UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

_____, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, v. MEDTRONIC PLC, OMAR ISHRAK, GEOFFREY S. MARTHA, KAREN L. PARKHILL, and SEAN SALMON, Defendants.	Case No. _____ CLASS ACTION **COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS** JURY TRIAL DEMANDED

_____ ("Plaintiffs"), by and through their counsel, allege the following based upon personal knowledge as to themselves and their own acts, and upon information and belief as to all other matters, including the investigation of Plaintiffs' counsel, which included, among other things, a review of Defendants' (defined below) United States

Securities and Exchange Commission ("SEC") filings, wire and press releases published by Medtronic plc ("Medtronic" or the "Company"), analyst reports and advisories about the Company, media reports concerning the Company, judicial filings and opinions, and other publicly available information. Plaintiffs believe that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION AND OVERVIEW

1. This is a securities class action on behalf of a class of all persons and entities who purchased or otherwise acquired Medtronic common stock between June 8, 2019, and May 25, 2022, inclusive (the "Class Period"), seeking to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act").

2. Medtronic is a medical device company. Among its products is the MiniMed insulin pump system for the treatment of diabetes, including the MiniMed 600 series models and the MiniMed 780G model. Medtronic is currently seeking regulatory approval for the MiniMed 780G model, which uses an advanced hybrid closed loop system.

3. During the Class Period, Defendants repeatedly assured investors that the MiniMed 780G model was "on track" for approval by the U.S. Food and Drug Administration (the "FDA") and would provide the Company with the edge it needed to close a growing gap with its competitors in the diabetes market.

4. Defendants made these representations despite known issues with the MiniMed 600 series models. Indeed, in November 2019, the Company issued a warning that certain MiniMed 600 series insulin pumps might have damaged pump retainer rings,

which could cause the system to release too much insulin, and instructed customers with damaged rings to contact the Company for replacements. On February 7, 2020, the FDA classified Medtronic's November 2019 notification as a Class I recall—the most serious type of recall.

5. Problems with the MiniMed 600 series mushroomed in October 2021, when the Company expanded its recall to *all* MiniMed model 630G and 670G insulin pump systems—whether or not any retainer ring damage was actually visible. Despite these serious issues with the 600 series, Defendants assured investors that they expected the MiniMed 780G "to drive growth." Consistent with these optimistic statements, Medtronic again assured investors that FDA approval of the MiniMed 780G was imminent.

6. Investors began to learn the truth about the Company's MiniMed operations on December 15, 2021, when Medtronic revealed that it had received a warning letter from the FDA regarding its Northridge, California facility (the "Warning Letter"). The Warning Letter followed an FDA inspection relating to the Company's MiniMed 600 series recall, and focused on "the inadequacy of specific medical device quality system requirements . . . in the areas of risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events." The Warning Letter further explained that Medtronic had known about the MiniMed quality issues for *several years* before the Company finally initiated the recall, and that it failed to appropriately respond to complaints and report safety issues.

7. As a result of the Warning Letter—including the resulting uncertainty about FDA approval of the MiniMed 780G and other products in Medtronic's diabetes operating

unit (the "Diabetes Group")—Medtronic lowered its guidance for its Diabetes Group, now projecting that Diabetes Group product revenues would decline in the mid-single digits range for fiscal year 2022. On this news, the price of Medtronic common stock declined $6.75 per share, or approximately 6%, from a close of $111.69 per share on December 14, 2021, to close at $104.94 per share on December 15, 2021.

8. The financial fallout from the FDA's findings continued to surface on May 26, 2022, when Medtronic reported its financial results for the fourth quarter and full year of fiscal year 2022, and provided guidance for fiscal year 2023. Notably, Defendants disclosed that as a result of the Company's need to improve its quality control system and its expectation that the MiniMed 780G model—which Defendants had repeatedly identified as crucial to future growth—would not be approved in 2023, the Company expected revenues from its Diabetes Group to decline between 6% and 7% in fiscal year 2023. On this news, the price of Medtronic common stock fell $6.10 per share, or nearly 6%, from a close of $105.54 per share on May 25, 2022, to close at $99.44 per share on May 26, 2022.

9. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts, about the Company's business and operations. Specifically, Defendants misrepresented and/or failed to disclose that: (1) Medtronic's product quality control systems were inadequate; (2) Medtronic had failed to comply with numerous regulations regarding risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events; (3) these failures increased the risk of regulatory investigation and action;

(4) as a result of the Company's misconduct, the FDA would delay the approval of additional Medtronic MiniMed devices, including the MiniMed 780G; (5) these delays in product approvals, as well as the Company's need to improve its quality control systems, would negatively affect the Company's financial performance and cause Medtronic to fall further behind its competitors; and (6) as a result of the foregoing, Defendants' statements about the Company's business, operations, and prospects lacked a reasonable basis.

10. Plaintiffs and other members of the Class (defined below) have suffered significant damages due to Defendants' wrongful acts and omissions, and the resulting declines in the market value of the Company's common stock when the truth was revealed.

II. JURISDICTION AND VENUE

11. Plaintiffs' claims arise under Sections 10(b) and 20(a) of the Exchange Act, 15 U.S.C. §§ 78j(b) and 78t(a), and the rules and regulations promulgated thereunder, including SEC Rule 10b-5, 17 C.F.R. § 240.10b-5.

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

13. Venue is proper in this District under Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b) because Medtronic's main operational offices are located in this District and many of the acts and conduct that constitute the violations of law complained of herein, including the dissemination to the public of materially false and misleading information, occurred in this District.

14. In connection with the acts, conduct, and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of

interstate commerce, including the United States mails, interstate telephone communications, and the facilities of the national securities markets.

III. PARTIES

15. Plaintiffs, as set forth in the accompanying certification, incorporated by reference herein, purchased Medtronic common stock at artificially inflated prices during the Class Period and have been damaged thereby.

16. Defendant Medtronic is an Irish corporation with its main operational offices at 710 Medtronic Parkway, Minneapolis, MN 55432. The Company's common stock trades on the New York Stock Exchange under the ticker symbol "MDT."

17. Defendant Omar Ishrak ("Ishrak") was the Company's Chief Executive Officer from June 2011 to April 2020, and the Company's Executive Chairman and Chairman of the Board of Directors until December 2020.

18. Defendant Geoffrey S. Martha ("Martha") has served as the Company's Chief Executive Officer since April 2020 and Chairman of the Board of Directors since December 2020, and was the Company's President from November 2019 until April 2020.

19. Defendant Karen L. Parkhill ("Parkhill") is and was the Company's Executive Vice President and Chief Financial Officer throughout the Class Period.

20. Defendant Sean Salmon ("Salmon") is and was the Company's Executive Vice President since October 2019 and President of Medtronic's Cardiovascular Portfolio since January 2021, and was President of Medtronic's Diabetes Group from October 2019 until May 2022.

21. Defendants Ishrak, Martha, Parkhill, and Salmon are collectively referred to herein as the "Individual Defendants."

22. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of Medtronic's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. Each Individual Defendant was provided with copies of the Company's reports alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and/or were being concealed from, the public, and that the positive representations that were being made were then materially false and/or misleading.

23. Medtronic and the Individual Defendants are collectively referred to herein as "Defendants."

IV. SUBSTANTIVE ALLEGATIONS

A. Background

24. Medtronic develops, manufactures, and distributes medical devices and therapies. Medtronic operates in four business segments: Cardiovascular, Medical Surgical, Neuroscience, and Diabetes.

25. Among Medtronic's products is the MiniMed insulin pump system for the treatment of diabetes. The MiniMed system is one of the principal products in Medtronic's

Diabetes Group, which earned $2.3 billion in net sales—or more than 7% of the Company's total net sales—for the fiscal year ended April 29, 2022.

26. As relevant here, certain models of the MiniMed system—including models 630G and 670G—are designed with a pump retainer ring that locks the insulin reservoir into the insulin pump.[1]

B. Defendants' False and Misleading Statements

27. The Class Period begins on June 8, 2019, when Medtronic announced the initiation of a pivotal trial of the Company's next-generation MiniMed 780G model, which would use an advanced hybrid closed loop system. According to Medtronic, the MiniMed 780G model would be a significant improvement over the MiniMed 670G because it would "automate the delivery of correction boluses [insulin injections] when the user experiences, or is predicted to experience, prolonged high glucose levels based on their sensor readings." Medtronic further touted the MiniMed 780G's "potential to improve overall glycemic control and simplify diabetes management for individuals who forget to administer a bolus of insulin at mealtime, carb count inaccurately or choose to forgo announcing meals." Moreover, Medtronic stated that 100% of participants in a feasibility study of the product "rated the MiniMed 780G system as the best therapy they have ever used, and reported their overall satisfaction as extremely satisfied or very satisfied."

28. Two weeks later, on June 21, 2019, Medtronic published its annual report for fiscal year 2019 on Form 10-K (the "2019 Annual Report"). In the 2019 Annual Report,

[1] *See MINIMED™ 630G AND MINIMED™ 670G INSULIN PUMPS WITH CLEAR RETAINER RING,* Medtronic plc, https://info.medtronicdiabetes.com/PumpRing.

which was signed by Defendants Ishrak and Parkhill, touted "continued demand" for the Company's MiniMed 670G insulin pump system, which drove 12% year-over-year growth in net sales for the Company's Diabetes Group. Defendants also assured investors that "***[q]uality is extremely important to us***" and that "[s]trong product quality is critical to the success of our goods and services."[2]

29. As required by the Sarbanes-Oxley Act of 2002, Defendants Ishrak and Parkhill certified that they had reviewed the 2019 Annual Report and that it "does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report."

30. On August 20, 2019, Defendants announced Medtronic's financial results for the first quarter of fiscal year 2020 and again touted strong growth in the Company's Diabetes Group revenues, "driven by the ongoing launch of the MiniMed™ 670G hybrid closed loop insulin pump system."

31. During an earnings conference call with analysts that same day, Defendant Ishrak stated that the MiniMed 670G "drove strong growth in the U.S. last year" and "is now experiencing that . . . same strong consumer demand internationally as we launched into new markets." Ishrak also represented that the Company was "preparing for the [European] launch of the MiniMed 780G, our advanced hybrid closed-loop system with Bluetooth connectivity[,] in the second half of this fiscal year."

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[2] All emphasis is added unless otherwise noted.

32. Throughout the Class Period, Defendants continued to tout the success of Medtronic's existing MiniMed models, while assuring investors that the forthcoming MiniMed 780G model would be a financial success for the Company in the face of increasing competition in the diabetes market.

33. For example, on November 19, 2019, Defendants announced Medtronic's financial results for the second quarter of fiscal year 2020. Among other things, Defendants reported revenue growth in the Company's Diabetes Group, which Defendants attributed to "the ongoing launch of the MiniMed™ 670G hybrid closed loop insulin pump system" in international markets. However, Defendants noted that growth in the Diabetes Group had declined in the United States because of "increased competition," but assured that a recovery was upcoming "***as the group awaits its expected upcoming product approvals***."

34. Indeed, during an earnings conference call that same day, Ishrak again assured investors that the MiniMed 780G would soon be approved to launch in the United States. Specifically, Defendant Ishrak stated:

> I just want to make it very clear that we're very excited about this pipeline. ***The 780G promises to be an outstanding product.*** We're making good progress in terms of our enrollment in the pivotal trial. We've already submitted for our next-generation hardware for approval with the FDA. ***And so that whole pipeline is on track.*** And we're going to go through a period of some pressure, especially with new patients in the U.S. But look, ***there should be no doubt about our enthusiasm for this pipeline and what we see into the future in Diabetes***. As Geoff pointed out earlier, ***this is an area of focus for us and one that we will win in***.

35. Notwithstanding these positive assurances, ***just two days later***, on November 21, 2019, Medtronic warned consumers about serious potential safety issues associated with certain MiniMed 600 series insulin pumps (specifically, certain MiniMed 630G pumps and MiniMed 670G pumps). Specifically, the Company indicated that it had received reports of loose insulin reservoirs in these MiniMed models, caused by broken or missing retainer rings. As Medtronic explained, "[i]f the reservoir is not properly locked into the pump, it could lead to over or under delivery of insulin, which could then result in hypoglycemia or hyperglycemia." Accordingly, Medtronic instructed MiniMed users to examine their pumps' retainer rings for any damage, and to contact the Company if a retainer ring was loose, damaged, or missing.

36. Several months later, on February 7, 2020, the FDA classified the Company's November 2019 notification as a Class I recall—the most serious type of recall.

37. Despite these serious issues with the MiniMed 600 series, Defendants continued to assure investors that the MiniMed line of products was strong and that the forthcoming MiniMed 780G product, in particular, would soon help the Company excel in a highly competitive market. For example, during a JPMorgan healthcare industry conference on January 13, 2020, Defendant Ishrak represented:

> And we've got to do some work in diabetes. But in the pump area, in the closed-loop system; this is a product -- this is a market that essentially we created 2 or 3 years ago through the launch of the closed-loop system. ***There's competitors now and we've got some work to do here, but we're really excited about the 780G, which is, again, very close to its launch phase.*** The 780G is a product, which has an advanced closed-loop algorithm, one that has better time and range than what we have today, approaching 80% in adult feasibility studies. It

> will target blood glucose levels of about 100 in average both day and night. Today's sort of state-of-the-art ours is 120. General market is more like 160. So in general performance for the user, it will be better. But in addition to that, it will have a feature set that will allow -- that will be more forgiving to user behaviors. We're actually going to be presenting at the ATTD use case studies under extreme conditions and extreme conditions means what happens when the patient misses a meal bolus and how does this product react to that, and we've got some pretty good data to share there. So it's going to be more forgiving and that will make a big difference to these patients.
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> And in addition to that, we'll have the full pivotal trial data at the ADA in June. ***The regulatory time lines are all on track.*** The CE mark has been submitted. FDA submission is forthcoming. And this is, again, a product that's forthcoming ***and will move the needle for us in diabetes***.

38. Similarly, during an earnings conference call on February 18, 2020, Defendant Ishrak again acknowledged "competitive challenges [in the diabetes market] while we await our new products." However, Defendant Salmon assured investors that he was "really very encouraged with how we're seeing some derisking of the pipeline that we have going forward," and that "***[t]he 780G is an important catalyst for us to drive growth***, and we expect that to begin." Defendant Salmon further noted that the Company intended to file clinical data with the FDA in March, and that "[t]hat review is going well" and "***[w]e're very interactive with FDA***."

39. Throughout the remainder of the Class Period, Defendants continued to emphasize the importance of the MiniMed 780G to the Company's future growth and ability to keep pace with competitors. For example, at a Barclays healthcare conference on March 11, 2020, when an analyst noted that Medtronic's Diabetes Group was struggling compared to its other business segments, Defendant Parkhill countered that the Company

was "confident that we can turn [the Diabetes Group] around" and was "focused on closing" product gaps, which Medtronic would "start to [achieve] with the 780G."

40. Similarly, during an earnings conference call on May 21, 2020, Defendant Martha represented that the Company expected imminent FDA approval of the MiniMed 770G model—a Bluetooth-enabled version of the 670G—"before ***launching our 780G later in the fiscal year***."

41. Additionally, during a management briefing for investors and analysts on June 12, 2020, Defendant Salmon explained that the "reinvigoration" of the Company's Diabetes Group "starts with 780G," and assured investors that the new features of the MiniMed 780G would "be a welcome innovation into the field."

42. Then, during an earnings conference call on August 25, 2020, when a JPMorgan analyst noted that Medtronic was "clearly investing heavily in Diabetes" and asked whether "this [is] a 3- to 5-year turnaround story" or "something we could see in the shorter term," Defendant Martha assured investors that "***[i]t's not 3 to 5 years***" and would "be faster than that." To this end, Martha reiterated that the launch of the MiniMed 780G is critical to Medtronic's success in the diabetes market, explaining that "***when we get 780 out there, it's going to be a big step forward***."

43. Likewise, at a Morgan Stanley conference on September 14, 2020, Defendant Martha further assured investors that the Company was adjusting its portfolio to "***get back more competitive in Diabetes, which is happening, and it's going to happen faster than you thought***." Defendant Martha again noted that, "***when the 780 comes out, that's going to be a big jump forward for us***" and "the long term, the holistic approach we have here,

having all of this, plus our service levels, we feel is going to make us not just competitive, but ***back to gaining share***."

44. Several weeks later, at a Wells Fargo conference on September 10, 2020, Defendants indicated that Medtronic would soon submit its application for FDA approval of the MiniMed 780G. Specifically, Defendant Parkhill explained that the Company had data from adult trials ready to submit, but was waiting for complete pediatric trial data. To this end, Defendant Parkhill assured investors that the company was "***working with [the FDA] right now*** to determine when to submit that supplement[al]" application.

45. During an investor and analyst meeting on October 14, 2020, Defendants again represented that the MiniMed 780G would help the Company keep pace with its competitors in the diabetes market. Specifically, when an analyst asked whether Medtronic's Diabetes Group would "be growing in line with the market" after the Company launched the MiniMed 780G, Defendant Salmon assured investors that "***with the new product approvals, we'll be in line with market growth***."

46. On February 23, 2021, Defendants reported that the Company had submitted its adult and pediatric trial data for the MiniMed 780G to the FDA, which was now reviewing its application. In connection with this announcement, Defendants once again assured investors that the FDA's imminent approval of the MiniMed 780G would drive substantial future growth, with Defendant Martha highlighting that "the device [is] very competitive, and I think we'll do well with it when we get into the marketplace."

47. The following quarter, on May 27, 2021, Defendants touted growth in the Company's Diabetes Group and assured investors that this growth would soon speed up, as the MiniMed 780G was "under active review with the FDA."

48. Similarly, during an earnings conference call on August 24, 2021, Defendants reassured investors that the FDA was actively reviewing Medtronic's application for approval of the MiniMed 780G. Specifically, Defendant Salmon stated that "***things are on track as far as we can tell***" and that there was "***good progress***" with the FDA.

49. Then, on October 5, 2021, Medtronic expanded its recall of the MiniMed 630G and 670G insulin pumps. While Medtronic had initially warned consumers in November 2019 about the dangers of damaged retainer rings in these pumps and instructed consumers to get a replacement if their rings were loose, damaged, or missing, Medtronic now expanded its recall to include all pumps with a clear retainer ring, which would be replaced with an updated black retainer ring regardless of whether or not the clear ring was showing signs of damage.

50. Despite these serious issues with the MiniMed 600 series models, Defendants continued to assure investors that Medtronic's MiniMed 780G model would soon reach U.S. markets and drive significant growth for the Company. For example, during an earnings conference call on November 23, 2021, Defendant Martha explained that "we remain pleased with the momentum we're building outside the U.S." in diabetes products, particularly the MiniMed 780G, and that "we expect our U.S. results to turn around as we launch these new products." Defendant Martha further emphasized that "[w]hen approved

and launched in the U.S., we expect the 780G system to drive growth as it will be highly differentiated and further address the burden of daily diabetes management." Additionally, in response to a Wells Fargo analyst's question about the timing of the MiniMed 780G's FDA approval, Defendant Salmon indicated that "we've had very good interactive conversations with FDA," and "***we're making excellent progress there***."

51. The above statements identified in ¶¶ 27-50 were materially false and misleading, and failed to disclose material adverse facts, about the Company's business and operations. Specifically, Defendants misrepresented and/or failed to disclose that: (1) Medtronic's product quality control systems were inadequate; (2) Medtronic had failed to comply with numerous regulations regarding risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events; (3) these failures increased the risk of regulatory investigation and action; (4) as a result of the Company's misconduct, the FDA would delay the approval of additional Medtronic MiniMed devices, including the MiniMed 780G; (5) these delays in product approvals, as well as the Company's need to improve its quality control systems, would negatively affect the Company's financial performance and cause Medtronic to fall further behind its competitors; and (6) as a result of the foregoing, Defendants' statements about the Company's business, operations, and prospects lacked a reasonable basis.

C. The Truth Emerges

52. On December 15, 2021, investors began to learn the truth about Medtronic's product quality and chances for further FDA approvals when Medtronic revealed that it had received the Warning Letter from the FDA regarding the Northridge, California facility

housing the Company's Diabetes Group headquarters. Specifically, Defendants stated that the Warning Letter "was issued following an inspection that concluded in July 2021 related to recalls of the MiniMed™ 600 series insulin infusion pump" and other products, and that "[t]he warning letter focuses on the inadequacy of specific medical device quality system requirements at the Northridge facility in the areas of risk assessment, corrective and preventive action, complaint handling, device recalls, and reporting of adverse events."

53. That same day, Medtronic announced that as a result of the Warning Letter, including new "uncertainty on the timing of U.S. Diabetes product approvals," the Company was "adjusting its expectations for its Diabetes business organic revenue." Specifically, Medtronic lowered its Diabetes Group guidance, now projecting "declines in the high-single digit range for the third fiscal quarter and the mid-single digits range for the full fiscal year 2022, down modestly from previous guidance of mid- and low-single digit declines, respectively."

54. On this news, the price of Medtronic common stock declined $6.75 per share, or approximately 6%, from a close of $111.69 per share on December 14, 2021, to close at $104.94 per share on December 15, 2021.

55. Several weeks later, on or about December 28, 2021, the FDA published the complete Warning Letter on its website. The Warning Letter extensively elaborated on Medtronic's significant errors and made clear that the Company had repeatedly failed to comply with relevant regulations.

56. First, Medtronic "failed to adequately establish procedures for corrective and preventive action." According to the Warning Letter, Medtronic was aware by at least June

2016—well before the beginning of the Class Period—that there were a number of complaints regarding damaged clear retainer rings in MiniMed 600 series insulin infusion pumps, and Medtronic's own investigation determined that the device failures were caused by the retainer ring. Nonetheless, Medtronic "failed to adequately analyze all sources of quality data, failed to identify actions needed to correct nonconforming product, and . . . did not appropriately verify or validate the change to [the] device to ensure corrective and preventive actions taken were effective and did not adversely affect the finished device." More specifically, Medtronic waited far too long (until November 2019) to communicate with customers about the retainer ring issues, even as thousands of complaints continued to pour in, and then failed to adequately remove faulty pumps from existing devices by declining to initiate a true recall (and instead instructing customers to do nothing if no damage was observed).

57. Second, Medtronic "failed to review, evaluate, and investigate complaints involving the possible failure of a device to meet any of its specifications." That is, Medtronic "failed to investigate over 800 complaints of defective black retainer rings," among other issues.

58. Third, Medtronic "failed to submit a report to FDA no later than 30 calendar days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury."

Specifically, Medtronic declined to submit reports regarding certain serious injuries to the FDA, in violation of FDA regulations.

59. Fourth, Medtronic "failed to submit a report to FDA no later than 30 calendar days after the day that the firm received or otherwise became aware of information, from any source, that reasonably suggests that a device that the firm markets has malfunctioned and this device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." For example, in some instances Medtronic entirely failed to submit a Medical Device Report ("MDR") to the FDA for reportable events, and in other instances Medtronic's MDRs were submitted beyond the 30-day deadline.

60. The Warning Letter further specified that the inspection of the Northridge facility occurred from June 7, 2021, through July 7, 2021—*before* some of Defendants' statements assuring investors that the FDA's review of the MiniMed 780G was "on track" and that the Company was having productive conversations with the FDA about the approval of the MiniMed 780G.

61. The Warning Letter instructed Medtronic to "investigate and determine the causes of any deficiencies, and take prompt actions to correct the deficiencies and bring the products into compliance." Further, the Warning Letter noted that "[t]he specific deficiencies noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems."

62. Given these revelations, analysts cautioned that FDA approval of the MiniMed 780G—which Defendants repeatedly admitted was critical to the Company's future growth—was now in doubt. For example, analysts from Cowen cautioned that the "warning letter may slow the timing of MDT's planned U.S. product approvals in its Diabetes division," including the MiniMed 780G pump and another diabetes product, the Guardian 4 glucose sensor. Similarly, J.P. Morgan analysts stated that "it's a realistic and prudent assumption" to believe that the Warning Letter would "halt[] the review process of 780G," and UBS lowered its own estimation of the Company's future Diabetes Group growth to account for a prolonged delay in the approval of the MiniMed 780G, "as based on history, in most cases, warning letters can hold back approvals."

63. Indeed, in announcing the Company's third quarter 2022 financial results on February 22, 2022, Defendants reiterated that the Warning Letter might further delay the FDA's approval (and the Company's subsequent U.S. launch) of the MiniMed 780G. For example, in an earnings conference call that day, Defendant Martha acknowledged that approval of the MiniMed 780G is "subject to our warning letter."

64. Then, on May 26, 2022, Medtronic reported its financial results for the fourth quarter and full year of fiscal year 2022. As previously projected, the Company's Diabetes Group revenue had decreased 3% for fiscal year 2022. However, Defendants further disclosed that the Company expected even *worse* performance for the Diabetes Group in fiscal year 2023, projecting that Diabetes Group revenue will decline 6% to 7% year-over-year. Moreover, Defendants admitted that the Company's projections assumed that the FDA would not approve the MiniMed 780G in fiscal year 2023. Defendant Salmon further

noted that the Company's need to invest in "sustainably improv[ing] the quality system," as outlined in the Warning Letter, was also driving its poor outlook for 2023.

65. On this news, the price of Medtronic common stock declined $6.10 per share, or nearly 6%, from a close of $105.54 per share on May 25, 2022, to close at $99.44 per share on May 26, 2022.

V. CLASS ACTION ALLEGATIONS

66. Plaintiffs bring this class action under Rule 23 of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired Medtronic common stock during the Class Period (the "Class"). Excluded from the Class are Defendants, their agents, directors and officers of Medtronic, and their families and affiliates.

67. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.

68. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether Defendants violated the Exchange Act;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. Whether the prices of Medtronic common stock were artificially inflated; and

f. The extent of damage sustained by members of the Class and the appropriate measure of damages.

69. Plaintiffs' claims are typical of those of the Class because Plaintiffs and the Class sustained damages from Defendants' wrongful conduct.

70. Plaintiffs will adequately protect the interests of the Class and have retained counsel who are experienced in securities class actions. Plaintiffs have no interests that conflict with those of the Class.

71. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Joinder of all Class members is impracticable.

VI. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD-ON-THE-MARKET DOCTRINE

72. Plaintiffs will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's common stock traded in an efficient market;

d. The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

e. Plaintiffs and the Class purchased Medtronic common stock between the time the Company and the Individual Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

73. At all relevant times, the market for the Company's common stock was efficient because: (1) as a regulated issuer, the Company filed periodic public reports with the SEC; and (2) the Company regularly communicated with public investors using established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services.

VII. NO SAFE HARBOR

74. Defendants' "Safe Harbor" warnings accompanying any forward-looking statements issued during the Class Period were ineffective to shield those statements from liability. Defendants are liable for any false and/or misleading forward-looking statements pleaded because, at the time each forward-looking statement was made, the speaker knew

the forward-looking statement was false or misleading and the forward-looking statement was authorized and/or approved by an executive officer of the Company who knew that the forward-looking statement was false. None of the historic or present-tense statements made by Defendants were assumptions underlying or relating to any plan, projection, or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by Defendants expressly related to or stated to be dependent on those historic or present-tense statements when made.

VIII. LOSS CAUSATION/ECONOMIC LOSS

75. Defendants' wrongful conduct directly and proximately caused the economic loss suffered by Plaintiffs and the Class. The prices of Company common stock significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses. As a result of their purchases of Medtronic securities during the Class Period, Plaintiffs and the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

IX. SCIENTER ALLEGATIONS

76. During the Class Period, Defendants had both the motive and opportunity to commit fraud. They also had actual knowledge of the misleading nature of the statements they made, or acted in reckless disregard of the true information known to them at the time. In so doing, Defendants participated in a scheme to defraud and committed acts, practices,

and participated in a course of business that operated as a fraud or deceit on purchasers of Company securities during the Class Period.

X. CLAIMS AGAINST DEFENDANTS

COUNT I

Violations of Section 10(b) of the Exchange Act and SEC Rule 10b-5 Promulgated Thereunder Against All Defendants

77. Plaintiffs incorporate by reference the allegations in the preceding paragraphs.

78. During the Class Period, Defendants carried out a plan, scheme, and course of conduct that was intended to and, throughout the Class Period, did: (1) deceive the investing public, including Plaintiffs and the Class; and (2) cause Plaintiffs and the Class to purchase Company common stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, the Defendants, and each of them, took the actions set forth herein.

79. Defendants: (1) employed devices, schemes, and artifices to defraud; (2) made untrue statements of material fact and/or omitted material facts necessary to make the statements not misleading; and (3) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices thereof in violation of Section 10(b) of the Exchange Act and SEC Rule 10b-5.

80. As a direct and proximate result of Defendants' wrongful conduct, Plaintiffs and the Class suffered damages in connection with their respective purchases of the Company's common stock during the Class Period.

COUNT II

Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

81. Plaintiffs incorporate by reference the allegations in the preceding paragraphs.

82. The Individual Defendants acted as controlling persons of Medtronic within the meaning of Section 20(a) of the Exchange Act. By virtue of their high-level positions, and their ownership and contractual rights, participation in and/or awareness of the Company's operations, and/or intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control—and did influence and control, directly or indirectly—the decision-making of the Company, including the content and dissemination of the various false and/or misleading statements. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports and other statements alleged by Plaintiffs to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

83. In particular, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, are presumed to

have had the power to control or influence the particular accounting practices giving rise to the securities violations as alleged herein, and exercised the same.

84. As described above, the Company and the Individual Defendants each violated Section 10(b) of the Exchange Act and SEC Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their positions as controlling persons, the Individual Defendants are liable under Section 20(a) of the Exchange Act. As a direct and proximate result of this wrongful conduct, Plaintiffs and other members of the Class suffered damages in connection with their purchases of Company securities during the Class Period.

XI. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for relief and judgment, as follows:

a. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

b. Awarding compensatory damages and equitable relief in favor of Plaintiffs and other members of the Class against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

c. Awarding Plaintiffs and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

d. Such other and further relief as the Court may deem just and proper.

XII. JURY TRIAL DEMANDED

Plaintiffs hereby demand a trial by jury.