Medtronic's progress with the FDA on the approval of AMPLIFY, had a duty to make a full disclosure and should have disclosed Medtronic's recent receipt of a non-approval letter," *id.* at 972. The court agreed that if the letter constituted a non-approval of AMPLIFY, Medtronic should have disclosed that information when it chose to state that it was otherwise working with the FDA on that very approval. *Id.*

But *West Virginia Pipe Trades I* is easily distinguishable. First, the statement the Medtronic executive made in that case was one of fact, not opinion. The executive

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fails to disclose, some fact cutting the other way" because "[r]easonable investors understand that opinions sometimes rest on a weighing of competing facts").

represented that Medtronic was "continuing to work with the FDA" on the approval of a product, which was sufficiently alleged to be demonstrably false because the FDA had already denied the approval. *Id.* at 971–72. Here, by contrast, Medtronic's statements that conversations were "good" or "interactive" are nothing more than opinions about the proper characterization of a back-and-forth process. *See* ECF No. 99 ¶ 149.

But perhaps more important, in *West Virginia Pipe Trades I*, the FDA *directly* informed Medtronic that the status of AMPLIFY's approval was in danger, and Medtronic nonetheless chose to state otherwise to the public. 57 F. Supp. 3d at 972. Here, Phoenix does not allege "particular (and material) facts" that the FDA made such a direct statement to Medtronic about the 780G. *Omnicare*, 575 U.S. at 194. That Phoenix believes the 780G's approval was imperiled by the unrelated Form 483 is not the same as the FDA unambiguously telling Medtronic that the 780G would not be approved. No such facts are alleged here.

Accordingly, because these statements are opinions, and because Phoenix does not sufficiently allege that those opinions were false, they are inactionable under the Exchange Act.

b) Statements on the Likelihood and Timing of the 780G's Approval

Phoenix next argues that the remainder of Salmon's August 24, 2021 statement, Martha's September 1, 2021 statement, and Salmon's November 23, 2021 statement misrepresented the "review status *and* timing of 780G approval." ECF No. 115 at 50–55 (emphasis added). Specifically, Phoenix points to the statements that the 780G was "still

on track" and "on track as far as we can tell"; and that Medtronic was "making good progress in the review," "in active dialogue with [the FDA] on these approvals," and "making excellent progress there." ECF No. 115 at 50. In analyzing the full context, the Court holds that these statements are inactionable puffery, constitute opinions, or are simply not misleading in the first place.

As to the portions of the statements that reference things like being "on track," or that Medtronic was "making good progress," such statements are puffery as a matter of law. As noted, statements of puffery are "so vague and such obvious hyperbole that no reasonable investor would rely upon" them. *In re Stratasys*, 864 F.3d at 882 (citation omitted). Examples of such corporate puffery are statements "which encompass optimistic rhetoric and promotional phrases used to champion the company but devoid of any substantive information," because such statements "cannot be supported by objective data or otherwise subject to verification by proof." *Id.* (citation modified). That is precisely what these statements represent. *See, e.g.*, *In re Cutera Sec. Litig*, 610 F.3d 1103, 1111 (9th Cir. 2010) ("When valuing corporations . . . investors do not rely on vague statements of optimism like 'good,' 'well-regarded,' or other feel good monikers."); *In re EDAP TMS S.A. Sec. Litig.*, No. 14-cv-6069 (LGS), 2015 WL 5326166, at *9–10 (S.D.N.Y. Sept. 14, 2015) (statements indicating "that the [FDA approval] process was 'on track' and making continued 'progress,'" or belief that the defendants "were 'moving through the approval process in a timely manner,'" constituted "inactionable puffery" in part because the plaintiffs did not allege that the defendants "guaranteed or even predicted FDA approval"); *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 757–58 (S.D.N.Y. 2018)

(citation omitted) (recognizing statements that a company is "on track" are puffery because they merely put a "positive spin on developments" in the FDA approval process); *Hills v. BioXcel Therapeutics, Inc.*, No. 3:23-cv-00915 (SVN), 2024 WL 3374145, at *10 (D. Conn. July 11, 2024) (statements that a product was "'on track,' had 'progressed' on a 'strong foundation,' and that the company was 'very excited' about the data are typical generic, indefinite statements of corporate optimism" (citation modified)).[17]

The Court also doubts that any of the statements were materially misleading in the first place, even if they could be considered more than puffery. First, the statements—in light of the context in which they were made—are tinged with caution. Although Phoenix would prefer the Court to focus exclusively on its italicized excerpts of the allegedly misleading statements, the Court must consider those statements "fairly and in context." *Omnicare*, 575 U.S. at 194. That additional context is instructive here, as each italicized portion is paired with a cautionary statement. For instance, Salmon's August 24, 2021 statement that "things are on track as far as we can tell" is directly preceded by his statement that "we'd love to bring [the 780G] to the U.S. as soon as possible" and followed by "[a]s you may know, that division of FDA has been very busy with COVID, so it's hard to handicap exactly when time lines happen." ECF No. 99 ¶ 133. Likewise, Martha's September 1, 2021 comment that "we're [in] active dialogue with them on these approvals" is preceded by the statement that the FDA had "been pretty busy with COVID and it's hard

[17] Judge Menendez found these statements inactionable because they are opinions. *Medtronic*, 726 F. Supp. 3d at 970. The Court agrees. Obviously, there is some overlap between puffery and statements of opinion, but the point remains the same: no reasonable investor would rely on these statements.

to handicap and approve it." *Id.* ¶ 139. Finally, Salmon's November 23, 2021 statement that "we're making excellent progress" was cautioned by the additional statements that "[w]e've got really strong uptake of 780G and Guardians 4 Sensor outside the United States" and that "we're waiting for that approval to come through." *Id.* ¶ 149. These are "exactly the kind of hopeful statements, tinged with caution, that cannot reasonably be found to be misleading and therefore relied upon to allege violations of the securities laws." *In re Nokia Oyj (Nokia Corp.) Sec. Litig.*, 423 F. Supp. 2d 364, 400 (S.D.N.Y. 2006); *see also Medtronic*, 726 F. Supp. 3d at 972 ("In context, these statements express a lack of certainty regarding timely approval by the FDA of the 780G and are not materially misleading due to Defendants' alleged omissions.").

Moreover, to demonstrate that the statements were misleading, Phoenix must show that the statements that the 780G was "on track as far as we can tell" and "making good progress in the review," and that Medtronic was "in active dialogue with [the FDA] on these approvals" and "making excellent progress there," ECF No. 115 at 50, were untrue. But the FACC provides no concrete allegations that the 780G process was not "on track." As noted above, the FACC provides *no* allegations of any kind regarding the status of the 780G's approval at the time those statements were made. Indeed, the Court knows nothing about the 780G approval process between July and December 2021. There are no facts alleged about what the FDA thought of the 780G, no indication that the FDA believed the 780G to be deficient in some identifiable way, and no indication that the FDA was ever

critical about the 780G's chances of approval. Critically, there is no allegation in the FACC that the FBA ever communicated this information to Medtronic.[18]

Instead of providing direct facts about the status of the 780G, Phoenix urges the Court to presume from the issuance of the Form 483 that the 780G was not "on track." *See* ECF No. 115 at 50–51 (arguing that "the severe and pervasive 'objectionable conditions' observed at the MiniMed Facility negatively impacted the FDA's review of 780G" because the MiniMed Facility was responsible for manufacturing the 780G). The problem with Phoenix's theory remains that there was no indication from the FDA that the 780G's approval process was doomed from the moment the Form 483 issued. As Judge Menendez observed, "nowhere does the [FCC] allege that the Form 483 mentioned the MiniMed 780G at all, and there is certainly no statement attributed to the FDA indicating that timely

[18] That the FDA had not communicated to Medtronic that the Form 483 would stall the 780G distinguishes this case from *Levon v. CorMedix Inc*., No. 21-cv-14020 (JXN) (CLW), 2025 WL 2400346, at *1 (D.N.J. Aug. 19, 2025), a case highlighted by Phoenix as supplemental authority. ECF No. 128. There, an internal audit informed the defendant, in 2018, that its chosen manufacturing facility "would never be able to pass an FDA inspection," but the company nevertheless opted to use that facility. *CorMedix*, 2025 WL 2400346 at *2. Sure enough, in 2021, the FDA rejected the company's proposed product in part because the facility was "found inadequate." *Id.* at *3. Nevertheless, the company continued to represent to the public for two years that the facility would pass inspection, despite being repeatedly told by the FDA that its remediation efforts were insufficient. *Id.* at *3–4. Its remediation efforts were so poor, in fact, that the FDA again rejected the product in August 2022. *Id.* at *5. Therefore, in *CorMedix*, it was alleged that the company itself knew a specific product would never be approved and then, after being told by the FDA that the specific product would not be approved, continued to tell the public that the specific product would be approved imminently. No similar allegations against Medtronic exist here.

The Court has also reviewed and considered the supplemental authority and letter briefing submitted by Medtronic, as well as Phoenix's response. ECF Nos. 130, 131.

approval of the 780G was jeopardized by the FDA's observations." *Medtronic*, 726 F. Supp. 3d at 982. The FACC does not change that finding.

Notably, a Form 483 does not inevitably lead to a Warning Letter. *See In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 42 (1st Cir. 2014) ("Forms 483 . . . do not represent the FDA's final word."); *KV Pharm.*, 679 F.3d at 982 (explaining that "[t]he issuance of a Form 483 represents a *risk*," not a *certainty*, "that the FDA may take corrective action against a company" (emphasis added)). Instead, even a damning Form 483 may be remedied in time to avoid any disruption to existing product approvals, and, as Judge Menendez noted, Medtronic was likely justified in believing that "the MiniMed 780G still had a meaningful chance of gaining timely FDA approval." *Medtronic*, 726 F. Supp. 3d at 982; *see also, e.g.*, *In re Genzyme Corp.*, 754 F.3d at 42 ("It is more likely that defendants made no mention of the October 2008 Form 483, because, given the observational nature of such forms [and] the fact that it made no mention of the Lumizyme approval process . . . they likely believed Genzyme continued to be on the path towards Lumizyme approval."); *In re Discovery Lab'ys Sec. Litig.*, No. 06-1820, 2007 WL 789432, at *5 (E.D. Pa. Mar. 15, 2007) (explaining that without some clear indication from the FDA that a product's approval was imperiled, "[w]e cannot hold defendants liable because they read [a Form 483] in much the same way as the FDA did and remained optimistic that the problems could be timely resolved"); *Schaeffer v. Nabriva Therapeutics PLC*, No. 19-cv-4183 (VM), 2020 WL 7701463, at *12 (S.D.N.Y. Apr. 28, 2020) (explaining that the "general weight of Form 483 cases across the country" hold that a Form 483 must "clearly contradict[]" a statement being made in order to render that statement misleading); *Hills*,

2024 WL 3374145, at *10 (noting that issuance of a Form 483 is not by itself sufficient to render statements misleading where "[n]one of the statements speak to FDA compliance or otherwise contradict the Form 483 itself").

Finally, to the extent that Phoenix argues that the statements were misleading about the *timing* of the 780G approval, ECF No. 115 at 51–53, the Court agrees that no changes to the FACC displace Judge Menendez's conclusion that Phoenix has "not alleged facts showing that Defendants ever 'assured' investors of timely approval for the MiniMed 780G, nor of what particular approval date would even constitute 'timeliness.'" *Medtronic*, 726 F. Supp. 3d at 971.

Phoenix insists that Medtronic led the market to believe that a pre-April 2022 approval was assured. ECF No. 115 at 51. For instance, Phoenix asserts that Salmon's August 24, 2021 statement that "things are on track as far as we can tell" was in response to a question about whether the 780G would be approved in the second half of Fiscal Year 2022. *Id.* at 51–52. But Phoenix strips that statement from its context. Before Salmon's answer, an analyst asked Salmon about whether "the 780G clearance" was "still expected in the second half" of Fiscal Year 2022. ECF No. 112-1 at 11. Salmon responded: "[W]e'd love to bring that to the U.S. as soon as possible. But things are on track as far as we can tell. . . . [The] FDA has been very busy with COVID, so it's hard to handicap exactly when time lines happen. But we do think we're making good progress." *Id.* at 12. In context, the statement cannot be reasonably read to suggest an imminent approval timeline but is more appropriately read as deflecting the questioner's request to set a specific timeline.

Phoenix also asserts that Medtronic informed the public that the 780G launch was anticipated by April 2022, pointing to a June 3, 2021 PowerPoint slide presented to investors that stated that Medtronic expected to launch the product "in [the] next few quarters." ECF No. 115 at 52 (alteration in original) (emphasis omitted).[19] But the broader context of the PowerPoint slide belies Phoenix's assertion. Notably, the first slide of the PowerPoint presentation contains an explicit disclaimer that the presentation contained "forward looking statements . . . subject to risks and uncertainties," thereby alerting investors to the uncertainty of Medtronic's expectations. ECF No. 116-1 at 3. Regardless, the vague reference to an expected launch in the "next few quarters" provides no specific timeline for the FDA's approval. In short, there remains no statement from Medtronic that the product would be approved by April 2022, and Phoenix therefore has not sufficiently pleaded that Medtronic's statements that the product was "on track" were misrepresentations.[20] *Medtronic*, 726 F. Supp. 3d at 971; *see* ECF No. 81 at 43 ("Nowhere in the Complaint is there a statement by any Defendant guaranteeing, promising, or

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[19] Medtronic argues that the Court should refuse to consider the PowerPoint slide because it was not included in Phoenix's complaint but was instead referred to for the first time in Phoenix's memorandum in opposition to Medtronic's motion to dismiss. ECF No. 118 at 12–13. Because the Court does not believe the PowerPoint slide supports Phoenix's assertion, the Court need not consider whether Phoenix's attempt to insert new factual allegations into its opposition memorandum was proper in the first place.

[20] There are plenty of statements by market analysts who anticipated the 780G would be approved by April 2022, but those statements cannot be imputed to Medtronic itself. *In re Navarre Corp.*, 299 F.3d at 743 ("Generally, securities issuers are not liable for statements or forecasts disseminated by securities analysts or third parties unless they have sufficiently entangled themselves with the analysts' forecasts so as to render those predictions attributable to the issuers." (citation modified)). There is no allegation Medtronic has "sufficiently entangled" itself with any analyst's forecast.

assuring that the FDA would, in fact, approve the 780G for use in the United States, nor that the FDA would approve it on a specific timeline.").

Because Phoenix's allegedly misleading statements relating to the 780G approval process are not material and misleading statements of fact, but rather are statements of opinion or puffery, the Court finds that they are inactionable under the Exchange Act.

ii. Statements About Medtronic's FDA Compliance

Next, Phoenix alleges that Medtronic's statements made in its October 12, 2021 IPR were misleading. First, Phoenix takes issue with Medtronic's statement that "[w]e adhere to regulatory requirements, such as those set by the U.S. FDA, and we update our procedures in line with emerging regulations and standards." ECF No. 99 ¶ 145. Second, Phoenix challenges a statement in the same report that "[i]n FY21, we received an average of . . . 0.02 findings per U.S. Food and Drug Administration (FDA) inspection—continuing to demonstrate year-on-year improvements." *Id.* ¶ 146. According to Phoenix, these statements were misleading because Medtronic was aware of "numerous, severe, and pervasive objectionable conditions which were outlined in [a] Form 483[]," so Medtronic could not possibly have represented truthfully that it was adhering to the FDA's regulatory requirements.[21] ECF No. 115 at 56–57 (alterations in original) (quoting *KV Pharm.*, 679 F.3d at 983–94).

In general, a company has no obligation to inform the public about the receipt of a Form 483. *See KV Pharm.*, 679 F.3d at 984 (quoting *Basic Inc. v. Levinson*, 485 U.S. 224,

[21] These specific misrepresentations in the FACC were not included in the first consolidated complaint and therefore were not discussed by Judge Menendez.

239 n.17 (1988)) ("Silence, absent a duty to disclose, is not misleading under Rule 10b-5."). But a company might be required to disclose a Form 483 "in some circumstances" if the company also represents that it is in compliance with FDA regulations. *Id.* at 982–83. The materiality of the FDA's issuance of a Form 483 depends "on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted by the FDA." *Id.* at 983.

Phoenix asserts that *KV Pharmaceutical*'s disclosure rule applies here. The Court disagrees. In that case, KV Pharmaceutical Company ("KV") filed five SEC Form 10-Ks from 2004 to 2008. *Id.* at 975. In the 10-Ks:

> KV explained in detail the extensive and complex governmental regulation of the pharmaceutical industry by the FDA. KV then made specific representations regarding its compliance with FDA regulations. In a section entitled "Manufacturing And Facilities," KV stated in all five of the applicable Form 10–Ks: "We believe that all of our facilities are in material compliance with applicable regulatory requirements." In the 2004 Form 10–K, in a section entitled "Risks Related To Our Industry," KV also represented: "We are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies." KV slightly modified this latter representation in its Form 10–Ks for fiscal years 2005 through 2008 by stating: "We believe that we are currently in material compliance with cGMP and are registered with the appropriate state and federal agencies."

Id. at 975–76 (footnote omitted).

The investors alleged that "KV's statements regarding its material compliance with FDA regulations were false or misleading" because KV had undergone "a series of inspections the FDA made of KV's facilities between 2003 and 2009" and the FDA "reported the results of its inspections to KV on Form 483s following inspections which

concluded in April 2003, January 2004, January 2005, March 2006, April 2007, March 2008, and February 2009." *Id.* at 976. KV's longstanding non-compliance finally came to light in 2009, when the FDA filed a complaint seeking "a permanent injunction to prevent KV from manufacturing and distributing pharmaceuticals" because of its "history of continuing . . . violations" and disregard of the deficiencies identified in "the last eight years." *Id.* In fact, the FDA alleged that KV's "noncompliance has continued despite repeated warnings" regarding its violations. *Id.* And the FDA's observations of regulatory noncompliance affected "the entire range of KV's operations and products." *Id.* at 983 n.9.

Under this set of circumstances, the Eighth Circuit found that KV's five-year period of SEC filings in which it represented its belief that it was in "material compliance" with FDA regulations was misleading and that KV had a duty to disclose the Form 483s and the investigation. *Id.* at 983–84. The Eighth Circuit noted that the investors alleged "numerous, severe, and pervasive objectionable conditions . . . a lengthy history of KV manufacturing adulterated, unapproved, and misbranded drugs in violation of FDA regulations," a failure to "address or correct serious manufacturing problems during the Class Period," "noncompliance" in the face of repeated FDA warnings, and a total company shutdown after the final FDA inspection. *Id.* at 983.

None of those circumstances is present here. First, the vehicle in which the statements in this case were made is materially different than that in *KV Pharmaceutical*. There, KV affirmed that it was in material compliance with FDA regulations in five consecutive SEC Form 10-Ks. Here, by contrast, the statements were included in a 121-page company-wide investor document. *See* ECF No. 112-3 at 63, 92. This distinction

matters, for documents filed with the SEC are "formal documents," and "[i]nvestors do not, and are right not to, expect opinions contained in those statements to reflect baseless, off-the-cuff judgments." *Omnicare*, 575 U.S. at 190.

Second, the statements themselves are not the same sort of "specific representations" of "material compliance with FDA regulations" as those present in *KV Pharmaceutical*, 679 F.3d at 975–76. There, KV explicitly and unequivocally affirmed material compliance with FDA regulations. *See id.* at 980. Here, the IPR statements simply stated that to "manage" patient safety and product quality, Medtronic "adhere[s] to regulatory requirements." ECF No. 112-3 at 92. These seem to be statements of general principles that all FDA-regulated entities are governed by. The Court struggles to see how a reasonable investor would take that statement as an implicit promise that Medtronic was not under FDA investigation.

Finally, the IPR appears to be an overview of *all* of Medtronic's various divisions, not simply the Diabetes Group. Notably, in *KV Pharmaceutical*, the court cited approvingly to *Acito v. IMCERA Group, Inc*., 47 F.3d 47 (2d Cir. 1995), which considered whether a company had a duty to disclose negative FDA inspections that involved "just one plant among thirty of the company's business locations, a plant which produced just ten of one thousand products manufactured by the company in over thirty countries." *KV Pharm.,* 679 F.3d at 983 n.9. The Second Circuit concluded, in part, that "[i]t would be unduly burdensome and impractical to publicly disseminate the results of every inspection of every plant." *Acito*, 47 F.3d at 52–53. In *KV Pharmaceutical*, by contrast, "the investors

allege[d] the FDA violations covered the entire range of KV's operations and products." *KV Pharm.,* 679 F.3d at 983 n.9.

Therefore, to the extent that *KV Pharmaceutical* is an exception to the general rule that a company has no duty to disclose a Form 483, the Eighth Circuit made clear that the exception applies when the "objectionable conditions noted" on a Form 483 are "numerous, severe, and pervasive." *Id.* at 983. Given that the Form 483 in this case only related to issues at a single Medtronic plant responsible for manufacturing products for only one Medtronic group, the flagrant and repeated misstatements alleged in *KV Pharmaceutical* are simply not present here. Medtronic therefore had no duty to disclose the Form 483.[22] *See id.* at 983 n.9; *Acito*, 47 F.3d at 52–53.

iii. Statements About Risk Factors in Medtronic's Form 10-Qs

Finally, Phoenix alleges that Medtronic misled its investors in its September and December 2021 Form 10-Qs. ECF No. 99 ¶¶ 155–56. In those documents, Medtronic identified "risk factors" by stating as follows:

> Both before and after a product is commercially released, *we have ongoing responsibilities under the U.S. FDA* and other applicable non-U.S. government agency regulations. For instance, *many of our facilities and procedures and those of our suppliers are also subject to periodic inspections by the U.S. FDA to determine compliance with applicable*

[22] Further, the statements do not appear to have been false when they were made. That is certainly true of Medtronic's statement that in Fiscal Year 2021 it only received "0.02 findings per U.S. Food and Drug Administration (FDA) inspection—continuing to demonstrate year-on-year improvements." ECF No. 99 ¶ 146. But the report (released in October 2021) in which the statement was made pertained *only* to FY21, which ended April 30, 2021, ECF No. 112-3 at 5—two months before the FDA's inspection even began on June 7, 2021, ECF No. 99 ¶ 57. The timeline is also true of Medtronic's statement that "[w]e adhere to regulatory requirements, such as those set by the U.S. FDA, and we update our procedures in line with emerging regulations and standards." ECF No. 112-3 at 92.

> *regulations. The results of these inspections can include inspectional observations on the U.S. FDA's Form 483,* warning letters, or other forms of enforcement. *If the U.S. FDA were to conclude that we are not in compliance with applicable laws or regulations*, or that any of our medical products are ineffective or pose an unreasonable health risk, the U.S. FDA could ban such medical products, detain or seize adulterated or misbranded medical products, order a recall, repair, replacement, or refund of such products, *refuse to grant pending pre-market approval applications or require certificates of non-U.S. governments for exports*, and/or require us to notify health professionals and others that the devices present unreasonable risks of substantial harm to the public health.

ECF No. 99 ¶¶ 155–56 (emphasis in original).

Judge Menendez previously held these statements in Medtronic's Form 10-Qs inactionable as "forward-looking" because they "explicitly identifie[d] the salient risk, namely, that a regulatory authority such as the FDA could deny or delay approval." ECF No. 81 at 48 (citation omitted). Judge Menendez further held that, although a company is not protected from liability for forward-looking statements "when they have actual knowledge of facts that meant those risks had already materialized," Phoenix did not "plausibly allege[] that at the times Defendants made the forward-looking statements, they knew that the potential risk of FDA delay or regulatory denial about which they cautioned had already been realized." *Id.* at 48–49. As discussed above, the FACC does not sufficiently establish that the Form 483 put Medtronic on notice that the risk of "delay or regulatory denial" had already been realized. *Id.* Accordingly, the Court finds these statements inactionable.

Because Phoenix fails to plead with particularity that any of the alleged misrepresentations are actionable, the Court dismisses the entirety of Phoenix's misrepresentation claim.

III. Scheme Liability

Alternatively, Phoenix asserts that Medtronic engaged in a scheme between May 23, 2019, and December 15, 2021, to cover up internal problems faced by the Diabetes Group and the MiniMed Facility. ECF No. 99 ¶¶ 64–66. For this claim, Phoenix names Medtronic itself, as well as Hakami and Salmon (who collectively served as President of the Diabetes Group from 2014 to 2022), as the "Scheme Defendants." *Id.* ¶ 64.

Phoenix asserts the same four deceptive acts in the FACC as in the FCC. First, Phoenix alleges that in July 2018 and May 2019, Medtronic released two studies that showcased positive health outcomes for individuals who used the 630G and 640G, which Phoenix argues were deceptive because they gave the false impression that the products were safe and allowed Medtronic to keep "quiet regarding the growing number of dangerous malfunctions" with the entire line of MiniMed products. ECF No. 99 ¶¶ 81–84; *see* ECF No. 115 at 35 (arguing that Medtronic "orchestrated and publicized small-scale, carefully controlled studies purporting to demonstrate the effectiveness and safety of those pumps, despite knowing that the retainer ring malfunction affected all 600 Series pumps and could cause serious harm"). Second, Phoenix alleges that in 2016 and 2021, Medtronic commissioned internal studies of the retainer rings in the MiniMed products following complaints from purchasers and that the studies used erroneous risk calculations to downplay the risk of harm from the products, which delayed Medtronic in taking corrective action. ECF No. 115 at 36–37. Third, Phoenix alleges that Medtronic failed to "report malfunctions" in the cybersecurity of its MiniMed products to the FDA, in violation of FDA regulations. *Id.* at 37–38. And fourth, Phoenix alleges that, even after the product

issues came to public light, Medtronic downplayed the severity by engaging in a series of "half-measures" instead of addressing the scope of the problems head on. *Id.* at 38–39.

Phoenix does not meet the particularity requirement of Rule 9(b) in pleading scheme liability because Phoenix fails to name any *specific* individual who performed any *specific* act. Instead, Phoenix repeatedly alleges that "the Diabetes Group" or the "Scheme Defendants" carried out the allegedly deceptive acts. ECF No. 115 at 35 (the "Diabetes Group . . . orchestrated and publicized small-scale, carefully controlled studies"); *id.* at 36 (the "Diabetes Group . . . implemented a risk analysis protocol to underestimate" likelihood of harm); *id.* at 37 (the "Scheme Defendants concealed ongoing product malfunctions, failed to take appropriate action to address malfunctioning devices, and failed to report malfunctions"); *id.* at 38 (the "Scheme Defendants issued incomplete and misleading information to the public"). This sort of pleading by "unit" or "group" does not satisfy Rule 9(b). *S.E.C. v. U.S. Env't, Inc.*, 82 F. Supp. 2d 237, 241 (S.D.N.Y. 2000); *see also, e.g.*, *Streambend Props. II, LLC v. Ivy Tower Minneapolis*, 781 F.3d 1003, 1013 (8th Cir. 2015) ("The [complaint] attributed fraudulent representations and conduct to multiple defendants generally, in a group pleading fashion. The district court correctly concluded that such vague allegations do not satisfy Rule 9(b). Where multiple defendants are asked to respond to allegations of fraud, the complaint should inform each defendant of the nature of his alleged participation in the fraud." (citation modified)); *Swartz v. KPMG LLP*, 476 F.3d 756, 764–65 (9th Cir. 2007) ("Rule 9(b) does not allow a complaint to merely lump multiple defendants together but requires plaintiffs to differentiate their allegations when suing more than one defendant." (citation modified)).

At its most specific, the complaint alleges that the deceptive acts took place while the Diabetes Group was under Hakami's or Salmon's "leadership." *See, e.g.*, ECF No. 99 ¶¶ 72, 74. But there is no allegation that either of those individuals committed the deceptive acts themselves or directed others to commit the deceptive acts. And heightened pleading requires much more than "[g]eneral allegations not tied to the defendants or resting upon speculation." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 102 (2d Cir. 2007); *see also Mizzaro v. Home Depot, Inc.*, 544 F.3d 1230, 1247 (11th Cir. 2008) (explaining that "simply alleging that a widespread fraud may have occurred is not enough" to connect fraudulent acts to leaders of a company).

Phoenix contends that it need not do more than plead that the executives were "'deeply involved' in the alleged deceptive conduct." ECF No. 115 at 34 (quoting *Mart v. Tactile Sys. Tech., Inc.*, 595 F. Supp. 3d 788, 823–24 (D. Minn. 2022)). In *Mart*, the plaintiffs alleged that Tactile and its executives and directors engaged in a scheme to artificially inflate Tactile's stock price 595 F. Supp. 3d at 823. Tactile did so in two ways, both related to "Flexitouch," a product that accounted for 90% of Tactile's revenues. *Id.* at 799. First, Tactile "[e]xaggerated and distorted clinical study results and claims data analyses to convey that Flexitouch's market size was three to four times greater than it actually was." *Id.* at 823 (alteration in original). Second, Tactile gave kickbacks to doctors in exchange for prescribing Flexitouch. *Id.* at 799–800. The kickback scheme was spearheaded by doctors recruited by Tactile to be "Key Opinion Leaders" to whom Tactile would give perks and benefits in exchange for referrals. *Id.* at 800.

In analyzing the scheme allegations, the court first criticized the complaint for its failure to "identify any specific individual defendant" and instead asserting its scheme claims against the group as a whole. *Id.* at 823–24. Although the court found this improper, it nevertheless endeavored to assess the specific defendants against whom the scheme claim was plausibly asserted. *Id.* at 823–24. After doing so, the court dismissed five of the named defendants because the complaint failed to identify any actions they took in furtherance of the alleged scheme, but the court found that the complaint was sufficient as to three of the defendant-company's executives. *Id.* at 824. Specifically, it held that the complaint's allegations that the "SVP of Sales[] directed the sales team to use the [Key Opinion Leaders] program" and that the SVP, CFO, and CEO were "deeply involved in Flexitouch sales, setting sales quotas, sales managers salaries, and closely monitoring Tactile representatives' sales of the Flexitouch," sufficiently alleged their participation in the scheme. *Id.*

Phoenix argues that because it alleges that Hakami and Salmon are "deeply involved" in the "alleged deceptive conduct," it has sufficiently pleaded its scheme liability claim. ECF No. 115 at 34. But nowhere does Phoenix allege that Hakami and Salmon were deeply involved in the deceptive conduct; in fact, Phoenix never alleges *any* specific action taken by either of those two with regard to the alleged deceptive practices. To the contrary, Phoenix merely argues that the deceptive conduct occurred during the years that Hakami and Salmon were leaders of the Diabetes Group. *See, e.g.*, ECF No. 99 ¶¶ 72, 74, 111. To be sure, Phoenix does allege that Salmon and Hakami were hands-on leaders, *id.* ¶ 110, but that does not necessarily mean that they directed or even knew of the deceptive

actions, *see, e.g.*, *S. Ferry LP, No. 2 v. Killinger*, 542 F.3d 776, 784–85 (9th Cir. 2008) (citation omitted) (explaining that "allegations regarding management's role in a company may be relevant" but that "corporate management's general awareness of the day-to-day workings of the company's business does not establish scienter").

Second, to the extent that Phoenix reads *Mart* to suggest that a plaintiff can meet their pleading burden under Rule 9(b) by generally alleging that some defendants are "deeply involved" in a fraudulent scheme, that outcome would be an outlier from the general rule that a complaint must plead with particularity "which defendants performed" the deceptive acts. *KV Pharm.*, 679 F.3d at 986. The Court believes the better approach remains that a plaintiff must show that a defendant was "deeply involved" in a fraudulent scheme by pleading with particularity *which* defendants committed *which* acts.

Put simply, Rule 9(b) requires plaintiffs to plead specific actions by specific defendants. That is where Phoenix falls short. Perhaps most illustrative of the lack of particularity in Phoenix's allegations in the FACC is a comparison to the other cases relied on by Phoenix. In *In re Galena Biopharma, Inc. Securities Litigation*, for instance, the plaintiffs alleged that certain executives fraudulently conspired with a third party to publish "false and misleading articles." 117 F. Supp. 3d 1145, 1191 (D. Or. 2015). The plaintiffs alleged with specificity the actions that each of the named executives took in furtherance of the scheme. *See id.* at 1165 (detailing fifteen actions taken by one executive in furtherance of the scheme); *id.* at 1168 (noting that another executive "corresponded extensively with [the third party]; reviewed, edited, and approved the articles; knew that the articles were part of the paid promotional scheme; admitted to the Special Committee

that she knew the articles were part of the paid promotional campaign; received copies of the published articles; and knew the articles did not disclose their paid connection to Galena"); *id.* at 1169 (detailing nine more actions taken by a third executive). This specificity allowed the Court to "consider[] whether each Defendant . . . committed a manipulative or deceptive act in furtherance of the scheme" because the complaint alleged "the roles of each of these defendants." *Id.* at 1197 (citations omitted) (internal quotation marks omitted). Notably, that court also criticized the plaintiffs for, at times, lumping the defendants together by merely alleging that the defendants "performed some act or knew about some fact," which the court found "improper" because Rule 9(b) requires a court to "consider[] the allegations and incorporated documents specific to each defendant and not the impermissible allegations attributing something to all Defendants as a single unit." *Id.* at 1164 n.15.

The same is true of *In re Able Laboratories Securities Litigation*, No. 05-cv-2681 (JAG), 2008 WL 1967509 (D.N.J. Mar. 24, 2008). There, the plaintiffs alleged that Able Laboratories and two of its executives, Shashikant Shah and Dhanajay Wadekar,[23] committed acts intended to hide quality control issues from the FDA. *Id.* at *20. Specifically, the complaint alleged that the executives themselves falsified "quality control data," orchestrated "the misreporting of quality control data to the FDA by instructing bench chemists . . . to falsify the results of quality control tests," failed "to report adverse drug events to the FDA," and "hir[ed] inexperienced and poorly trained bench chemists

[23] Shah was Able's Vice President of Quality Control and Wadekar was Able's CEO. *In re Able Lab'ys*, 2008 WL 1967509, at *1 n.6, n.8.

and foster[ed] a culture of dishonesty to conceal adverse quality control results." *Id.* (alterations in original). In total, the complaint highlighted "three years of conduct—during the relevant class period—in which all of the defendants, including Shah and Wadekar, 'falsif[ied] test results, tamper[ed] with computer data, forge[d] records . . . [and] fabricated in house test data to meet FDA standards.'" *Id.* at *21 (alterations in original). In so doing, the complaint "adequately allege[d] specific instances of manipulative and deceptive conduct on the part of Shah and Wadekar." *Id.* Unlike in *Able*, Phoenix here rests its allegations against Hakami and Salmon not on any specific action they allegedly took, but on the fact that the alleged deceptive acts occurred during their "leadership." *See, e.g.*, ECF No. 99 ¶¶ 72, 74. This is simply too general to meet their heightened pleading burden.

Likewise, in *West Virginia Pipe Trades I*, plaintiffs alleged that "Medtronic, its officers, and its consulting physicians manipulated early clinical studies of [a product] in order to conceal its significant safety risks."[24] 57 F. Supp. 3d at 977. But the allegations there were far more specific as to who did what: the complaint named as defendants the consulting physicians who allegedly created the false articles and explained how Medtronic

[24] In *West Virginia Pipe Trades I*, Medtronic did not argue that the complaint lacked the required specificity regarding which defendants acted and what actions they took. 57 F. Supp. 3d at 983 n.18 (noting that Medtronic made a specificity argument for the first time in its reply brief, which it declined to consider). The court therefore had no occasion to consider whether the complaint pleaded the necessary specificity as to the Plaintiffs' allegations against Medtronic. And, although the consulting physicians argued that the plaintiffs' complaint lacked the requisite specificity under Rule 9(b), the court did not address that argument because it found that the plaintiffs' claims against the consulting physicians were barred by the Exchange Act's statute of limitations. *Id.* at 977.

paid them for that falsification. *Id.* at 957, 978–79. The plaintiffs also alleged specifically that "Medtronic personnel edited journal articles published by the physician consultants and failed to disclose that it paid them millions of dollars during the drafting process." *Id.* at 977.

There is no similar specificity in any of Phoenix's allegations. And because general allegations that proceed in "group pleading fashion" are insufficient to plead a scheme liability claim under Rule 9(b), Phoenix is unable to state a claim in Count I. *See Streambend Props. II*, 781 F.3d at 1013.

IV. Controlling-Person Liability

Phoenix's second count alleges that Defendants violated Section 20(a) of the Exchange Act, which provides that "[e]very person who, directly or indirectly, controls any person liable under any provision of this chapter or of any rule or regulation thereunder shall also be liable jointly and severally with and to the same extent as such controlled person to any person to whom such controlled person is liable." 15 U.S.C. § 78t(a). But, as discussed above, so-called "controlling person" claims are derivative of misrepresentation and scheme liability violations, and if a misrepresentation or scheme claim fails, the derivative controlling-person claims fail, as well. *See Lustgraaf*, 619 F.3d at 874. Because the Court dismisses Phoenix's misrepresentation and scheme claims in Count I, the Court must also dismiss its controlling-person claim in Count II.

CONCLUSION

The Court concludes that neither of Phoenix's theories of liability under Section 10(b) of the Exchange Act withstand the applicable heightened pleading standards,

so Count I is dismissed. For that reason, the Court also dismisses Count II, Phoenix's derivative controlling-person claim. Finally, because this was Phoenix's second chance at amending its complaint, *see* ECF Nos. 58, 99, the FACC will be dismissed with prejudice. *See Knowles v. TD Ameritrade Holding Corp.*, 2 F.4th 751, 758 (8th Cir. 2021) (affirming dismissal with prejudice where the district court allowed the plaintiff "to amend his complaint multiple times" but the plaintiff "was still unable to plead adequate claims").

Accordingly, based on the foregoing, and on all of the files, records, and proceedings herein, **IT IS HEREBY ORDERED THAT**:

1. Medtronic's Motion to Dismiss (ECF No. 108) is **GRANTED**;

2. The First Amended Consolidated Complaint (ECF No. 99) is **DISMISSED WITH PREJUDICE**.

LET JUDGMENT BE ENTERED ACCORDINGLY.

Date: September 30, 2025

s/Laura M. Provinzino
Laura M. Provinzino
United States District Judge