UNITED STATES DISTRICT COURT DISTRICT OF MINNESOTA

MINNEAPOLIS FIREFIGHTERS'
RELIEF ASSOCIATION, Individually and
on behalf of All Others Similarly Situated,

Civil No.

Plaintiff,

CLASS ACTION

COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

MEDTRONIC, INC., WILLIAM A. HAWKINS, III, and GARY ELLISS,

v.

JURY TRIAL DEMANDED

Defendants.

CLASS ACTION COMPLAINT

Plaintiff Minneapolis Firefighters' Relief Association ("Plaintiff"), by its undersigned counsel, brings this action alleging violations of the federal securities laws on behalf of itself and all other similarly situated persons or entities (the "Class"), other than Defendants and their affiliates (as described herein), who purchased or otherwise acquired securities issued by Medtronic, Inc. ("Medtronic" or the "Company") from November 19, 2007 through November 17, 2008 (the "Class Period"). Plaintiff seeks to recover damages caused to the Class by Defendants' violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). The allegations of this Complaint are based on Plaintiff's personal knowledge as to itself and on information and belief (including the investigation of counsel and review of publicly available information) as to all other matters.

SUMMARY OF THE ACTION

1. This federal securities class action arises from Defendants' false and misleading public statements concerning the INFUSE Bone Graft ("INFUSE").

- 2. INFUSE is a surgically-implanted medical device containing a genetically engineered protein designed to stimulate bone growth. The United States Food and Drug Administration ("FDA") has approved INFUSE only for limited applications. Specifically, INFUSE is FDA-approved solely for the treatment of degenerative discs in the lower lumbar region of the spine; fractures of the tibia; and certain facial/oral surgeries. Its principal application (and the one originally approved by the FDA) is for the treatment of degenerative lumbar discs.
- 3. Throughout the Class Period, Defendants presented INFUSE to the investing public as a valuable, reliable, and continuously increasing material source of revenues for the Company, responsible, for example, for approximately \$800 million in reported revenue during Medtronic's last fiscal year. This portrayal of INFUSE and its material positive effect on the Company's financial condition were false and misleading because Defendants concealed and failed to disclose material facts known to or recklessly ignored by them about INFUSE that were necessary to make their otherwise positive statements about the product and its financial benefits accurate, truthful, and not misleading to investors. In particular, Defendants did not disclose the extent to which revenues from sales of INFUSE were dependent on applications of the product not approved by the FDA (so called "off-label" uses); did not disclose that a significant and increasing number of patients subjected to such off-label uses of INFUSE were suffering severe medical complications; and did not disclose that the extensive off-label usage of INFUSE was the result of an unlawful campaign by Defendants to market and encourage off-label use of the product. This undisclosed material information was known to or recklessly ignored by the Defendants.

- 4. As set forth herein, Defendants false and misleading statements concerning INFUSE artificially inflated the price of the Company's publicly traded securities during the Class Period. Revelations concerning Defendants' material non-disclosures during the Class Period caused significant losses to investors as the prices of the Company's securities experienced severe declines as a direct result of these revelations, with the Company's stock price closing the day after the end of the Class Period at \$31.20 per share, down from a Class Period high of \$55.65 per share immediately after the Company's misleading earnings release for the previous financial quarter.
 - 5. This action seeks to recover those losses on behalf of Class members.

PARTIES

- 6. Plaintiff Minneapolis Firefighters' Relief Association ("Minneapolis Firefighters") finances and pays service, disability and dependency pensions to its eligible members—firefighters of the City of Minneapolis, Minnesota—and their dependents. Minneapolis Firefighters purchased Medtronic securities during the Class Period on the New York Stock Exchange as detailed in the attached certification and suffered damages as a result of the violations of the federal securities laws alleged herein.
- 7. Defendant Medtronic is a corporation that manufactures medical devices. The Company is incorporated in the State of Minnesota and maintains its principal executive offices at 710 Medtronic Parkway, Minneapolis Minnesota, 55432. The Company's common shares are traded on the New York Stock Exchange under the symbol "MDT."

- 8. Defendant William A. Hawkins, III ("Hawkins") was, at all relevant times, the Chief Executive Officer of Medtronic and has served as the Chairman of the Board of Medtronic since August, 2008.
- 9. Defendant Gary Elliss ("Elliss") was, at all relevant times, the Chief Financial Officer and a Senior Vice President of Medtronic.
- 10. Defendants Hawkins and Elliss are referred to collectively herein as the "Individual Defendants," and, together with Medtronic, are referred to as the "Defendants."

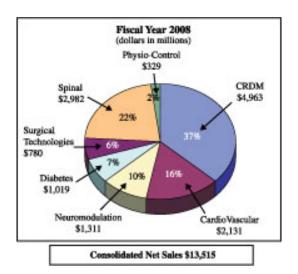
JURISDICTION AND VENUE

- 11. The claims asserted herein on behalf of the Class arise under Sections 10(b) and 20(a) of the Exchange Act, and Rule 10b-5 (17 C.F.R. § 240.10b-5), promulgated by the SEC.
- 12. This Court has jurisdiction pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. §§ 1331.
- 13. Venue is proper in this district pursuant to Section 27 of the Exchange Act and 28 U.S.C. § 1391(b). Many of the acts giving rise to the violations of law complained of herein occurred in this district.
- 14. In connection with the acts, conduct and other wrongs complained of herein, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, the United States mails, and the facilities of a national securities market.

FACTUAL ALLEGATIONS

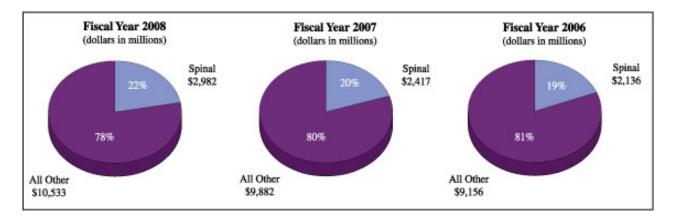
A. MEDTRONIC AND INFUSE

- 15. Medtronic is a manufacturer of medical devices and describes itself as a "global leader in medical technology alleviating pain, restoring health, and extending life for millions of people around the world." Medtronic operates on a fiscal year ending on April 25th.
- 16. Medtronic conducts its business through seven operating segments: Spinal, Cardiac Rhythm Disease Management ("CRDM"), CardioVascular, Neuromodulation, Diabetes, Surgical Technologies, and Physio-Control. As indicated in the Company's most recent Annual Report, filed on Form 10-K with the Securities and Exchange Commission ("SEC"), the Spinal operating segment is highly material to the Company's operations, responsible for over one-fifth of Medtronic's net sales during its last fiscal year:



17. The company describes the Spinal segment as "a leading supplier for innovative medical devices and implants used in the treatment of the Spine." Not only is the Spinal segment a material component of the Company's operations, but the segment

has experienced steady growth as a percentage of the Company's net sales in recent years:



- 18. The Spinal segment is itself divided into two distinct operating units and the Company has traditionally reported the results from each as separate line-items in its financial statements. These are the "Core" Spinal unit and the Spinal "Biologics" unit. The Core Spinal unit focuses on spinal instrumentation and stabilization devices—such as implantable screws and artificial discs—for use in connection with spinal surgeries. The Biologics unit focuses on medical devices and other products that are manufactured through biological processes, frequently using recombinant DNA technology (and often described as involving "genetic engineering"). In addition, in November of 2007, Medtronic acquired another company called "Kyphon," focused on minimally invasive spinal treatments for elderly patients. Since consummating the Kyphon acquisition, Medtronic has also reported its Kyphon results as a separate line-item within the Spinal segment, alongside the Core and Biologics units.
- 19. INFUSE is a medical device containing a collagen sponge that is treated with the biologically manufactured protein, recombinant human bone morphogenetic protein-2 (rhBMP-2), which stimulates bone growth. In the limited spinal application

approved by the FDA, INFUSE is implanted in place of a degenerative disc in the lower lumbar region of the spine. The bone growth stimulated by INFUSE causes the two adjacent vertebrae to fuse together, thus helping alleviate the pain caused by the (now removed) degenerative disc. In this application, INFUSE is intended to replace traditional spinal fusion surgeries, which, unlike INFUSE, require a second surgical procedure to harvest the bone graft from another part of the body (typically the hip).

20. INFUSE is the principal product marketed through the Biologics unit of the Company's Spinal operating segment, and has been portrayed to the investing public as a primary and material driver of growth for the entire segment. As a J.P. Morgan research analyst covering Medtronic recently explained:

InFuse is an \$800 million product for Medtronic (6% of sales), having enjoyed robust growth since its initial approval in the U.S. in July 2002. In fact, it is the one piece of Medtronic's Spine business that continues to post strong double-digit growth without any issues (LTM: +16.9%). That is, until now.

B. DEFENDANTS' FALSE AND MISLEADING STATEMENTS

21. On November 19, 2007, Medtronic reported its financial results for the second quarter (ended October 26, 2007) of its 2008 fiscal year in a press release that was filed with the SEC as an attachment to Form 8-K (the "2Q 8-K"). The Company recorded revenue of \$3.124 billion and net earnings for the quarter of \$666 million, or \$0.58 per diluted share. The 2Q 8-K noted strong results in the Company's Spinal Biologics business:

Spinal revenue of \$660 million grew 10 percent, *driven by sales of the biologics product line* and strong growth outside the U.S. With the acquisition completed earlier than anticipated, the company expects Kyphon will contribute to revenue in the second half of the fiscal year as

Medtronic expands its presence in the aging spine market. (emphasis added).

- 22. On the same day, the Company conducted a conference call with analysts to discuss its second quarter earnings. During this conference call, Defendant Hawkins reiterated the same statements concerning strong sales in the Company's Biologics business: "So, turning to our spine business, we saw 10% growth in the quarter, driven by sales of biologics and strong growth outside the US."
- 23. On December 4, 2007, the Company filed its Quarterly Report for the second quarter of its 2008 fiscal year on Form 10-Q with the SEC (the "2Q 10-Q"). The 2Q 10-Q reiterated the same financial results set forth in the 2Q 8-K. The 2Q 10-Q also contained additional detail concerning the Spinal segment and the material role that INFUSE played in the performance of that segment:

Spinal net sales for the three and six months ended October 26, 2007 were \$660 million and \$1.304 billion, an increase of 10 percent and 11 percent, respectively, over the same periods of the prior fiscal year.

* * *

Spinal Biologics net sales for the three and six months ended October 26, 2007 were \$198 million and \$388 million, an increase of 11 percent and 14 percent, respectively, over the same periods of the prior fiscal year. These *increases were primarily driven by continued strong acceptance of INFUSE Bone Graft in the U.S.* INFUSE Bone Graft contains a recombinant human bone morphogenetic protein, or rhBMP-2, that induces the body to grow its own bone, eliminating the need for a painful second surgery to harvest bone from elsewhere in the body. (emphasis added).

24. These statements were knowingly or recklessly materially false and misleading because they did not disclose the extent to which revenues from sales of INFUSE were significantly dependent on off-label applications of INFUSE not approved

by the FDA; did not disclose that a significant and increasing number of patients subjected to such off-label uses of INFUSE were suffering severe medical complications; and did not disclose that the extensive off-label usage of INFUSE was the result of an unlawful campaign by Defendants to market and encourage off-label use of the product.

25. On February 19, 2008, the Company reported its financial results for the third quarter (ended January 25, 2008) of its 2008 fiscal year in a press release that was filed with the SEC as an attachment to Form 8-K (the "3Q 8-K"). The Company recorded revenue of \$3.405 billion and net earnings for the quarter of \$77 million, or \$0.07 per diluted share. Adjusting for one-time special charges (including in relation to the Kyphon acquisition), the Company disclosed non-GAAP net earnings of \$713 million, or \$0.63 per share. The 3Q 8-K disclosed strong results in Medtronic's Spinal Biologics business:

Spinal revenue of \$808 million grew 35 percent, driven by \$147 million in Kyphon revenue. Excluding Kyphon, revenue grew 11 percent with *strong double digit performance in worldwide Biologics*, and strong growth in Core Spinal outside the U.S. (emphasis added).

26. On the same day, the Company conducted a conference call with analysts to discuss its third quarter earnings. During this conference call, Defendant Hawkins again described the strong growth in the Biologics business, noting that this growth was offsetting competitive pressures related to the Core business:

When you look at our Spinal business excluding Kyphon, revenue grew 11% in the third quarter, driven by *strong double-digit performance in our worldwide Biologics business*, along with solid growth in our core Spinal business outside the U.S. Taken together, Kyphon and *Biologics helped to partially offset competitive pressures on our core spinal products in the U.S.* (emphasis added).

27. On March 4, 2008, Medtronic filed its Quarterly Report for the third quarter of its 2008 fiscal year on Form 10-Q with the SEC (the "3Q 10-Q"). The 3Q 10-Q reiterated the same financial results set forth in the 3Q 8-K. The 3Q 10-Q also contained additional detail concerning the Spinal segment and highlighted the material role that INFUSE played in the performance of that segment:

Spinal net sales for the three and nine months ended January 25, 2008 were \$808 million and \$2.112 billion, an increase of 35 percent and 19 percent, respectively, over the same periods of the prior fiscal year.

* * *

Spinal Biologics net sales for the three and nine months ended January 25, 2008 were \$206 million and \$594 million, an increase of 20 percent and 16 percent, respectively, over the same periods of the prior fiscal year. *These increases were primarily driven by continued strong acceptance of INFUSE Bone Graft in the U.S.* INFUSE Bone Graft contains a recombinant human bone morphogenetic protein, or rhBMP-2, that induces the body to grow its own bone, eliminating the need for a painful second surgery to harvest bone from elsewhere in the body. Additionally, although on smaller bases, we have continued to experience strong growth in the sales of InductOs Bone Graft, the outside the U.S. equivalent of INFUSE Bone Graft, for both the three and nine months ended January 25, 2008. (emphasis added).

- 28. These statements were knowingly or recklessly materially false and misleading because they did not disclose the extent to which revenues from sales of INFUSE were significantly dependent on off-label applications of INFUSE not approved by the FDA; did not disclose that a significant and increasing number of patients subjected to such off-label uses of INFUSE were suffering severe medical complications; and did not disclose that the extensive off-label usage of INFUSE was the result of an unlawful campaign by Defendants to market and encourage off-label use of the product.
- 29. On May 20, 2008, the Company reported its fourth quarter and full-year financial results for the 2008 fiscal year (ended April 25, 2008) in a press release that was

filed with the SEC as an attachment to Form 8-K (the "4Q 8-K"). The Company recorded fiscal year revenues of \$13.515 billion and net earnings of \$2.231 billion, or \$1.95 per diluted share. Excluding one-time charges, the Company reported full-year non-GAAP net earnings of \$2.973 billion, \$2.60 per diluted share. For the fourth quarter, the Company recorded revenue of \$3.860 billion and net earnings of \$812 million, or \$0.72 per diluted share. Excluding one-time charges, Medtronic recorded fourth quarter non-GAAP net earnings of \$884 million, or \$0.78 per diluted share.

30. The 4Q 8-K disclosed strong results in the Company's Spinal Biologics business:

Spinal annual revenue of \$2.982 billion increased 23 percent and fourth quarter revenue of \$869 million increased 35 percent, driven by \$298 million and \$150 million, respectively, in Kyphon revenue. Strong performance in Biologics continued again this quarter with growth of 16 percent. The impact of Kyphon and Biologics offset continued competitive pressures on Core Spinal products in the United States. (emphasis added).

31. On the same day, the Company held an analyst conference call to discuss its fourth quarter and full-year earnings. During this conference call, Defendant Hawkins described the strong growth in the Biologics business, noting again that this growth was offsetting competitive pressures related to the Core business:

Strong performance in Biologics continued again this quarter, with growth of 16%. Taken together, Kyphon and Biologics helped to partially offset continued competitive pressures on our core spinal products in the United States. We remain committed to our strategy of raising the bar of competition through continuous innovation and supporting the safety, efficacy and cost effectiveness of our products with robust clinical data. (emphasis added).

- 32. On June 24, 2008, the Company filed its Annual Report for of its 2008 fiscal year on Form 10-K with the SEC (the "2008 10-K"). The 2008 10-K reiterated the same financial results set forth in the 4Q 8-K. The 2008 10-K also contained additional detail concerning the Spinal segment and, in particular, INFUSE and its material and increasingly important role within the Company's operation and financial condition.
- 33. In the overview of the business set forth in the 2008 10-K, the Company stated as follows with respect to INFUSE:

Our INFUSE Bone Graft, used in spinal fusion, contains a recombinant human bone morphogenetic protein, or rhBMP-2, that induces the body to grow its own bone, eliminating the need for a painful second surgery to harvest bone from elsewhere in the body. In Europe, INFUSE Bone Graft is marketed as InductOs Bone Graft for spinal fusion. We also offer INFUSE Bone Graft for the treatment of certain types of acute, open fractures of the tibial shaft, a long bone in the lower leg, as well as certain oral maxillofacial indications.

* * *

Late in April 2007, we began to market INFUSE Bone Graft for certain oral maxillofacial and dental regenerative bone grafting procedures. It is estimated that more than 350,000 bone grafting procedures of this type are performed in the U.S. each year. Medtronic has also submitted a premarket approval (PMA) with the FDA for a posterolateral spinal indication for INFUSE Bone Graft.

34. The 2008 10-K discussed the material role that INFUSE played in the Company's performance:

Spinal net sales for fiscal year 2008 increased by 23 percent from the prior fiscal year to \$2.982 billion. Foreign currency translation had a favorable impact on net sales of \$44 million when compared to the prior fiscal year.

* * *

Biologics net sales for fiscal year 2008 increased 16 percent from the prior fiscal year to \$815 million. *This increase was primarily driven by continued strong acceptance of INFUSE Bone Graft in the U.S.* INFUSE Bone Graft contains a recombinant human bone morphogenetic protein, or rhBMP-2, that induces the body to grow its own bone,

eliminating the need for a painful second surgery to harvest bone from elsewhere in the body. In addition to FDA approval for use of INFUSE Bone Graft for spinal fusion, we received FDA approval to use INFUSE Bone Graft for the treatment of certain types of acute, open fractures of the tibial shaft in fiscal year 2005, and for certain oral maxillofacial and dental regenerative bone grafting procedures late in fiscal year 2007. Additionally, although on a smaller base, we have continued to experience strong fiscal year 2008 growth in the sales of InductOs Bone Graft, the outside the U.S. equivalent of INFUSE Bone Graft. (emphasis added).

- 35. These statements were knowingly or recklessly materially false and misleading because they did not disclose the extent to which revenues from sales of INFUSE were dependent on off-label applications of INFUSE not approved by the FDA; did not disclose that a significant and increasing number of patients subjected to such off-label uses of INFUSE were suffering severe medical complications; and did not disclose that the extensive off-label usage of INFUSE was the result of an unlawful campaign by Defendants to market and encourage off-label use of the product.
- 36. On August 19, 2008, Medtronic reported its financial results for the first quarter (ended July 25, 2008) of its 2009 fiscal year in a press release that was filed with the SEC as an attachment to Form 8-K (the "1Q 8-K"). The Company recorded revenue of \$3.706 billion and net earnings for the quarter of \$747 million, or \$0.66 per diluted share. The 1Q 8-K noted strong results in the Company's Spinal Biologics business, which helped offset continued competition with respect to the Core Spinal business:

Spinal revenue of \$859 million grew 33 percent, including Kyphon, which contributed \$161 million in revenue. Excluding Kyphon, revenue increased 8 percent, driven by 16 percent growth in Biologics. The impact of Kyphon and continued growth in Biologics offset continued competitive pressure on Core Spinal products. (emphasis added).

37. On the same day, the Company held an analyst conference call to discuss its first quarter earnings. During this conference call, Defendant Hawkins described the competitive pressures facing the Core Spinal business and the strong performance of the Biologics unit:

As we have described previously, although the market for Core Spine products in the US continues to grow in the low double digits, our market share position remains under pressure, primarily from the proliferation of smaller, privately-held companies.

Strong performance in Biologics continued again this quarter, with growth of 16%. During the quarter, we announced approval to market two smaller kit sizes of INFUSE bone graft for use in certain spinal fusion and oral maxillofacial procedures, which helped contribute to the largest revenue quarter ever for INFUSE. We estimate the OMF market potential for INFUSE to be in the \$200 million to \$250 million range.

Since its market introduction, INFUSE has been successfully used to treat thousands of patients. Expanding our portfolio of INFUSE products will help broaden availability to a larger group of patients. (emphasis added).

38. Defendant Hawkins went on to predict future growth based on successful innovation of, among other things, the INFUSE Bone Graft:

The key to our future success in the Spinal business will be our commitment to driving long-term innovation. This commitment is reflected in the breadth of innovative products in the long-term Spinal product development and clinical pipeline, including . . . a series of expanded indications for our INFUSE bone graft. These innovative products will strengthen our existing portfolio and position us to continue our market leadership.

39. On September 3, 2008, Medtronic filed its Quarterly Report for the first quarter of its 2009 fiscal year on Form 10-Q with the SEC (the "1Q 10-Q"). The 1Q 10-Q reiterated the same financial results set forth in the 1Q 8-K. The 1Q 10-Q also

contained additional detail concerning the Spinal segment and highlighted the material role played by INFUSE in the Company's performance:

Spinal net sales for the three months ended July 25, 2008 were \$859 million, an increase of 33 percent over the same period of the prior fiscal year.

* * *

Spinal Biologics net sales for the three months ended July 25, 2008 were \$221 million, an increase of 16 percent over the same period of the prior fiscal year. *This increase was primarily driven by continued strong acceptance of INFUSE Bone Graft in the U.S.* The U.S. growth was influenced by the introduction of extra small and a double extra small INFUSE kits for use in spinal and oral maxillofacial procedures. These smaller kits expand the potential user population. INFUSE Bone Graft contains a recombinant human bone morphogenetic protein, or rhBMP-2, that induces the body to grow its own bone, eliminating the need for a painful second surgery to harvest bone from elsewhere in the body. (emphasis added).

40. These statements were knowingly or recklessly materially false and misleading because, as would later be learned by the investing public, they did not disclose the extent to which revenues from sales of INFUSE were significantly dependent on off-label applications of INFUSE not approved by the FDA; did not disclose that a significant and increasing number of patients subjected to such off-label uses of INFUSE were suffering severe medical complications; and did not disclose that the extensive off-label usage of INFUSE was the result of an unlawful campaign by Defendants to market and encourage off-label use of the product.

C. SOME, BUT NOT ALL, OF THE TRUTH BEGINS TO EMERGE

41. On September 4, 2008—the day after the Company had filed its 1Q 10-Q—the *Wall Street Journal* published a front-page article entitled "Medtronic Product Linked to Surgery Problems." The article stated:

A potent substance used in spine surgery to promote bone growth has been linked to life-threatening complications in dozens of patients.

Many of the complications involving the product, Medtronic Inc.'s "Infuse Bone Graft," have occurred during "off label" uses, when surgeons use it in ways that haven't been approved by the Food and Drug Administration. (emphasis added).

- 42. The article went on to describe financial ties between Medtronic and numerous physicians advocating the off-label use of INFUSE.
- 43. On the same day, the *Wall Street Journal Health Blog* published an entry entitled, "Surgeons with Ties to Medtronic Touted Unapproved Use of Bone Graft." As the piece stated:

Medical device makers aren't allowed to market their products for uses that haven't been approved by the FDA. But that doesn't stop doctors from doing what they want with the stuff and telling their colleagues all about it.

Seems some spine surgeons with financial ties to Medtronic have touted the company's Infuse Bone Graft . . . for use in surgeries of the cervical spine — a part of the spine for which the device, which prompts the growth of bone, has not been approved.

- 44. As a direct result of these revelations, the Company's stock price declined, falling on high volume from the previous day's close of \$55.14 per share to \$53.78 per share on September 4, 2008.
- 45. Then, on November 18, 2008, Medtronic reported its financial results for the second quarter (ended October 24, 2008) of its 2009 fiscal year in a press release that was filed with the SEC as an attachment to Form 8-K (the "November 18th 8-K"). The November 18th 8-K reported sales from the Spinal segment of \$829 million, a decline of \$30 million from the previous quarter, a significant shortfall from analysts' consensus

estimates, and a sharp deviation from the Company's repeated reporting, in consecutive previous quarters, of double digit growth in the Spinal segment.

- 46. Analysts reacted sharply to this information. J.P. Morgan's Medtronic analyst wrote that "[f]or the quarter, InFuse came in flat YOY, missing Street consensus by a shocking \$28M." An analyst from the Stanford Financial Group echoed this dismay, noting that "[s]pine sales of \$829 million fell well short of our \$898 million estimate," and noted further that, based on the Company's earlier disclosures, "[w]e had underestimated the level of off-label use of InFuse in the cervical spine."
- 47. On the same day, the Company conducted an analyst conference call to discuss this "shocking" shortfall. During that call, Defendant Hawkins stunned investors even further by disclosing a previously received subpoena concerning the Company's marketing of INFUSE from the Department of Justice. As Defendant Hawkins stated:

The biggest surprise in the quarter was the result in our biologics business where revenue of \$198 million was flat. These results reflected the impact of several external factors, including the FDA public health notice regarding the cervical use of bone morph genetic protein, several negative stories from the news media and a recent whistleblower lawsuit filed against a number of spine surgeons. These issues are unfolding against a broader backdrop of increased scrutiny regarding off-label use of medical devices in general. *In fact, we recently received a subpoena from the Department of Justice looking into off-label use of INFUSE.* (emphasis added).

48. The news shocked the marketplace, causing an over 13% decline in Medtronic's stock price from \$36.42 per share on the previous day to \$31.60 per share on November 18, 2008—a single-day decline in market capitalization of over \$5 billion on over three times the average daily volume for the stock.

CLASS ACTION ALLEGATIONS

- 49. Plaintiff brings this action on its own behalf and as a class action pursuant to Rule 23(a) and Rule 23(b)(3) of the Federal Rules of Civil Procedure on behalf of all persons or entities who purchased or acquired Medtronic securities during the Class Period, from November 19, 2007 through November 17, 2008
- 50. Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of each of the Defendants; (iii) any person who was an executive officer and/or director of Medtronic during the Class Period; (iv) any person, firm, trust, corporation, officer, director, or any other individual or entity in which any Defendant has a controlling interest or which is related to or affiliated with any of the Defendants; and (v) the legal representatives, agents, affiliates, heirs, successors-in-interest or assigns of any such excluded party.
- 51. The members of the Class, purchasers of Medtronic securities, are so numerous that joinder of all members is impracticable. While the exact number of Class members can only be determined by appropriate discovery, Plaintiff believes that Class members number in the thousands, if not higher. As of June 19, 2008, Medtronic reported that it had 1,125,244,102 shares of common stock issued and outstanding.
- 52. Plaintiff's claims are typical of the claims of members of the Class. Plaintiff and all members of the Class sustained damages as a result of the conduct complained of herein.
- 53. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained court-appointed counsel competent and experienced in class and securities litigation. Plaintiff has no interests that are contrary to or in conflict with those of the members of the Class that Plaintiff seeks to represent.

- 54. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Because the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it virtually impossible for the Class members individually to seek redress for the wrongful conduct alleged herein.
- 55. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual Class members. Among the questions of law and fact common to the Class are:
- (a) whether the federal securities laws were violated by Defendants' acts and omissions, as alleged herein;
- (b) whether documents, including the Company's SEC filings, press releases and other public statements made by Defendants, during the Class Period contained misstatements of material fact or omitted to state material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- (c) whether the market price of Medtronic stock during the Class Period was artificially inflated due to the material misrepresentations and/or non-disclosures complained of herein;
- (d) with respect to Plaintiff's claims under Section 10(b) of the Exchange Act, whether Defendants acted with the requisite state of mind in omitting and/or misrepresenting material facts in the documents filed with the SEC, press releases and public statements;

- (e) with respect to Plaintiff's claims pursuant to Section 20(a) of the Exchange Act, whether the Defendants named in those counts are controlling persons of the Company; and
- (f) whether the members of the Class have sustained damages as a result of the misconduct complained of herein and, if so, the appropriate measure thereof.
- 56. Plaintiff knows of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.
- 57. The names and addresses of the record owners of Medtronic shares purchased during the Class Period are obtainable from information in the possession of the Company's transfer agent(s). Notice can be provided to such record owners via first class mail using techniques and a form of notice similar to those customarily used in class actions.

COUNT I

<u>Violation of Section 10(b) of the Exchange Act and</u> Rule 10b-5 of the Securities and Exchange Commission

(Against All Defendants)

- 58. Plaintiff repeats and realleges each and every allegation set forth above as if fully set forth herein.
- 59. This Claim is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder, on behalf of Plaintiff and all other members of the Class, against all Defendants.
- 60. Throughout the Class Period, Defendants individually, and in concert, directly and indirectly, by the use and means of instrumentalities of interstate commerce, the mails and the facilities of a national securities exchange, employed devices, schemes

and artifices to defraud, made untrue statements of material fact and/or omitted to state material facts necessary to make statements made not misleading, and engaged in acts, practices and a course of business which operated a fraud and deceit upon Class members, in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

- 61. Defendants' false and misleading statements and omissions were made with scienter and were intended to and did, as alleged herein, (i) deceive the investing public, including Plaintiff and the other members of the Class; (ii) artificially create, inflate and maintain the market for and market price of the Company's securities; and (iii) cause Plaintiff and the other members of the Class to purchase Medtronic securities at inflated prices.
- 62. By knowingly or recklessly making affirmative statements concerning INFUSE while failing to inform the market of the true facts concerning INFUSE, as alleged herein, these Defendants presented a misleading picture of the Company's current and expected future financial condition. This caused and supported artificial inflation in the trading prices of Medtronic's publicly traded securities throughout the Class Period until the true state of affairs was revealed.
- 63. Defendants were individually and collectively responsible for making the statements and omissions alleged herein, by virtue of having prepared, approved, signed and/or disseminated documents which contained untrue statements of material fact and/or omitted facts necessary to make the statements therein not misleading and/or making direct statements to the investing public on the conference calls detailed herein.

- 64. During the Class Period, the Individual Defendants occupied executive-level positions at Medtronic and were privy to non-public information concerning the Company and INFUSE. Each of them knew or recklessly disregarded the adverse facts specified herein and omitted to disclose those facts.
- 65. As described herein, Defendants made the false statements and omissions knowingly, or in such an extremely reckless manner as to constitute willful deceit and fraud upon Plaintiff and other members of the Class who purchased Medtronic securities during the Class Period. Throughout the Class Period, Defendants had a duty to disclose new, material information that came to their attention, which rendered their prior statements to the market materially false and misleading.
- 66. Defendants' false statements and omissions were made in connection with the purchase or sale of the Company's securities by members of the Class.
- 67. In ignorance of the false and misleading nature of Defendants' statements and/or in reliance upon the integrity of the market price for Medtronic securities, Plaintiff and the other members of the Class purchased the Company's securities at artificially inflated prices during the Class Period. But for the fraud, they would not have purchased the Company's securities at artificially inflated prices.
- 68. The market price for Medtronic securities declined materially upon the public disclosure of the facts that had previously been misrepresented or omitted by the Defendants, as described above.
- 69. Plaintiff and the other members of the Class were substantially damaged as a direct and proximate result of their purchases of Medtronic securities at artificially

inflated prices and the subsequent decline in the price of those securities when the true state of affairs was revealed.

- 70. This claim was brought within two years after discovery of this fraud and within five years of the making of the statements alleged herein to be materially false and misleading.
- 71. By virtue of the foregoing, Defendants have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder, and are liable to Plaintiff and the members of the Class, each of whom has been damaged as a result of such violation.

COUNT II

Violation of Section 20(a) of the Exchange Act

(Against the Individual Defendants)

- 72. Plaintiff repeats and realleges each and every allegation above as if set forth fully herein. This Claim is brought pursuant to Section 20(a) of the Exchange Act against the Individual Defendants on behalf of Plaintiff and all members of the Class who purchased Medtronic securities during the Class Period.
- 73. As alleged herein, Medtronic is liable to Plaintiff and the members of the Class who purchased its securities based on the materially false and misleading statements and omissions set forth above, pursuant to Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.
- 74. Throughout the Class Period, the Individual Defendants were controlling persons of Medtronic within the meaning of Section 20(a) of the Exchange Act, and culpable participants in Medtronic's fraud and violation of the federal securities laws, as detailed herein.

- 75. Each of the Individual Defendants exercised control over Medtronic during the Class Period by virtue of, among other things, their executive positions with the Company, the key roles they played in the Company's management, and their direct involvement in its day to day operations, including its public disclosures.
- 76. This claim was brought within two years after the discovery of this fraud and within five years of the making of the statements alleged herein to be materially false and misleading.
- 77. By virtue of the forgoing, each of the Individual Defendants are liable to Plaintiff and the members of the Class, each of whom has been damaged as a result of Medtronic's underlying violations.

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

- A. Declaring this action to be a proper class action pursuant to Rule 23(a) and Rule 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein:
 - B. Awarding Plaintiff and the members of the Class compensatory damages;
- C. Awarding Plaintiff and the members of the Class pre-judgment and postjudgment interest, as well as reasonable attorneys' fees, expert witness fees and other costs; and
 - D. Awarding such other relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Plaintiff hereby demands a trial by jury in this action for all issues so triable.

Dated: December 10, 2008

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