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,

Plaintiffs,

v.

MEDTRONIC PLC, et al.,

Defendants.

No. 22-cv-2197 (KMM/JFD)

ORDER

This is a putative federal securities class action brought on behalf of all purchasers of Medtronic PLC ("Medtronic") common stock between May 23, 2019, and May 26, 2022 ("the Class Period"). In their Consolidated Complaint, Plaintiffs assert that despite knowing of problems with Medtronic's efforts to develop and obtain approval to sell a new generation of insulin pumps in the United States, Defendants engaged in a scheme to hide product issues and their financial impact on Medtronic's business from investors and misrepresented the degree to which timely FDA approval for the company's latest insulin pump was in jeopardy. Defendants allegedly engaged in this fraud to keep Medtronic's share prices artificially high, selling off substantial interests in Medtronic shortly before information finally became public that caused the share price to drop and led to millions in losses for non-insiders. Defendants move to dismiss Plaintiffs claims, raising a throng of

issues. Defs.' Mot., Doc. No. 63. For the reasons that follow, the motion is granted in part and denied in part.

BACKGROUND

The following background is drawn from the Consolidated Complaint for Violations of the Federal Securities Laws ("Complaint"), documents embraced by the pleadings, and materials that are part of the public record.[1]

I. The Parties

Plaintiffs are investors who purchased Medtronic common stock during the Class Period. The named plaintiffs in the Complaint are The Phoenix Insurance Company Ltd. and The Phoenix Provident Pension Fund Ltd (collectively "Lead Plaintiffs" or "Phoenix").[2] Compl. ¶ 18. Defendant Medtronic plc ("Medtronic") is an Irish corporation with its principal place of business in Minneapolis. *Id.* ¶ 19. Medtronic is a medical device company whose stock trades on the New York Stock Exchange under the ticker symbol "MDT." *Id.*

Other Defendants include current and former officers of Medtronic. Omar Ishrak was Medtronic's Chief Executive Officer from June 2011 through April 26, 2020. *Id.* ¶ 20.

[1] Consolidated Compl. ("Compl."), Doc. No. 58. *See In re K-tel, Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 889 (8th Cir. 2002) (explaining that on a motion to dismiss "[t]he court may consider, in addition to the pleadings, materials 'embraced by the pleadings' and materials that are part of the public record").

[2] This case was originally filed in September 2022 by the Trustees of the Welfare and Pension Funds of Local 464A, but Phoenix moved for appointment as lead plaintiff and for appointment of lead counsel in a consolidated securities class action. On November 30, 2022, United States Magistrate Judge John F. Docherty appointed Phoenix as Lead Plaintiffs. Doc. No. 43. Phoenix filed the Complaint on February 14, 2023.

Geoffrey S. Martha was Medtronic's President from November 2019 through April 2020. He took over for Ishrak as Medtronic's CEO on April 27, 2020, and became the Chairman in December 2020. *Id.* ¶ 21. Karen Parkhill has been Medtronic's Executive Vice President ("EVP") and Chief Financial Officer throughout the Class Period. *Id.* ¶ 22. Sean Salmon has been Medtronic's EVP since October 2019, and he was President of Medtronic's Diabetes Group from October 2019 until May 2022. *Id.* ¶ 23. Bradley Lerman was Medtronic's Senior Vice President, Corporate Secretary, and General Counsel during the Class Period until he left the company in December 2021. *Id.* ¶ 24. And Hooman Hakami served as the EVP of the Diabetes Group from May 13, 2014, through October 21, 2019. *Id.* ¶ 25.

II. Insulin Pumps and Continuous Glucose Monitors

The human pancreas produces insulin, which regulates the amount of glucose in the bloodstream by causing cells to become porous to glucose. Diabetes is a disease of this system and can occur in two types. In Type 1 diabetes, the body's immune system mistakenly destroys pancreatic cells so that the human body has insufficient insulin. In Type 2 diabetes, the body produces enough insulin, but the body's cells are not responsive to it, so glucose cannot be absorbed. For those with Type 2 diabetes, treatment can be minimal, requiring only medication and lifestyle changes, but Type 1 diabetics require a more complex management of the disease involving precisely calibrated infusions of insulin. Compl. ¶¶ 26–27.

Non-diabetic adults maintain glucose concentrations typically between 80-120 milligrams per deciliter ("mg/dL"). Glucose levels outside this range can be dangerous.

Hyperglycemia (too much glucose) can result in neuropathy, retinopathy, blindness, and other complications, while hypoglycemia (too little glucose) can be fatal within hours. *Id.* ¶ 27. For many years, Type 1 diabetics had to monitor their glucose levels and give themselves manual injections with a syringe multiple times a day to keep their glucose levels within a healthy range. But that all changed with the development of the insulin pump. *Id.* ¶ 28.

Insulin pumps connect to an insulin cartridge with a "retainer ring" and can be carried by a patient throughout the day. *Id.* They provide micro-infusions of insulin over time allowing a diabetic person to have longer periods with their glucose level in the target range, also called "time in range." *Id.* This baseline drip of insulin is called a "basal rate," and at mealtimes, to control a spike in blood glucose, a patient can also use the pump for a one-time delivery of insulin known as a "bolus." *Id.*

However, early insulin pumps could only respond to the patient's input and had no way of independently responding to a real-time reading of the wearer's blood glucose level. *Id.* ¶ 29. More recently, advanced insulin pumps integrate continuous glucose monitors, which automatically monitor the wearer's blood glucose level. These are referred to as "hybrid closed loop systems" that can adjust the basal rate of insulin in response to changes in the blood glucose level, thereby increasing patient convenience. *Id.* But the original hybrid closed loop systems could not deliver a bolus at mealtimes. Further advancements in insulin pumps have resulted in "advanced hybrid closed loop systems" capable of performing all the operations of the hybrids, but also delivering mealtime boluses. *Id.*

A. Medtronic's Insulin Pump Business

Medtronic has grown over the years into a leading global healthcare technology company that develops medical devices. Compl. ¶ 30. It is organized into four groups: Cardiac and Vascular; Minimally Invasive Therapies; Restorative Therapies; and Diabetes." *Id.* ¶ 31. The Diabetes Group is the smallest of the four groups. *Id.* For example, in fiscal year 2020, each group had the following net sales revenue: Cardiac and Vascular – $10.5 billion; Minimally Invasive Therapies – $8.4 billion; Restorative Therapies – $7.7 billion; and Diabetes – $2.4 billion. Doc. No. 65 ("MacDonald Decl."), Ex. 1 at 7. Nevertheless, the Diabetes Group has generated billions of dollars in top-line revenue for the company. Compl. ¶ 32. Part of the Diabetes Group's value to the company has been achieved through its development of insulin pumps. By 2017, it was estimated to have 70% of the insulin pump market. *Id.* ¶ 32.

Prior to the Class Period, Medtronic obtained its large market share by developing and selling the MiniMed 600 Series of insulin pumps, which included the 620G, 630G, 640G, and 670G. *Id.* ¶ 33. The 670G was released in 2017 and was the first-ever hybrid closed-loop system. *Id.* By introducing the 670G to the market, Medtronic had an advantage over growing competition in the insulin pump market, and the 670G was largely responsible for keeping the Diabetes Group's revenue outlooks positive. *Id.* ¶ 34.

B. Competitors' Advancements & Medtronic's Response

By fiscal year ("FY") 2019 and FY20, the Diabetes Group's financial performance had slowed, in part, because the MiniMed 670G was not an *advanced* hybrid closed-loop system. Compl. ¶ 35. A competitor—Tandem Diabetes Care—had developed a hybrid

closed-loop system pump that was a competitor for the 670G. Though considerably smaller than Medtronic's overall insulin pump market share, Tandem's business was booming, nearly tripling between 2018 and 2020. *Id.* ¶ 36. At the same time, Medtronic was in the process of developing its own advanced hybrid closed-loop system, the MiniMed 780G.[3] *Id.* ¶ 37. In an August 2019 SEC filing, Medtronic reported that the Diabetes Group's sales were up, but attributed it primarily to "growth in international markets resulting from strong consumer demand of the MiniMed 670G." MacDonald Decl., Ex. 4 at 3.

As competition from other companies increased, in October 2019, Medtronic's head of the Diabetes Group, Mr. Hakami, retired, and Sean Salmon took over that position. *Id.* ¶¶ 39–40. Not long after, in November 2019, Medtronic hosted an earnings call announcing that Geoffrey Martha would be taking over for Mr. Ishrak as CEO in April 2020. Martha identified reinvigorating the diabetes business as a priority in his first public address as a CEO, and Ishrak stated that the company was excited about the expected launch timeline of the MiniMed 780G. *Id.* ¶ 41.

In December 2019, Tandem announced that it had gained approval for the first-ever advanced hybrid closed-loop system in the United States. *Id.* ¶ 42. Tandem's software upgrade for its pumps was also going to be available to all users of its previous generation of pumps. *Id.* Market analysts suggested that Tandem's advancements would lead consumers to choose its pumps over Medtronic's, at least until Medtronic was able to

[3] Medtronic had also developed a hybrid closed-loop system for patients aged 2 through 6 that launched in 2020. It gained FDA approval on August 31, 2020, and began selling in the United States in November 2020. Doc. No. 64 ("Defs.' Mem.") at 7 (citing MacDonald Decl., Exs. 8–9).

release the MiniMed 780G in the United States. *Id.* ¶ 43. Given Ishrak's statements that the company was making progress in its trial of the pump, that its hardware had already been submitted to the FDA, and that there was no signal that the approval process would be delayed, analysts at Morgan Stanley believed that the 780G remained on track to launch late in FY20. *Id.* ¶ 41, 43. But nonetheless, Medtronic's insulin pump market share was declining in late 2019 and early 2020. *Id.* ¶¶ 43–44.

III. Problems with the 600 Series

Plaintiffs allege that while Medtronic and its executives communicated to market analysts and investors that its efforts to obtain FDA approval of the MiniMed 780G was "on track" and its Diabetes Group business was poised to rebound, they concealed and misrepresented the reality that there were significant product quality issues with not only the MiniMed 670G, but the entire MiniMed 600 Series of pumps.

A. Retainer Ring Issues

Medtronic's 600 Series pumps used a clear retainer ring that suffered from a manufacturing defect. Plaintiffs allege that this defect could cause potentially life-threatening problems for patients. Specifically, a malfunctioning retainer ring could cause the insulin pump to seat improperly on the insulin reservoir. As a result, the pump could unexpectedly deliver more or less insulin than commanded by a user, causing potentially harmful hyper- or hypoglycemia. Compl. ¶ 47.

Medtronic allegedly became aware of this problem as early as June 2016. *Id.* ¶ 48. At that time, Medtronic began receiving complaints from customers concerning the clear 600 Series retainer rings. By November 2019, Medtronic had already received over 74,000

retainer ring complaints, at least one report of a patient being hospitalized, and one report of a death. *Id.* ¶ 50.

When Medtronic began receiving these complaints, Plaintiffs allege that it implemented a "flawed risk analysis protocol . . . to determine the risk associated with the complaint . . . about the malfunctioning retainer rings." *Id.* ¶ 51. That flawed protocol underestimated the risk of serious adverse health consequences.

At the same time Medtronic's risk analysis protocol was underestimating the risks posed by the retainer ring problems, Medtronic developed and publicized the results of "small, controlled studies" to illustrate that its insulin pumps were safe. *Id.* ¶ 61. In July 2018, Medtronic released the results of a year-long study involving 6,000 patients in cooperation with an insurer, which cited clinical results compiled by a Medtronic data scientist. *Id.* ¶ 62. The July 2018 study suggested that the MiniMed 630G had the ability to reduce hospital admissions by twenty-seven percent over diabetes patients who manually inject insulin. *Id.* Again, in May 2019, Medtronic released the results of a study regarding the MiniMed 640G that followed 153 adult patients. The press release indicated that the study showed the 640G's effectiveness in reducing hypoglycemia. *Id.* ¶ 63. According to Plaintiffs, these studies hid the larger problems facing Medtronic's 600 Series pumps among the larger population of users, which "presented a misleading picture to customers, the FDA, and investors regarding the safety and efficacy of Medtronic's insulin pumps." *Id.* ¶ 64.

B. Cybersecurity Issues

In addition to the issues with the retainer rings, Medtronic began an internal study in 2018 concerning a vulnerability with the remote controllers for the MiniMed 508 insulin pumps. That vulnerability would allegedly allow unauthorized persons to access the software in ways that could result in catastrophic harm to patients according to Medtronic's own investigation. *Id.* ¶ 57. Medtronic recalled approximately 15,000 of these units, but it had been selling the remotes that were susceptible to a cybersecurity breach for nearly 20 years. Its partial recall meant that many of the at-risk devices were left on the market and that Medtronic did not notify all customers of the safety issue. *Id.* ¶¶ 57–58. In December 2019, there was a report that a Medtronic "Paradigm" insulin pump user had experienced over-injections of insulin that the customer had not programmed. *Id.* ¶ 60. Medtronic allegedly failed to conduct an adequate investigation into these cybersecurity issues in violation of federal regulations. *Id.* ¶¶ 59–60.

C. Field Safety Notification and Recall

Medtronic did not voluntarily recall its MiniMed 600 Series products in response to customer complaints regarding the clear retainer rings. Compl. ¶ 65. Instead, starting in August 2019, Medtronic released 600 Series pumps with a purportedly more robust black retainer ring, but did so without advising users of previously purchased pumps that used the clear retainer rings of any risks those rings presented. *Id.* ¶ 66. It was not until November 21, 2019, that Medtronic issued a voluntary Field Safety Notification that instructed users of the 600 Series pumps to examine their retainer rings and inform Medtronic if the ring appeared damaged or was missing. *Id.* ¶ 67. The November 2019

Field Safety Notification only identified concerns with two models—the 630G and 670G—but the same pump body design was used throughout the 600 Series. *Id.* ¶ 68.

Medtronic instructed its employees to tell customers that the November 2019 Field Notification was not a recall. However, on February 7, 2020, the FDA determined that it was, in fact, a Class I recall, and identified additional 600 Series pumps—beyond the 630G and 670G—in the recall notices. *Id.* ¶¶ 69–70. A Class I recall indicates there is "a reasonable probability that the use or exposure to a violative product will cause serious adverse health consequences or death." *Id.* ¶ 70. The recall was made public on February 12, 2020, but Medtronic allegedly conveyed to the public that the retainer ring defect was the only quality issue with its pumps. *Id.* ¶¶ 70–71. On March 5, 2020, Medtronic also allegedly downplayed the seriousness of the recall in a letter to its customers, telling them that if the retainer rings properly functioned, they could safely continue using the pumps. *Id.* ¶ 72.

On February 18, 2020, during an earnings call, Salmon told analysts and investors that the 780G review by the FDA was "going well." *Id.* ¶ 73. Ten days later, Medtronic filed a Form 10Q with the SEC that stated the company expected "sustained strong consumer demand" for the 600 Series, despite the recall and the FDA's concerns. *Id.* But, between December 2019 and May 2021, Medtronic began receiving hundreds of complaints about the new black retainer rings that it had recently begun releasing in its 600

Series pumps. *Id.* ¶ 74. Medtronic also faced several product-liability lawsuits in 2020 concerning alleged defects with its 600 Series pumps.[4] *Id.* ¶ 75.

Meanwhile, on June 5, 2020, the MiniMed 780G was approved for use in the European Union, and launched in twelve countries outside the United States, primarily in Europe, in October 2020. *Id.* ¶ 159.

IV. The Investigation, Form 483, and Warning Letter

More than a year after the February 2020 Class I recall, the FDA initiated an inspection of Medtronic's facility in Northridge, California, which lasted from June 7 through July 7, 2021. Compl. ¶ 77. At the end of the investigation, the FDA issued a report of its findings concerning issues with the facility at a "closing meeting." *Id.* ¶ 78. The FDA also issued a "Form 483"[5] that reported its observations about the Northridge facility, including:

> (1) Medtronic failed to establish adequate "procedures for corrective and preventive action" – referring to Medtronic's inappropriate risk analysis procedures;

[4] Although the Complaint discusses the existence of these lawsuits, Plaintiffs do not appear to argue that Defendants committed securities fraud by failing to acknowledge the existence of such lawsuits when they made the statements forming the basis of the claims at issue in this litigation. It appears on the face of the Complaint that each of the lawsuits mentioned was publicly filed and could have been discovered by a reasonably prudent investor.

[5] The Complaint asserts that "[a]ccording to the FDA, a Form 483 is issued to firm management at the conclusion of an inspection when an investigator(s) has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts." Compl. ¶ 90 n.8. The Eighth Circuit Court of Appeals has similarly explained that "Form 483s are issued pursuant to FDA regulation to notify a company's 'top management in writing of *significant objectionable conditions*, relating to products and/or processes, or other *violations* of the [FDA] which were observed during the inspection' of a facility." *Public Pension Fund Gr. v. KV Pharm. Co.* ("*K-V Pharm.*"), 679 F.3d 972, 976 (8th Cir. 2012) (quoting FDA Investigations Operations Manual, Ch. 5, § 5.2.3 (2009)) (emphasis and alteration added in *KV Pharm.*).

> (2) Medtronic failed to investigate "[c]omplaints involving the possible failure of a device to meet any of its specifications"; and
>
> (3) Medtronic failed to implement "[w]ritten MDR [Medical Device Report] procedures."

Id. ¶ 78 (brackets in Compl.).

The concerns raised in the Form 483 went beyond the retainer ring issues and problems with the 600 Series pumps about which Medtronic had been receiving complaints. *Id.* ¶¶ 77–79. However, in August 2021, Defendant Martha told analysts and investors on an earnings call that the 780G was "under active review with the FDA" and that "things are on track as far as we can tell." *Id.* ¶ 79. Salmon and Martha repeated similar reassurances to investors on an earnings call in November 2021, but made no mention of the FDA's inspection, the FDA's statements in the Form 483, or the delay that those issues presented for gaining FDA approval of the 780G pump. *Id.* ¶ 79. Between the issuance of the Form 483 and those November 2021 statements, Salmon had signed five letters on behalf of Medtronic responding to the FDA's observations of potential violations cited in the Form 483. *Id.* ¶ 80.

Eventually, the FDA concluded that Medtronic had not resolved the deficiencies identified by the FDA inspection and issued a formal "warning letter" on December 9, 2021.[6] *Id.* ¶ 81. The Complaint describes the warning letter as follows:

[6] A warning letter "notifies a company that the FDA considers one or more products, practices, processes, or other activities to be in violation of the Federal Food, Drug, and Cosmetic Act, its implementing regulations, and other federal statutes. Warning letters are only issued for violations of regulatory significance, *i.e.*, those that may actually lead to an enforcement action if the documented violations are not promptly and adequately corrected." Compl. ¶ 90 n.8.

> The Warning Letter found that Medtronic used an incorrect risk threshold when it evaluated 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 a report that its device may be malfunctioning in a manner "likely to cause or contribute to a death or serious injury, if the malfunction were to recur."

Id. ¶ 81. An FDA warning letter can prevent a medical device manufacturer like Medtronic from obtaining premarket approval of an application for a new Class III medical device that is reasonably related to the regulatory deficiencies highlighted in the letter. *Id.* ¶ 207. The prohibition lasts until those deficiencies are corrected. *Id.*

On December 15, 2021, Medtronic filed a Form 8-K with the SEC indicating that on December 15th, the company "issued a press release announcing it had received a warning letter from the [FDA] following an inspection of its Northridge . . . facility." MacDonald Decl., Ex. 20 at 4. Further, the 8-K advised that Medtronic did not expect the warning letter to impact its "total company organic revenue growth and adjusted earnings per share guidance for the third quarter or full fiscal year 2022," which had been issued toward the end of November 2021. *Id.* The update also indicated that Medtronic did expect that, as a result of the warning letter, its Diabetes business revenue would see "declines in the high-single digit range for the third fiscal quarter and the mid-single digits range for the full fiscal year 2022," which was "modestly" lower than previous guidance had suggested. *Id.* Medtronic's press release indicated that "[t]he warning letter focuse[d] on the inadequacy of specific medical device quality system requirements at the Northridge

facility in the areas of risk assessment, corrective and preventative action, complaint handling, device recalls, and reporting of adverse events." *Id.* at 5; Compl. ¶ 256.

In response to the warning letter, Martha told investors that the 780G remained under active review with the FDA, and that approval was "subject to our warning letter." Compl. ¶ 82. Martha said that Medtronic was in "ongoing dialogue [with the FDA] on the 780G approval" when asked if the Warning letter was a separate issue from the approval process. *Id.* ¶ 82. On March 3, 2022, Medtronic filed an SEC Form 10-Q that indicated its

> Diabetes [business] could be affected by . . . [r]esolution of findings contained in a December 2021 U.S. FDA warning letter relating to the MiniMed 600 Series insulin pump and a remote controller device for the MiniMed 508 and Paradigm pumps. We are currently working with the U.S. FDA to resolve the findings. The existence of the warning letter may limit our ability to launch certain new Diabetes products in the U.S. prior to resolution of the findings.

MacDonald Decl., Ex. 22 at 4.

By May 26, 2022, in response to the Warning letter, Medtronic informed investors during a Q4 earnings call that the company no longer expected to receive timely FDA approval of the MiniMed 780G. As a result, it did not rely on such approval in its financial guidance for fiscal year 2023 and expected a decline of 6–7% in the Diabetes Group's earnings. Compl. ¶ 237. The company's May 26th Form 8-K filed with the SEC acknowledged a significant decline in "U.S. revenue . . . given the absence of new product approvals." MacDonald Decl., Ex. 24 at 2. The FDA ultimately approved the 780G on April 21, 2023. Pls.' Opp'n at 13 & n.7; Doc. No. 72 ("Second MacDonald Decl."), Ex. 37 (Medtronic Press Release).

V. Alleged Regulatory Violations

According to Plaintiffs, Medtronic violated federal regulations in several ways in connection with the facts described above. For example, Plaintiffs assert that Medtronic was required to submit Medical Device Reports ("MDRs") to the FDA identifying dangers posed by the 600 Series pumps within thirty days of receiving information indicating that its devices may have caused or contributed to death or serious injury or malfunctioned and the device would be likely to cause or contribute to death or serious injury if the problem occurred again. Compl. ¶ 83 (citing 21 C.F.R. §§ 803.50(a)(1), (2). When the FDA inspected Medtronic's facility, it found violations of this provision. *Id.* ¶ 83. The Warning letter identified an example where Medtronic failed to submit any MDR at all, and another where it provided the MDR after the thirty-day deadline. *Id.* ¶¶ 84–85.

In addition, Plaintiffs contend that Medtronic failed to disclose "known trends or uncertainties" in violation of Item 303 of SEC Regulation S-K, 17 C.F.R. § 299.303, when it filed Form 10-Ks and Form 10-Qs during the Class Period.[7] Compl. ¶ 87. These regulations require a narrative explanation for financial statements, and 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

[7] During the Class Period, Medtronic filed Form 10-Ks with the SEC on June 21, 2019, June 19, 2020, and June 25, 2021. It filed Form 10-Qs on August 30, 2019, December 3, 2019, February 28, 2020, September 3, 2020, December 3, 2020, March 5, 2020, September 2, 2021, December 2, 2021, and March 3, 2022. Plaintiffs reference these filings in their Complaint, and excerpts of each were provided by Defendants. MacDonald Decl., Exs. 1–2, 4–7, 13–15, 22, 31. "[I]t is permissible for courts to take judicial notice of SEC filings at the 12(b)(6) stage in securities fraud cases for the purpose of determining what statements the documents contain." *In re Guidant Corp. Sec. Litig.*, 536 F. Supp. 2d 913, 921 (S.D. Ind. 2008) (quoting *Selbst v. Coca–Cola Co.*, 262 F. App'x 177, 179 (11th Cir. 2008)).

or revenues or income from continuing operations." *Id.* ¶¶ 87–88. Plaintiffs assert that the complaints regarding the 600 Series retainer rings, the lawsuits that were filed, the death of at least one user of a 600 Series device, the Class I recall, the Northbridge facility inspection by the FDA, the Form 483, and the warning letter were all events and uncertainties related to the diabetes business that should have been disclosed under Item 303. Instead, Medtronic's SEC filings during the Class Period attributed declining sales numbers in the Diabetes Group to issues with the COVID-19 pandemic and competitive pressure in the U.S. and international markets, while misleadingly suggesting that the outlook for the Diabetes Group would depend on the company's ability to develop and bring to market new products, including the MiniMed 780G. *Id.* ¶¶ 90–116.

VI. Confidential Witness Accounts

Plaintiffs obtained information from two former Medtronic employees that they contend demonstrate that Defendants knowingly or recklessly made false statements during the Class Period. Compl. ¶ 190. These former employees provided information to Plaintiffs' counsel or their investigators confidentially and are identified by the abbreviation "CW" for "confidential witness." Plaintiffs reveal their job descriptions, responsibilities, and the duration of their employment. *Id.*

Confidential Witness No. 1 ("CW-1") was a Diabetes Management Consultant, then a Senior Territory Manager from June 2006 through April 2018, and a Principal Territory Manager from April 2018 to January 2022. CW-1 sold the 630G, 670G, 770G pumps and other Medtronic's diabetes products. Compl. ¶ 191. CW-1 identified that there was fierce competition facing Medtronic during the Class Period, and Medtronic's MiniMed 670G

had at least four product problems—a retainer ring issue, a blood glucose loop issue, a reservoir clogging issue, and an alarm sounding issue. *Id.* According to CW-1, these issues led physicians and patients to switch to competitor products. The issues arose when Hakami started instituting huge cost cuts and "took an axe to the diabetes' operational budget." *Id.* According to CW-1, "executive management tracked revenues on a daily basis" using specific sales database tools. *Id.* CW-1 left Medtronic "in part, because they grew tired of having to constantly apologize to physicians and patients for issues with the MiniMed products." *Id.*

Confidential Witness No. 2 ("CW-2") was a Senior Director, U.S. Regulatory Affairs, from October 2020 through August 2022. Compl. ¶ 192. CW-2 managed a team of regulatory employees seeking FDA approval for Medtronic devices, including the 780G. *Id.* CW-2 was responsible for regulatory submissions and worked in the Diabetes Group. CW-2 stated that executive management knew before receiving the Warning letter that the 780G was not going to receive timely approval but continued to communicate misinformation to the public. *Id.* The "executive management" referred to by CW-2 included Defendants Martha, Parkhill, and Salmon, and other individuals not named as Defendants. *Id.* ¶ 192 n.12. According to CW-2, the issues raised in the Form 483 would take between one to two years to remediate, and it was "physically impossible" to get a product approved for the market while under an FDA warning letter. *Id.* ¶ 192. CW-2 also stated that the 600 Series recall would cause delays for all associated or similar products in the premarket approval phase. CW-2 had monthly meetings with the FDA concerning the progress of the 780G application as well as monthly internal Medtronic meetings, attended

by Salmon and Parkhill, where the status of the 780G application was discussed. *Id.* According to CW-2, executive management did not share clear information about the 780G's regulatory progress with the public and "knew that they were disseminating unrealistic timelines and dates to shareholders." *Id.* CW-2 allegedly informed executive management that there was no chance of obtaining "timely approval" of the 780G, but CW-2 was told that such information would not be shared with the public until an analyst call that was two weeks away.[8] *Id.* "CW-2 explained that in November 2021, problems with FDA approval of the MiniMed 780G system became clear when a different FDA submission was stalled – CW-2 stated that 'the FDA gave us a hint that a warning letter was coming.'" *Id.* CW-2 left Medtronic, in part, because of how executive management provided misinformation to the public. *Id.*

VII. Claims

According to the Plaintiffs, Defendants alleged misrepresentations caused the price of Medtronic's stock to be artificially inflated. During the Class Period, there were partial disclosures through the FDA's Class I recall and the warning letter. However, those disclosures did not fully correct the market for the company's stock because the Defendants' ongoing scheme and misleading statements still concealed the extent of the problems that continued to jeopardize the share price. When the company issued a press release on May 26, 2022, concerning its financial results for fiscal year 2022 and advising that it could no longer include FDA approval of the 780G in its guidance for fiscal year

[8] The precise timing of this alleged communication to and from executive management is not included in the complaint.

2023, the stock price dropped 5.8%. This allegedly caused economic loss to Plaintiffs and all those who purchased or acquired Medtronic common stock during the Class Period. Compl. ¶¶ 251–57.

Based on the foregoing allegations, Plaintiffs' claims are organized into two separate counts. Count One alleges that all Defendants are liable for violations of § 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and SEC Rule 10b-5, 17 C.F.R., § 240.10b-5. Through Count One, Plaintiffs are pursuing both a claim of liability based on Defendants' alleged false statements and a scheme-liability claim. Count Two asserts that the individual Defendants are liable for violations of § 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), for controlling-person liability. Plaintiffs seek certification of a Rule 23 class, compensatory damages, reasonable costs and expenses, including attorney's fees and other professional fees, and other appropriate relief.

DISCUSSION

Defendants argue that Plaintiffs fail to state a claim for relief under the federal securities laws. Defendants raise six distinct arguments. First, they contend that the Complaint does not allege any actionable misstatements. Second, they argue that Plaintiffs fail to plead any violation of Item 303 of Regulation S-K. Third, Defendants contend that Plaintiffs do not assert a cognizable "scheme" for purposes of their scheme-liability claim. Fourth, they assert that Plaintiffs fail to plead a strong inference of scienter. Fifth, they argue that Hakami is not a proper defendant. And finally, they contend that Plaintiffs' control person claims are inadequately alleged.

I. Securities Fraud Claims and Pleading Requirements

A. Section 10(b) and Rule 10b-5

"The Exchange Act § 10(b) and related rules prohibit 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) (internal quotations omitted). Plaintiffs pursue both forms of liability available under Rule 10b-5: false-statement liability and scheme liability. *W. Va. Pipe Trades Health & Welfare Fund v. Medtronic, Inc.* ("*Medtronic*"), 845 F.3d 384, 389 (8th Cir. 2016) (explaining that under Rule 10b-5 there "two kinds of liability: false statement liability (17 C.F.R. § 240.10b-5(b)) and scheme liability (17 C.F.R. § 240.10b-5(a), (c))").

To state a claim for false-statement liability, plaintiffs must allege: (1) a material misrepresentation or omission; (2) scienter, or intent to deceive, manipulate, or defraud; (3) a connection with the purchase or sale of a security; (4) reliance; (5) economic loss; and (6) loss causation, meaning a causal connection between the misrepresentation and the loss. *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 341–42 (2005); *see also McAdams v. McCord*, 584 F.3d 1111, 1113 (8th Cir. 2009).

A scheme-liability claim has the following elements: (1) the defendant engaged in a deceptive act; (2) scienter; (3) the defendant's act affected the market for securities or was connected to the purchase or sale of securities; and (4) the defendant's actions caused the plaintiff's injuries. *Medtronic*, 845 F.3d at 389. Scheme-liability claims "must be based on conduct beyond misrepresentations or omissions actionable under Rule 10b-5(b)." *Medtronic*, 845 F.3d at 392 (quoting *KV Pharm*, 679 F.3d at 987).

B. Control-Person Liability

Plaintiffs controlling-person claims are governed by § 20(a) of the Exchange Act. Under that provision, "[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). As this language contemplates, controlling-person claims are derivative of other violations, meaning plaintiffs must establish an underlying violation of the Exchange Act. *See Lustgraaf v. Behrens*, 619 F.3d 867, 874 (8th Cir. 2010). If a plaintiff's false-statement and scheme-liability claims fail, then relate controlling-person claims will necessarily fail as well.

Because section 20(a) is remedial, courts construe it liberally. *See Farley v. Henson*, 11 F.3d 827, 836 (8th Cir. 1993) (noting that section 20(a) "has been interpreted as requiring only some indirect means of discipline or influence short of actual direction to hold a 'controlling person' liable"). To state a claim that a person is liable under this statute a plaintiff must plausibly allege "(1) that a primary violator violated the federal securities laws; (2) that the alleged control person actually exercised control over the general operations of the primary violator; and (3) that 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 v. Behrens*, 619 F.3d 867, 873 (8th Cir. 2010).

C. Special Pleading Requirements

In 1995, Congress passed the Private Securities Litigation Reform Act ("PSLRA")[9] to impose heightened pleading requirements that are unique to securities-fraud litigation. *In re Stratasys Ltd. Shareholder Sec. Litig.* ("*Stratasys II*"), 864 F.3d 879, 882 (8th Cir. 2017); *see also In re K-tel Int'l Sec. Litig.*, 300 F.3d 881, 889 (8th Cir. 2002). The PSLRA's purpose was to act "[a]s a check against abusive litigation by private parties." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 313 (2007). Under its mandates, plaintiffs must first identify each allegedly misleading statement, state the reason or reasons why it is misleading, and provide the particular facts forming the basis for any allegation asserted on information and belief. *In re Stratasys Ltd. S'holder Sec. Litig.* ("*Stratasys I*"), No. 15-cv-0455 (PJS/FLN), 2016 WL 3636992, at *7 (D. Minn. June 30, 2016), *aff'd sub nom. In re Stratasys Ltd. S'holder Sec. Litig.*, 864 F.3d 879 (8th Cir. 2017).

Second, for every act or omission that allegedly constitutes securities fraud, plaintiffs must "state with particularity facts giving rise to a strong inference" of scienter, meaning "the intent to deceive, manipulate, or defraud" or recklessness amounting to "an extreme departure from the standards of ordinary care." *Id.* (internal quotation marks omitted). Allegations of "motive and opportunity" may also suffice, *Podraza v. Whiting*, 790 F.3d 828, 836 (8th Cir. 2015), but in the securities-fraud context, this phrase is a "term of art that is "far narrower" than it appears on its face, *In re Navarre Corp. Sec. Litig.*, 299 F.3d 735, 745 (8th Cir. 2002) (quotations omitted).

[9] 15 U.S.C. § 78u-4(b)(2).

Courts must look at the factual allegations as a whole to determine whether they give rise to a strong inference of scienter, "not whether any individual allegation, scrutinized in isolation, meets the standard." *Rand-Heart of New York, Inc. v. Dolan*, 812 F.3d 1172, 1177 (8th Cir. 2016) (quoting *Tellabs, Inc.*, 551 U.S. at 314). However, "in determining whether the pleaded facts give rise to a strong inference of scienter, we must take into account plausible opposing inferences." *Podraza*, 790 F.3d at 837 (quoting *Tellabs*, 551 U.S. at 323) (cleaned up). After comparing the plausible nonculpable inferences with the inferences favoring a finding that a defendant acted with the requisite scienter, courts should deny a motion to dismiss when "a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged." *Id.* (quoting *Tellabs*, 551 U.S. at 324). A complaint must be dismissed if it fails to meet the PSLRA's pleading requirements. *Stratasys I*, 2016 WL 3636992, at *7.

In pleading scheme-liability claims, plaintiffs must comply with the specificity requirements of Federal Rule of Civil Procedure 9(b). *KV Pharm.*, 679 F.3d at 986. "Scheme liability claims are subject to the PSLRA pleading standard with respect to scienter." *Menaldi v. Och-Ziff Cap. Mgmt. Gr. LLC*, 277 F. Supp. 3d 500, 517 (S.D.N.Y. 2017). For scheme-liability claims, plaintiffs must therefore 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." *K-V Pharm*, 679F.3d at 986 (quoting parenthetically *In re Parmalat Sec. Litig.*, 414 F. Supp. 2d 428, 432 (S.D.N.Y. 2006)).[10]

II. Actionable Misstatements

Defendants do not argue that Plaintiffs' false-statement claims should be dismissed for failure to identify the alleged misstatements or omissions with adequate particularity. Instead, Defendants argue that the Complaint fails to allege any actionable misrepresentations or omissions. Defs.' Mem. at 14–34.

A. Legal Standards

It is unlawful, under the Exchange Act § 10(b) and Rule 10b-5, for a person to make "any untrue statement of a material fact . . . in connection with the purchase or sale of any security." 17 C.F.R. § 240.10b-5(b). It is also unlawful for a person "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." *Id.*; *In re K-Tel Int'l Sec. Litig.*, 300 F.3d 881, 888 (8th Cir. 2002) (quoting Rule 10b-5(b)).

For a claim based on alleged omissions, a defendant's statement is not actionable if the speaker had no duty to disclose the omitted information. *See KV Pharm.*, 679 F.3d at 984 ("Silence, absent a duty to disclose, is not misleading."); *In re Sanofi Aventis Sec. Litig.*, 774 F. Supp. 2d 549, 560 (S.D.N.Y. 2011) ("*Sanofi*") (same, citing cases). "'A corporation is not required to disclose a fact merely because a reasonable investor would

[10] The PSLRA's heightened pleading requirements and Rule 9(b)'s particularity requirements do not apply to controlling-person claims under section 20(a). *Medtronic*, 57 F. Supp. 3d at 984.

very much like to know that fact.'" *Sanofi*, 774 F. Supp. 2d at 561 (quoting *ZVI Trading Corp. Employees' Money Purchase Pension Plan & Trust v. Ross* (*In re Time Warner Inc. Sec. Litig.*), 9 F.3d 259, 267 (2d Cir. 1993)) (brackets omitted). However, there is a duty to disclose when public statements "'have been inaccurate, incomplete or misleading. . . .'" *Medtronic I*, 57 F. Supp. 3d at 972 (quoting *Sailors v. N. States Power Co.*, 4 F.3d 610, 612 (8th Cir. 1993)).

Statements that are too "vague" or that are "obvious hyperbole" are not actionable because "no reasonable investor would rely upon them." *In re Stratasys, Ltd.*, No. 15-cv-455 (PJS/FLN), 2016 WL 3636992, at *7 (D. Minn. June 30, 2016) (quoting *Parnes v. Gateway 2000, Inc.*, 122 F.3d 539, 547 (8th Cir. 1997)). Statements considered puffery include broad or indefinite predictions of growth untethered to substantive information that a reasonable investor could use to make a decision whether or not to invest. *See Parnes*, 122 F.3d at 547 (citing cases); *In re Stratasys*, 2016 WL 3636992 at *7–8 (finding several statements concerning the company's 3D printers to be inactionable puffery).

Similarly, statements are inactionable where they are merely "simple economic projections [or] expressions of optimism[.]" *In re Medtronic Inc., Sec. Litig.*, 618 F. Supp. 2d 1016, 1031 (D. Minn. 2009). While "objective statements of material fact" are actionable, "subjective statements of opinion are generally not" unless they "were both false and were not honestly believed when they were made." *In re Sanofi Sec. Litig.* (*Sanofi II*), 87 F. Supp. 3d 510, 528 (S.D.N.Y. 2015) (quotations and citations omitted).

The PSLRA also includes a safe-harbor provision that protects forward-looking statements when 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." 15 U.S.C. § 78u-5(c)(1)(A); *see also In re Resideo Tech., Inc. Sec. Litig.*, 2021 WL 1195740, at *5 (D. Minn. Mar. 30, 2021). But this provision does not apply if the person making the forward-looking statement knew "'that the statement was false or misleading.'" *Resideo*, 2021 WL 1195740, at *5 (quoting 15 U.S.C. § 78u-5(c)(1)(B)).[11]

B. Categories of Alleged Misrepresentations and Omissions

The Complaint lays out at least four broad categories of misleading statements and omissions regarding Medtronic's Diabetes Group business. Compl. ¶¶ 117–89.[12] The first category includes allegedly misleading statements about the MiniMed 600 Series pumps, specifically the 670G, and its effect on the Diabetes Group's financial performance. Between May 23, 2019, and early 2020, in SEC filings and in public statements to investors, Defendants repeatedly identified sales of the MiniMed 670G as being responsible for growth in the Diabetes Group, including its performance in overseas markets. Defendants also repeatedly stated that such growth was offset by increased competition in the United States. Plaintiffs point to positive statements regarding the 670G's importance to the company's financial performance by Defendants Ishrak, Hakami,

[11] For example, in *Resideo*, the court found that the defendants could not rely on the safe-harbor rule to obtain dismissal of plaintiffs' claims, although the defendants had included cautionary language in projections of future performance. The court reasoned that the defendants could not rely on the rule because plaintiffs had alleged that defendants knew about existing issues at the time they cautioned that those issues "*might* pose a problem in the future," thereby rendering "any cautionary language . . . not meaningful." 2021 WL 1195740, at *5 (emphasis in original).

[12] The paragraphs of the Complaint are interspersed with allegations concerning the reactions by market analysts to Defendants' allegedly false and misleading statements.

Parkhill, Lerman, Martha, and Salmon. *Id.* ¶¶ 117, 121–22, 125–27, 131–35, 141, 144–45, 147–48, 150. But when Defendants made these remarks about the 670G and market competition, they omitted: (a) that the company had received 74,000 retainer ring complaints between June 2016 and November 20, 2019; (b) that Medtronic had used a flawed methodology in two internal studies, which minimized the risk posed by the retainer ring issue; (c) that the company failed to warn users about the potential dangers posed by the clear retainer rings in the 600 Series pumps that it left in the field, while simultaneously releasing new 600 Series pumps with black retainer rings; and (d) that the limited November 21, 2019 Field Safety Notification warning was, in fact, a Class I recall. *Id.* ¶ 138(a)–(d), 162(a)–(e). Defendants also omitted from these statements that it had received hundreds of complaints about the black retainer rings from December 2019 through May 2021, and downplayed the severity of the FDA's Class I recall in a March 5, 2020, letter to users of 600 Series pumps. *Id.* ¶ 162(f)–(g).

The second category of alleged misrepresentations involves the Defendants' statements concerning the FDA approval process for the MiniMed 780G—Medtronic's effort to bring an advanced hybrid closed-loop system insulin pump to the U.S. market. In May 2019, Defendants discussed their expectations that they would launch the 780G in fiscal year 2020, and in November 2019, they assured investors "that whole pipeline is on track." Compl. ¶¶ 118, 128, 135. Defendants touted the 780G's improvement over previous models, repeatedly assured investors that the 780G was on track, things were going well with the FDA's review process, and the company was in an ongoing interactive process with the agency. *Id.* ¶¶ 120, 128, 135, 142, 146, 148–49, 153–60. Even after the FDA

publicly disclosed that the November 2019 Field Safety Notification was, in fact, a Class I recall, Defendants continued to repeat these same allegedly false assurances publicly. Compl. ¶¶ 146, 149, 153–58.

Defendants continued making similar statements about their expectations for the launch of the 780G after the FDA inspected Medtronic's Northridge facility in June and July of 2021 and after Medtronic received the Form 483. But Defendants did not mention the inspection or the Form 483 when they discussed the forecasts for the 780G. *Id.* ¶¶ 165, 169–70, 174(a)–(e). In August 2021, after the FDA inspection, the receipt of the Form 483, and the exchange of multiple letters with the FDA regarding issues with Medtronic's products and facility, Defendants Martha, Parkhill, and Salmon responded to analyst questions regarding the status of the application for approval of the 780G on an earnings call. *Id.* ¶ 165. Martha indicated the application was "under active review with the FDA," and Salmon suggested the discussions were positive, but neither mentioned the recent issues and how they "imperiled approval of the 780G pump." *Id.* Similar statements and omissions followed in late November 2021 SEC filings and earnings calls. *Id.* ¶ 169. Medtronic issued its press release regarding the warning letter on December 15, 2021,[13] and afterward Defendants publicly acknowledged that it required "extensive remediation," but failed to specifically inform the investing public whether the issues identified would

[13] In November 2020, Martha told investors that the MiniMed 780G was doing well in Europe and that the 770G had just launched in the U.S. MacDonald Decl., Ex. 11. Throughout 2021, Medtronic's international sales of the 780G were strong, and the sales of the 770G in the United States contributed to the company's diabetes business' success. MacDonald Decl., Ex. 12 at 6; *id.*, Ex. 13 at 3; *id.*, Ex. 14 at 3; *id.*, Ex. 15 at 3.

impact financials for fiscal year 2023. *Id.* ¶¶ 171–72. At a conference in March 2022, Parkhill stated that Medtronic continued to have good interactions with the FDA on remediating warning letter issues and in making progress on the 780G application. *Id.* ¶ 172. Plaintiffs assert that such statements omitted that the severity of the problems and delays would prevent the company from earning any revenue on U.S. sales of the MiniMed 780G in fiscal year 2023. *Id.* ¶¶ 172, 174.

The third category of misleading statements identified in the Complaint concerns the "risk warnings" Medtronic included in its Form 10-K and Form 10-Q filings with the SEC. The company filed reports on June 21, 2019, August 30, 2019, December 3, 2019, February 28, 2020, and June 19, 2020, each of which referenced the same risk factors that were published in Medtronic's 2019 Annual Report on Form 10-K.[14] Compl. ¶¶ 176–180. These documents disclosed the following risks associated with Medtronic's business: (a) a highly competitive industry and the possibility that the company could lose market share due to product problems, safety alerts, and publications about its products; (b) regulatory concerns, including in Form 483s, warning letters, and other enforcement mechanisms; (c) product quality problems, product liability claims, manufacturing and design defects and associated recalls; (d) reputational harm caused by issues with product quality; (e) inability to guarantee marketing clearance from regulatory agencies for new products or enhancements to existing products; and (f) issues with cyber-attacks or other

[14] The June 21, 2019 Form 10-K is found in Exhibit 2 to the MacDonald Declaration. The August 30, 2019 Form 10-Q is Exhibit 4. The December 3, 2019 Form 10-Q is Exhibit 5. The February 28, 2020 Form 10-Q is Exhibit 6. And the June 19, 2020 Form 10-K is Exhibit 1.

interference with integrated software. *Id.* ¶¶ 176(a)–(f). According to Plaintiffs, these warnings were materially misleading because they were presented as potential problems that had not yet occurred when, in reality, Medtronic had already experienced an array of product problems and customer complaints, customers moving to competitors' products due to quality issues, and software integrity issues. *Id.* ¶¶ 181(a)–(g). Subsequent filings on September 2, 2020, December 2, 2020, March 5, 2021, June 25, 2021, September 2, 2021, and December 2, 2021[15] included similar risk warnings but were allegedly misleading because they failed to disclose that regulatory actions had in fact already taken place. *Id.* ¶¶ 182–88.

The fourth category concerns alleged omissions from Medtronic's SEC filings that purportedly violated Item 303 of SEC Regulation S-K. Compl. ¶¶ 87–88, 90–116, 189(a)–(*l*). In twelve separate Form 10-K and Form 10-Q filings between June 2019 and March 2022, Defendants allegedly violated Item 303 (and consequently Rule 10b-5(b)) by omitting the same critical events and issues described above. *Id.* ¶ 189 (discussing allegations in Section VII of the Complaint).

C. Analysis

1. Statements Regarding the 600 Series

Defendants argue that Plaintiffs fail to state a claim based on any alleged statements regarding the 600 Series pumps both because they have only identified truthful statements

[15] Excerpts of these SEC filings respectively are found at the following docket entries: MacDonald Decl., Ex. 7 (9/3/20 Form 10-Q); *id.*, Ex. 14 (12/3/20 Form 10-Q); *id.*, Ex. 13 (3/5/2021 Form 10-Q); *id.*, Ex. 31 (6/25/21 Form 10-K); and *id.*, Ex. 15 (12/2/21 Form 10-Q).

about the effect of overseas sales of the 670G, and because the allegedly omitted details were publicly disclosed during the Class Period. Defs.' Mem. at 16–17; Defs.' Reply at 2–3. Plaintiffs argue that Defendants misled investors by highlighting the importance of the 670G's sales while, in reality, quality problems with the 600 Series pumps meant that the Group's revenues were unsustainable, and any public disclosures of quality issues failed to inform investors of the full extent of the Group's struggles. Pls.' Opp'n at 24–28.

Based on a careful review of the allegations, the Court finds that the Complaint alleges no facts showing that any of the backward-looking statements that Plaintiffs identify[16] within this category are literally false statements of material fact. And although literal falsity is not the only way in which a plaintiff can establish a Rule 10b-5(b) violation, Plaintiffs' argument that they have stated a claim based on material omissions also falls short. Courts have found that companies do not have an "affirmative independent duty . . . to disclose all information that could potentially affect [their] stock price, unless such silence renders an affirmative statement misleading." *In re Guidant Corp. Sec. Litig.*, 536 F. Supp. 2d at 928.[17]

Here, in the relevant statements found in the SEC filings regarding the 670G or in various investor calls, Medtronic affirmatively averred that the growth seen in its Diabetes

[16] Compl. ¶¶ 117, 121–22, 125–27, 131–35, 141, 144–45, 147–48, 150; Pls.' Opp'n at 24.

[17] The *In re Guidant Corp. Sec. Litig.* court found that the plaintiffs failed to show with sufficient particularity "how omission of product defect information rendered any specific affirmative statements misleading," and therefore concluded that they had not met the pleading burden. 536 F. Supp. 2d at 928. That is not the flaw here, where the Plaintiffs allege clearly the statements at issue. Instead, here, the information omitted simply doesn't render any of Defendants' admittedly true statements attributing growth to international sales of the 670G materially misleading.

business was attributable to either the ongoing launch of, or positive sales of, the 670G in international markets. Plaintiffs argue that Defendants allegedly failed to disclose information about customer complaints, quality issues with retainer rings, and other product concerns.[18] But failing to mention those issues does not make it misleading to truthfully tell the investing public that revenue from overseas sales of the 670G was, in fact, contributing to earnings growth and otherwise legitimately buoying the Diabetes Group's financials. The Complaint does not suggest that the earnings data Medtronic reported in the referenced SEC filings and investor calls was manipulated. Nor does the pleading allege that Medtronic's statements about the diabetes business' source of revenue was misleading, for instance, because the company was actually relying upon an unsustainable or illegal business model to generate those numbers. *Cf. Mart v. Tactile Sys. Tech., Inc.*, 595 F. Supp. 3d at 810–11 (D. Minn. 2022) ("[A] duty to disclose can arise 'when a corporation puts the reasons for its success at issue, but fails to disclose that a material source of its success is the use of improper or illegal business practices,' even when the corporation has not been charged with wrongdoing.") (quoting *Menaldi v. Och-Ziff Cap. Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 581 (S.D.N.Y. 2016)).

Plaintiffs argue that Defendants' 670G revenue statements were misleading because they implied that the product would continue to experience the same growth. They claim that by touting such international "sales growth," Defendants took on a duty to disclose the significant problems with the 600 Series pumps, which jeopardized Medtronic's likely

[18] Compl. ¶ 138(a)–(d); Compl. ¶ 162(a)–(l).

ability to continue to see positive sales numbers. For example, Plaintiffs point to a June 21, 2019, statement in Medtronic's Form 10-K and an August 30, 2019, statement in the company's Form 10-Q indicating that the future earnings in the Diabetes Group could be affected by continued patient demand for the 670G and continued international growth. Compl. ¶¶ 122, 130. The Court disagrees that more was required of the Defendants based on these allegations.

To support their theory, Plaintiffs cite *Minneapolis Firefighters' Relief Association v. Medtronic, Inc.* ("*Medtronic III*"), No. CV 08-6324 (PAM/AJB), 2010 WL 11469576 (D. Minn. Feb. 3, 2010). Pls.' Opp'n at 25. But *Medtronic III* does not help them. In *Medtronic III*, the plaintiffs specifically alleged that Medtronic made statements that "attribute[d] the growth of [the Infuse bone graft system] sales to FDA-approved, on-label uses" while omitting that "Medtronic knew that the growth in Infuse sales was due to off-label uses and not to any increase in on-label uses or in new FDA approvals." 2010 WL 11469576, at *5. By contrast, Medtronic's statements in this case do not affirmatively attribute the sales growth to particular characteristics of the 670G pumps, but to general high overseas demand. After all, "companies can control what they have to disclose under [Section 10(b) and Rule 10b-5] by controlling what they say to the market." *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 45 (2011). In fact, in the very same portion of the opinion cited by the Plaintiffs, the *Medtronic III* court found that the defendant's "general statements that Infuse experienced sales growth, with no explanation as to why or whether that growth would continue, are not actionable" because "Infuse did experience strong sales" and these statements did not "imply that Infuse growth was attributable to

any particular factor." 2010 WL 11469576, at *5. Here, Plaintiffs' allegations do not show that Medtronic attributed growth in the diabetes unit to sales of the 670G knowing that no such growth was occurring (*i.e.*, manipulated earnings data), nor that the Diabetes Group's revenue was attributable to a hidden unsustainable source (*e.g.*, illegal sales practices). The identified statements are simply not false or misleading.

For similar reasons, Plaintiffs' reliance on *Steiner v. MedQuist, Inc.*, No. 04-cv-5487 (JBS), 2006 WL 2827740 (D.N.J. Sept. 29, 2006), and *In re CenturyLink Sales Pracs. & Sec. Litig.*, 403 F. Supp. 3d 712, 724–25 (D. Minn. 2019), is misplaced. The *Steiner* court found the plaintiffs adequately pled a section 10(b) claim based on SEC filings which attributed increased sales to various legitimate sources of revenue when, in fact, the defendant omitted that its revenue was generated by fraudulent billing practices. 2006 WL 2827740, at *16. In *CenturyLink*, the defendants made specific representations about business strategies that resulted in revenue growth, while allegedly relying on a secret deceptive "cramming" billing strategy for that revenue. *Id.*; *see also Tactile Sys.*, 595 F. Supp. 3d at 809–11 (finding adequate allegations that the defendants misleadingly failed to disclose that their consistent reported earnings growth was overstated due to the company's reliance on illegal kickbacks and inflated Medicare revenue). These decisions are not instructive for the claims at issue here.

Another weakness with the Plaintiffs' position is that some of the identified forward-looking statements concerning the 670G's importance to sales growth made during the Class period came after Medtronic or the FDA publicly disclosed product issues with the 600 Series pumps, even if those disclosures did not occur in precisely the manner

that Plaintiffs would have preferred. Compl. ¶¶ 147, 150, 155, 159, 162(j). Many of these challenged statements about the 670G came after Medtronic's November 2019 Field Safety Notification and the February 2020 Class I recall, which put prudent investors on notice of the existence of the very quality issues with the 600 Series pumps that Plaintiffs claim Defendants should have included in their revenue forecasts.[19] *In re AIG Advisor Grp. Sec. Litig.*, 309 Fed. App'x 495, 498 (2d Cir. 2009) (finding that dismissal of plaintiffs' complaint was appropriate where defendants' websites publicly "disclosed the existence of the very 'conflict of interest' at the heart of the plaintiffs' complaint, barring any claim based thereon")[20]; *accord Foley v. Transocean Ltd.*, 861 F. Supp. 2d 197, 210–12 (S.D.N.Y 2012) (finding that the plaintiffs failed to allege actionable misrepresentations based on omissions where the defendant disclosed the "concerns to the market at various points in time" even though it did not provide a "laundry list of internal information" to investors and analysts on conference calls). In light of such disclosures, the Court finds that Plaintiffs fail to state a claim based on Defendants' allegedly misleading forward-looking statements about revenue from sales of the 600 Series pumps.

[19] Plaintiffs also allege that once the recall was publicized on February 12, 2020, "numerous news articles discussed how the MiniMed 600 Series products had caused a whole host of previously undisclosed health problems in its users, and resulted in at least one death." Compl. ¶ 96. As an example, they point to a CNN article identifying that Medtronic had received over 2,000 complaints and a report of one death. *Id.*

[20] One holding of *AIG Advisor Grp.* has been abrogated by subsequent authority. *See Merck & Co., Inc. v. Reynolds*, 559 U.S. 633 (2010) (reaching a conclusion concerning the triggering of the statute of limitations defense that is at odds with that embraced by the *AIG Advisor Grp.* Court). However, *Merck* does nothing to undermine the *AIG Advisor Grp.* court's conclusions about the impact of the website disclosures.

2. Statements Regarding Market Competition

Defendants also argue that Plaintiffs cannot base their misrepresentation claim on Defendants' statements that increased competition was contributing to slowed growth and revenue decline in the Diabetes Group during the Class Period. Defendants assert that the Complaint repeatedly alleges that competitors' advancements were hurting Medtronic's business, Defendants disclosed that fact throughout the Class Period, and the alleged omission of the fact that some of that pressure also came from product quality issues with the 600 Series pumps does not render those statements misleading. Defs.' Mem. at 17–19. Plaintiffs contend that Defendants' repeated statements concerning the impact of competition in the U.S. diabetes market were misleading because customers were, in fact, leaving Medtronic due to quality problems with its pumps. Pls.' Opp'n 28–29.

For several reasons, the Court finds the alleged omission of product problems from statements concerning competitive pressures in the Complaint does not render those statements misleading. First, the Complaint itself alleges that competition was causing Medtronic to lose market share throughout the Class Period. Compl. ¶¶ 35–45. Second, as noted above, the Plaintiffs' own allegations demonstrate that Medtronic's insulin pump issues were publicly disclosed through the 2019 Field Safety Notification, the Class I recall, and numerous news articles. Third, the allegedly misleading statements identified in the Complaint refer only generally to "competition" as a contributing factor in Medtronic's

insulin-pump market share.[21] These statements did not assert that other medical device manufacturers' technological advancements were the sole, or even the primary, source of the competition Medtronic was facing in the insulin pump market. In fact, the statements Plaintiffs rely upon in their pleading do not identify any particular reason that competition was eating into Medtronic's market share. *See Medtronic III*, 2010 WL 11469576, at *5 (reasoning that without implying that product growth was "attributable to any specific factor" truthful statements regarding strong sales were not actionable). This is not a case in which Defendants' statements created a misleading impression that the competitive pressure was attributable to a specific factor or set of factors, when in reality, it was due to something else.[22]

[21] Compl. ¶¶ 117 ("increased competition in the U.S."), 127 ("declining" U.S. business "because of competitive challenges"), 129 ("We've had more competitive pressure than we'd like..."), 133–34 ("increased competition" and "competitive challenges"), 142 ("There's competitors now" in the closed-loop system market), 144–45 ("increased competition" and "competitive challenges"), 150 ("competitive pressure in the U.S."), 152 ("continued competitive pressure"), 155 ("Continued pump competition"), 158–59 ("continued competitive pressure" and "Continued pump competition").

[22] For similar reasons, the Court is not persuaded by Plaintiffs' comparison of this case to *In re St. Jude Medical, Inc. Securities Litigation*, 836 F. Supp. 2d 878 (D. Minn. 2011). There, the plaintiffs alleged that the defendants engaged in fraudulent sales practices known as "channel stuffing"—*e.g.*, plaintiffs accused defendants of requiring hospitals to purchase significant excess inventory at the end of sales periods so that defendants' sales numbers would appear to remain unaffected by a general economic downturn. Failing to disclose these alleged practices was misleading because the channel stuffing inflated the actual sales figures. *Id.* at 891. Because the "undisclosed sales and accounting practices materially exacerbated the negative impact of the underlying deteriorating economic conditions," the *St. Jude* court found that the defendants' attempted reliance on cautionary language regarding other negative factors such as "increasing price competition" was unavailing. *Id.* at 893–94. Here, Plaintiffs have alleged no facts suggesting that Defendants failed to accurately report the level of sales or the impact that competition had on those sales.

The parties also disagree about whether Confidential Witness No. 1's account is sufficient, for purposes of a motion to dismiss, to show that Defendants made misleading statements concerning competition during the Class Period. The Court finds CW-1's account does not show that Defendants made misleading omissions in this context. The account provided by CW-1 is purely anecdotal and none of the facts alleged by CW-1 alters the reality that Plaintiffs own allegations show that Medtronic was facing competition. Moreover, the CW-1 allegations cannot change the fact that Defendants' challenged statements contained no implication that competitive pressures were attributable to any particular factor and were, therefore, not misleading. For these reasons, the Complaint fails to identify misleading omissions in Defendants' statements concerning the effect of competition on the Diabetes Group's revenue.

3. Statements of Optimism and Opinions

Defendants argue that a long list of statements forming the basis of Plaintiffs' misrepresentation claim are inactionable because they are vague statements of optimism or puffery. Defs.' Mem. at 19 (citing *e.g.*, Compl. ¶¶ 146, 148, 169, 222, 225, 146). Examples of such statements include those indicating that Defendants were "laser-focused on doing what it takes to return to market growth" (Compl. ¶¶ 5, 225); that the Diabetes business was "a priority" and the 780G was "the most important product" (*id.* ¶ 41); that the 780G was an "important catalyst" for growth in the Diabetes Group (*id.* ¶ 146); that Defendants were "excited about" the 780G (*id.* ¶ 142); that they "fe[lt] really good about the pipeline" for the Diabetes Group's products (*id.* ¶ 148); and that the 780G would represent a "big step forward" when it got to the market, would be a "growth driver," and "move the needle"

(*id.* ¶¶ 154, 157, 232). The Court finds that these statements and others like them found throughout the Complaint are not actionable.[23]

Many of these statements are the type of vague, optimistic assertions about growth and company performance on which reasonable investors would not rely. *Parnes*, 122 F.3d at 547. Some are "soft, puffing statements—which encompass optimistic rhetoric and promotional phrases used to champion the company but devoid of any substantive information." *In re Stratasys Ltd. Shareholder Sec. Litig.*, 864 F.3d 879, 882 (8th Cir. 2017) (cleaned up). These statements constitute puffery because they simply "cannot be 'supported by objective data or otherwise subject to verification by proof.'" *Id.* (quoting *In re NVE Corp. Sec. Litig.*, 551 F. Supp. 2d 871, 894–95 (D. Minn. 2007), *aff'd,* 527 F.3d 749 (8th Cir. 2008)) (brackets omitted).

Defendants further argue that Plaintiffs rely on a number of inactionable opinions. Defs.' Mem. at 19 (citing *e.g.*, Compl. ¶¶ 148, 157).[24] Among these statements, Defendants point to Hakami's remarks in June 2019 about the prospects for growth based on the 670G's international sales and his comment that "we feel very good about our ability to

[23] Defendants argue that the following paragraphs of the Complaint contain inactionable statements of optimism and inactionable puffing statements: 5, 10, 12, 13, 41, 73, 79, 82, 113–14, 120–22, 129, 131, 134–35, 142, 145–46, 148–49, 153–54, 156–58, 160, 165, 169, 172, 193, 205, 210–11, 213–15, 222, 224–25, 232, and 248. Defs.' Mem., App. I at A-1–A-2. A careful review of these paragraphs demonstrates that they contain inactionable statements of optimism or puffery. In many instances, more than one type of inactionable statement can be found in these paragraphs.

[24] Defendants argue that the following paragraphs of the Complaint contain inactionable statements of opinion: 12, 41, 79, 114, 121, 148, 154, 157, 165, 169, 193, 205, 211, 213–15, 232, and 248. Defs.' Mem., App. I at A-1–A-2. Again, a careful review of these paragraphs reveals that they include numerous statements of inactionable opinions, while also containing other forms of inactionable statements as well.

grow 45% of our business in the double-digit category." Compl. ¶ 121. In May 21, 2020, Martha told investors on an earnings call that he believed the Diabetes Group was "adequately derisked" and that he "fe[lt] really good about the pipeline." Compl. ¶ 148. In August 2020, Martha suggested that launching the 780G would be a "big step forward" and would lead to a "turnaround" for the diabetes business that was quicker than the three- or five-year timeline others had suggested. Compl. ¶ 154; *see also id.* ¶ 157 ("big jump forward"). In addition, Defendants point to statements concerning the prospects for FDA approval of the MiniMed 780G at various times during the Class Period. For example, at a conference on June 2, 2021, Salmon stated that it was important to have "good familiarity" and "good connections" with the FDA reviewers. Compl. ¶ 213. Similarly, on November 23, 2021, after the inspection and issuance of the Form 483, Salmon told investors that the company had engaged in "very good interactive conversations with the FDA" and that he thought "we're making excellent progress there." Compl. ¶¶ 12, 79.

"Opinions are actionable under the Exchange Act only if: (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.'" *Mart v. Tactile Sys. Tech., Inc.*, 595 F. Supp. 3d 788, 812 (D. Minn. 2022) (quoting *Omnicare, Inc. v. Laborers Dist. Council Constr. Indus. Pension Fund*, 575 U.S. 175, 184–89 (2015)).

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. So too were Defendants' statements that they believed they were "making excellent progress" toward FDA approval, or that they believed it was important to be familiar with and have "good connections" at the FDA. Likewise, Defendants' remarks about how they "felt" about the prospects for the Diabetes Group and their hopes that the launch of the 780G would mark a "big turnaround" for that sector of the business are not actionable. These are all vague, subjective statements or statements of corporate optimism that fail to state a claim for securities fraud. *See In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 528 (S.D.N.Y. 2015), *aff'd sub nom. Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016) (indicating that "subjective statements of opinion are generally not actionable"); *In re EDAP TMS S.A. Sec. Litig.*, No. 14-cv-6096 LGS, 2015 WL 5326166, at *10 (S.D.N.Y. Sept. 14, 2015) (explaining that putting a "positive spin on developments" with the FDA "constitutes inactionable puffery and corporate optimism").

4. Statements Regarding FDA Approval of the 780G

The parties dispute whether Plaintiffs have adequately stated a misrepresentation claim based on statements Defendants made about the progress of the approval process for the MiniMed 780G throughout the Class Period. Defs.' Mem. at 20–26; Pls.' Opp'n at 31–40. The Complaint identifies statements by Defendants about the prospect of FDA approval of the 780G from both before and after the agency's June–July 2021 inspection of Medtronic's Northridge facility and issuance of the Form 483. There are several statements by Defendants prior to the inspection about expectations for the 780G to launch in fiscal year 2020 (Compl. ¶ 118 (5/13/2019)); statements that Medtronic received positive reviews

in a feasibility study[25] (*id.* ¶ 120 (6/18/2019)); statements that Medtronic was preparing for the new product's launch (*id.* ¶¶ 128 (8/20/2019), 142 (1/13/2020), 149 (6/3/2020), 153 (8/25/2020)); statements that the company was making good progress and that its submission was "on track" (*id.* ¶ 135 (11/19/2020); statements that the company was continuing to work with the FDA on a strategy for the best timing to submit its application in light of the agency's obligations with the COVID pandemic (*id.* ¶ 158 (11/24/2020)); and statements indicating that Medtronic had submitted its application for approval of the 780G and a new sensor to the FDA and the submission was "under active review"[26] (*id.* ¶ 160 (6/3/2021)). The inspection began on June 7, 2021, and Plaintiffs assert that one day later, Defendant Martha mentioned that the company was "making steps" to launch the 780G. *Id.* ¶ 113.

Plaintiffs also rely on statements made by Defendants after the FDA completed its inspection and issued the Form 483. Defendants made statements indicating that the 780G had done well in international sales and in Europe (*id.* ¶¶ 165 (8/24/2021), 169 (11/23/2021); and that its application with the FDA was "on track as far as we can tell" (*id.* ¶ 169 (11/23/2021). Following the public disclosure of the FDA's warning letter on December 15, 2021, Defendant Parkhill indicated that the company "continue[d] to have

[25] There are no facts alleged in the Complaint to suggest that any of the statements indicating that the application for pre-market approval was "under active review" were false or that any Defendant had received a notification from the FDA prior to making such a statement that the FDA had stopped considering its application or rejected it. In the absence of such allegations, Defendants' statements to investors that the application process remained "on track" and that they felt they were making good progress toward FDA approval of the 780G were not misleading.

[26] The application for FDA approval of the 780G was submitted by Medtronic in February 2021. MacDonald Decl., Ex. 17 at 4.

very good engagement and interaction with the FDA" concerning remediation of issues at Northridge and on the 780G submission. *Id.* ¶ 172.

(a) No "Assurances" of Timely Approval

For several reasons, the Court finds that Plaintiffs have failed to state a securities fraud claim based on these alleged misstatements or omissions. First, looking at both the statements that precede the issuance of the Form 483 and that post-date it, the Court finds that Plaintiffs have 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."[27] Nowhere in the Complaint is there a statement by any Defendant guaranteeing, promising, or 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. It is not a plausible inference from the facts alleged that a reasonable investor would understand Defendants' statements concerning the FDA's potential to approve the company's next-generation insulin pump as a guarantee. *In re Delcath Sys., Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 333–34 (S.D.N.Y. 2014) (finding that reasonable investors would not have relied on

[27] The absence of any clear statement from the Plaintiffs regarding what would have constituted "timely approval" of the 780G illustrates how the Complaint is guilty of pleading the kind of fraud-by-hindsight theory that the law forbids. There is no promise of a specific timeline for approval of the 780G alleged anywhere in the Complaint. And Plaintiffs do not offer a date that they say would have actually constituted "timely approval" based on either when Medtronic began developing the device or when submitted its application for pre-market approval. Instead, Plaintiffs point to the December 2021 warning letter that caused Medtronic to adjust its projected revenues for the upcoming fiscal year, removing anticipated U.S. sales of the device. Seemingly from that fact, Plaintiffs assert that approval was delayed, without ever alleging what would have been "timely."

forward-looking statements concerning FDA approval where defendants provided warnings about possible rejections and "did not express certainty of approval").

In fact, the record illustrates that on several occasions during the Class Period, the Defendants made clear that a specific timeline could not be predicted. For example, Plaintiffs point to Defendant Parkhill's November 19, 2019, statements about the 780G pipeline being "on track," and they emphasize that this was just two days before Medtronic issued the Field Safety Notification regarding certain 600 Series pumps. Compl. ¶ 135. But during that same discussion, Defendant Ishrak made clear that "the exact timing is up to the FDA." MacDonald Decl., Ex. 28 at 2. Similarly, Plaintiffs allege that in May 2021, Defendant Salmon told analysts, "I don't have an update on the timing. . ." and "there's no update on timing at this point" in response to pointed questions on the topic. Compl. ¶ 211. Plaintiffs selectively quote Defendant Martha's June 8, 2021, statement that Medtronic was "making steps as we launch our 780G" (*id.* ¶ 113), and "actively reviewing our files now," (*id.* ¶ 214), but in context he acknowledged that it was "hard to predict the FDA right now, especially around diabetes," (MacDonald Decl., Ex. 18 at 3). 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.

(b) Forward Looking Statements & Risk Warnings

In addition, the Court finds that many of the statements concerning FDA approval of the 780G are forward-looking statements that were accompanied by warnings about the risks and uncertainties inherent in seeking regulatory approval for new medical devices. As such, these statements fall within the PSLRA's "safe harbor" for statements that (1) are

identified as forward-looking and "accompanied by meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the forward-looking statement," or (2) that are "immaterial." 15 U.S.C. § 78u-5(c)(1)(A). These include statements projecting revenues or income, statements about plans for future operations or future products, and statements regarding future economic performance. *Id.* § 78u-5(i)(1)(A)–(D). To be protected by the safe-harbor provisions, a statement must be accompanied by "meaningful cautionary language" that is "extensive, specific, and directly related to the alleged misrepresentation." *Julianello v. K-V Pharm. Co.*, 791 F.3d 915, 921 (8th Cir. 2015) (quotations omitted).

Defendants' forward-looking statements that fall within the PSLRA's safe harbor include both statements about the prospects for FDA approval of the 780G and the prospects for future revenues that Defendants made in Medtronic's Form 10-K, Form 10-Q, and Form 8-K SEC filings.[28] The Court finds *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510 (S.D.N.Y. 2015) instructive. There, the defendant acquired a pharmaceutical company, Genzyme, that was developing and testing a new drug to treat multiple sclerosis, and the defendant issued contingent value rights ("CVRs") to Genzyme's shareholders. *Id.* at 517. The CVRs could be traded on the open market and gave the holder the right to cash

[28] Forward-looking statements concerning future revenues contained in SEC filings that were accompanied by risk warnings are found in the following paragraphs from the pleading: Compl. ¶¶ 122, 131, 147, 148, 150, 155, and 159. Other forward-looking statements regarding the prospects of FDA approval of the 780G are found at Compl. ¶¶ 41, 79, 114, 118, 128, 131, 135, 142, 149, 154, 156, 157, 158, 165, and 169. The Complaint also notes that in an August 25, 2020, earnings call, Martha explained that the company had "received CE Mark approval for our MiniMed 780G advanced hybrid closed-loop system, and we'll launch this fall." Compl. ¶ 153. "CE Mark" approval refers to approval for marketing a device in Europe, and Plaintiffs do not allege that this statement was literally false.

payments upon the occurrence of certain events. One such event was if the defendant obtained FDA approval of the new drug by a specific cutoff date. *Id.* During the clinical-trial phase of seeking approval of the drug, the defendant designed a single-blind study as opposed to the FDA's preferred double-blind design. *Id.* at 518–19. The FDA expressed concerns with the design of the clinical trial, explained that the use of the single-blind design could affect the chances of approval, and suggested the results would have to show an "extremely large effect" for the FDA to accept the study as designed. *Id.* at 519–20.

The defendant in *Sanofi* made several statements concerning the prospect of FDA approval by the CVR cutoff date that the plaintiffs alleged were misleading because the defendant failed to disclose that the FDA had expressed concerns with the design of clinical trials. *Id.* at 531. The defendant's statements indicated that the company expected and anticipated the FDA to approve the drug prior to the cutoff date. *Id.* Some statements predicted the likelihood of FDA approval with certain percentages attached to the statements. *Id.* The court found that even with a suggestion of a particular approval deadline and the use of percentages to quantify their predictions, the statements failed to form the basis of a securities fraud claim for a variety of reasons, including application of the PSLRA's safe harbor for forward-looking statements. *Id.* at 535–36. The court found that the statements "about FDA approval are classically forward-looking—they address what defendants expected to occur in the future." *Id.* at 535. In particular, the *Sanofi* court found that the defendant's risk warnings sufficiently brought its forward-looking statements within the PSLRA's safe harbor. Those risk warnings stated that a "regulatory authority may deny or delay approval because it was not satisfied with the structure or

conduct of clinical trials or due to its assessment of the data we supply." *Id.* at 536 (quoting the relevant Form 10-K filing).

This case is similar, though the statements here are much less specific than those in *Sanofi*. In several SEC filings, among many other risk warnings accompanying forward-looking statements, Medtronic provided warnings to the effect that:

> [W]e have ongoing responsibilities under the U.S. FDA and other applicable non-U.S. government agency regulations. For instances, many of our facilities and procedures and those of our suppliers are also subject to periodic inspection 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.
>
> . . . .
>
> We cannot guarantee that we will be able to obtain or maintain marketing clearance for our new products or enhancements or modifications to existing products, and the failure to maintain approvals or obtain approval or clearance could have a material adverse effect on our business, results of operations, financial condition and cash flows.

Compl. ¶ 176(b), (e).[29] As in *Sanofi*, this language "explicitly identifies the salient risk, namely, that a regulatory authority such as the FDA could deny or delay approval. . . ." *Sanofi*, 87 F. Supp. 3d at 536.

Certainly, the safe harbor for forward-looking statements does not preclude liability for companies that use cautionary language about *potential* future risks when they have actual knowledge of facts that meant those risks had already materialized. *See In re Nash Finch Co.*, 502 F. Supp. 2d 861, 873 (D. Minn. 2007) ("[I]f Defendants knew that the specific risks and uncertainties stated to be 'potential' in their cautionary language had already been realized, and that their forward-looking statement were false or misleading, then their forward-looking statements are not protected by the safe harbor."). Here, however, the Court finds this exception to the safe-harbor rule inapplicable.[30] Plaintiffs have not plausibly alleged that at the times Defendants made the forward-looking

[29] Defendants also provided warnings regarding their forward-looking statements on investor calls where they made remarks about the prospects of FDA approval of the 780G. *Julianello*, 791 F.3d at 921–22 (finding that cautionary language incorporated by reference in an investor call was sufficient to bring forward-looking statements within the safe-harbor).

[30] In support of their argument on this point, Plaintiffs also rely on *KV-Pharm.*, 679 F.3d at 983, *In re Resideo*, 2021 WL 1195740, at *5, and *In re Mylan N.V. Sec. Litig.*, No. 16-cv-7926 (JPO), 2018 WL 1595985, at *10 (S.D.N.Y. Mar. 28, 2018). However, in *K-V Pharm.*, the court did not explicitly address the safe-harbor provision, and the defendants made specific representations that they were in material compliance with FDA regulatory requirements. 679 F.3d at 983 & n.8. There is no comparable allegation here. The *In re Resideo* court explains that the defendants could not rely on the safe harbor of cautionary language that warned of potential problems from supply chain issues, unavailable production facilities, and shortage of engineers when the defendants already knew that each of those problems already existed. 2021 WL 1195740, at *5. The *In re Mylan* court observed that "to caution that it is only possible for the unfavorable events to happen when they have already occurred is deceit." 2018 WL 1595985, at *10. But here, at the time Defendants made their forward-looking statements accompanied by cautionary language, there is no plausible allegation that the FDA had made a determination that the 780G would not be approved, nor that such approval would necessarily be pushed back to any specific (longer) timeline.

statements, they *knew* that the potential risk of FDA delay or regulatory denial about which they cautioned had already been realized. Contrast this with *In re CenturyLink Sales Practices and Securities Litig.*, 403 F. Supp. 3d 712 (D. Minn. 2019), where the court found that the plaintiffs adequately "allege[d] falsity when it assert[ed] that Defendants issued misleading statements about regulatory risks when they represented as merely possible risks that had already materialized (such as inquiries and enforcement actions instituted by regulatory bodies) and concealed the fact that CenturyLink's illegal sales practices were unsustainable when they should have disclosed" that these details would impact revenues. *Id.* at 726.

Again, *Sanofi* is instructive. In that case, the defendant's warnings accompanying its forward-looking statements identified that it was a possibility that a regulatory body would deny or delay approval based on the way a clinical trial was designed, and the defendant had already received notice from the FDA that approval of its new drug was in jeopardy based on the design of its clinical trial. *Id.* at 535–36. But this did not prevent the PSLRA's safe harbor from shielding the forward-looking statements because the warnings addressed the specific risk. *Id.* Here, at its core, the Plaintiffs' theory is indistinguishable. And although, in *Sanofi*, the FDA had informed the defendant that its drug *might* gain approval with the use of the less preferred study only if there were extremely favorable results, *id.* at 519–20, the FDA had not told the defendant that the possibility of achieving approval was definitely lost. Here, too, the Complaint does not allege that the FDA explicitly informed Medtronic or any of the individual Defendants—whether through the

inspection, the Form 483, the correspondence that followed the Form 483, or otherwise—that the MiniMed 780G was not going to be approved or was going to be delayed.

(c) Post-Form 483 Statements

The closest question in this case is presented by the Defendants' failure to disclose the fact of the Form 483 when they made statements about the prospect for FDA approval after the Northridge inspection was completed.[31] The Plaintiffs' theory that Defendants had a duty to disclose information they omitted from their public statements is perhaps strongest here because (1) Defendants were aware that the FDA had inspected the Diabetes Group's headquarters and observed severe and pervasive compliance issues; (2) the FDA had informed Defendants of those observations in the Form 483, and Defendants began an ongoing effort to remediate the potential violations the agency noticed; and (3) Defendants told investors that they were engaged in an ongoing dialogue with the FDA about the approval of the 780G and that the application process remained on track. Therefore, the theory goes, Defendants arguably created a duty to disclose by making representations about the company's interactions with the FDA when a fuller picture of what those interactions involved and how they arose may have been necessary to give a prudent investor an accurate indication of what was really going on. Section 10(b) and Rule 10b-5

[31] Plaintiffs appear to suggest that Defendants' statements regarding the prospect for timely FDA approval of the 780G were misleading because they failed to disclose that there had been an inspection of the Northridge facility, independent of the results of that inspection. To the extent that is part of the Plaintiffs' theory, the Court is not persuaded that any duty to disclose arose from the mere fact that the FDA chose to conduct an inspection. Here, the Complaint alleges nothing about the fact of the inspection that would, independent of its results, possibly give rise to a duty to disclose its existence.

do not themselves create a duty to disclose, but that duty can arise when a defendant chooses to affirmatively speak. *See K-V Pharm.*, 679 F.3d at 983 n.8 ("Having chosen to represent it was in material compliance with FDA regulations and cGMP, KV was obligated to make a full disclosure of any material facts.").

However, the Court ultimately determines that these allegations do not suffice to state a securities fraud claim for two reasons: (1) the facts do not give rise to a duty to speak under these circumstances; and (2) even if such a duty does exist, the allegations in the Complaint do not give rise to a strong inference of scienter.[32] The Eighth Circuit has held that the "issuance of Form 483s may render a defendant's statement about its compliance with FDA regulations or [current good manufacturing practices] false, or at least misleading, in some circumstances." *Id.* at 982–83. In *K-V Pharm.*, the court found a duty to disclose the existence of a Form 483 outlining "numerous, severe, and pervasive objectionable conditions," *id.* at 983, that "covered the entire range of [the defendant's] operations and products," *id.* at 983 n.9, and the defendant "affirmatively represented it was compliant with FDA regulations," *id.* at 983 n.8. Here, while Plaintiffs assert that the Form 483 identified severe and pervasive objectionable conditions—presumably to bring this case within the ambit of *K-V Pharm*—the Complaint does not allege facts showing that Defendants made a comparable affirmative representation regarding compliance with FDA regulations, so the duty to disclose did not arise. Moreover, there are no facts alleged indicating that the Form 483 stated that FDA approval of the 780G, or the timeline for the

[32] The Court addresses the issue of scienter in detail below.

same, had been compromised by the inspection or the issuance of the form. *See In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 41–42 (1st Cir. 2014) (finding that defendants had no duty to disclose a Form 483 that did not inform them approval of a drug had been compromised).

5. Item 303 of Regulation S-K

The parties dispute whether Plaintiffs have adequately pled a violation of Item 303 Regulation S-K. Plaintiffs suggest that Item 303 makes certain omissions by the Defendants actionable even if they do not support liability under a traditional Section 10(b) omissions analysis. Defendants counter that the omissions at issue fail for the same reason as the rest of the omissions discussed in the Complaint.

For several reasons, the Court finds that the allegations concerning alleged violations of Item 303 do not state an actionable securities fraud claim in this case. First, the Item 303 allegations essentially repackage the omissions that the Court has otherwise found insufficient to state a claim. The Complaint suggests that the violations of Item 303 form the basis of liability for omission claims under Rule 10b-5 and Section 10(b). Compl. ¶ 97. The alleged violations of Item 303 overlap entirely with the other information that Defendants allegedly should have disclosed—problems with the retainer rings, significant numbers of complaints, ongoing quality problems with insulin pumps, the inspection of the Northridge facility, and the FDA's issuance of the Form 483. *Id.* ¶¶ 87–116. Having already addressed the viability of the Defendants' alleged omissions on these issues, and because the Court finds that the Plaintiffs' claims fail to support a strong inference of scienter, the Court finds that Plaintiffs' attempt to breathe life into these claims through

allegations that the omissions violated Item 303 is insufficient. *See In re DraftKings Inc. Sec. Litig.*, 650 F. Supp. 3d 120, 180 (S.D.N.Y. 2023) (determining that a complaint the court found insufficiently alleged misrepresentations and omissions was equally flawed where the same allegations were largely repackaged as violations of Item 303).

Second, Plaintiffs certainly appear to imply that Medtronic's alleged violations of Item 303 can form the basis of liability under Section 10(b) and Rule 10b-5 even if the omissions would not otherwise be actionable under a traditional omissions inquiry. However, Plaintiffs cite no cases that support the proposition that Item 303 creates a broader independent duty to disclose than otherwise exists in the securities fraud context. Nor do Plaintiffs explain why, in the circumstances of this case, it would be appropriate to hold Defendants liable for securities fraud due to alleged violations of Item 303 if the same omissions from their other public statements are not otherwise actionable under Section 10(b) and Rule 10b-5. Plaintiffs simply accuse the Defendants of engaging in circular reasoning and state that "[v]iolations of Item 303 simply give rise to an additional basis for omission liability." Pls.' Opp'n at 43. But the one case they cite was not forced to grapple with the difficult questions presented by finding an independent basis for disclosure liability under Item 303 because it also found that the complaint pled actionable misstatements under a traditional omissions analysis. *See Tactile*, 595 F. Supp. 3d at 814.

Finally, the Court notes that the Eighth Circuit has not held that a violation of Item 303 on its own can form the basis of a duty to disclose underlying a Section 10(b) and Rule 10b-5 claim. Of the courts that have weighed in on the issue, the majority have held that Item 303 does not create a private right of action or an independent, broader duty to

disclose than that already found in Section 10(b). *Oran v. Stafford*, 226 F.3d 275, 285–86 (3rd Cir. 2000) ("Neither the language of [Item 303] nor the SEC's interpretive releases construing it suggest that it was intended to establish a private right of actions. . . ."); *id.* at 288 (reasoning that violations of Item 303 could form the basis of a private securities suit if a duty to disclose was otherwise demonstrated); *In re NVIDIA Corp. Sec. Litig.*, 768 F.3d 1046, 1054 (9th Cir. 2014) (holding that Item 303 does not create an independent duty to disclose); *In re Sofamor Danek Grp.*, 123 F.3d 394, 403 (6th Cir. 1997); *Carvelli v. Ocwen Fin. Corp.*, 934 F.3d 1307, 1330–31 (11th Cir. 2019); *but see Stratte-McClure v. Morgan Stanley*, 776 F.3d 94, 101 (2d Cir. 2015) (holding that a failure to disclose under Item 303 can amount to an actionable omission for a Section 10(b) claim). Further underscoring the unsettled nature of this area of the law, the Supreme Court has granted review in *Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, 144 S. Ct. 479 (2023), to resolve the circuit split between the Second Circuit, on the one hand, and the Third, Ninth, and Eleventh Circuits, on the other, about whether "a failure to make a disclosure required under Item 303 can support a private claim under Section 10(b), even in the absence of an otherwise-misleading statement." Brief for Petitioner, *Macquarie Infrastructure Corp. v. Moab Partners, L.P.*, No. 22-1165, 2023 WL 3778765, at *i. Here, because no binding authority supports the Plaintiffs' reliance on Item 303 as an independent basis for Section 10(b) liability, and in light of the other flaws identified with the Plaintiffs' reliance on that

regulation, the Court finds that the alleged violations of Item 303 in this case do not support a misrepresentation claim under Section 10(b) and Rule 10b-5.[33]

III. Scienter

The PSLRA requires plaintiffs to "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2)(A). This requires a showing of the "defendant's intention to deceive, manipulate or defraud," or that the defendant acted with "severe recklessness." *In re Ceridian Corp. Sec. Litig.*, 542 F. 3d 240, 244 (8th Cir. 2008) (quotation omitted). The Court has found that the Complaint fails to adequately state a Section 10(b) or Rule 10b-5 claim due to the absence of allegations showing actionable, material misrepresentations and omissions. But even if some of these statements could be considered actionable, the Court finds that the absence of adequate allegations supporting a strong inference of scienter provides an independent basis for dismissal of the Plaintiffs' claims. Failure to show scienter also means that Plaintiffs are unable to establish an essential element of their scheme-liability claims. The Court begins with a discussion of the Complaint's allegations, specifically addressing the issue of scienter.

[33] Even under the Second Circuit's *Stratte-McClure* decision, where the failure to make a disclosure required by Item 303 can form the basis of a Section 10(b) claim, the other elements of such a claim must be sufficiently alleged. *Moab Partners, L.P. v. Macquarie Infrastructure Corp.*, No. 21-2524, 2022 WL 17815767, at *2 (2d Cir. Dec. 20, 2022) ("The failure to make a disclosure required by Item 303 can serve as the basis . . . for a claim under Section 10(b) if the other elements have been sufficiently pleaded.").

A. Scienter Allegations

Overall, Plaintiffs argue that an array of allegations demonstrate the Defendants' knowledge of problems plaguing the insulin pump business throughout the Class Period, which show they acted with scienter when they omitted information from the statements regarding the prospects for FDA approval of the 780G. For example, Plaintiffs allege that Defendants did not suddenly become aware of flaws in the quality of its medical device systems when the December 15, 2021 Warning letter was publicly released. Compl. ¶ 193. Instead, Martha admitted that the company had been working on improving the "quality system" of the Diabetes Group "for the past couple years" during a January 2022 conference call hosted by JP Morgan. *Id.*

Plaintiffs also focus on the FDA's issuance of the Form 483 as establishing the individual Defendants' knowledge. The FDA's Form 483 Manual explains that its purpose is to inform "top management" of significant objectionable conditions observed during the inspection. Compl. ¶¶ 195–96. On June 7, 2021, after the inspection of the Northridge facility was completed, Plaintiffs allege the FDA gave the Form 483 to Medtronic's Vice President of Quality. The FDA included the following observations in the Form 483:

- Medtronic's assessment of the risks associated with failed retainer rings in the MiniMed 600 Series pumps used an underestimated calculation for probability of occurrence "even after a significant increase in complaints";
- Medtronic's "probability of occurrence" calculations were "underreported" because it based its calculations on the total products shipped rather than the number of products actually in the field;
- Medtronic had received significant complaints regarding the clear retainer ring by November 2019, including information concerning three deaths and other serious injuries, all prior to its safety notification;

- Medtronic instructed technical support personnel to tell customers that its November 21, 2019 Field Safety Notification was not a recall;
- Medtronic continued receiving reports of failures with the redesigned black retainer rings, including of serious injuries, but failed to initiate a formal investigation;
- Medtronic failed to submit Medical Device Reports for customer complaints related to the 600 Series pump retainer ring failures when the product analysis on a returned device confirmed that the reservoir could not lock into place; and
- Medtronic failed to submit MDRs in a timely fashion when it became aware of information indicating that its MiniMed infusion pumps may have caused or contributed to a death or serious injury.

Id. ¶ 197.

After the FDA issued the Form 483, it held a "closing meeting" led by the agency's investigator. *Id.* ¶ 198. Three weeks after that meeting, on July 28, 2021, Salmon and another executive (not a named Defendant) responded in a letter to two of the "Management Discussion topics" that were discussed at that closing meeting. *Id.* ¶ 199. Salmon also sent correspondence to the FDA concerning the company's response to the Form 483 on September 3, 2021, October 8, 2021, November 5, 2021, and December 3, 2021. *Id.* ¶¶ 200–06. During that time, Salmon participated in earnings calls in which he told investors that the FDA's review of the MiniMed 780G remained "on track" and that Medtronic was making "excellent progress." *Id.* The letters to the FDA copied Medtronic's Senior Vice President ("SVP") and Chief Quality Officer, and its SVP and Chief Clinical and Regulatory Officer. *Id.* ¶¶ 199–206.

While Salmon was personally involved in communications with the FDA, he also participated in a monthly meeting with other members of Medtronic's Executive

Committee. *Id.* ¶ 208. This Executive Committee included Defendants Martha, Parkhill, and Lerman, and at their meetings, they would discuss strategic issues affecting the company. *Id.* Plaintiffs allege that this demonstrates the knowledge of other members of the Executive Committee of the problems of which Salmon was aware. *Id.*

Plaintiffs also assert that scienter is established through Defendants' regular communications with the FDA throughout the Class Period. They allege that because the 600 Series was being scrutinized for a recall, such scrutiny necessarily jeopardized any timely FDA approval of the 780G. *Id.* ¶ 209. Defendants Ishrak and Salmon made statements to investors touting the company's interactions and frequent meetings with the FDA. *Id.* ¶¶ 210–11, 213–15.

In addition, Plaintiffs allege that Ishrak and Martha (in their successive roles as CEO), Parkhill (as CFO), and Lerman (as General Counsel) became aware of product quality failures and FDA inspections. *Id.* ¶¶ 217–218. Defendants were also allegedly "hands-on executives" when it came to the performance of the Diabetes Group because the company's insulin pump business had been under-performing leading up to and during the Class Period. *Id.* ¶ 219. In response to questions about the Diabetes Group's place within the company, Martha discussed making the business a priority and firsthand efforts he and Salmon were making to reinvigorate its performance. *Id.* ¶¶ 220–25. CW-2 "reported that the management team at Medtronic was very hands-on, with 'all developments in the Diabetes units [being] reported up the chain of command to the CEO.'" *Id.* ¶ 226 (brackets in Consolidated Compl.). CW-2 also stated that Salmon and Parkhill were in monthly meetings where issues with the progress of the 780G were reported. [*Id.*] According to

CW-2, Martha, Parkhill, and Salmon all "closely monitored the progress of the MiniMed 780G's FDA approval" due to its importance to the Diabetes Group's business. *Id.*

Plaintiffs also allege that the departures of Hakami, Ishrak, and Lerman during the Class Period support an inference of scienter. Ishrak stepping down as CEO was announced on August 28, 2019, which coincided with Medtronic's release of redesigned retainer rings, and was shortly before the company issued the November 2019 Field Safety Notification. Compl. ¶ 227. Hakami stepped down as President of the Diabetes Group as problems for the MiniMed 600 Series were increasing, and just prior to the November 2019 Field Safety Notification. *Id.* ¶ 228. And on June 24, 2021, during the FDA's inspection of the Northridge facility that precipitated the Form 483, Lerman notified Medtronic's Board that he was retiring. *Id.* ¶ 229.

Further, Plaintiffs allege that the individual Defendants were motivated to mislead the market so they could buy time until the MiniMed 780G was approved by the FDA. In June 2019, Hakami acknowledged that the 670G was going to be three years old in September in the United States, and as a result, the company was "off cycle from an innovation standpoint in the U.S." *Id.* ¶ 230. While Defendants made repeated statements about competition in the marketplace for its diminishing market share, Ishrak discussed Medtronic's focus on innovation, and Martha discussed the need to reinvigorate the diabetes business in the face of recent declines. *Id.* ¶ 231. In earnings calls and at conferences, Ishrak, Parkhill, Martha, and Salmon all repeatedly pointed to the MiniMed 780G as a future driver of growth for the Diabetes Group's business throughout the Class Period. *Id.* ¶¶ 232–35.

In addition, Plaintiffs allege that the December 2021 warning letter had a significant impact on Medtronic's overall fiscal year 2023 revenue. *Id.* ¶ 236. By May 26, 2022, Defendants told investors that the Diabetes Group's revenue for fiscal year 2023 was expected to decline 6% to 7%, with each percentage point equal to approximately $325 million in revenue. *Id.* ¶ 237. That same day, on an earnings call, Salmon acknowledged that patients who had been waiting on the 780G would now move on to competitive products. *Id.* ¶ 238. At a conference in November 2022, Martha stated that the Warning letter had backed up "a lot of technology" and that progress in obtaining regulatory approvals was better in foreign markets. *Id.*

Finally, Plaintiffs allege that Martha, Salmon, Hakami, and Lerman were motivated to engage in deception to capitalize on an artificially high stock price by selling off over 360,000 shares of personally held company stock during the Class Period in suspiciously timed transactions. *Id.* ¶¶ 241–42. Martha sold 11,000 shares in June 2019, "when Medtronic had received more than 74,000 customer complaints, which led to Medtronic redesigning and reissuing its MiniMed 600 Series pump." *Id.* ¶ 243. He sold more shares in April 2021, right after Medtronic revised its risk assessment protocol in a manner that would continue to underrepresent the probability of harm and allow the company to avoid a full recall of the 600 Series pumps. *Id.* Martha sold another 11,500 shares on June 28, 2021, while the FDA was in the middle of its inspection of the Northridge facility, and he sold more shares on August 25, 2021, one day after he made representations about the pending approval of the 780G. *Id.* ¶ 244. Salmon, Hakami, and Lerman are similarly alleged to have sold off shares in close proximity to events that they could only have known

about as insiders of the company and that were omitted from public statements about the company's diabetes business. *Id.* ¶¶ 245–250.

B. Analysis

Mere suggestions of intentional conduct are not enough to plead claims under Section 10(b) and Rule 10b-5. *In re Target Corp. Sec. Litig.*, 955 F.3d 738, 743 (8th Cir. 2020) ("We disregard blanket or catch-all assertions of scienter.") (quotations omitted). Instead, the PSLRA requires a private securities plaintiff to "state with particularity facts giving rise to a strong inference that the defendant acted with [scienter]." 15 U.S.C. § 78u-4(b)(2)(A). To do so, a plaintiff must show "reckless or intentional wrongdoing." *Podraza v. Whiting*, 790 F.3d 828, 836 (8th Cir. 2015) (quotations omitted).

Scienter "can be established in three ways: (1) from facts demonstrating a mental state embracing an intent to deceive, manipulate or defraud; (2) from conduct which rises to the level of severe recklessness; or (3) from allegations of motive and opportunity." *Id.* (quotations omitted). In deciding whether a complaint adequately alleges facts giving rise to a strong inference of scienter, courts (1) accept facts that are alleged in the complaint as true; (2) review the complaint as a whole, along with "'documents incorporated into the complaint by reference,'" and matters of which they "'may take judicial notice'"; and (3) consider "'plausible opposing inferences.'" *Id.* (quoting *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322–23 (2007)). "This means we compare 'plausible, nonculpable explanations for the defendant's conduct' with 'inferences favoring the plaintiff.'" *Id.* (quoting *Tellabs*, 551 U.S. at 324).

The complaint provides a strong inference of scienter "'only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.'" *Id.* (quoting *Tellabs*, 551 U.S. at 324). In assessing whether the allegations support a strong inference of scienter, courts must consider "whether all of the facts alleged, taken collectively, give rise" to such an inference, "not whether any individual allegation, scrutinized in isolation, meets that standard." *Tellabs*, 551 U.S. at 323. For several reasons, the Court finds that Plaintiffs fail to sufficiently allege facts supporting a strong inference of scienter.

Having considered the allegations as a whole, the Court finds that Plaintiffs have failed to allege that any Defendant acted with scienter. Certainly, Plaintiffs have alleged facts sufficient to support an inference that one or even all of the individual Defendants were aware of the retainer-ring complaints with the 600 Series pumps, the controlled studies, the FDA recall, the Northridge inspection, the Form 483, and the company's subsequent efforts to remediate the Form 483 issues identified by the FDA. But awareness of a problem on its own is not enough to demonstrate that a defendant acted with the requisite mental state—Plaintiffs must show that Defendants made "highly unreasonable omissions . . . that . . . present a danger of misleading buyers or sellers which is either known to the defendant, or is so obvious that the defendant must have been aware of it." *In re Ceridian Corp. Sec. Litig.*, 542 F.3d 240, 244 (8th Cir. 2008) (quotation omitted); *Sanofi*, 87 F. Supp. 3d at 534 (finding that the focus on the defendants' knowledge of problems with the design of clinical trials and nondisclosure of those problems was insufficient on its own to support a strong inference of scienter).

Here, the allegations do not show that the information available to Defendants in May 2019, at the outset of the Class Period, ensured that the FDA would issue a recall in February of 2020. Nor do the facts alleged indicate that Defendants knew, or necessarily should have known, that the FDA would eventually decide, more than fifteen months after the recall, to initiate an inspection of the Northridge facility. There are no facts suggesting that Defendants knew or should have known that such an inspection was inevitably going to lead to the issuance of a Form 483, nor that the company's efforts to remediate those issues would be unsuccessful in holding off a warning letter that would ultimately delay approval of the MiniMed 780G. In short, Plaintiffs' theory only brings the issue of scienter into focus when viewed through the lens of hindsight.

To support their argument that Defendants knew "the quality problems imperiled timely FDA approval of the 780G," Plaintiffs point to allegations in the Complaint regarding the FDA Investigations Operations Manual and the observations in the Form 483 following the summer 2021 Northridge facility inspection. Pls.' Opp'n at 46 (citing Compl. ¶¶ 195–98). To be sure, these allegations suggest that the significant observations that are made part of a Form 483 should be discussed with a firm's management, that the Form 483 issued for the Northridge inspection noted possible violations of the FDCA, and that the FDA held a closing meeting with Medtronic on July 7, 2021. However, nowhere does the Complaint allege that the Form 483 mentioned the MiniMed 780G at all, and there is certainly no statement attributed to the FDA indicating that timely approval of the 780G was jeopardized by the FDA's observations.

The First Circuit's decision in *Genzyme*—where the plaintiffs' theory rested on failure to disclose details that allegedly made public statements about the likelihood of FDA approval for a drug misleading—is instructive here. 754 F.3d at 42–43. The *Genzyme* court found that the plaintiffs failed to allege facts giving rise to a strong inference of scienter based on a failure to disclose issues raised by the FDA in a Form 483. *Id.* at 42. The court acknowledged that the inference of scienter was "possible." *Id.* However, because the Form 483 was "observational," an FDA advisory committee had endorsed clinical effectiveness, and "other significant factors" suggested approval might be forthcoming, the court found that it was "more likely the defendants made no mention of the . . . Form 483 because . . . they believed [the company] continued to be on the path toward . . . approval." *Id.* In addition, the court noted that the Form 483 "made no mention of the . . . approval process" for the drug at issue. *Id.* Further, the court found that the fact the defendant made a prompt disclosure of a subsequent warning letter "undercut any inference of fraudulent intent on the part of defendants." *Id.* at 42–43. The facts of this case, discussed at length above, align with *Genzyme*'s and this Court finds the *Genzyme* court's reasoning persuasive.

Just as in *Genzyme*, here the Court finds it is more likely that Defendants believed that the MiniMed 780G still had a meaningful chance of gaining timely FDA approval. The facts alleged in the Complaint do not demonstrate that the inspection of the Diabetes Group's headquarters in Northridge was directed specifically to processes affecting the 780G, and the Form 483 did not specifically mention that approval of the 780G could be jeopardized. It is especially noteworthy that, even after the FDA had issued a recall for the

600 Series pumps in February 2020, it had approved Medtronic's application for marketing of the MiniMed 770G in the United States in August 2020.[34] Medtronic's application for pre-market approval of the 780G was based, after all, off the 770G, not a 600 Series pump.[35] Moreover, Plaintiffs do not contend that the Defendants' statements—made after the issuance of the Form 483—that the MiniMed 780G was experiencing strong sales in international markets were false. That reality, coupled with the absence of any specific statement from the FDA that timely approval of the 780G was in jeopardy, gave Medtronic a reasonable basis on which to believe that approval of its advanced hybrid closed-loop system could be forthcoming. The facts alleged in the Complaint do not support an equally compelling inference of scienter. *In re Ceridian Corp. Sec. Litig.*, 542 F.3d 240, 244 (8th Cir. 2008) ("Strong means strong. Under the PSLRA, it is not sufficient for the facts alleged to give rise to a weak or plausible or even reasonable inference of scienter.") (internal quotation marks omitted).

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[34] https://www.fda.gov/news-events/press-announcements/fda-approves-first-its-kind-automated-insulin-delivery-and-monitoring-system-use-young-pediatric.

[35] *See* MacDonald Decl., Ex. 16 at 2. Exhibit 16 is a transcript of Parkhill's remarks during a virtual healthcare conference specifically referenced in Plaintiffs' Complaint, Compl. ¶ 156, but Plaintiffs excerpted only a portion of the statement Parkhill made to investors and left out the part where she explained that the FDA had requested that Medtronic submit a pre-market approval supplement off the 770G, which had just been approved. Because the Complaint relied on a portion of Parkhill's testimony, the Court takes notice of the remainder. *See In re PEC Solutions, Inc. Sec. Litig.*, 418 F.3d 379, 388 n.7 (4th Cir. 2005) ("Because the CAC relied on Mead's public testimony it is proper to consider the full text of the testimony."); *see also Patel v. Parnes*, 253 F.R.D. 531, 547 (C.D. Cal. 2008) (discussing propriety of reviewing complete transcripts of conference calls excerpted less completely in the pleading); *Malin v. XL Capital Ltd.*, 499 F. Supp. 2d 117, 131 (D. Conn. 2007), *aff'd*, 312 F. App'x 400 (2d Cir. 2009) ("[W]hen a complaint quotes documents only in part and omits critical portions of the documents, it is permissible for the court ruling on a motion to dismiss to consider the full texts of the quoted documents.").

Another useful comparison is found in *Schaeffer v. Nabriva Therapeutics plc*, 19 Civ. 4183 (VM), 2020 WL 7701463 (S.D.N.Y. Apr. 28, 2020). There the FDA issued a Form 483 for significant issues discovered at a facility for the manufacturing of a drug that was the subject of a pending new drug application, and the defendant made several statements during the class period about the prospects of timely FDA approval, but failed to mention the Form 483. *Id.* at *1–3. The *Schaeffer* court found that the plaintiffs failed to adequately allege that the defendants knew their statements about the prospects of FDA approval were false or misleading because the complaint did not provide a basis to say that "the risk of delayed FDA approval had effectively materialized" at the time defendants spoke. *Id.* at *10. The mere fact that the complaint alleged that the observations of possible violations were significant and concerning was insufficient to indicate that defendants had the required knowledge. *Id.* The court explained "Plaintiff needs to plead something that suggests why [the observed] violations could not be remedied within [the relevant] timeframe, rather than conclusorily stating it was so."[36] *Id.* And in discussing scienter, the *Schaeffer* court found that the allegations that the defendants knew about the Form 483 and that the observed violations were so serious that the drug could not be approved in a timely manner were not sufficient to support an inference that the defendants "recklessly disregarded the potentially misleading nature of some statements" that was "cogent or at

[36] The *Schaefer* court found that a statement in the defendant's Form 10-K indicating that the company's failure to comply with regulatory requirements could result in "warning or untitled letters" was potentially misleading to a reasonable investor because the circumstances could indicate that the Form 483 was "more akin to a warning than a routine inspectional observation." *Id.* at *11. However, the court found the complaint did not allege a strong inference of scienter. *Id.* at *12–13.

least as compelling as an inference that they made the statements either negligently or reasonably believing in their accuracy." *Id.* at *12.

Here, for reasons explained at length above, the same is true. The facts alleged by Plaintiffs do not tether the quality issues with the 600 Series to the application for approval of the 780G, and the FDA was not alleged to have ever stated that the 780G would not be approved or that the approval would be delayed because of the issues identified in the Form 483.

The cases cited by Plaintiffs do not persuade the Court otherwise because they involve situations in which defendants made public statements directly contradictory to the information known to them. For example, in *Schueneman v. Arena Pharmaceuticals, Inc.*, the Ninth Circuit reversed a district court's dismissal of a complaint and found the plaintiffs adequately alleged scienter where the defendants publicly stated that they believed the company's weight-loss drug was non-carcinogenic and would be approved by the FDA based on the results of completed animal studies, but they knew at the time they made those statements that ongoing animal studies were showing a correlation with cancer. 840 F.3d 698, 701, 708 (9th Cir. 2016) ("[Defendant] knew that the animal studies were *the* sticking point with the FDA. Contrary to [defendant's] representations to investors, it was not true that the preclinical, animal studies demonstrated the long-term safety and efficacy of [the drug] or the potential risk that it may be toxic or cause cancer in humans.") (internal quotes omitted). Similarly, the Court finds *Yanek v. Staar Surgical Co.*, 388 F. Supp. 2d 1110 (C.D. Cal. 2005) is unhelpful to Plaintiffs here. In *Yanek*, the medical device company sought expedited FDA approval of an implantable contact lens (ICL). The FDA conducted

an inspection of its manufacturing facility in connection with the expedited review process, which ultimately led to the issuance of a Form 483, a warning letter, and a decision to delay approval. *Id.* at 1118–20. With respect to the defendants' public statements made after receipt of the Form 483 that discussed interactions with the FDA staff, review of the ICL, and prospects for commercialization, the *Yanek* court found that the plaintiffs adequately alleged scienter. *Id.* at 1129–30. But the court reached that conclusion noting that the "Defendants understood that the Aug. 2003 inspection of the Monrovia facility was *in connection with the ICL application*." *Id.* at 1130 (quotations and brackets removed) (emphasis added). Here, such a clear connection between the issues with the 600 Series and the Form 483 are not tied to the 780G approval at the heart of Plaintiffs' case.

Plaintiffs also argue that Salmon (and perhaps other Defendants) acted with scienter because Salmon signed several letters on behalf of Medtronic in response to the Form 483 between the July 28, 2021, and November 5, 2021, and Salmon made several statements to investors during the same period indicating that the prospect for approval of the 780G remained on track. *See* Compl. ¶¶ 199–204. This alleged basis for drawing a strong inference of scienter based on Salmon's statements that the application remained under review and his predictions of timely FDA approval fails for the same reasons discussed above. The allegations in the Complaint simply do not support the purported "huge uncertainty that existed in gaining FDA approval of the MiniMed 780G due to the MiniMed [600 Series] quality problems[.]" Compl. ¶ 205. Given that the Complaint does not draw a clear line between the retainer ring issues, the recall, the inspection, the Form 483, Salmon's letters and the application for FDA approval of the 780G, the more likely

inference to be drawn from the facts here is that Salmon was, indeed, aware of the issues with the 600 Series pumps, but was working to try and overcome the FDA's concerns with respect to those issues and avoid the issuance of a warning letter. At the same time, it is more likely that he believed in the truthfulness of his statements to investors regarding the prospects for timely FDA approval of the 780G than that he was attempting to deceive investors by failing to disclose details of the company's response to the FDA's concerns.

C. Additional Factual Arguments

Plaintiffs further contend that they have adequately alleged scienter based on the confidential witness accounts; Defendants' high-level positions and hands-on management style; signed certifications by several Defendants under the Sarbanes Oxley Act; departures of several high-level executives from Medtronic at "suspicious" times; and the defendants' motives to commit fraud, evidenced by their insider sales of stock and desire to conceal the 600 Series' quality problems so they could buy time to win approval of the 780G. Pls.' Opp'n at 50–65. The Court has considered all of these allegations in the context of the Complaint as a whole, and finds they do not support a strong inference of scienter.

1. Confidential Witness Accounts

The Complaint includes the accounts of two confidential witnesses, and Plaintiffs argue that these accounts support an inference that Defendants acted with scienter. Courts sometimes treat allegations in a complaint based on the accounts of confidential witnesses with skepticism. *Minneapolis Firefighters' Relief Ass'n v. MEMC Elec. Materials, Inc.*, 641 F.3d 1023, 1030 (8th Cir. 2011) (disregarding allegations from confidential source and citing *Higginbotham v. Baxter Int'l, Inc.*, 495 F.3d 753, 757–58 (7th Cir. 2007); *see also*

Shoemaker v. Cardiovascular Sys., Inc., 300 F. Supp. 3d 1046, 1055 (D. Minn. 2018) ("Unlike other factual allegations in a complaint, courts are not required to wholly accept as true statements from a confidential witness."). In this context, courts "conduct an examination of the detail provided by the confidential sources, the sources' basis of knowledge, the reliability of the sources, the corroborative nature of other facts alleged, including from other sources, the coherence and plausibility of the allegations, and similar indicia." *In re NVE Corp. Sec. Litig.*, 551 F. Supp. 2d 871, 881 (D. Minn. 2007), *aff'd*, 527 F.3d 749 (8th Cir. 2008) (quotations omitted).

The Court finds that CW-1's account set forth in the Complaint adds little, if anything, to the scienter calculus. CW-1 is alleged to be a former manager of a territory responsible for selling the 630G, 670G, and 770G pumps; they were aware of product issues with some pumps and advancements by competitors; they stated that some physicians and patients moved to competitor products as a result; Hakami made large cuts to the Diabetes Group's operational budget, which CW-1 attributed to the Group's setbacks; and CW-1 understood that executive management tracked revenues on a daily basis using sales databases. Compl. ¶ 191. Broad allegations about what CW-1 "understood" about "executive management" do not support an inference of scienter, let alone a strong inference of scienter, as to any particular Defendant. CW-1 is not alleged to have interacted with any Defendant or to have overheard any admissions by any Defendant. And as the manager of a single sales territory, there are no allegations establishing how CW-1 was in a position to discuss or understand what any of the individual Defendants

knew or should have known about what customers and physicians were doing in any other territory.

Moreover, even if CW-1's allegations could be said to support an inference that the individual Defendants were aware of daily sales data for the Diabetes Group, that adds little to the overall picture of scienter. As discussed above, Plaintiffs do not allege that Defendants made affirmative misrepresentations about their sales numbers to investors. Rather, throughout the Class Period, Defendants truthfully stated that although sales of the 670G in international markets were doing well and helping the Group's revenues, competition was offsetting those gains. And even if Defendants knew that Medtronic's insulin pump sales had stagnated overall due to product quality issues and some customers leaving to use competitors' products, that does not support a compelling inference that they acted with intent to deceive or severe recklessness when they made positive statements about the prospects for approval of the 780G.

Similarly, although perhaps presenting a closer issue, the Court finds that CW-2's account does not move the scienter issue across the line. CW-2 was a Senior Director of U.S. Regulatory Affairs for Medtronic during the Class Period. CW-2 indicated that they were in monthly meetings that were also attended by 150 other people, including "executive management," which included Martha, Parkhill and Salmon. According to CW-2, remediation of the issues identified in the Form 483 would take one to two years. CW-2 informed "executive management" that "MiniMed 780G had no chance of obtaining timely approval, but CW-2 was informed that 'this information would not be disseminated to the public before the next analyst call, which was two weeks away.'" And in November 2021,

according to CW-2, "problems with FDA approval of the MiniMed 780G system became clear when a different FDA submission was stalled – CW-2 stated that 'the FDA gave us a hint that a warning letter was coming.'" CW-2 communicated with CW-2's boss and stated that "'all developments in the Diabetes units were reported up the chain of command to the CEO.'" "CW-2 stated that executive management knew before receiving the Warning Letter that the MiniMed 780G would not receive timely approval but stated that 'executive management continued to communicate misinformation to the public.'" Compl. ¶ 192.

Ultimately, the Court finds these allegations insufficient to support a strong inference of scienter as to any Defendant. CW-2's account regarding the length of time it would take to remediate problems identified in the Form 483, the opinion that it was impossible for the 780G to obtain "timely" approval, and the broad statement that executive management knew timely approval would not be possible, all reflect CW-2's personal assessments as opposed to factual allegations indicating that the Defendants acted with scienter in making any public statement. These allegations fail to show the mental state of any individual Defendant. *See Villare v. Abiomed, Inc.*, 19 Civ. 7319 (ER), 2021 WL 4311749, at *23 (S.D.N.Y. Sept. 21, 2021) (discounting account confidential witnesses that were found to "largely reflect the subjective assessments" of those witnesses . . . not the mental states of [defendants]"). In addition, CW-2's own assessments of the prospects for timely approval of the 780G by the FDA, even if they were specifically communicated to the individual Defendants during the monthly product meetings or after, do not establish that Defendants agreed with CW-2's view and did not, in fact, believe it when they publicly stated that prospects for approval of the 780G were good, that the application for approval

remained on track, and similar remarks. *Cf. City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 170–71 (3rd Cir. 2014) (noting that several confidential witnesses expressed reservations about the approach taken in various phases of clinical trials for a drug in development but finding that those disagreements did not "render defendants' decisions unreasonable or their statements false").

Critically, CW-2's account is too vague in key places that might otherwise draw connections that could add something meaningful to the scienter analysis. For example, although CW-2 says that they reported information about the dire prospects for approval of the 780G to their own boss and that *all developments* in the Diabetes units were reported up the chain of command to the CEO, this is insufficiently particular for purposes of demonstrating what either Martha, Parkhill, or Salmon received about CW-2's skeptical prognostication. If that were sufficient, any confidential witness could adequately provide an account supporting a strong inference of scienter with little more than conclusory allegations of an executive's knowledge. *See, e.g.*, *Sakkal v. Anaplan, Inc.*, 557 F. Supp. 3d 988, 998–99 (N.D. Cal. 2021) (finding that confidential witness accounts were insufficient where they were not specific as to time, were not tied to false or misleading statements, and the witnesses did not have interactions with the defendants; the remaining confidential witness who shared information in reports at monthly CFO meetings was insufficient to support a strong inference of scienter). Further, although CW-2 says that the FDA gave "us" a "hint" that a warning letter was on its way, CW-2 provides no specific statement indicating what the substance of the purported hint was or who was included in the "us" at Medtronic that received that hint. Nor does CW-2 assert that any of the

defendants ever admitted to believing that FDA approval of the 780G was going to be delayed. *See In re Adient plc Sec. Litig.*, No. 18-CV-9116 (RA), 2020 WL 1644018, at *27 (S.D.N.Y. Apr. 2, 2020) (finding that plaintiffs failed to allege facts supporting a strong inference of scienter where, in part, CW accounts did not allege that individual defendants "ever admitted, suggested, or believed" that goals reflected in public statements could not be achieved). Overall, the Court finds that CW-2's account, considered in the context of the Complaint as a whole, does not create a strong inference of scienter.

2. Executive Positions and Hands-on Involvement

The Court finds no basis to conclude that simply by virtue of their ranks within the organization, Plaintiffs have identified a valid basis to determine that the individual Defendants had the requisite mental state to support a securities fraud claim. Indeed, the argument that their positions and roles as hands-on managers does little more than buttress the flawed argument that Defendants were aware of the product issues, and as the Court has discussed above, that knowledge alone is insufficient under the circumstances here to support a strong inference of scienter.

3. Executive Departures

The Court similarly places little weight on the executive departures which Plaintiffs allege are sufficiently suspicious to support the inference of scienter. Specifically, the Complaint includes no "particularized allegations connecting the departures [of Hakami, Ishrak, or Lerman] to the alleged fraud" as required to "strengthen an inference of scienter" based on corporate departures. *In re Hertz Global Holdings, Inc.*, 905 F.3d 106, 118 (3rd Cir. 2018). "For a resignation to add to an inference of scienter, a pleading must set forth

allegations suggesting a compelling inference that the resignation was the result of something other than 'the reasonable assumption that the resignation occurred as a result of' the release of bad news." *Id.* (quoting *Zucco Partners, LLC v. Digimarc Corp.*, 552 F.3d 981, 1002 (9th Cir. 2009)). Here, none of the executive departures are accompanied by allegations giving rise to such a compelling inference. Indeed, the Complaint itself suggests that Hakami's resignation was the result of the Diabetes Group losing ground to competitors under his leadership. Compl. ¶ 39. It presents no facts suggesting that in October 2019, when his retirement was announced, that he knew the product complaints about the 600 Series (of which one might reasonably infer he was aware) would lead to an FDA recall in February 2020, an inspection of one Medtronic facility in June 2021, the issuance of a Form 483 in July 2021, and a warning letter in December 2021 that would ultimately delay approval of the MiniMed 780G. To conclude otherwise would base Hakami's liability entirely on hindsight.

The departures of Defendants Ishrak and Lerman are similarly unpersuasive on the issue of scienter. Medtronic announced that Ishrak was stepping down as CEO in August 2019, and Martha replaced Ishrak as CEO in April 2020. Plaintiffs suggest that Ishrak's departure was suspicious because he stepped down just before Medtronic released new retainer rings for the MiniMed 600 Series and just before the company issued the November 2019 Field Safety Notification. On June 24, 2021, Lerman notified the Medtronic board of directors that he was retiring from the Company as of December 31, 2021. Plaintiffs point out that this announcement came right in the middle of the FDA's inspection of the Northridge facility. Compl. ¶¶ 227, 229. Plaintiffs argue that the timing

of these departures, at a minimum, supports an inference that Medtronic may have believed Ishrak and Lerman had been involved in wrongdoing related to quality failures found in the 600 Series pumps. Pls.' Opp'n at 57 (citing *Plymouth Cnty. Ret. Sys. v. Patterson Cos., Inc.*, No. 18-cv-871 (MJD/SER), 2019 WL 3336119, at *20 (D. Minn. July 25, 2019), *R&R adopted as modified by*, No. 18-cv-871 (MJD/SER), 2019 WL 4277302 (D. Minn. Sept. 10, 2019)).

The Court does not agree. The mere fact that Ishrak and Lerman's departures were announced when they were does not support a compelling inference that they were terminated for a role in covering up issues with the 600 Series pumps. *See Zucco Partners*, 552 F.3d at 1002 (finding that allegations of retirement of defendant CFO prior to disclosure of improper accounting practices did not support a strong inference of scienter where there were no allegations about whether the CFO was nearing retirement age, nor other details indicating whether his retirement was unusual).

It is worth noting that publicly available SEC filings indicate that both Ishrak and Lerman left Medtronic at the company's mandatory retirement age of 65. MacDonald Decl., Ex. 29 at 3 (8/28/2019 Form 8-K noting Ishrak's age); *id.*, Ex. 30 at 3 (6/30/2021 Form 8-K noting Lerman's retirement age); *id.*, Ex. 31 at 7 (4/30/2021 Form 10-K noting Lerman's age). *See Glenbrook Cap. Ltd. P'ship v. Kuo*, 525 F. Supp. 2d 1130, 1137 (N.D. Cal. 2007) (taking judicial notice of Form 8-K and Form 10-Q on a motion to dismiss). Thus, these were not "earlier than expected resignations" which have sometimes been found to "at least marginally assist[] . . . in alleging scienter." *CenturyLink*, 403 F. Supp. 3d at 734. And both Ishrak (CEO) and Lerman (General Counsel) were high-level

executives at Medtronic itself, not simply leaders within the Diabetes Group, which comprised only a small percentage of Medtronic's overall business. This reality makes the inference that they actually left because of problems with one line of products in the smallest division of Medtronic even less plausible. In light of all of these facts, one cannot readily infer that they acted with the required mental state in omitting details from their public statements based on the timing of their departures.

4. Sarbanes Oxley Certifications

Under the Sarbanes-Oxley Act ("SOX"), CEOs and CFOs must certify in each annual and quarterly report that "based on such officer's knowledge, the . . . financial information included in the report, fairly present[s] in all material respects the financial condition and results of operations of the issuer as of, and for, the periods presented in the report." 15 U.S.C. § 7241(a)(3). The Complaint alleges that Ishrak (before he left), Martha, and Parkhill all signed such SOX certifications upon the filing of Medtronic's reports,[37] and that such certifications establish that "they knowingly misled the market, or were reckless in making such representations and executing such certifications" because they disregarded weaknesses in Medtronic's system of controls that were not disclosed to the investing public. Compl. ¶ 240. But Plaintiffs do not allege facts showing how Ishrak, Martha, and Parkhill knew, at the time they made these SOX certifications, that Medtronic's SEC filings contained false information. *See In re Ceridian Corp. Sec. Litig.*, 542 F.3d 240, 248 (8th Cir. 2008) (finding that scienter is not established in every case

[37] Compl. ¶¶ 122–23 (2019 Form 10-K); ¶¶ 150–51 (2020 Form 10-K).

where a SOX certification is "later proven to be inaccurate"). And Plaintiffs' allegations that these defendants "disregarded material weaknesses in Medtronic's system of internal controls concerning financial reporting and disclosures regarding the same," Compl. ¶ 240, is far too conclusory to support a strong inference of scienter.

5. "Motive and Opportunity" and Insider Trading

Plaintiffs argue that their allegations support a strong inference of scienter because they show that Defendants had a *motive* "to hide and downplay the problems with the 600 Series to buy time for the FDA's approval of the 780G" and that their own trading activity in Medtronic stock allowed them an *opportunity* to personally benefit from the inflated stock price during the Class period. Pls.' Opp'n at 58. Plaintiffs' theory is that Defendants kept investors in the dark about the issues plaguing the Diabetes Group so that the stock price would remain artificially inflated. Meanwhile, knowing that the complaints, the inspection, the Form 483, and the company's response to it jeopardized timely approval of the 780G, but assuring investors otherwise, Defendants offloaded significant shares of their own stock at the artificially inflated market rate to personally enrich themselves.

"'Motive and opportunity' evolved into a term of art, meaning something far narrower than what it appears to mean." *Florida State Bd. of Admin. v. Green Tree Fin. Corp.*, 270 F.3d 645, 656 (8th Cir. 2001). Pleading that a defendant has motive and opportunity "is not per se required under the heightened PSLRA pleading requirements," but such allegations can help support a showing that a defendant acted with scienter. *In re Navarre Corp. Sec. Litig.*,299 F.3d 735, 745–46 (8th Cir. 2002) (quoting *Green Tree*, 270 F.2d at 660). However, it is not enough for private securities plaintiffs to assert simply that

"highly ranked executives and officers of [a defendant] have self-serving motives for the company to appear profitable." *Id.* at 746. "[I]nsider sales are probative of motive, which may provide circumstantial evidence of scienter." *Id.* But the Eighth Circuit requires more than simply alleging insider stock sales were made by the defendant in connection with an allegedly misleading statement:

> Insider stock sales are not inherently suspicious; they become so only when the level of trading is dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information. . . . Complaints based on insider trading must allege more than that the defendant benefitted from trading because of a false statement or misleading omission; the insider trades have to be unusual, either in the amount of profit made, the amount of stock traded, the portion of stockholdings sold, or the number of insiders involved, before they will give rise to the required inference of scienter.

Id. at 747.

Here, Plaintiffs identify trades made by the individual Defendants during the Class Period that they contend support a strong inference of scienter. They reference trades by Martha, Hakami, and Lerman from May 23, 2019 and November 19, 2019 (Compl. ¶ 137); trades by Martha and Lerman between November 20, 2019 and August 23, 2021 (*id.* ¶ 161); and trades by Martha, Salmon, and Lerman from August 24, 2021 through September 30, 2021 (*id.* ¶ 173). There are no allegations differentiating these trades within the Class Period from trading activity prior to it. Therefore, Plaintiffs do not allege that Defendants' trades represent a "level of trading [that] is dramatically out of line with prior

trading practices."[38] *Navarre*, 299 F.3d at 747. The Eighth Circuit has found complaints lacking similar allegations of prior trading activity to be insufficient. *In re K-tel Int'l, Inc. Sec. Litig.*, 300 F.3d 881, 896 (8th Cir. 2002) ("The Class failed to allege the prior history of sales for the defendants or even the number of shares held by each. . . . Therefore, the Class failed to allege facts to show the trading activity was unusual or how it was unusual.").

Moreover, Martha sold only 7.5% of his stock, and the Eighth Circuit has "found sales of up to 32% of an individual's stock not inherently suspicious."[39] *In re Target Corp. Sec. Litig.*, 955 F.3d at 743 (citing *In re Navarre*, 299 F.3d at 747). And Hakami sold his stock at the very outset of the Class Period, in June and September 2019, which is not suggestive of a later motive to defraud investors. *Id.* ("The bulk of the sales were made early in the class period and provide no motive for defrauding investors in the following months.").

In their opposition the Plaintiffs rely, in part, on the Eighth Circuit's consideration of the motive allegations in *Green Tree* that were considered sufficient to buttress the

[38] Plaintiffs know about each of these Class Period trades and can compare that trading to prior trading practices because any director, officer, or owner of a company who trades that company's stock must file a statement of ownership regarding those transactions with the SEC. *See* 15 U.S.C. § 78p(a)(1). The initial filing concerning the ownership is made on a Form 3, and annual statements of ownership interest are made on Form 5s. 17 C.F.R. §§ 240.16a-3(a), (f). Changes in beneficial ownership, such as when an officer of a company sells shares of his or her stock in that company, are reported on publicly filed Form 4s. 17 C.F.R. § 240.16a-3(g). "Forms 3, 4, and 5 are publicly available through the SEC's EDGAR website." U.S. Securities and Exchange Commission, Investor.gov, Updated Investor Bulletin: Insider Transaction and Forms 3, 4, and 5 (accessed Feb. 27, 2024), https://www.investor.gov/introduction-investing/general-resources/news-alerts/alerts-bulletins/investor-bulletins-69 [https://perma.cc/LB24-DVSQ].

[39] Lerman also allegedly sold 27.1% of his stock during the Class Period. Compl. ¶ 241.

complaint's showing of scienter. Pls.' Opp'n at 62. But the Court finds *Green Tree* distinguishable. In *Green* Tree, the corporate defendant was a mortgage company that securitized loans and used a low loan-prepayment rate when it calculated and reported its earnings. *Green Tree*, 270 F.3d at 649. However, the plaintiffs alleged that when the defendants reported those earnings, they knew that the actual prepayment rate was much higher. *Id.* The plaintiffs also alleged that the CEO of the company had a compensation agreement with a looming expiration date, and the overstated earnings were made public at times that would maximize his compensation under that contract. *Id.* at 661. The Eighth Circuit found that these allegations were suggestive of motive and lent support to an inference of scienter in light of other circumstantial allegations in the complaint. *Id.* at 662. But this case does not involve allegations that Medtronic reported earnings based upon data that Defendants knew was inaccurate. Nor are there allegations that information was publicized in such a way or at such a time as to maximize profit from the identified stock sales. But most importantly, whereas the plaintiffs in *Green Tree* alleged facts indicating that the defendants actually knew the prepayment numbers they used in the reported earnings were false, there is no comparable explicit contradiction between the information known to the Defendants in this case and their public statements.

As explored above, the allegations do not establish that any of the individual Defendants actually knew that the 780G approval would be delayed or recklessly

disregarded a very serious risk that the issues with the 600 Series pumps would render timely approval of the 780G all but impossible.[40]

IV. Scheme Liability

Scienter is also an element of a scheme-liability claim Rule 10b-5(a) and (c). *Medtronic*, 835 F.3d at 389. For the same reasons the Court finds that Plaintiffs have failed to allege scienter with respect to the misrepresentation claims under Section 10(b) and Rule 10b-5(b), the Court finds that they have failed to adequately allege scienter sufficiently supporting their scheme liability claim as well. Accordingly, the Court declines to address Defendants' alternative argument that Plaintiffs have failed to allege a scheme separate from the alleged misrepresentation claims.

V. Defendant Hakami

Defendants argue that irrespective of the Court's decision on any other issue, it should dismiss the claims against Defendant Hakami. Specifically, they argue that the Complaint alleges that Hakami left Medtronic in 2019, before the Field Safety Notification, before the recall, before the inspection of the Northridge facility, before the Form 483, and

[40] In their opposition, Plaintiffs argue that Salmon, Martha, and Lerman are liable under Section 10(b) for violating the abstain-or-disclose rule discussed in *Laventhall v. Gen. Dynamics Corp.*, 704 F.2d 407, 410 (8th Cir. 1983). Plaintiffs' only mention of the alleged requirement to abstain from selling shares unless they disclosed adverse information is in three paragraphs included within the Complaint's recitation of alleged misrepresentations and omissions. Compl. ¶¶ 139, 163, 175. Plaintiffs did not clearly identify such alleged violations as part of either of the Counts asserted. Under these circumstances, the Court finds that Plaintiffs have failed to adequately assert any claim based on these passing allegations. *See McDonald v. Compellent Techs., Inc.*, No. 10-cv-1566 (PJS/SER), 2011 WL 13228408, at *13 (D. Minn. Aug. 3, 2011) (finding that the complaint failed to adequately plead a Section 10(b) insider-trading claim where the entire complaint read like a typical securities-fraud complaint and the pleading made only one passing reference to the defendants alleged insider trades "while in possession of material, non-public information").

two years before the warning letter. He is alleged only to have made statements in June 2019 that international sales of the 670G generated revenue for the Diabetes Group, and in August 2019 that the Diabetes Group's "pipeline" remained on track. Finally, Defendants argue that Plaintiffs claims against Hakami are time-barred based on the statute of limitations established in 28 U.S.C. § 1658(b). Defs.' Mem. at 48–49.

Plaintiffs counter that Hakami made actionable misstatements because he knew there were problems with the MiniMed 600 Series pumps when he cut costs to the Diabetes Group's operational budget; knew that Medtronic had received thousands of complaints about the 600 Series pumps, and was aware of the 2018 and 2019 studies that understated the risks associated with the retainer ring issues. They further argue that they have demonstrated scienter with respect to his allegedly actionable statements because he engaged in trades in which he sold off more than 81% of his shares. They also disagree with Defendants' assessment of the statute of limitations issue. Pls. Opp'n at 66–68.

The Court finds that Plaintiffs have not stated any actionable claim against Hakami. First, Plaintiffs' do not allege that a failure to disclose made any statement by Hakami materially misleading. Although Plaintiffs contend that Hakami's remarks in May, June, and August of 2019 were misleading because he did not mention details about "increasing numbers of customer complaints concerning the damaged pumps and retainer rings," Compl. ¶ 248, the Complaint contains no allegations showing that he had any duty to make such a disclosure. Plaintiffs attribute no statement to Hakami that created a duty to make disclosures about customer complaints and product quality issues because they allege only that he disclosed that the 670G was (truthfully) contributing to revenues, stated to investors

that the Diabetes Group's pipeline remained on track, and attributed competition to the 670G after three years on the market as a headwind. *See Matrixx*, 563 U.S. at 45 (noting that defendants "can control what they have to disclose under [Section 10(b) and Rule 10b-5] by controlling what they say to the market"). Competition was, by Plaintiffs' own allegations, hurting Medtronic's insulin pump business going into the Class Period, and sales of the 670G pump were contributing to the Group's revenue, which ramped up as international sales increased following Hakami's departure.

Second, the Court's discussion above concerning the absence of sufficient allegations of scienter applies with even greater force to Hakami than any other Defendant. Plaintiffs' allegations that Hakami was aware of the fact that there were problems with the 600 Series pumps, that Medtronic had received a significant number of complaints regarding the retainer ring issues, and that the company had (prior to the Class Period) developed studies that the FDA would later determine had understated the risks associated with the 600 Series pumps are not enough to show that Hakami acted with reckless disregard of the falsity of his alleged misstatements. And of course, none of the events that post-date Hakami's alleged misrepresentations can factor into the scienter analysis as to him. The Court finds that the claims against Hakami would merit dismissal even if the Court had not found the broader flaws with the Complaint explored above.

VI. Control Person Liability

Because the Court has found that Plaintiffs fail to plead a primary violation of Section 10(b) of the Exchange Act, the Court concludes that their control-person liability

claims under Section 20(a) must also be dismissed. *See Lustgraaf v. Behrens*, 619 F.3d 867, 874 (8th Cir. 2010) (explaining that control person claims are derivative claims).

CONCLUSION & ORDER

Because the Court finds that Plaintiffs have failed to allege that Defendants made actionable misrepresentations and failed to adequately allege facts supporting a strong inference of scienter, the Court concludes that Plaintiffs have failed to state a claim for relief under Section 10(b) and Rule 10b-5. As a result, Count I of the Complaint will be dismissed with prejudice. The absence of scienter also supports dismissal of Plaintiffs' scheme liability claim under Rule 10b-5(a) and (c). And because the Court finds no primary violation of Section 10(b), the Court also dismisses Count II of the Complaint under Section 20(a) for control-person liability.

Finally, in their opposition to Defendants' motion, Plaintiffs request leave to amend if the Court finds that the Complaint fails to state a claim. Pls.' Opp'n at 69. At this time, the Court does not have before it a motion to amend or a proposed amended pleading to evaluate. In some circumstances, especially where the flaw with a complaint is that a plaintiff has failed to plead sufficient factual matter to permit the Court to evaluate whether the plaintiff could state a plausible entitlement to relief, the undersigned will allow the plaintiff an opportunity to amend the complaint within a specified time of the order granting a motion to dismiss. However, the Court will not take that approach here for two reasons. First, as this opinion makes clear, the Court does not find that the flaws with the Plaintiffs' Complaint in this case are insufficient specificity or based on merely a failure to plead enough factual content. Rather, the Court has found the Plaintiffs' claims are flawed

for more substantive reasons. Second, Plaintiffs have already amended their pleading once, and it is not clear that further amendment could resolve the deficiencies identified by the Court in this Order. Nor does the Court assume that, after receiving this Order, Plaintiffs would still prefer to seek leave to amend rather than pursue an appeal. However, to ensure that Plaintiffs are not deprived of an opportunity to seek post-dismissal leave to amend, the Court will delay entry of judgment in this matter for a period of 30 days. If Plaintiffs have not filed a motion to amend within 30 days of the date of this Order, the Court will direct the Clerk of Court to enter a final judgment in this matter. If Plaintiffs determine that they do not wish to file a motion to amend prior to the expiration of this 30-day deadline, they may notify the Court so that the Court can promptly direct the Clerk to enter judgment.

For the reasons discussed above, **IT IS HEREBY ORDERED THAT**:

1. Defendants' Motion to Dismiss, Doc. 63, is **GRANTED**.
2. Plaintiffs' Consolidated Complaint for Violations of the Federal Securities Laws, Doc. 58, is **DISMISSED WITH PREJUDICE**.

Date: March 28, 2024

s/Katherine Menendez
Katherine Menendez
United States District Judge