UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

MINNEAPOLIS FIREFIGHTERS' RELIEF ASSOCIATION,

Plaintiffs,

v.

MEDTRONIC, INC., et al.,

Defendants.

Civil No. 08-6324 (PAM/AJB)

CLASS ACTION

CONSOLIDATED COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

CONSOLIDATED CLASS ACTION COMPLAINT

Lead Plaintiffs, the Teachers' Retirement System of Oklahoma; Oklahoma Firefighters Pension Fund; Union Asset Management Holding AG; and Danske Invest Management A/S, by their undersigned counsel, bring this action alleging violations of the federal securities laws on behalf of themselves and all other similarly situated persons or entities, other than Defendants and their affiliates (as described herein), who purchased or otherwise acquired common stock issued by Medtronic, Inc. ("Medtronic" or the "Company") from November 20, 2006 through November 17, 2008 (the "Class Period") and were damaged thereby (the "Class"). Lead Plaintiffs bring this class action to recover damages proximately caused to the Class by Defendants' violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act"). These allegations are based on Lead Plaintiffs' personal knowledge as to themselves and their own acts and on information and belief as to Defendants' acts and all other matters based upon all of the facts set forth below which were obtained through an investigation made by Lead Counsel. Lead Counsel's investigation on Lead Plaintiffs' behalf has included, among other things, a review of filings by Defendants with the United States Securities and

Exchange Commission ("SEC") and the United States Food and Drug Administration ("FDA"); press releases and other public statements made by Defendants; interviews of former Medtronic employees; and other data and sources set forth below. Lead Plaintiffs believe that further substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

SUMMARY OF THE ACTION

1. This federal securities class action arises from Defendants' materially incomplete, false and misleading public statements concerning one of Medtronic's most important products, the INFUSE® Bone Graft ("INFUSE Bone Graft"). INFUSE Bone Graft is a surgically-implanted medical device containing a genetically engineered protein designed to stimulate bone growth. The FDA has approved INFUSE Bone Graft only for limited surgical applications. Specifically, INFUSE Bone Graft 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 through a specified spinal fusion procedure—Anterior Lumbar Interbody Fusion ("ALIF")—that is used in a small percentage of overall spinal fusion surgeries.

2. Throughout the Class Period, Defendants presented INFUSE Bone Graft to the investing public as an increasing source of material revenue for the Company, responsible for over $800 million in reported sales during Medtronic's fiscal year ended April 25, 2008. Defendants repeatedly stated that increases in sales were driven by "continued strong acceptance of INFUSE Bone Graft" and expanded FDA-approved indications for the product without disclosing material facts known to or recklessly ignored by them that were necessary to make their statements about the product and the quality and nature of its financial success complete,

accurate, truthful, and not misleading to investors. Defendants' materially incomplete, false and misleading statements throughout the Class Period created the false impression that the Company adhered to FDA regulations, and that sales of INFUSE Bone Graft were driven by expanding the indications for which the product was approved by the FDA. Further, Defendants led investors to believe that Medtronic strictly complied with all applicable health regulations, in contrast to its smaller competitors in the spinal market.

3. In particular, Defendants failed to disclose that, notwithstanding a recently announced settlement with the United States Department of Justice ("DOJ") shortly before the start of the Class Period for alleged unlawful kickbacks to doctors to use and promote its products, Medtronic continued to rely on payments to doctors to drive INFUSE Bone Graft sales, primarily for non-FDA approved (or "off-label") usage. Off-label use of INFUSE Bone Graft was especially a concern for that product given the adverse (and in certain cases dangerous) side effects already known to Defendants and specifically raised as an issue by an FDA Advisory Panel at the time of the product's original limited use approval back in 2002. Nonetheless, according to Lead Counsel's investigation, off-label use of INFUSE Bone Graft increased year-after-year from the time of its original limited use approval by the FDA in 2002, to the point where off-label use of INFUSE Bone Graft reached an astounding 85% of all sales by the start of the Class Period.

4. Although undisclosed to investors, the first-hand accounts from over a dozen former Medtronic employees referred to below demonstrate that this extraordinarily high off-label use was driven by the Company's sales force, which would direct doctors to Medtronic-compensated consultants or "Key Opinion Leaders" in the medical field who were surgeons paid by Medtronic to promote off-label use of INFUSE Bone Graft. Through these practices, the

Company continued to increase INFUSE Bone Graft sales year-after-year and throughout the Class Period.

5. As a result of these undisclosed practices, the consistent quarter-after-quarter INFUSE Bone Graft sales figures reported by Defendants and the statements they made regarding those sales throughout the Class Period materially misled investors regarding the true facts and risks known to Defendants at all relevant times: ***that INFUSE Bone Graft sales were primarily dependent on higher risk off-label use of a product that was marketed through means that invited, and eventually brought about, the scrutiny of federal regulators and led to an abrupt decline in sales***.

6. Indeed, when questions began to be raised about INFUSE Bone Graft marketing practices near the end of the Class Period, a Medtronic spokesperson adamantly (and falsely) stated: "***Medtronic does not promote off-label use***." (Emphasis added.)

7. At no time prior to the end of the Class Period did Defendants quantify either the amount of INFUSE Bone Graft sales for off-label applications or the amount Medtronic continued to pay surgeons as "consultants," including those who primarily promoted off-label use of INFUSE Bone Graft, even after its settlement with the DOJ shortly before the start of the Class Period.

8. At the end of the Class Period, Medtronic was forced to disclose that it was subject to a DOJ investigation (which at the time of the filing of this Complaint remains pending) regarding its promotion of INFUSE Bone Graft for off-label uses and to admit that INFUSE Bone Graft sales declined as a result of the DOJ investigation, a severe warning letter by the FDA, a United States Congressional inquiry led by Senator Charles Grassley (R-Iowa), and an

avalanche of negative media attention focused on Medtronic's massive payments to doctors to promote off-label sales of INFUSE Bone Graft.

9. As set forth herein, Defendants' materially incomplete, false and misleading Class Period statements and omissions concerning INFUSE Bone Graft artificially inflated investors' view of the Company and the price of the Company's publicly traded securities. Revelations concerning the adverse consequences of Defendants' material non-disclosures then promptly caused losses to investors as the price of the Company's shares experienced severe and statistically significant declines, with the Company's stock price closing at $31.60 per share the day after the end of the Class Period, down from a Class Period high of $57.86 per share, a decline of approximately 45%.

JURISDICTION AND VENUE

10. This Complaint asserts claims arising under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 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 ("Rule 10b-5").

11. This Court has jurisdiction over the subject matter of this action pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and pursuant to 28 U.S.C. § 1331 because this is a civil action arising under the laws of the United States.

12. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa, and 28 U.S.C. §§ 1391(b), (c), and (d). Many of the acts and transactions that constitute the violations of law complained of herein, including the dissemination to the public of materially false and misleading statements, occurred in this District.

13. In connection with the wrongful acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but

not limited to, the United States mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

A. LEAD PLAINTIFFS

14. Lead Plaintiff Teachers' Retirement System of Oklahoma ("Oklahoma Teachers") is a public retirement program established for the benefit of the current and retired employees of Oklahoma's local school districts, career technology schools, and public colleges and universities. Oklahoma Teachers provides retirement benefits to more than 100,000 members and their beneficiaries, and has billions of dollars in assets under its management. As set forth in the chart attached hereto as Exhibit A, Oklahoma Teachers purchased Medtronic common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

15. Lead Plaintiff Oklahoma Firefighters Pension Fund ("Oklahoma Firefighters") is a public retirement system established for the benefit of the current and retired firefighters of the State of Oklahoma. Oklahoma Firefighters provides retirement benefits to more than 20,000 members and their beneficiaries, and has over a billion dollars in assets under its management. As set forth in the chart attached hereto as Exhibit B, Oklahoma Firefighters purchased Medtronic common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

16. Lead Plaintiff Union Asset Management Holding AG ("Union") is one of Germany's largest fund management groups serving private and institutional investor clients, and managing hundreds of billions of dollars in assets. Union is based in Frankfurt, Germany. As set forth in the chart attached hereto as Exhibit C, Union purchased Medtronic common stock

during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

17. Lead Plaintiff Danske Invest Management A/S ("Danske") is a fund manager based in Copenhagen, Denmark, serving investors in Denmark and numerous European countries. Danske manages approximately $40 billion in assets. As set forth in the chart attached hereto as Exhibit D, Danske purchased Medtronic common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

B. ADDITIONAL NAMED PLAINTIFFS

18. Plaintiffs Iron Workers Locals 40, 361 & 417 Union Security Funds ("Iron Workers 40") and Iron Workers Local 580 Joint Funds ("Iron Workers 580") (collectively, the "Iron Workers") are funds invested for the benefit of the members of several New York iron worker union locals and their families. As set forth in the chart attached hereto as Exhibit E, Iron Workers purchased Medtronic common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein.

19. Plaintiff Westmoreland County Employees Retirement System ("Westmoreland") is a public pension fund for over 2,600 current and retired employees of Westmoreland County, Pennsylvania which manages assets of approximately $280 million. As set forth in the chart attached hereto as Exhibit F, Westmoreland purchased Medtronic common stock during the Class Period and suffered damages as a result of the violations of the federal securities laws alleged herein. Further, Westmoreland has submitted a certification signed by Carmen Pedicone, its Secretary and County Controller, which is attached hereto as Exhibit G.

C. DEFENDANTS

20. Defendant Medtronic, Inc. is a manufacturer of medical devices, including devices used in spinal surgery. The Company is incorporated in the State of Minnesota, and maintains its headquarters and principal executive offices at 710 Medtronic Parkway, Minneapolis, Minnesota, 55432. The Company also maintains additional offices and facilities throughout the United States. Medtronic's common shares are traded on the New York Stock Exchange ("NYSE") under the symbol "MDT." As of November 28, 2008, the Company had 1,118,224,679 shares of common stock outstanding. Medtronic operates on a fiscal year ending in April, with quarters ending in July, October, January, and April.

21. Defendant Arthur D. Collins, Jr. ("Collins") served as the Chairman of the Board of Medtronic from April 2002 until August 2008. Defendant Collins served as Chief Executive Officer ("CEO") of Medtronic from May 2002 to August 2007; as President and CEO from May 2001 to April 2002; as President and Chief Operating Officer ("COO") from August 1996 to April 2001; as COO from January 1994 to August 1996; and as Executive Vice President of Medtronic and President of Medtronic International from June 1992 to January 1994. As Medtronic's CEO, Defendant Collins certified Medtronic's annual and quarterly reports filed with the SEC pursuant to the requirements of the Sarbanes-Oxley Act of 2002. Defendant Collins had direct operational control over all aspects of the Company's affairs during his tenure with the Company during the Class Period, and is liable for materially incomplete, false and misleading statements, as set forth herein. Defendant Collins is not charged with statements made by Medtronic after his resignation from the Board in August 2008.

22. Defendant William A. Hawkins ("Hawkins") served as Chairman of the Board of Medtronic and CEO from August 2008 through the end of the Class Period. Defendant Hawkins served as President and CEO of Medtronic from August 2007 to August 2008; as President and

COO from May 2004 to August 2007; as Senior Vice President and President, Medtronic Vascular from January 2002 to May 2004; and as a Director of Medtronic since March 2007. As Medtronic's CEO, Defendant Hawkins certified Medtronic's annual and quarterly reports filed with the SEC pursuant to the requirements of the Sarbanes-Oxley Act. Defendant Hawkins had direct operational control over all aspects of the Company's affairs during the Class Period, and is liable for materially incomplete, false and misleading statements, as set forth herein.

23. Defendant Gary L. Ellis ("Ellis") served as Senior Vice President and Chief Financial Officer ("CFO") of Medtronic from May 2005 through the end of the Class Period. Defendant Ellis served as Vice President, Corporate Controller and Treasurer from October 1999 to May 2005; Vice President Corporate Controller from August 1994 to October 1999; Vice President of Finance for Medtronic Europe from 1992 to 1994; and Assistant Corporate Controller from 1989 to 1992. As Medtronic's CFO, Defendant Ellis certified Medtronic's annual and quarterly reports filed with the SEC pursuant to the requirements of the Sarbanes-Oxley Act. Additionally, Defendant Ellis signed the Company's periodic reports on Forms 8-K filed with the SEC throughout the Class Period. Defendant Ellis is liable for materially incomplete, false and misleading statements issued during the Class Period, as set forth herein.

24. Defendants Collins, Hawkins and Ellis each had a duty to promptly disseminate accurate, complete and truthful information regarding the Company's business, operations, and financial condition. These Defendants also had a duty to correct any previously-issued statements that were or had become materially misleading or untrue so that the market price of Medtronic's common stock would be based upon truthful and accurate information.

25. Defendants Collins, Hawkins and Ellis are referred to collectively herein as the "Individual Defendants," and, together with Defendant Medtronic, are referred to herein as the "Defendants."

CLASS ACTION ALLEGATIONS

26. Lead Plaintiffs bring this action on their 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 otherwise acquired Medtronic common stock during the Class Period, from November 20, 2006 through November 17, 2008, and who were damaged thereby.

27. Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of each of the Individual 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.

28. The members of the Class, purchasers and acquirers of Medtronic common stock, are so numerous that joinder of all members is impracticable. As of November 28, 2008, the Company had 1,118,224,679 shares of common stock outstanding, and these shares were actively traded on the NYSE throughout the Class Period. While the exact number of Class members can only be determined by appropriate discovery, Lead Plaintiffs believe that Class members number in the thousands, if not higher. Record owners and other members of the Class may be identified from records maintained by Medtronic or its transfer agent, and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

29. Lead Plaintiffs' claims are typical of the claims of other members of the Class as all members of the Class are similarly affected by, and sustained damages as a result of, the Defendants' wrongful conduct in violation of the federal securities laws that are complained of herein.

30. Lead Plaintiffs will fairly and adequately protect the interests of the members of the Class and have retained court-appointed Lead Counsel competent and experienced in class and securities litigation. Lead Plaintiffs have no interests that are contrary to or in conflict with those of the members of the Class that Lead Plaintiffs seek to represent.

31. 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.

32. 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 and statements, 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 omissions complained of herein;

(d) with respect to Lead Plaintiffs' 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; and

(e) whether the members of the Class have sustained damages as a result of the misconduct complained of herein and, if so, the appropriate measure of damages thereof.

33. Lead Plaintiffs know of no difficulty that will be encountered in the management of this litigation that would preclude its maintenance as a class action.

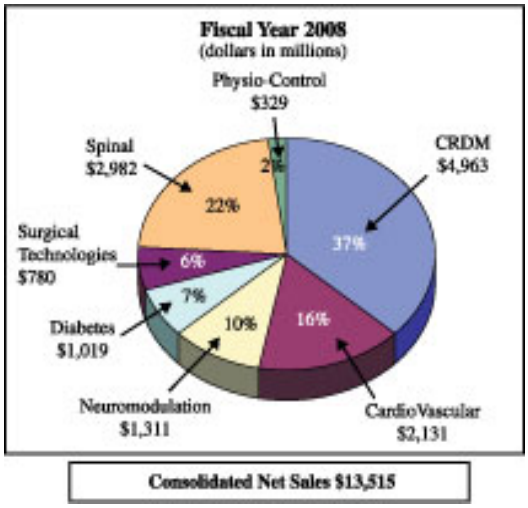
FACTUAL ALLEGATIONS

A. MEDTRONIC COMPANY BACKGROUND

34. Medtronic is a manufacturer of medical devices and describes itself in its filings with the SEC as the "global leader in medical technology." Medtronic conducts its business through seven operating segments: Spinal, Cardiac Rhythm Disease Management ("CRDM"), CardioVascular, Neuromodulation, Diabetes, Surgical Technologies, and Physio-Control.

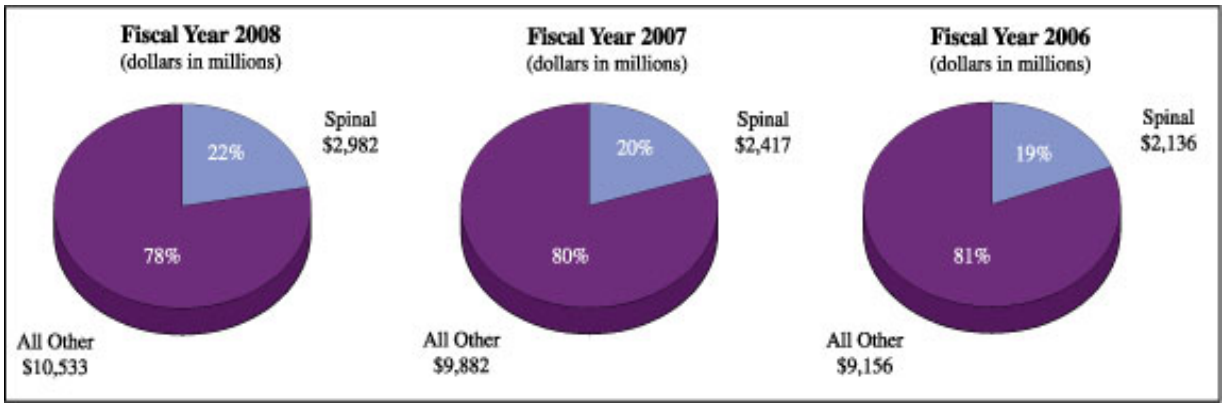
35. The Company describes its Spinal operating segment in its SEC filings as "a leading supplier for innovative medical devices and implants used in the treatment of the spine."

36. As reported in the Company's Annual Report for the fiscal year ended April 25, 2008, filed on Form 10-K with the SEC (the "2008 Form 10-K"), Medtronic's Spinal segment is highly material to the Company's overall operations, responsible for over one-fifth of Medtronic's overall net sales:



37. Indeed, as stated in a press release issued by *The Journal of the American Medical Association* ("JAMA") on June 30, 2009, "[b]ack pain continues to be a leading cause of disability in the United States and is one of the most common reasons for seeking evaluation by a physician, second only to the common cold." Similarly, Medtronic reported in its 2008 Form 10-K that: "Each year approximately 25 million Americans experience back pain that is severe enough to visit a healthcare professional. Of the approximately 25 million Americans, 13 million endure a significant impairment of activity."

38. Not only was the Spinal segment a material component of the Company's operations, but that segment experienced steady growth as a percentage of the Company's net sales from 2006-08, reported as follows in the Company's 2008 Form 10-K:



39. According to the Company's SEC filings, Medtronic's Spinal segment focuses on spinal instrumentation and stabilization devices—such as implantable screws and artificial discs—for use in connection with spinal surgeries and on biologic products, using recombinant DNA technology, used for spinal fusions (which join two or more vertebrate to eliminate pain caused by movement of unstable vertebrae). According to Medtronic's 2008 Form 10-K, spinal fusions are one of the most common types of spine surgery and the Company's biologics products have been a strong source of earnings growth for Medtronic.

40. Because of the importance of its biologics products, as part of its financial reporting, the Company separately reports its "Core" Spinal and "Biologics" Spinal results. Medtronic's Biologics Spinal results primarily consist of INFUSE Bone Graft sales, which have exceeded $3.6 billion since the launch of INFUSE Bone Graft in July 2002. As a J.P. Morgan research analyst covering Medtronic noted in a report dated November 12, 2008 (shortly before the end of the Class Period):

> InFuse is an $800M 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***. [Emphasis added.]

B. SPINAL FUSION SURGERY

41. Surgeons have for decades employed spinal fusion—a surgical technique in which one or more of the vertebrae of the spine are united together ("fused") so that motion no longer occurs between them—to treat a number of conditions, including treatment of a fractured vertebra, spinal deformities (spinal curves or slippages), back pain from instability, or abnormal or excessive movement between vertebrae. Similar to the concept of welding, spinal fusion surgery joins vertebrae together to eliminate or reduce movement between vertebrae through the use of bone grafts.

42. In a bone graft procedure, the graft—usually bone or bone-like material—is placed around the vertebrae during surgery. Over the following months, a physiological mechanism similar to that which occurs when a fractured bone heals causes the graft to join, or "weld," the vertebrae together. The goal of spinal fusion is to obtain a solid fusion of the vertebrae.

43. For years, autologous bone graft has been considered the "gold standard" in spinal fusion surgery. In an autologous bone graft, or "autograft," the surgeon procures bone graft material from another part of the patient's body, typically from the patient's pelvis or iliac crest, and implants the bone graft in the site where fusion is desired. As the harvested bone exhibits all the properties necessary for bone growth—including osteogenic, osteoconductive and osteoinductive properties—successful fusions occur at significantly higher rates in autograft procedures. However, autografts require additional surgery to extract the bone material needed for the graft. Along with increased costs and patient risks associated with additional surgery, patients undergoing an autologous bone graft often suffer from pain at the harvest site.

44. As an alternative to autograft, patients can undergo an allograft procedure, in which bone is taken from the cadavers of deceased people who have donated their bone to so-called "bone banks." Although healing and fusion is not as predictable as with the patient's own bone, an allograft eliminates the need for—as well as the pain and patient risk associated with—the harvest procedure required in an autograft. However, allografts are less likely to result in a successful fusion, and present a risk that the patient will suffer a negative immune response and reject the graft.

45. Consequently, studies revealing the ability for biologically manufactured protein to generate bone growth in laboratory animals represented a potential to provide a third surgical

option to traditional bone graft procedures. If fusion could be accomplished through the use of biologically manufactured proteins, patients could forego the harvest surgery required in an autograft, but could still benefit from the superior fusion rates associated with autograft procedures.

46. Attempting to seize on this potentially lucrative opportunity to develop an alternative spinal fusion procedure, Sofamor Danek Group, Inc., a Memphis, Tennessee-based spinal device maker ("Sofamor Danek"), acquired the exclusive rights to recombinant human bone morphogenetic protein-2 ("rhBMP-2") for spinal applications in February 1995. rhBMP-2 is a genetically engineered version of a naturally occurring protein that stimulates bone growth, developed as a commercially viable bone morphogenetic protein ("BMP") technology.

47. In October 1996, Sofamor Danek filed an application for an Investigational Device Exemption with the FDA to conduct a pilot study on the effects of rhBMP-2 in humans, marking the first step to obtaining approval to commercially market BMP.

48. In January 1999, Medtronic purchased Sofamor Danek for $3.6 billion. Thereafter, on July 2, 2002, the FDA approved INFUSE Bone Graft, a medical device containing an absorbable collagen sponge that is treated with rhBMP-2, for certain limited uses.

49. The FDA's limited use approval of INFUSE Bone Graft was based on concerns about potential adverse events that already had been reported with the product at the time of approval. As a result, the FDA approved INFUSE Bone Graft for a small percentage of overall spinal fusion surgeries, with the device label specifying the limited surgical application to be used.

C. FDA MEDICAL DEVICE APPROVAL REQUIREMENTS AND THE FDA'S LIMITED USE APPROVAL OF INFUSE BONE GRAFT FOR ANTERIOR LUMBAR INTERBODY FUSION

50. The current regulatory framework for medical device approval was established in the Medical Device Amendments of 1976 ("MDA") to the Federal Food, Drug, and Cosmetic Act of 1938 ("FDCA"). The MDA, passed in the wake of the health debacle surrounding women's safety issues resulting from the use of the Dalkon Shield intrauterine contraceptive device, contains a three-class classification system for medical devices: Class I devices pose the lowest risk to consumers' health, do not require FDA approval for marketing, and include devices such as tongue depressors; Class II devices pose intermediate risk and often include special controls including post-market surveillance and guidance documents; and Class III devices pose the greatest risk of death or complications and include most implantable surgical devices such as cardiac pacemakers, coronary artery stents, automated external defibrillators, and several types of implantable orthopedic devices for spine and hip surgery. INFUSE Bone Graft is a Class III device.

51. Manufacturers seeking to market Class III devices such as INFUSE Bone Graft are required to submit a Premarket Approval Application ("PMA") that must be evaluated and approved by the FDA. The PMA requires the manufacturer to demonstrate the product's safety and efficacy to the FDA through an exhaustive process that extensively analyzes clinical and other data, including: (1) technical data and information on the product, including non-clinical laboratory studies and clinical investigations; (2) non-clinical laboratory studies that provide information on microbiology, toxicology, immunology, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests of the device—all of which must be conducted in compliance with federal regulations which set forth, *inter alia*, criteria for researcher qualifications, facility standards and testing procedures; and (3) clinical investigations in which

study protocols, safety and effectiveness data, adverse reactions and complications, device failures and replacements, patient information, patient complaints, tabulations of data from all individual subjects, results of statistical analyses, and any other information from the clinical investigations are provided, including the results of any investigation conducted under an Investigational Device Exemption ("IDE").[1]

52. A PMA requires that all pertinent information about the device be articulated in the application and requires the manufacturer to specify the medical device's "intended use." This process is costly and time consuming. On average, the FDA spends 1,200 hours researching and investigating each submission, and, as in the case of the INFUSE Bone Graft, the approval process can take years.

53. In addition, each PMA submission must include copies of all proposed labeling for the device, which must comply with federal requirements. Specifically, the label must include the common name of the device, quantity of contents, and the name and address of the manufacturer, as well as any prescription use restrictions, information for use (including indications, effects, routes, methods, and frequency and duration of administration; and any relevant hazards, contraindications, side effects, and precautions), instructions for installation and operation, and any other information, literature, or advertising that constitutes "labeling" under the FDCA.

54. The indications for use required on the label are based on the nonclinical and clinical studies described in the PMA. Indications for use for a device include a general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended. Approval of

[1] An IDE allows for the limited use of not yet approved medical devices to enable the FDA to investigate their safety and effectiveness, a process the FDA stringently oversees. Products exempted through an IDE can only be used in approved clinical trials on patients who volunteer and give their informed consent to be treated with such devices.

the product's labeling is conditioned on the applicant incorporating any labeling changes exactly as directed by the FDA, and a copy of the final printed labeling must be submitted to the FDA before marketing.

55. In October 1996, Sofamor Danek submitted an IDE to the FDA to study the use of rhBMP-2 as applied to an absorbable collagen sponge ("ACS") inserted into an LT-CAGE interbody fusion device to treat patients with degenerative disc disease. Designed as a pilot study intended to support the initiation of a larger pivotal study, the IDE involved 14 patients—11 of which received spinal fusion procedures using the rhBMP-2/ACS/LT-CAGE device and 3 who received the LT-CAGE with autologous bone—and marked the first time rhBMP-2 was used in patients undergoing spinal fusion. In this initial clinical trial, all eleven patients who had been implanted with rhBMP-2 achieved successful fusion within six months from the time of surgery. Because these patients did not require bone grafting from the pelvis, their hospital stays were shorter and their post-surgical pain was less than typically seen with traditional bone grafting techniques.

56. Sofamor Danek used the results of the pilot study to petition the FDA to initiate a pivotal trial of rhBMP-2 with the LT-CAGE. This trial, which was approved by the FDA in July 1998, involved 135 investigational patients who had rhBMP-2 implanted in a single-level Anterior Lumbar Interbody Fusion (or ALIF) procedure and 135 control patients who underwent the same procedure except that autologous bone graft was applied instead of rhBMP-2.

57. Medtronic, after acquiring Sofamor Danek in 1999, filed the INFUSE Bone Graft PMA on January 12, 2001, and was granted expedited review status by the agency.

58. As presented in Medtronic's original PMA and eventually approved by the FDA in July 2002, the initially-approved INFUSE Bone Graft product consisted of two components:

1) the LT-CAGE® Lumbar Tapered Fusion Device Component, a thimble-sized hollow metal cylinder which keeps the two vertebrae in place and provides a frame that contains and directs the development of new bone growth; and 2) the INFUSE Bone Graft Component, which includes an ACS that acts as a carrier and scaffold for the active ingredient in INFUSE Bone Graft, and rhBMP-2, the actual active ingredient that is reconstituted in sterile water and applied to the ACS. Although these two components are sold separately, the initial approved labeling for the product indicates that the INFUSE Bone Graft must be used with the LT-CAGE component. The labeling also directs the specific manner in which both components are to be used in a fusion procedure.

59. Furthermore, according to the label sought by Medtronic in the PMA and subsequently approved by the FDA, INFUSE Bone Graft can only be used in an ALIF procedure, involving a single-level fusion in the L4-S1 region of the lumbar spine.[2] ALIF is performed by approaching the spine from the front through an incision in the abdomen and is primarily used to treat pain resulting from disc collapse.

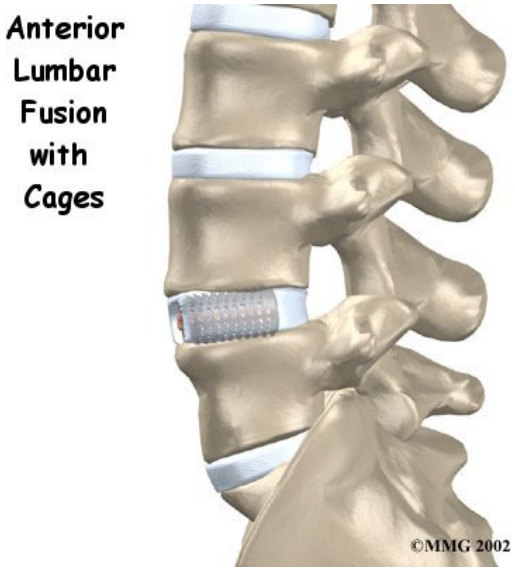
60. By contrast, Posterior Lumbar Interbody Fusion ("PLIF"), a procedure that is used to treat nerve compression and back pain resulting from a number of causes, involves approaching the spine from the back. PLIF, however, is a more sensitive surgical approach and procedure because the spinal canal and nerves are posterior to (behind) the vertebral body, and because a surgeon must manipulate the dural sac (the membranous sac that encases the spinal cord within the vertebral column) to perform the PLIF procedure. The sensitive nature of this

[2] While the product's label remains substantially the same as that approved by the FDA in 2002, the FDA has made minor amendments to the label through post-approval supplements. For example, on July 29, 2004, the FDA approved a supplement expanding the indicated spinal region from L4-S1 to L2-S1. As explained below, while INFUSE Bone Graft also has been approved for treatment of certain tibial fractures and certain oral maxillofacial uses, these uses represent a relatively minor percentage of the product's overall sales.

surgery has led to increased rates of observed neurological injury, which has resulted in this procedure becoming less preferred among spine surgeons.

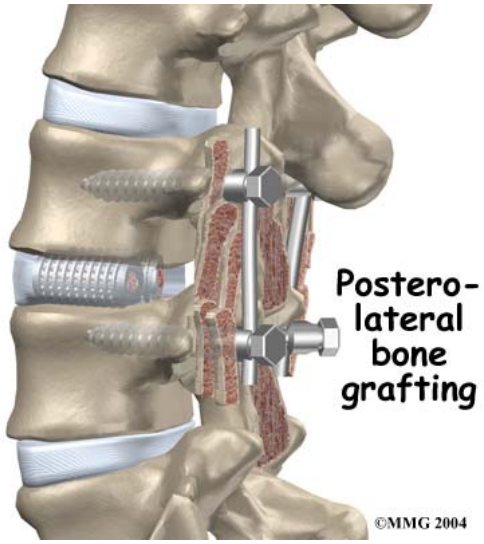
61. Consequently, two other procedures have become more commonplace. The first, Posterolateral Fusion, is similar to the PLIF procedure, but instead of removing the disc space and replacing it with a bone graft, the disc space remains intact and the bone graft is placed between the transverse processes in the back of the spine. This allows the bone to heal and stabilizes the spine by fusing the transverse process of one vertebra to the transverse process of the next vertebra. The second commonplace procedure, Transforaminal Lumbar Interbody Fusion ("TLIF"), is also similar to the PLIF procedure, and is the preferred technique when an interbody fusion is performed via a posterior approach. TLIF is preferred by spine surgeons because it allows the surgeon to perform a fusion from a posterior approach without disturbing the dural sac by approaching the spine via a more lateral, or sideways, approach. The difference between these procedures is demonstrated in the diagrams below:

Anterior Lumbar Interbody Fusion[3]

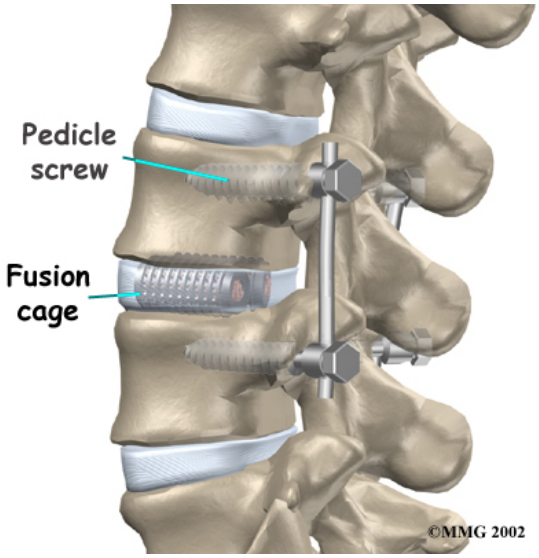


[3] *Source:* http://www.eorthopod.com/images/ContentImages/spine/spine_lumbar/fusion_cages/lumbar_fusion_cage_intro01.jpg

Posterolateral Fusion[4]



Posterior Lumbar Interbody Fusion[5]



62. Not only was the application of INFUSE Bone Graft with the LT-CAGE in an ALIF single-level fusion the only procedure and indication used in the pivotal study that formed the basis of Medtronic's PMA submission, but the use of rhBMP-2 in other applications revealed

[4] *Source:* http://www.eorthopod.com/images/ContentImages/spine/spine_lumbar/lumbar_PLIF/lumbar_PLIF_rationale04a.jpg

[5] *Source:* http://www.eorthopod.com/images/ContentImages/spine/spine_lumbar/fusion_cages/lumbar_fusion_cage_surgery03.jpg

instances of adverse events. In particular, a Medtronic-sponsored trial examining the application of rhBMP-2 using the PLIF procedure was halted in December 1999 when heterotopic bone growth—defined as any bone growth that occurs in areas of the body where such growth is not desired—developed in a number of patients. A doctor who participated in the study reported that one of the patients he treated required two extra surgeries to clear the excessive bone growth from the spinal canal. The complications observed in the PLIF trial were particularly serious given the potential of neural impingement (or nerve pinching) from such bony overgrowth in that procedure, potentially triggering the very sort of pain that a fusion procedure attempts to eliminate.

63. Complications such as those noted in the PLIF trial result from INFUSE Bone Graft's very mechanism of action. As previously discussed, INFUSE Bone Graft is effective in fusion surgeries because rhBMP-2 actually stimulates the growth of new bone. But adverse events can result when the rhBMP-2 leaks out of the area in which bone growth is desired or when too much rhBMP-2 is used. In such cases, INFUSE Bone Graft can stimulate bone growth where new bone is not desired or can lead to excessive bone growth in the target area, which is often associated with other complications, such as swelling. Such unintended bone growth and swelling can be especially problematic in spinal surgeries because of the sensitive areas in which INFUSE Bone Graft is used—i.e., near the spinal cord. One of the reasons these complications are thought to occur is because the medical community does not yet fully understand the proper dosages of rhBMP-2 to use in different procedures or the expected responses to the protein in different biological environments (i.e., the neck areas, etc.). Indeed, many adverse events associated with the use of INFUSE Bone Graft result from off-label use of the product by surgeons who do not fully understand the powerful nature of this protein.

64. At the FDA Advisory Committee panel hearing on January 10, 2002 concerning FDA approval of Medtronic's INFUSE Bone Graft, the panel members stressed concerns regarding potential off-label use of the product and asked Medtronic presenters repeated questions about how the Company would seek to guard against off-label applications of the product.

65. Referencing the pedicle screw cases of the mid-1990s, in which thousands of injured patients alleged the screws' manufacturer fraudulently manipulated the FDA's Class III approval process, panel member Dr. John Kirkpatrick asked, "in light of the history of the pedicle screw issue and the off-label use there and resulting litigation, how would you guard against off-label use of this product especially with rhBMP-2?" Likewise, another panel member, Dr. Edward Hanley, framed the central issue to be addressed by the FDA Advisory Panel as the proper limits on the use of the device: "I think the issue here at the table today is mainly one of labeling, indications for use, trying to put in the proper perspective for—if approved for people utilizing a device, how best it can be controlled and doing some appropriate follow-ups on it."

66. Later in the hearing, Dr. Hanley again probed a Medtronic representative, Dr. Scott Boden, regarding the potential danger posed by an off-label application: "We have one question and that relates to one of those letters that was read earlier about putting the BMP adjacent to the nerve for a posterior approach. It doesn't relate to the indication being sought for here but any comments from people on that?" Dr. Boden, a paid Medtronic consultant who, according to a whistleblower lawsuit described below, has allegedly received hundreds of thousands of dollars in consulting agreements in the period from 2004 through 2007, dismissed the suggestion. He stated that because "this specific application before the panel today is

through an anterior approach," Dr. Hanley's question, which was related to a different surgical approach, "seems to me to be outside the scope of what we ought to be focusing on today."

67. At the conclusion of the hearing, the FDA Advisory Panel again reiterated concerns regarding the potential for off-label use, specifically admonishing the Company to guard against procedures other than the specific ALIF procedure provided in the labeled application. Dr. Kirkpatrick noted his concern that procedures other than ALIF—especially the PLIF procedure—could result in harm to patients. According to Dr. Kirkpatrick, the use of the ***tapered*** LT-CAGE—which is difficult to implant in a posterior approach—would, if required, "prevent a majority of surgeons from applying this from a Posterior Lumbar Interbody Fusion perspective."

68. In other words, even at the time of its FDA approval, Medtronic and its senior management, including the Individual Defendants named herein, were well aware of the concern regarding off-label uses of INFUSE Bone Graft and the potential dangers posed by them.

69. Subsequent medical studies confirmed the fears of the FDA Advisory Panel that use of INFUSE Bone Graft outside of the studied application sought in the PMA could present severe risks to patient safety. Although the adverse outcomes reported in medical journals and other sources were known to Defendants, the dangers posed by the increasing off-label use of INFUSE Bone Graft and their impact on the sustainability of the valuable revenue stream generated by off-label sales of the product were concealed by Defendants throughout the Class Period.

70. In fact, numerous medical studies published since the introduction of INFUSE Bone Graft have shown that its use in procedures not approved by the FDA can lead to potentially serious, and even deadly, adverse events, particularly in the cervical spine. A May

15, 2006 medical article in *Spine* entitled "Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic Protein-Stimulated Bone Growth Using Fibrin Glue" observed that these complications often result from the product's mechanism of action. As the authors stated, "rhBMP-2 may stimulate bone growth in areas in which bone is not desired, especially as the material 'leaks' into such spaces. . . . Although this phenomenon has not been thoroughly studied, it implies that the release of rhBMP-2 into the soft tissues stimulates a rapid, potentially life-threatening, inflammatory reaction." Such an "inflammatory reaction," or swelling, is particularly problematic considering that INFUSE Bone Graft is primarily used in the spine, and often in the very sensitive cervical spine region.

71. Other medical studies have addressed adverse events from off-label use of INFUSE Bone Graft in more detail. An article published in *Spine* on November 15, 2006 titled "Increased Swelling Complications Associated with Off-Label Usage of rhBMP-2 in the Anterior Cervical Spine" noted a significantly greater risk of swelling from off-label use of INFUSE Bone Graft in cervical spine fusions than in surgeries where more traditional techniques and devices were used. Of the 234 patients studied, 27.5% of those patients treated with INFUSE Bone Graft had significant swelling after the surgery, while only 3.6% of those patients not treated with INFUSE Bone Graft had similar complications. After further analyzing their data and controlling for other factors that could have affected the likelihood of swelling, the authors determined that "patients receiving rhBMP-2 were 10.1 times more likely to have a swelling complication *versus* those who did not receive rhBMP-2."

72. An article published in the *European Spine Journal* in August 2007 titled "Complications of anterior cervical discectomy and fusion using recombinant human bone morphogenetic protein-2" found that use of INFUSE Bone Graft in certain cervical spine fusions

led to a statistically significant increase in the number of complications, including dysphagia (difficulty in swallowing) and swelling in the neck area. The authors determined that "[d]ysphagia was a common complication and it was significantly more frequent and more severe in patients in whom rhBMP-2 was used. Post operative swelling . . . was significantly larger in the rhBMP-2 group." Of the patients the authors evaluated, 85% of those treated with INFUSE Bone Graft reported difficulty swallowing after the surgery, and this complication was more severe and persistent than in those who were not treated with INFUSE Bone Graft; in fact, one of the patients evaluated required a feeding tube for six weeks after the surgery as a result of the complication.

73. A September 2008 article in *The Spine Journal* titled "Complications of BMP Use in Cervical Spine Surgery" found similar results, observing that the use of INFUSE Bone Graft in the cervical spine "has been associated with reports of serious [] adverse events. Postoperative hematoma formation [a collection of blood outside the blood vessels, generally manifesting as bruises], prevertebral soft tissue swelling, [and] swallowing difficulty . . . are a few examples." Of the complications the authors observed in their patient study group, 17% occurred in patients treated with traditional techniques, while 83% were in patients treated off-label with INFUSE Bone Graft. The authors concluded that the "cervical spine has proven much less forgiving with the institution of rhBMP2 use. Complications induced by . . . rhBMP-2 were clearly evident in our review."

74. Although these articles illustrate the types of adverse events that can occur as a result of off-label use of INFUSE Bone Graft, a March 2007 individual patient case study in *The Spine Journal* highlights the severity of such complications. The article, titled "Adverse swelling associated with use of rh-BMP-2 in anterior cervical discectomy and fusion: a case

study," describes the severe complications that resulted from one patient's off-label treatment with INFUSE Bone Graft. Five days after doctors implanted INFUSE Bone Graft in a cervical spine fusion surgery, the patient went to the emergency room because of serious swelling of the neck and difficulty swallowing. The emergency room physicians noted "massive neck swelling" and that "[t]he diameter of the tracheal opening was remarkably narrowed." The swelling was so severe that the patient was "urgently" brought to the operating room, where surgeons had to put in a breathing tube and reopen the patient's neck for examination. The patient remained on a ventilator for twenty-four hours, and was only discharged after a four-day hospital stay.

75. Also illustrating the severity of the potential complications from off-label use of INFUSE Bone Graft is the case of Shirley Nisbet, discussed *infra* at ¶¶ 111–12, who lapsed into a vegetative state and later died as a result of severe neck swelling following a cervical spine fusion in which surgeons used INFUSE Bone Graft.

76. Notwithstanding these reports and the FDA Advisory Panel's earlier concerns, as set forth below, throughout the Class Period, Medtronic's senior management concealed the Company's surreptitious effort to promote the widespread off-label use of INFUSE Bone Graft. Medtronic provided millions of dollars in undisclosed payments to doctors (including so-called "Key Opinion Leaders") who published articles in medical journals, delivered presentations at continuing medical education courses, and appeared at consulting engagements addressing off-label applications of INFUSE Bone Graft, including in the cervical spine. In turn, as demonstrated by the numerous confidential witnesses described below, Medtronic's sales force would direct other doctors to these consultants and Key Opinion Leaders or their written work to further drive off-label sales of the INFUSE Bone Graft. Moreover, Defendants engaged in such conduct throughout the Class Period, notwithstanding that Medtronic had just agreed to settle a

whistleblower action with the DOJ shortly prior to the start of the Class Period and specifically represented in connection with that settlement that it would engage in stricter compliance with regulatory requirements regarding the sale and marketing of its devices.

77. At no time prior to the end of the Class Period did Defendants quantify either the amount of INFUSE Bone Graft sales for off-label applications or the amount Medtronic continued to pay surgeons as "consultants" or "Key Opinion Leaders," including those who primarily promoted off-label use of INFUSE Bone Graft. As a result of this undisclosed conduct, the consistent quarter-after-quarter INFUSE Bone Graft sales figures reported by Defendants and the statements they made regarding those sales materially misled investors regarding the true facts and risks known to Defendants at all relevant times: ***that INFUSE Bone Graft sales were primarily dependent on higher risk off-label applications of a product that was marketed through means that invited, and eventually brought about, the scrutiny of federal regulators and led to an abrupt decline in sales***.

D. MEDTRONIC SETTLES WHISTLEBLOWER LITIGATION WITH THE DOJ AND AGREES TO ENTER INTO A CORPORATE INTEGRITY AGREEMENT SHORTLY BEFORE THE START OF THE CLASS PERIOD

78. On July 18, 2006, Medtronic announced that it had entered into a settlement with the DOJ and agreed to pay $40 million to resolve two whistleblower lawsuits that alleged that the Company's Spinal division had engaged in illegal marketing and sales practices, including the payment of improper consulting fees to doctors to promote its Spinal products.

79. According to the DOJ's press release accompanying the settlement, Medtronic's Spinal division paid unlawful and improper kickbacks to doctors in a number of forms, including consulting agreements, royalty agreements and lavish trips to desirable locations between 1998 and 2003, to induce surgeons to use the Company's Spinal products.

80. The DOJ settlement attempted to resolve two separate whistleblower lawsuits brought by former employees of the Company. The two whistleblower suits, one filed in 2002, *United States ex rel. [UNDER SEAL] v. Medtronic, Inc.*, Civil Action No. 02-2709, and another in 2003, *United States ex rel. Poteet v. Zdeblick*, Civil Action No. 03-2979 ("*Poteet I*"), in the U.S. District Court for the Western District of Tennessee, alleged that sales and marketing practices at Medtronic's acquired Spinal business segment violated the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), *et seq.*, which prohibits individuals from offering, soliciting or making any payment or remuneration to induce business reimbursed under a federal or state health care program, and the False Claims Act, 31 U.S.C. § 3729, *et seq.*, which provides penalties for the submission of false claims to the federal government.[6]

81. Both lawsuits were filed under seal pursuant to provisions in the False Claims Act that permit individuals to file whistleblower lawsuits—or *qui tam* actions—on behalf of the government and to share in any recovery. The DOJ joined in the first lawsuit, but declined to intervene in the second action under the first-to-file and previous disclosure provisions of the False Claims Act.

82. Brought by a former Medtronic in-house counsel, the first whistleblower suit alleged that Medtronic's "aggressive and illegal" sales and marketing efforts were intended to and did serve the goal of improperly inducing doctors to use Medtronic's Spinal products. The conduct alleged included, *inter alia*: (1) lucrative consulting and royalty agreements with physicians that used Medtronic Spinal products, "the true purpose [of which were] to funnel money to the physicians so that they will be induced to use [Medtronic Spinal] products;" and (2) "[l]avish all expense paid trips to fine resorts . . . disguised as Medical Education seminars, think

[6] Medtronic had been sued previously by a former Regional Sales Manager who claimed that he was wrongfully terminated after he had refused to comply with his supervisors' directives to pay illegal kickbacks and bribes to Medtronic's physician customers in exchange for their business.

tanks, or discussion groups . . . held in places such as Hawaii, Cancun, Alaska, Beaver Creek, Whistler, Malaysia, Amelia Island, Teton Valley, and New Orleans at Mardi Gras . . . [t]he purpose of these lavish trips was to induce the physicians to use [Medtronic Spinal] products." The complaint further alleged that: "Most of the illegal kickback practices described herein were begun by Sofamor Danek and continued by [Medtronic] after the acquisition. Kickbacks were the culture and way of doing business at Sofamor Danek and the company was determined to continue that culture, and did continue that culture, when Sofamor Danek became part of the Medtronic empire."

83. The *Poteet I* complaint, which was brought by a former Medtronic employee who helped arrange travel (including expense reimbursement) for numerous spinal surgeons to attend Company-sponsored events and other professional meetings, also alleged that Medtronic paid surgeons substantial fees—sometimes up to hundreds of thousands of dollars per year—for consulting services that were grossly in excess of their fair market value, entered into royalty agreements that were designed to disguise illegal remuneration, and provided doctors opportunities for lavish travel and recreational activities, including "upgraded lodging for physicians, dinners, entertainment and activities such as golf, snorkeling, sailing, fishing, shopping trips, [and] horse-back riding" for using Medtronic products. According to the *Poteet I* complaint, the consulting agreements and other payments were illegitimate means of inducing physicians to use Medtronic products and to recommend to other physicians that they do the same.

84. As part of the DOJ settlement, Medtronic agreed to enter into a five-year Corporate Integrity Agreement ("CIA") with the Office of the Inspector General/Health and Human Services that, as Medtronic described in its July 18, 2006 press release, implemented

substantial oversight structures and procedures meant to ensure "top-level attention to corporate compliance measures." Among other things, the CIA required Medtronic to establish an electronic database to capture and manage all non-sales related transactions between Medtronic's Spinal segment and its physicians or customers, with all such transactions subject to an established set of internal controls and review processes, including monitoring by Medtronic senior management and the Company's Chief Compliance Officer.

85. In addition, in the CIA, Medtronic made several representations regarding the procedures and policies to be adopted by the Company to ensure stricter regulatory compliance and the agreement obligated Medtronic to institute a number of changes to improve oversight of its Spinal division. Perhaps most significantly, the CIA required the Company to adopt procedures to ensure that any "arrangements"—a term intended to cover doctor consulting agreements and broadly defined as engagements involving "directly or indirectly, the offer, payment, solicitation, or receipt of anything of value; [] between [Medtronic] and any actual or potential source of health care business [e.g., doctors]"—would not violate federal law. Such procedures were to include, among other things: (1) creating a database of all existing and new or renewed arrangements; (2) tracking remuneration from Medtronic to all other parties to such arrangements; (3) tracking service and activity logs to ensure that parties to an arrangement are performing their duties under the applicable arrangement; (4) implementing procedures that ensure all arrangements are reviewed for adherence to the Anti-Kickback Statute; and (5) regular (at least quarterly) review by the Medtronic Compliance Officer of the arrangements database along with reporting (at least quarterly) to the Medtronic Compliance Committee.

86. Although the CIA, which was signed and executed by Medtronic on July 14, 2006, did not become effective until after the dismissal of the two whistleblower actions, the

CIA and the previous whistleblower and wrongful termination litigation placed Medtronic and all Individual Defendants on actual notice, before the start of the Class Period, of the material risk of continuing with the lucrative consulting agreements that Medtronic previously used to promote use of its Spinal products. Indeed, the Medtronic analyst from ThinkEquity Partners LLC observed in a June 8, 2006 report that the whistleblower lawsuits would result in Medtronic curtailing its use of consulting agreements in the future, specifically noting: "[w]e understand that Medtronic is exercising extreme caution with all physician agreements going forward and we do not anticipate this becoming an ongoing issue." Nonetheless, undisclosed to investors, these financial arrangements continued as did the Company's aggressive efforts to drive INFUSE Bone Graft sales, primarily for off-label applications, leading to both FDA and DOJ action, which had an immediate adverse impact on INFUSE Bone Graft sales and Medtronic's financial performance at the end of the Class Period as set forth below.

E. UNDISCLOSED TO INVESTORS, DEFENDANTS CONTINUED THEIR LUCRATIVE CONSULTING ARRANGEMENTS THROUGHOUT THE CLASS PERIOD TO PROMOTE HIGHER RISK OFF-LABEL USE OF INFUSE BONE GRAFT, CREATING THE MATERIAL RISK OF FURTHER ADVERSE REGULATORY ACTION

87. Notwithstanding the fact that Medtronic had agreed to settle allegations relating to nearly identical conduct with the DOJ on July 14, 2006, Lead Counsel's investigation has revealed that Defendants determined to continue their aggressive and surreptitious off-label promotion of INFUSE Bone Graft throughout the Class Period through the very practices that led to the initiation of the whistleblower litigation and the DOJ settlement. Moreover, Defendants were strongly motivated to do so because they knew that unless INFUSE Bone Graft continued to be used in growing numbers off-label, its sales—which were primarily driven by and dependent upon off-label use—would decline dramatically. Thus, as set forth herein, undisclosed to investors, the lucrative "consulting" arrangements continued after the July 18,

2006 DOJ settlement announcement, off-label INFUSE Bone Graft use increased, and Defendants, while reporting growing INFUSE Bone Graft sales throughout the Class Period, failed to disclose the material risk of another adverse regulatory response from either the FDA or DOJ, or as, in fact happened in this case, ***both***.

88. As set forth above, INFUSE Bone Graft was approved by the FDA for very limited surgical applications. Acknowledging these limited on-label indications, the Medtronic analyst from BernsteinResearch noted in a report issued November 21, 2006, the day after the start of the Class Period, that analysts were "expecting ***continued indication expansion (e.g., recent dental approval and likely approval for posterior lateral fusion) for InFuse to be the main driver for the spinal business*** in the mid-term." (Emphasis added.) What this analyst and the investor community in general did not know was that, despite the limited FDA-approved applications of INFUSE Bone Graft, Defendants had been continuing to drive sales from off-label indications notwithstanding the CIA and the material risk of further regulatory action. As a result of Defendants' undisclosed misconduct, the percentage of off-label INFUSE Bone Graft usage increased over time, including after the DOJ settlement on July 14, 2006.

89. Although the FDCA specifically provides that the FDA has no authority to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed [medical] device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship,"[7] and physicians are free to prescribe or use medical devices in any manner they deem medically appropriate, device and drug manufacturers such as Medtronic cannot actively promote products for uses not approved by the FDA. Indeed, federal law provides for significant penalties for manufacturers that promote their products in ways

[7] 21 U.S.C. § 396.

inconsistent with a product's labeling. Severe penalties for off-label promotion (which, in some cases, can result in fines of up to twice the amount of the gross pecuniary gain from the offense) were designed to ensure that the FDA's careful, deliberate consideration of product's suitability for public consumption is not undermined by manufacturers seeking to circumvent that process.

90. Under the FDCA, device manufacturers can be held liable for off-label promotion when their products are deemed "misbranded" under the statute. A product is "misbranded" when the directions and indications for the unapproved uses that the manufacturer "intends" the product to be used for have not been included on the label. Further, a device's intended uses are evidenced by the manufacturers' conduct, not by reference to what the FDA has approved.

91. A product's intended uses can be derived from oral statements by persons speaking on behalf of a company about its product. In other words, a manufacturer is potentially liable under the statute if its aim is to have its products used in a manner inconsistent with or outside the scope of the approved label. The company's conduct and all other relevant facts and circumstances exhibiting an intent to sell its products inconsistent with or outside the scope of the FDA-approved label are examined in determining whether the manufacturer has violated federal law. Although manufacturers have recently become increasingly sophisticated and creative in devising means of off-label promotion that are harder to detect by regulators, the costs to companies guilty of such practices can be enormous. Indeed, Pfizer, Inc. and Eli Lilly & Company alone agreed to pay a combined $3.7 billion to resolve allegations of illegal off-label marketing earlier this year.

92. Any application of INFUSE Bone Graft outside of its FDA approved usage is considered off-label. Examples of off-label uses of the INFUSE Bone Graft include: when the rhBMP-2 is applied without using the LT-CAGE or with a substitute cage; use of INFUSE Bone

Graft in a PLIF, a Posterolateral Fusion, TLIF or any other procedure besides an ALIF using the LT-CAGE; use of INFUSE Bone Graft in an ALIF procedure that involves a multiple-level fusion; or any use of INFUSE Bone Graft in the cervical spine. Nonetheless, numerous former Medtronic employees report that the Company actively promoted off-label use of INFUSE Bone Graft by providing doctors with information about other doctors using the product off-label (including those "Key Opinion Leaders" targeted and paid by the Company as "consultants") and by having Medtronic sales force personnel in the hospital operating rooms at the time of the off-label surgeries to provide doctors with information and instruction during the actual surgeries. These former employees worked on behalf of Medtronic in regions across the United States, demonstrating that these practices were widespread throughout the Company, rather than isolated to particular areas. The Medtronic former employees have provided information in confidence, therefore these confidential witnesses will be identified herein by number (e.g., CW 1, CW 2, etc.) and job description, consistent with legal precedent.

93. According to CW 1, who was employed by Medtronic as a territory sales manager in the Southeast United States from 2002 through 2005 and who specifically promoted sales of the INFUSE Bone Graft product during CW 1's tenure with the Company, Medtronic "absolutely" promoted off-label use of INFUSE Bone Graft in a number of ways, including through Medtronic-sponsored physician meetings. CW 1 explained that Medtronic would set up a breakfast meeting or dinner in a particular area of the country and then have a number of local physicians attend for a presentation on off-label use of the product by a Medtronic-paid consultant or "Key Opinion Leader," or "KOL," who was a surgeon selected by the Company. According to CW 1, these consultants included surgeons from the Leatherman Clinic, formerly known as the Leatherman Spine Center in Louisville, Kentucky. CW 1 stated that Medtronic's

local sales representatives would also attend such meetings. CW 1 stated that Medtronic expected KOLs to use the Company's products exclusively, write articles and to give talks at such meetings to train other doctors. According to CW 1, another way Medtronic promoted off-label use of INFUSE Bone Graft was by bringing surgeons to Memphis for a "corporate visit" that included off-label training by guest surgeons or KOLs.

94. CW 1 also reported that Medtronic held regional and national sales team meetings during which Medtronic sales representatives received oral instruction on various off-label uses of INFUSE Bone Graft including with regard to how much (or little) rhBMP-2 to use with off-label cervical fusions, so that when doctors questioned sales representatives, they could tell them why and how to use the product off-label. According to CW 1, Medtronic shared this information with the sales representatives orally and there were no marketing documents created by Medtronic for this purpose. Instead, according to CW 1, Medtronic sales representatives were expected to pass on the information they received to doctors orally, without marketing documentation.

95. CW 1 further stated that the Company also expected its sales representatives to be present in the operating room during procedures with INFUSE Bone Graft "to assist and direct and give advice when asked." CW 1 also reported that Medtronic created sales quotas for INFUSE Bone Graft that were much higher than could possibly be reached with only FDA-approved indications of the product and that "there was no way" that Medtronic executives could have expected the sales quotas to be met without off-label sales.

96. According to CW 2, who was employed by Medtronic as a product manager for Medtronic's Biologics Marketing Department from 2005 to 2008 and specifically promoted sales of INFUSE Bone Graft during CW 2's tenure with the Company, when doctors inquired about

off-label use of INFUSE Bone Graft, Medtronic sales representatives cited data from published literature and provided doctors with information regarding techniques for off-label procedures. CW 2 reported that posterior lumbar application of INFUSE Bone Graft was a more common procedure than FDA-approved ALIF surgery (which was considered by physicians to be an older surgical approach) and that Medtronic sales representatives would share medical literature with doctors regarding that off-label use.

97. CW 2 stated that in 2006, doctors continued reporting adverse events concerning off-label use of INFUSE Bone Graft in the cervical spine, including swelling, dysphagia and dysphonia. According to CW 2, Medtronic sought to address this issue by informing surgeons who used INFUSE Bone Graft that smaller doses of rhBMP-2 should be used in the cervical spine (an off-label use of the device). CW 2 reported that "our goal was to tell surgeons, don't put 2.8 on, put 1.4 or 0.7 [in off-label cervical applications]." CW 2 further noted that INFUSE Bone Graft kits are now available in these smaller sizes (although the FDA-approved uses remain the same). CW 2 also reported that Medtronic sales representatives were present in the operating room during surgical procedures with INFUSE Bone Graft and would instruct surgeons on INFUSE Bone Graft procedures.

98. CW 2 stated that INFUSE Bone Graft sales accounted for approximately three-quarters of a billion dollars of Medtronic sales by the time CW 2 left the Company and that such sales were primarily dependent on off-label uses that accounted for the vast majority of total sales. One way in which CW 2 and his/her peers were able to estimate the high off-label use of INFUSE Bone Graft was by comparing sales of the rhBMP-2 component with sales of the LT-CAGE, which were packaged and sold separately. Although these components must be used together according to INFUSE Bone Graft's FDA-approved label, sales of the rhBMP-2

component greatly outpaced those of the LT-CAGE component. CW 2 also confirmed that the Company set very high sales targets with sales expected to grow 15-20% year-over year and that Medtronic's Spine (and mainly) Biologics division was considered "one of the big growth engines of Medtronic." CW 2 further reported that 95% of INFUSE Bone Graft revenues related to spinal usage (cervical and lumbar) with only 5% for trauma and oral maxillofacial applications.

99. According to CW 3, who was employed by Medtronic as a Biologics sales representative in the Mid-Atlantic United States from the end of 2005 through 2008 and specifically promoted sales of the INFUSE Bone Graft product during CW 3's tenure with the Company, off-label use of INFUSE Bone Graft was necessary to meet sales quotas and at least 20% annual sales growth expected by the Company. CW 3 further stated that if a doctor asked how to use INFUSE Bone Graft off-label, a Medtronic sales representative would direct the doctor to other surgeons who used the product off-label and also would demonstrate or explain how to do so. CW 3 stated, for example, that if a doctor was going to use INFUSE Bone Graft in the lateral gutter (the area of the spine adjacent to the lateral, or side, edge of the dural sac), a Medtronic sales representative would show the doctor how to place the rhBMP-2 material and roll the ACS sponge up "like a burrito" to place into the lateral spine. According to CW 3, a Medtronic sales representative would be in the operating room to show the doctor how to assemble the sponge or to explain other procedures. CW 3 also stated that Medtronic held quarterly meetings in CW 3's sales region and that, periodically, a national Biologics specialist attended the quarterly meetings to explain how to conduct off-label applications of INFUSE Bone Graft. CW 3 further stated that INFUSE Bone Graft was "tremendous" to Medtronic's overall sales growth.

100. According to CW 4, who was employed by Medtronic as a Spinal sales representative in the Northeast United States from 2002 until 2006 and specifically promoted sales of INFUSE Bone Graft during CW 4's tenure with the Company, at Medtronic national sales meetings, the Company would have a surgeon speak to a group of doctors regarding a specific off-label use of INFUSE Bone Graft. CW 4 confirmed that Medtronic sales representatives advised doctors to use roughly half the indicated dosage of rhBMP-2 (or 1.4 cc) in cervical applications. CW 4 also confirmed that Medtronic was aware of swelling in the neck caused by cervical applications of INFUSE Bone Graft and Medtronic sales representatives were told by Medtronic's Product Manager to inform surgeons to use steroids to treat swelling resulting from off-label use of INFUSE Bone Graft in the cervical spine. CW 4 reported that Medtronic sales representatives were instructed to inform surgeons about how other surgeons had used INFUSE Bone Graft successfully off-label and were commonly in the operating room during surgical procedures involving INFUSE Bone Graft. CW 4 reported that when surgeons first began to use INFUSE Bone Graft in cervical fusion surgery they were not aware of the potential adverse consequences of using an entire sponge (or full rhBMP-2 dosage) in the cervical spine, but after Medtronic's national sales meetings, word would spread throughout the medical community regarding how to use INFUSE Bone Graft in the cervical spine although the product was only FDA-approved for lumbar anterior fusion. CW 4 further reported that Medtronic increased sales commissions for selling INFUSE Bone Graft after a salesperson reached his or her sales quota for the product, thereby providing an incentive to promote the product for off-label usage.

101. According to CW 5, who was employed by Medtronic as an associate sales representative in various regions of the country—including the South, Southwest, and

Midwest—from 2005 until 2006 and specifically promoted sales of the INFUSE Bone Graft product during CW 5's tenure with the Company, when doctors inquired about off-label use of INFUSE Bone Graft, Medtronic sales representatives were expected to state whether the off-label use in question was successful in prior surgeries and explain how other doctors used the product off-label. In addition, CW 5 stated that it was common practice for Medtronic sales force representatives to be present in the operating room for surgeries with INFUSE Bone Graft and that sales force representatives were encouraged by Medtronic to attend such surgeries. CW 5 stated that Medtronic's sales representatives would participate in the surgeries by giving surgeons step-by-step instructions on the required procedures, even when the product was being used off-label. Moreover, CW 5 reported that off-label use of INFUSE Bone Graft was far more common than "on-label" use of the product, which was "few and far between." CW 5 further reported that when adverse reactions were being reported with cervical applications of INFUSE Bone Graft in the first part of 2006, Medtronic organized a conference call with its sales representatives to instruct them that surgeons should not be using the "whole sponge" (or full rhBMP-2 dosage) in cervical fusion surgery, which was an off-label, non-FDA approved use of INFUSE Bone Graft.

102. According to CW 6, who was employed by Medtronic from 2000 through 2007 including as a clinical data director and involved with promotion of INFUSE Bone Graft, if a doctor was interested in off-label use of the product, Medtronic employees would direct the physician to other surgeons doing that work. CW 6 confirmed that it was standard practice at Medtronic for a sales representative to be present in the operating room during procedures to assist with any issues that might come up with the product. CW 6 further reported that with regard to off-label cervical applications of the product, the then-packaged dosage of rhBMP-2

was far too large for the cervical spine and Medtronic's marketing department advised doctors using the product in the cervical spine that they would have to throw away a big portion or half of the rhBMP-2 dosage and that "more is not better" in the cervical spine.

103. According to CW 7, who was employed by Medtronic as a Spinal sales representative in the Northwest United States from 1998 until 2003 and specifically promoted sales of the INFUSE Bone Graft product during CW 7's tenure with the Company, when CW 7 was at the Company CW 7 received a small booklet the size of an address book that was about five pages long and contained information regarding the volume or dosage of rhBMP-2 that should be used for off-label applications of INFUSE Bone Graft. CW 7 knows the book was prepared by Medtronic because CW 7 received it from the Company, but stated that Medtronic's name could not be found anywhere in the book. CW 7 stated that if a doctor inquired about off-label use of the product, Medtronic employees would state what they know about other surgeons using the product off-label. CW 7 further stated that during CW 7's tenure with the Company INFUSE Bone Graft kits were too large to fully use in the cervical spine and that today Medtronic markets smaller sizes of INFUSE Bone Graft and that doing so does not make sense if the product is intended to be limited to FDA-approved usage.

104. CW 8, who was employed by Medtronic as a sales associate in the Southwest United States from 2000 until 2004 and specifically promoted sales of the INFUSE Bone Graft product during CW 8's tenure with the Company, also stated that CW 8 received a small booklet from the Company that outlined measurements of rhBMP-2 to be used in all types of procedures, including off-label cervical applications. CW 8 further stated that the vast majority of INFUSE Bone Graft procedures during CW 8's tenure with the Company were off-label procedures and that the product was "tremendous" with regard to Medtronic's overall growth. CW 8 stated that

Medtronic instructed CW 8 and others during Medtronic sales presentations run by regional management of Medtronic how to "get around" restrictions on off-label promotion. As one example, CW 8 recalled that the use of INFUSE Bone Graft in the lateral gutters was discussed in such meetings: "They talked about rolling [it] into almost a little taco in the lateral gutters."

105. According to CW 9, who was employed by Medtronic as a Spinal sales representative in the Southwest United States from 2004 through 2008 and specifically promoted sales of INFUSE Bone Graft during CW 9's tenure with the Company, Medtronic provided sales representatives with a chart or graph in booklet form showing the INFUSE Bone Graft dosage amounts to be used in different bone graft cages (even though the product was only FDA-approved for use with the LT-CAGE). According to CW 9, surgeons could use the chart to determine how much of the INFUSE Bone Graft material to apply in off-label procedures. CW 9 further stated: "You definitely had to tell surgeons who chose to put it in cervical how much to use and it [the dosage] was very low." CW 9 further stated that the vast majority of INFUSE Bone Graft surgeries were off-label applications of the product because very few surgeons were using the LT-CAGE or ALIF procedure. According to CW 9, the PLIF and TLIF off-label procedures were far more common surgeries than ALIF surgery in the lumbar region. CW 9 further reported that there was significant pressure on Medtronic sales representatives, especially Biologics sales representatives, to reach high sales targets (which were increased every year) because of the Company's bonus and commission structure.

106. According to CW 10, who was employed by Medtronic for over five years, including as a Spinal regional sales manager in the Northwest United States from 2002 to 2004, when CW 10 had experience with INFUSE Bone Graft, Medtronic sales representatives would "get around" off-label promotion by directing doctors who inquired about off-label use to others

who were using the product successfully off-label. CW 10 reported that the vast majority of INFUSE Bone Graft sales were for off-label uses, citing the relatively high volume of sales and the very low numbers of ALIF procedures (the only FDA-approved spinal procedure) actually being performed. CW 10 stated that Medtronic sales representatives knew that they would not reach Company sales targets without off-label sales.

107. According to CW 11, who was employed by Medtronic as a Spinal sales representative in the Northeast United States from 2002 to 2003 and specifically promoted sales of the INFUSE Bone Graft product during CW's 11 tenure with the Company, "the way around" promoting INFUSE Bone Graft off-label was to bring doctors (including Medtronic-paid consultants) using the product off-label to meetings or dinners with other doctors who would attend and be educated regarding off-label uses. CW 11 stated that while CW 11 was at Medtronic, it was common knowledge within the Company that most of the INFUSE Bone Graft sales were for off-label applications and that there was "no way" Medtronic was achieving such high sales with on-label applications alone because the on-label applications were very narrow. CW 11 further stated that sales of the INFUSE Bone Graft rhBMP-2 component far outsold sales of the LT-CAGE, which was required for an on-label application of the device. CW 11 reported that the Company pressured its sales representatives to reach high sales targets, which Medtronic increased every year.

108. According to CW 12, who was employed by Medtronic as a Spinal financial analyst from 2002 through 2007, INFUSE Bone Graft was "extensively" dependent on off-label use and was a hugely significant product in terms of Medtronic's overall growth. CW 12 reported that it was known within the Company that most of the INFUSE Bone Graft sales were for off-label applications and INFUSE Bone Graft sales and LT-CAGE sales were packaged and

sold separately and kept track of internally through a newly-upgraded SAP accounting system. CW 12 further stated that the Company placed "a lot of pressure on Medtronic Spine to reach a sales target that was unreasonable."

109. CW 13, who worked at Medtronic from 1993 through 2005 primarily in the Northeastern region of the United States, stated that many of the methods used to promote INFUSE Bone Graft for off-label uses were part of a marketing plan originally developed during the product's launch. CW 13 stated that CW 13 was specifically brought over to Medtronic Sofamor Danek at the time of INFUSE Bone Graft's launch to help develop a "referral marketing" campaign, which was designed to promote the product for off-label uses via a physician referral network. CW 13 stated that CW 13 helped identify which surgeons would be targeted as part of this campaign and what claims the Company would make about the product, and also helped develop a "cookie-cutter" CD series that outlined the campaign and included information on off-label procedures that was distributed to Medtronic sales representatives. According to CW 13, the referral marketing program involved having surgeons meet with other surgeons as a means of prompting discussion of off-label uses of INFUSE Bone Graft among practitioners. CW 13 stated that Medtronic also used a physician training program involving cadaver labs as a way of instructing surgeons on off-label applications.

110. When CW 13 raised concerns about off-label promotion with supervisors—informing them that "We were clearly training these guys to use [INFUSE Bone Graft] in an off-label manner"—CW 13 was rebuffed. CW 13 stated that on several occasions, CW 13 was pulled aside by Vice President and Group Director of Sales for the Northeast Region, Joe Leroy, who told CW 13, "We're paying you a lot of money to launch this. Shut your mouth and take the money. Let us worry about what is off-label or isn't." According to CW 13, the off-label

promotion of INFUSE Bone Graft was "all done with a wink and a nod." Contrary to what senior management would say publicly, CW 13 said, the vice president-level managers would stress the sales quotas to sales representatives, which, according to CW 13, could not be met without having products sold for off-label uses.

111. Furthermore, in at least one wrongful death civil case, the family of an INFUSE Bone Graft patient sued the Medtronic sales representative who was allegedly present in the operating room and directing the off-label cervical procedure that appears to have caused her death. On August 21, 2008, Shirley Nisbet, a resident of Vista, California, underwent a cervical fusion procedure in which a Medtronic sales representative allegedly encouraged and recommended to her surgeon, prior to and during the surgery, that the surgeon use INFUSE Bone Graft in Ms. Nisbet's cervical spine. Following the operation, Ms. Nisbet had difficulty breathing and swallowing, and experienced severe pain and swelling in her neck. In the following days, her symptoms became progressively worse until her breathing became so compromised due to neck swelling and compression of her airway that she stopped breathing and fell into a coma on August 23, 2008. She remained in a vegetative state but was kept alive by artificial means for several days, until she died on August 30, 2008.

112. Although Medtronic is under an obligation to report all serious "adverse events" associated with the use of its products, whether or not the Company believes that a particular product caused the event, Medtronic did not report Ms. Nisbet's death until three months after it occurred. FDA guidelines recommend that a manufacturer make a minimum of three attempts to retrieve additional information regarding any adverse events, with at least one attempt in writing. While the Company filed an adverse event report with the FDA noting Ms. Nisbet's complications immediately following the procedure, the Company did not inform the agency of

her death until after a lawsuit was filed by Ms. Nisbet's family and reported in *The Wall Street Journal*.

113. Evidence produced in another lawsuit filed by Laurie DeNeui, of Rushmore, Minnesota, a patient also injured in a cervical procedure involving INFUSE Bone Graft in October 2005, further corroborates the numerous CWs who state that Medtronic promoted and encouraged the off-label use of INFUSE Bone Graft. During a sworn deposition, Ms. DeNeui's surgeon, Dr. Bryan J. Wellman of Sioux Falls, South Dakota, admitted that he visited a Medtronic facility in Memphis, Tennessee on multiple occasions and attended numerous national spine meetings, including a meeting held by the Congress of Neurosurgeons in San Diego in October 2007 and the spine section of the Congress of Neurosurgeons in Phoenix, Arizona in March 2007, where the off-label use of rhBMP-2 in the cervical spine was discussed. Dr. Wellman stated that a Medtronic sales representative, Curt Messler, whom Dr. Wellman considered a friend and saw socially, was present in the operating room "a lot" when Dr. Wellman would perform procedures involving the off-label use of INFUSE Bone Graft, and that he had used rhBMP-2 in "well over" 100 cervical procedures. Dr. Wellman also testified under oath that he had discussions with Mr. Messler about using INFUSE Bone Graft for off-label applications, and that Mr. Messler "wanted me to use it," and discussed with Dr. Wellman the appropriate dosing to be used in Ms. DeNeui's off-label cervical procedure.

114. Lead Counsel also have been able to estimate the growing percentage of INFUSE Bone Graft off-label usage from 2003-07, based on a collection and analysis of surgical procedural codes used by hospitals from the *International Classification of Diseases, 9th Revision, Clinical Modification* ("ICD-9-CM"). ICD-9-CM coding is an official system of assigning individual codes to patient diagnoses and procedures, and is used by physicians and

hospitals throughout the United States. These codes identify the diagnosis and specific treatments received by individual patients, and are used for statistical reporting, research, and for reimbursement purposes (i.e., when providers seek reimbursement from Medicare, Medicaid, insurance plans, or other third-party payors for fees incurred during patient care). By reviewing the ICD-9-CM codes assigned to a patient, an analyst or researcher can determine the patient's diagnosis, which part of the patient's body has been affected, and what procedures were performed on the patient. Through ICD-9-CM codes, an analyst or researcher can identify whether a specific use of BMP was on-label or off-label. For example, if a patient's records indicate the use of BMP via the 84.52 procedural code, and the records also contain a diagnosis code indicating the spinal fusion was performed in the cervical spine, then that usage of BMP would be off-label. But if the records indicate the application of BMP and a spinal fusion in the lumbar spine using an FDA-approved approach, then the usage would be on-label.

115. Lead Counsel obtained hospital patient discharge databases—which list ICD-9-CM codes—from the Nationwide Inpatient Sample ("NIS") compiled by the Health Cost and Utilization Project of the Agency for Healthcare Research and Quality. The NIS is a database of hospital inpatient stays used by researchers and analysts to identify, track, and analyze national trends in health care utilization, access, charges, quality, and outcomes. This database contains data from approximately eight million hospital stays each year for the years 1998 to 2007. The 2007 NIS data contains all discharge data from 1,044 hospitals located in 40 states, which represents an approximate 20% sample of U.S. community hospitals. This sample data can be weighted to produce national estimates.[8]

[8] Lead Counsel's methodology is consistent with a recent July 1, 2009 post-Class Period report in the JAMA that conducted a retrospective cohort study of 328,468 patients undergoing spinal fusion procedures from 2002-06, also using ICD-9-CM codes from the NIS database. The results of that JAMA-reported study concerning post-operative complications following BMP use is described below.

116. After obtaining the NIS data, Lead Counsel analyzed the various ICD-9-CM diagnosis codes associated with the use of BMP (which is indicated by the 84.52 procedural code). For spinal applications, Lead Counsel classified any use of BMP associated with an on-label location, diagnosis, and procedure code as an on-label use. If the mix of codes did not indicate an on-label location, diagnosis, and procedure, the use of BMP was classified as off-label.[9] With respect to tibial and oral maxillofacial applications, Lead Counsel identified the codes associated with on-label use of BMP in these applications, and classified the procedure as on-label if the procedure occurred after FDA approval; or, after April 2004 for the tibial indication and after March 2007 for the oral maxillofacial indication. Procedures that occurred before these dates of FDA approval were classified as off-label. The results from this analysis of the sample databases were then weighted to produce national estimates of on-label and off-label use of BMP.[10]

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[9] This methodology of classifying spinal procedures results in a conservative estimate of off-label procedures for at least two reasons. First, although there is an ICD-9-CM code for interbody fusion devices, that code does not enable one to distinguish between an interbody fusion device specified in the INFUSE Bone Graft's labeling—e.g., the LT-CAGE—and one that is not, and thus the methodology may incorrectly categorize as on-label applications of BMP that are, in fact, off-label. Second, the methodology designates any questionable situation as an on-label procedure, rather than as an off-label procedure. Such questionable situations occur where a patient's records indicate the use of BMP and that the patient underwent both what would typically be an off-label procedure (e.g., cervical fusion), as well as a procedure that would be on-label (i.e., an ALIF in the proper area of the spine), but do not specify which fusion involved the use of BMP.

[10] One minor limitation of this analysis is that the ICD-9-CM procedure codes do not differentiate between different manufacturers of bone morphogenetic proteins. Therefore, the 84.52 code encompasses the use of both Medtronic's INFUSE Bone Graft and of Stryker Corporation's OP-1 products. However, the influence of OP-1 use on this analysis is minimal. First, during the Class Period, the OP-1 products were only approved in the United States under Humanitarian Device Exemptions that limited total use of the product to no more than 8,000 applications per year. Second, a comparison of INFUSE Bone Graft and OP-1 revenue indicates that INFUSE Bone Graft was by far the predominant bone morphogenetic protein product used in the United States during the Class Period. INFUSE Bone Graft sales were $572 million in 2006, $697 million in 2007, and $815 million in 2008. In comparison, OP-1 sales were only $50.2 million in 2006, $52.7 million in 2007, and $51.9 million in 2008. Therefore, from 2006-08 INFUSE Bone Graft sales represented a dominant 93% share of the total bone morphogenetic protein market. As such, notwithstanding the limitations of the available data, the vast majority of the procedures represented by the 84.52 code involved the use of INFUSE Bone Graft product rather than the OP-1 product.

117. The results of this analysis demonstrate that off-label usage of INFUSE Bone Graft was high from the inception of FDA approval and grew steadily throughout the Class Period as follows:

Year	Estimated On-Label Procedures	Estimated Off-Label Procedures
2003	25.7%	74.3%
2004	20.6%	79.4%
2005	15.8%	84.2%
2006	15.3%	84.7%
2007	14.8%	85.2%

118. Moreover, the data further demonstrate that use of INFUSE Bone Graft in the cervical spine grew to as much as 18% of overall INFUSE Bone Graft use as of 2007 despite the increased medical risks associated with that application.

119. Not only did off-label use of INFUSE Bone Graft continue to increase after the DOJ settlement (and throughout the Class Period), but (undisclosed to investors) Medtronic's lucrative payments to surgeons who used and promoted INFUSE Bone Graft "off-label" continued as well. In fact, just one of Medtronic's highly compensated "consultants"—Dr. Timothy Kuklo, a former Army doctor who retired from the military as chief of orthopaedic surgery at Walter Reed Army Medical Center ("Walter Reed"), the nation's premier military research hospital in December 2006—received hundreds of thousands of dollars per year in fees in the years following the DOJ settlement. Specifically, it has now been revealed by *The Wall Street Journal* (after the end of the Class Period) that Dr. Kuklo received $356,242 in 2007, $249,772 in 2008 and $132,453 in the first few months of 2009 from Medtronic for consulting, speaking, travel, and training services. The Company paid Dr. Kuklo $42,627 in 2006 while he was still on active duty at Walter Reed, as well as amounts totaling $42,295 from 2001 through

2005, primarily for travel to medical conferences and speeches at Medtronic events, including direct payments to hotels and airlines.

120. Until a U.S. Army investigation into a falsified study reporting favorable results for INFUSE Bone Graft recently uncovered shocking misconduct by this former Army surgeon (only after the end of the Class Period), Dr. Kuklo had worked closely with Medtronic and was an active promoter of off-label usage of INFUSE Bone Graft. For example, Dr. Kuklo appeared as a "distinguished guest surgeon" at a Medtronic Spine Division Business Overview Conference Call on September 28, 2006, alongside another Medtronic consultant, Dr. Rick Sasso—who received $150,000 in consulting fees in 2006—as well as Defendant Ellis and Medtronic Spinal Division Senior Vice President Peter Wehrly ("Wehrly"). During the call, a Merrill Lynch analyst asked about "issues that have come up in the past in terms of potential side effects with using INFUSE in the cervical region," and whether it was a concern for surgeons. Dr. Sasso responded by referring to a "Level 1, controlled randomized study which was published in 2002" which, according to Dr. Sasso, demonstrated that "when you used the appropriate dosage of INFUSE, you did not get problems with esophageal obstruction and problems swallowing." Wehrly then asked whether Dr. Kuklo had anything to add, and Dr. Kuklo responded that the question "was well answered as far as appropriate dosage. I think it's really the bottom line."

121. Although Dr. Kuklo's and Dr. Sasso's rendition of the medical literature may not have been entirely accurate—and in fact downplayed the seriousness of the adverse events that Defendants knew were occurring in the cervical spine—this infraction only hinted at the influence of Medtronic's payments on its consultants' medical judgment. Indeed, an Army investigation later revealed (after the end of the Class Period) that Dr. Kuklo deliberately falsified data that exaggerated the benefits of off-label use of Medtronic's INFUSE Bone Graft

product in a study published in the August 2008 issue of *The Journal of Bone and Joint Surgery*, a peer-reviewed medical journal based in Britain.[11]

122. The study, which purported to compare the fusion results of 67 patients who received an autogenous bone graft and 62 that were treated with INFUSE Bone Graft to treat certain tibial (shin bone) fractures in injured soldiers, including certain off-label uses, reported that employing INFUSE Bone Graft resulted in "strikingly" better outcomes than a traditional bone graft. In the article, Kuklo reported that those receiving autogenous bone graft had successful fusions in 76% of procedures, while the union rate for the INFUSE Bone Graft group was significantly better at 92%, a claimed "striking finding." Not only were the reported union rates claimed better with INFUSE Bone Graft than with an autograft, but patients who received INFUSE Bone Graft also reportedly experienced favorable outcomes in other clinical measures. Specifically, the study concluded that "the primary outcome measures of union, rate of infection, and reoperation were all improved with rhBMP-2," and that those treated with INFUSE had a "strikingly lower infection rate (3.2%), which we believe is directly attributable to rhBMP-2." While the article noted the unique nature of combat injuries and potential differences in treatment at military facilities, the claimed (but now understood to be fabricated) findings had clear implications at the time they were released for treatment in the general patient population, and recommended that the study's favorable results "should therefore be considered in the management of similar non-combat injuries."

123. Medtronic continued paying Dr. Kuklo as a consultant even after his article was retracted by *The Journal of Bone and Joint Surgery* and only placed him on "inactive status"

[11] As set forth below, on May 12, 2009, after the end of the Class Period, *The New York Times* disclosed that an Army investigation into a study authored by Dr. Kuklo concluded that Kuklo made false claims in this article that overstated the benefits of INFUSE Bone Graft in treating wounded soldiers injured in Iraq.

when reports that Dr. Kuklo falsified the study's data were published in *The New York Times* after the end of the Class Period.

124. Another highly compensated Medtronic consultant, Dr. David Polly, a professor and Chief of the Spine Service at the University of Minnesota Department of Orthopaedic Surgery, received total consulting fees from Medtronic of $1.14 million from 2003 to 2007 (according to information recently made public by Senator Charles Grassley after the end of the Class Period) and promoted off-label use of INFUSE Bone Graft. As with Dr. Kuklo, Medtronic's financial relationship with Dr. Polly began while the surgeon was on active military duty at Walter Reed. Although Dr. Polly has claimed that his consulting relationship with Medtronic did not begin until 2004, documents obtained through requests under the Freedom of Information Act ("FOIA"), reveal that the Company paid almost $30,000 in travel expenses for Dr. Polly to speak at various medical conferences in the Bahamas, San Diego, and a $10,000 trip to Switzerland, while he was still stationed at Walter Reed in 2003. Dr. Polly attended these conferences to report on his research that purportedly demonstrated that INFUSE Bone Graft was more cost effective than traditional spinal fusion procedures.

125. After his discharge from the military, Dr. Polly authored an article with Dr. Kuklo reporting positive results in treating wounded soldiers with rhBMP-2 at Walter Reed. According to an article in the November 2004 issue of *Minnesota Medicine* published by Dr. Polly and Dr. Kuklo, rhBMP-2 was used in more than 100 military patients with traumatic bone fractures who had served in Iraq and Afghanistan. Although the use of INFUSE Bone Graft in tibial fractures was not approved until April 30, 2004, Dr. Polly reported that the "decision to use rhBMP-2 was made early in the Afghanistan conflict and was based on evidence from clinical trials in Europe on open tibial fractures that suggested use of rhBMP-2 not only improved bone healing but led to

a decreased number of secondary interventions and lower rates of infection." According to Dr. Polly, "the military's experience with rhBMP-2 has been favorable." Documents obtained by Lead Counsel in response to a FOIA request show that Medtronic reimbursed Dr. Kuklo for a meeting with Company representatives in Memphis, Tennessee on April 20, 2004 regarding "Review of BMP Trauma and spine Surgery," shortly before this November 2004 article was published.

126. Dr. Polly later sought a government grant for a similar study in May 2006, when he testified before the Defense Subcommittee of the U.S. Senate Appropriations Committee regarding research that would examine the use of INFUSE Bone Graft and antibiotics to treat traumatic and infected bone fractures. During his testimony before the Senate subcommittee, Dr. Polly stated that he was "speaking on behalf of the American Academy of Orthopedic Surgeons." But according to information recently released by Senator Grassley, who has been conducting an inquiry into Medtronic's consulting payments, Dr. Polly actually billed Medtronic $7,000 in connection with his Senate testimony, and was therefore speaking on behalf of the Company. Furthermore, Dr. Polly billed Medtronic a total of $50,000 over several months for his lobbying efforts in securing the $466,644 Department of Defense grant for this INFUSE Bone Graft research study.

127. The information recently released by Senator Grassley, which includes billing reports submitted to Medtronic by Dr. Polly and approved by the Company, indicates that throughout this period, and throughout the Class Period, Dr. Polly had frequent meetings, telephone calls, and email correspondence with numerous Medtronic senior executives, including Defendant Hawkins, former COO Michael DeMane ("DeMane"), and former President of Medtronic Spinal and Biologics Wehrly, while speaking frequently regarding INFUSE Bone

Graft at medical conferences and other events. For example, the records show meetings and other contacts between Dr. Polly and Defendant Hawkins on the following dates during the Class Period: February 13, 2007; June 15, 2007; July 27, 2007; August 8, 2007; August 24, 2007; September 26, 2007; and September 27, 2007. Indeed, they further show that Dr. Polly billed for a meeting with Defendant Hawkins before the start of the Class Period on July 13, 2005 to discuss a "spine surgery advocacy effort."

128. Medtronic's well-compensated physician "consultants" were crucial to the Company's scheme to promote the extensive off-label use of INFUSE Bone Graft since its launch in 2002. In fact, almost immediately after the product was approved, spinal surgeons who were paid Medtronic consultants began writing favorably about uses in the cervical spine.

129. For example, several doctors who authored a May 2003 article describing positive results of INFUSE Bone Graft used in the cervical region of the spine were paid tens of thousands of dollars in consulting fees by Medtronic. The article, "New Technologies in Anterior Cervical Spine Fixation," which was published on SpineUniverse, a website intended for the general public that provides information regarding spinal disorders and treatment, described how the doctors had used INFUSE Bone Graft "in the cervical spine with very good results." According to the authors, "Preliminary results are promising and INFUSE™ may be especially appropriate in people undergoing multiple level fusions"—i.e., for indications not approved by the FDA, which limits device's application to single-level fusion procedures.

130. One of the authors of this article, Dr. Regis Haid, Jr., received Medtronic consulting fees of $50,000 in 2006 and similar amounts in the previous two years, and another author, Dr. Gerald Rodts, received payments of $80,000 from Medtronic in 2006 and similar amounts in the previous two years. The SpineUniverse article does not mention that its authors

received compensation from Medtronic, nor do the website profiles of Dr. Haid and Dr. Rodts, both of whom serve on the publication's editorial board, disclose their financial relationships with the Company.

131. Dr. Haid also was the lead author of an article describing the results of the study of INFUSE Bone Graft in PLIF procedures that was halted in December 1999 after several patients experienced incidents of bony overgrowth. In addition, two of the article's other authors—Dr. J. Kenneth Burkus and Dr. Charles L. Branch—received consulting fees from Medtronic. Specifically, Medtronic paid Dr. Branch $154,900 in 2006 and similar amounts in the preceding two years, while Dr. Kenneth Burkus— who has written over a dozen articles addressing the use of BMP, including studies examining the use of INFUSE Bone Graft in off-label PLIF and anterior cervical procedures—received $416,775 in 2006 and similar amounts in the two preceding years.

132. Although the negative outcomes in the PLIF study prompted the FDA Advisory Panel to recommend a more restrictive labeling and indication in approving INFUSE Bone Graft, the Medtronic-funded authors reviewing the study's results surprisingly did not find the incidents of bony overgrowth to be a clinically significant concern. The doctors noted that "[a]lthough not desirable, bone formation in the spinal canal does not appear to have a discernible effect on patient outcomes," and that "the de novo rhBMP-formed bone occurred predictably, not compressing the neural structures."

133. In a commentary on the study, Dr. Neil Kahanovitz, an independent surgeon, questioned the authors' interpretations, suggesting that they may have been "overwhelmed by their enthusiasm of using" rhBMP-2 in a PLIF procedure. Dr. Kahanovitz noted that while there are "lengthy discussions of various trends throughout this study, which imply the superiority of

rhBMP over autograft . . . one fact remains: in every clinical measure examined in this study, there were no statistically superior outcomes in the rhBMP group except one, and the clinical significance of this one statistically significant finding is unclear." Moreover, Dr. Kahanovitz disagreed with the authors' conclusion that the presence of bone growth in the spinal canal and foramina (the two apertures between vertebrae) in those patients who received rhBMP-2 had no clinical implications. Rather, Dr. Kahanovitz predicted that "most surgeons would be less than enthusiastic to see this statistically significant variable present in the majority of their patients."

134. Another prominent Medtronic consultant, Dr. Scott Boden, who assisted in presenting Medtronic's PMA application before the FDA Advisory Panel in January 2002, received consulting fees of $75,000 in 2006 and similar amounts in prior years. Dr. Boden also has written extensively on the use of INFUSE Bone Graft in off-label procedures. In one example, Dr. Boden wrote that when used in situations slightly altered from its approved use, rhBMP-2 is likely to be effective. The article, published in Orthopaedic Nursing, also praises the cost benefits of the product, noting that while rhBMP-2 "is quite expensive, [its] potential to lessen morbidity, accelerate healing, and provide more consistent results undoubtedly justify these costs in appropriately selected patients."

135. According to information revealed after the Class Period, Dr. Thomas A. Zdeblick, the Chairman of the Department of Orthopedics and Rehabilitation at the University of Wisconsin, received over $19 million from the Company from 2003 to 2007 for consulting services and royalty payments. Although Dr. Zdeblick only disclosed annual payments exceeding $20,000 in university conflict of interest forms (according to information revealed by Senator Grassley after the end of the Class Period), he actually received between $2.6 and $4.6 million per year. In 2007 alone, Dr. Zdeblick received $2,641,000 in fees from Medtronic.

From 1998 through 2004, Dr. Zdeblick was paid an annual salary of $400,000 by Medtronic under a contract that only required him to work eight days per year at a Company site in Memphis, Tennessee, and to participate in numerous workshops for surgeons.

136. Dr. Zdeblick also has been a significant contributor to Medtronic's promotion of INFUSE Bone Graft, authoring seven peer-reviewed articles on rhBMP-2 and appearing as a presenter at medical conferences and symposia in which the topics included discussion of off-label uses of the INFUSE Bone Graft. On a Medtronic website, Back.com, Dr. Zdeblick describes the advantages of INFUSE Bone Graft and appears in an online video discussing the product.

137. As revealed in a June 20, 2009 article in the *Milwaukee Journal Sentinel* (after the end of the Class Period), Dr. Paul A. Anderson, an orthopedic surgeon and colleague of Dr. Zdeblick at the University of Wisconsin School of Medicine and Public Health, was paid $150,000 by Medtronic for just eight days of work. Along with Medtronic consultants Drs. Boden, Keith H. Bridwell, and Jeffrey C. Wang, Dr. Anderson authored an article, titled "What's New in Spine Surgery" in the July 2007 issue of the *Journal of Bone and Joint Surgery*, which, among other things, discussed a study that examined the use of INFUSE Bone Graft in an off-label Posterolateral Fusion procedure. The study reported that the use of INFUSE Bone Graft improved fusion rates when used in combination with iliac crest bone graft in a procedure in which the BMP was wrapped around local bone as a bulking agent. According to the authors, the study's findings suggested that "the current [INFUSE Bone Graft] kit, while likely not sufficient as a stand-alone graft substitute for the posterolateral spine, can provide a significant enhancer effect, improving the success of an autogenous bone graft."

138. Another set of highly compensated surgeons affiliated with the Norton Hospital Leatherman Spine Center in Louisville, Kentucky collectively received over a million dollars in consulting fees in 2006 alone, including Drs. John R. Johnson ($162,750), Steven D. Glassman ($200,300), Rolando M. Puno ($106,000), John R. Dimar, II ($192,300), David Rouben ($109,300), Mitch Campbell ($212,000) and Mladen Djurasovic ($55,900). According to CW 1, several surgeons from the Leatherman Spine Center would be asked to speak at Medtronic-sponsored physician talks attended by between 10 and 25 surgeons, including several "pretty high profile" doctors. At these physician talks—which included a dinner attended by about 25 surgeons, another dinner with about 10 doctors, and a breakfast meeting attended by between 10 and 15 surgeons—a Medtronic consultant, such as one of the surgeons at the Leatherman Spine Center, would provide a presentation of off-label usage of INFUSE Bone Graft. According to CW 1, "What [Medtronic] would do is bring in one of their 'paid consultants' and set up a dinner in the area and invited a number of physicians to attend." The guest surgeon—the "paid consultant"—would then "basically give a presentation on off-label usage." Typically, "a canned presentation . . . was given, and the surgeon would talk about his experience with the product, and then there would be a Q&A at the end." According to CW 1, these physician talks were also attended by all Medtronic sales representatives who worked in the area.

139. The Medtronic-funded surgeons associated with the Leatherman Spine Center have also written extensively on off-label uses of INFUSE Bone Graft. For example, Dr. Rouben, authored a study published in *The Internet Journal of Minimally Invasive Spinal Technology* in 2007, titled "Mast TLIF Lumbar Spinal Fusion Technique: A Twenty-Four Month Retrospective Analysis For The Treatment of Symptomatic Segmental Lumbar Disc Disease – 'SSLDD'" that examined post-operative results from patients who had undergone minimally

invasive TLIF procedures in which INFUSE Bone Graft was used—an off-label application of the product. The results of the study reported that this procedure, which featured off-label use of INFUSE Bone Graft, "is a viable and appropriate treatment option for symptomatic segmental lumbar disc disease-SSLDD." In addition to this study, separately and often together, the surgeons associated with the Leatherman Spine Center have collectively authored at least 15 articles addressing the use of BMP, including some of the leading medical articles on the use of INFUSE Bone Graft in off-label posterolateral and anterior cervical fusion procedures. Specifically, Dr. Campbell has contributed to at least eight articles examining the use of BMP; Dr. Dimar, nine; Dr. Djurasovic, four; Dr. Johnson, five; Dr. Puno, five; and Dr. Glassman has written at least fifteen articles addressing the use of BMP, the vast majority of which involve applications of the product in off-label procedures.

140. CW 1 also stated that Drs. Lawrence ("Larry") G. Lenke and Keith H. Bridwell, two other surgeons from Washington University in St. Louis, where Dr. Kuklo worked as an associate professor until recently, similarly acted as KOLs or "guest surgeons" during "corporate visits" in which Medtronic would invite targeted surgeons to attend training sessions in Memphis, Tennessee. While in Memphis, the visiting surgeons would meet with Medtronic corporate officers, product managers and guest surgeons, such as Drs. Lenke and Bridwell. The visiting surgeons also received "hands-on training" on INFUSE Bone Graft, including instruction in cadaver labs. According to CW 1, who personally attended two such meetings, "There was training on off-label procedures, for sure." The visiting surgeons "would bring up the use of INFUSE and ask how to use it, and [the guest surgeons] would show them how to do it." CW 1 stated that Medtronic chose which surgeons to invite to these corporate visits based in part upon the volume of INFUSE Bone Graft procedures they performed.

141. The guest surgeons identified by CW 1 also received significant fees from Medtronic. Dr. Bridwell received $10,000 in consulting fees from Medtronic in 2006, while Dr. Lenke received payments totaling $175,000 over the same period. Dr. Daniel Riew, another Washington University faculty member, received $80,000 from Medtronic in consulting fees during 2006.

142. Dr. Todd M. Lanman, a Medtronic consultant who received consulting fees of $50,000 in 2006, was described by CW 10 as a "big guy" on the West Coast —i.e., an important KOL for the Company—who would speak about off-label procedures involving the use of INFUSE Bone Graft in the cervical spine. Dr. Lanman authored an article, "Early findings in a pilot study of anterior cervical interbody fusion in which recombinant human bone morphogenetic protein-2 was used with poly (L-lactide-co-D, L-lactide) bioabsorbable implants," published in the March 2004 issue of *Neurosurgical Focus,* which reported bridging bone in 100% of cases in which INFUSE Bone Graft was used in anterior cervical fusion procedures, an off-label application. In the article, Dr. Lanman reported no device-related complications and concluded that "Infuse Bone Graft may be an alternative treatment for cervical spine fusion." According to CW 10, Dr. Lanman would speak about the positive results he achieved in his research and that if one of CW 10's customer surgeons wanted to use the product in the cervical spine, CW 10 knew that CW 10 could send the surgeon to Dr. Lanman because of a study he performed.

143. Another prominent Medtronic consultant, Dr. Jeffrey Wang, the Chief of Spine Surgery for the Department of Orthopaedic Surgery and Executive Co-Director of the University of California, Los Angeles's ("UCLA") Comprehensive Spine Center, also spoke about off-label uses of INFUSE. In fact, it has been recently revealed by Senator Grassley (after the end of the

Class Period) that Dr. Wang received $275,000 in royalty and consulting payments from the Company from 2003 until 2008.

144. Further, Dr. Wang failed to disclose his substantial financial relationship with Medtronic while researching Company products, in violation of UCLA policy. Although required to report funding by nongovernmental entities that financed the research he conducted, Dr. Wang repeatedly failed to disclose Medtronic payments in financial disclosure forms submitted to the university. For example, although Medtronic was then funding a study he was conducting, on a disclosure form to UCLA dated January 10, 2007, Dr. Wang checked "no" when asked if he received income of $500 or more from Medtronic. In fact, according to information released by Senator Grassley, Dr. Wang received $14,600 on January 4, 2007 for "lecture and teachings at spine meetings and universities in Korea for one week." As set forth below, Dr. Wang lost his position as co-executive director of UCLA's Comprehensive Spine Center as a result of his repeated failures to disclose payments received from, *inter alia*, Medtronic.

145. In addition to the compensation to Medtronic consultants discussed in ¶¶ 119 to 144, Medtronic collectively paid 22 other surgeons $943,000 from 2003 to 2008 to work on matters specifically relating to INFUSE Bone Graft, according to financial information recently supplied by the Company to Senator Grassley in response to his inquiry that was entered into the Congressional Record on May 19, 2009, after the end of the Class Period.

146. Defendants also were well aware of the significantly increased risk of adverse events from off-label uses of INFUSE Bone Graft. CW 2, who is discussed *supra* at ¶¶ 96–98, stated that Medtronic was aware of adverse events resulting from the use of INFUSE Bone Graft in the cervical spine in particular, including swallowing and breathing problems. In response to

these reports of adverse events, CW 2 stated that Medtronic tried to get information out to the medical community regarding what it considered to be the proper dose of INFUSE Bone Graft for this off-label application. Medtronic also issued a "Safety Alert" letter to surgeons on September 14, 2004, informing them that the Company had received reports of complications associated with off-label use of INFUSE Bone Graft in anterior cervical fusion procedures. As Medtronic itself informed the recipient surgeons, "***[l]ocalized soft tissue edema has been reported in anterior cervical spine fusion surgery following the use of INFUSE Bone Graft…. Some reports were accompanied by patient complaints of swelling and difficulty in swallowing and breathing, three of which resulted in surgical intervention***." (Emphasis added.)

147. These adverse events were not isolated incidents. Indeed, a review of the FDA's Manufacturer and User Facility Device Experience Database of adverse event reports ("MAUDE Database") indicates that more than 396 adverse event reports regarding rhBMP-2 have been submitted to the FDA since 2003, and most of these reports were submitted from 2005 to 2008, or immediately prior to and during the Class Period. The MAUDE Database consists of reports of adverse events and complications ***voluntarily*** submitted by medical professionals, patients, device distributors, and device manufacturers, and the FDA's website specifically states that because submission is voluntary, it may not include reports of all adverse events that actually occur when a particular product is used. The submitted reports generally provide a short description of the adverse event, with varying degrees of specificity. Because of this varying specificity, it can be difficult to classify some reports as representing an on-label or off-label use. Notwithstanding this limitation, of the 396 INFUSE Bone Graft-related adverse events reported since 2003, at least 276, or 69.7%, occurred during off-label use of the product. The true percentage is likely significantly higher because approximately 26% of the reports examined do

not contain sufficient information to classify the use of INFUSE Bone Graft as on-label or off-label.

148. The adverse event reports from off-label uses of INFUSE Bone Graft indicate complications similar to those noted in the studies discussed above, including swelling, difficulty swallowing and breathing, excessive bone growth, etc., often requiring emergency medical intervention or a second surgery. For example, a July 21, 2008 report indicates that a patient developed massive neck swelling, very thick tracheal and bronchial secretions, and required a tracheostomy—a procedure in which an incision is made in the neck and a tube inserted to allow the patient to breathe—following a cervical fusion procedure involving INFUSE Bone Graft. A November 3, 2006 report indicates that a patient reported neck swelling, difficulty swallowing and possible shortness of breath two to three days after a cervical spine fusion using INFUSE Bone Graft; as a result, the patient had to undergo another surgery four days after the initial fusion. Similarly, a December 12, 2005 report indicates that four or five days after an off-label PLIF procedure using INFUSE Bone Graft, a patient's swelling became so severe that surgical intervention was required. These are only a few examples of the hundreds of similar reports of serious complications related to off-label uses of INFUSE Bone Graft found on the MAUDE Database.

149. Through Medtronic's monitoring procedures—which include written procedures for complaints, corrective and preventative actions and adverse event reporting—all complaints and adverse events are documented, tracked and trended in a database. Medtronic is required to "establish and maintain" such an adverse event database by federal regulation. 21 C.F.R. § 803.1(a). In addition, a report from a June 2006 FDA inspection of a Medtronic facility at 1800 Pyramid Place in Memphis, Tennessee, reveals that Medtronic had initiated a Preventative

Action, dated April 21, 2006, and was "studding [sic] the reason for an increase in the number of reported fluid collection, hematoma, and seroma complaints since 4/2005." According to the report, the "study indicated that sales for the Infuse Bone Graph [sic] have increased and more graphs [sic] are being implanted," and that the "study is still open."

F. THE FDA STRONGLY WARNS DOCTORS OF OFF-LABEL USAGE AND INFUSE BONE GRAFT SALES GO DOWN AS ADDITIONAL ADVERSE INFORMATION IS REVEALED

150. On July 1, 2008, the FDA issued a Public Health Notification to healthcare practitioners, entitled "Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion" (the "FDA Notification"), strongly warning medical professionals who used INFUSE Bone Graft and other BMP products of serious complications that had occurred from the off-label use of these products in the cervical spine. The FDA Notification stated that the agency has received numerous reports of complications from BMP use in the cervical spine that "were associated with swelling of neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck. Some reports describe difficulty swallowing, breathing or speaking." The notification further stated that these complications had resulted in "the need for emergency medical intervention," which included "respiratory support with intubation, anti-inflammatory medication, tracheotomy and most commonly second surgeries to drain the surgical site." The FDA Notification concluded that "in light of the serious adverse events described above, FDA recommends that practitioners either use approved alternative treatments or consider enrolling as investigators in approved clinical studies."

151. The following day, a Medtronic analyst from ThinkPanmure noted that the FDA Notification was both a "rare" comment from the agency on off-label usage of a product and contained "***strong language***" that would hurt enthusiasm for off-label use of INFUSE Bone

Graft, especially in the cervical spine. The analyst noted: "***[s]eldom does the FDA make such a strong comment on the off-label usage of a product***. We think this will discourage the cervical use of BMP entirely. . . . We also think that this letter will make some doctors think twice about off-label usage in the lumbar spine." (Emphasis added.) Later reports echoed this observation.

152. However, Defendants' continued false and misleading statements during the Class Period (set forth below) obscured the warning's significance. For example, a July 4, 2008 article in the Memphis, Tennessee *Commercial Appeal* quoted an RBC Capital Markets health care analyst who said the warning letter was unlikely to affect sales of INFUSE Bone Graft because it was limited to off-label uses. According to the article:

> Because the FDA warning focused on an off-label use, it is unlikely to affect Medtronic's sales or stock price, said Phil Nalbone, an analyst with RBC Capital Markets in San Francisco. "This advisory from the FDA is important for patients and doctors, but it in no way should be seen as a negative for Medtronic," he said.

153. On September 4, 2008, *The Wall Street Journal* published a front-page article entitled "Medtronic Product Linked to Surgery Problems," which discussed both the complications resulting from the use of INFUSE Bone Graft in the cervical spine already disclosed in the FDA Notification and additional complications resulting from other off-label applications of the product. The article stated:

> The FDA's alert about Infuse was specific to neck surgeries. But a review of FDA records and medical literature shows there have been scores of other cases in which serious complications arose after the product was used in other off-label situations. Many of these cases involve unwanted bone growth near nerves or in areas outside targeted fusion sites. That can lead to pain, repeat surgeries and, in some cases, emergency intervention.

The article further stated that at least three-quarters of the adverse events reported to the FDA involved off-label use of INFUSE Bone Graft. This news had serious implications for Medtronic because off-label use of INFUSE Bone Graft represented a high percentage of all INFUSE Bone Graft sales, as set forth above. In addition, *The Wall Street Journal* report noted ongoing

whistleblower litigation against the Company related to alleged off-label promotion of INFUSE Bone Graft, including claimed kickbacks to doctors to promote the product.

154. Thereafter, on November 12, 2008, J.P. Morgan issued the results of a proprietary survey of fifty U.S. spine surgeons that sought to gauge their expected use of INFUSE Bone Graft following the FDA Notification and the adverse reports since the issuance of that FDA warning regarding complications from off-label use of INFUSE Bone Graft, and the whistleblower suits alleging illegal off-label promotion through payments to doctors. J.P. Morgan's report on this survey, entitled "InFuse at Risk: Proprietary JPM Spine Survey and F2Q Preview," concluded that although INFUSE Bone Graft had been a significant driver of growth for Medtronic and was one of the Company's most consistent products, "in the wake of an FDA warning letter on off-label use in the cervical spine, a whistleblower suit targeting leading InFuse surgeons, and a resulting increase in reimbursement scrutiny tied to off-label use, sales are starting to slow and likely [will] come in below consensus expectations over the next several quarters." J.P. Morgan further opined that cervical use of INFUSE Bone Graft "is likely to decline considerably" and that lumbar use would moderate in the wake of the FDA Notification and coverage of the whistleblower suits. It found that "[o]ne third of surgeons said they expect to reduce InFuse use in the wake of these events, forecasting a 57% reduction in cervical applications and 24% decline in lumbar." The surgeons as a whole forecast a 6% decline in INFUSE Bone Graft use in the coming year, which is a significant reversal for a product that grew 16.9% over the previous year.

155. Several days later, on November 18, 2008, in connection with reporting Medtronic's financial results for its 2009 second quarter (ended October 24, 2008), Medtronic reported that revenue from its Spinal segment had, in fact, declined to $829 million for the

quarter, down $30 million from the previous quarter. The decreased sales in the Spinal segment stemmed from a significant decline in INFUSE Bone Graft sales and were a sharp deviation from the Company's reports of repeated double-digit growth in the Spinal segment in previous quarters. Moreover, the Company disclosed, for the first time, that: "***we recently received a subpoena from the Department of Justice looking into off-label use of INFUSE***." (Emphasis added.)

156. In response to an analyst's question, Defendant Hawkins referred to the reasons for the decline in INFUSE Bone Graft sales as "kind of the perfect storm," yet this storm was of Defendants' own making. Indeed, the FDA Notification, a subpoena from the DOJ and the numerous other negative media reports noted by Defendant Hawkins were precisely the undisclosed risks that Medtronic was taking by engaging in its surreptitious off-label promotional practices.

157. Thereafter, as set forth below, Medtronic continued to report lower sales of INFUSE Bone Graft after the end of the Class Period, which it admittedly linked to "a public health notice from the FDA regarding off-label use of recombinant human bone morphogenetic protein in the cervical spine that was issued in July 2008, a previously disclosed government investigation, negative newspaper stories, and a whistleblower lawsuit filed against a number of spine surgeons and distributors of INFUSE bone graft."

G. DEFENDANTS ACTED WITH SCIENTER

158. As alleged herein, numerous facts collectively give rise to a strong inference that all Defendants acted with scienter in that they knew or disregarded with deliberate recklessness that the public documents and statements they issued and disseminated throughout the Class Period were materially incomplete, false and misleading, and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements. As set forth

herein in detail throughout this Complaint, Defendants, by virtue of their receipt and knowledge of information reflecting the true facts regarding Medtronic's promotion of INFUSE Bone Graft and the extent of its off-label use, their control over, and/or receipt and/or modification of Medtronic's materially incomplete, false and misleading misstatements and/or their positions within the Company which made them privy to confidential proprietary information concerning Medtronic and its INFUSE Bone Graft sales, knowingly or recklessly participated in the fraudulent scheme alleged herein.

159. Defendants knew and/or recklessly disregarded the materially incomplete, false and misleading nature of the information that they caused to be disseminated to the investing public regarding INFUSE Bone Graft and the Company's undisclosed activities to promote the product for uses that had not been evaluated or approved by the FDA. The ongoing scheme described in this Complaint could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of the personnel at the highest level of the Company, including each of the Individual Defendants.

160. Numerous facts collectively establish a strong inference that each of the Individual Defendants acted with scienter and intentionally, or recklessly, misled investors regarding the Company's true state of affairs and concealed that the consistent, double-digit growth in sales of INFUSE Bone Graft were unsustainable because they were made possible only by aggressive off-label marketing tactics that posed a substantial risk to patients and subjected the Company to a severe regulatory response.

161. Defendant Collins, who assumed the role of CEO in May 2001, and Defendant Ellis, who was then Vice President, Corporate Controller and Treasurer, were both in senior management positions at the time the FDA granted premarket approval of INFUSE Bone Graft

and therefore were made aware of and/or had actual knowledge of the Advisory Committee's concerns regarding the potential off-label use of the product, the dangers posed by off-label use, as well as the Advisory Committee's warnings that the Company guard against off-label use. Thus, even prior to the FDA's approval, Defendants Collins and Ellis were on actual notice of the potential dangers that off-label use of INFUSE Bone Graft posed to patients, as well as the highly material risk that significant off-label promotion and use could prompt a regulatory response from the FDA.

162. Defendants Collins, Ellis, and Hawkins had actual knowledge of the FDA regulations regarding the promotion and marketing of medical devices, as evidenced by the fact that each of these Defendants signed SEC Form 10-K filings and Medtronic Annual Reports to shareholders that directly acknowledged the risks and repercussions of failing to comply with these regulations. The following statement appears in each of Medtronic's SEC Form 10-K filings for fiscal years 2007 (signed by Defendants Collins and Ellis) and 2008 (signed by Defendants Hawkins and Ellis), and Medtronic's Annual Reports to shareholders for fiscal years 2007 (signed by Defendants Collins and Ellis) and 2008 (signed by Defendants Hawkins and Ellis):

> Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. ***To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our medical devices.***
>
> ...
>
> Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experience and other information to identify potential problems with marketed medical devices. ***We may be subject to periodic inspection by the FDA for compliance with the FDA's good manufacturing practice regulations among other FDA requirements, such as restrictions on***

> ***advertising and promotion***. . . . ***The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the Department of Justice.*** [Emphasis added.]

163. Defendants Collins, Ellis, and Hawkins, who was then President and COO, due to their positions and responsibilities at the Company, also had knowledge of and/or were directly involved in reviewing and approving the terms of the July 2006 settlement with the DOJ and the CIA that Medtronic entered into to resolve allegations of strikingly similar misconduct as alleged herein at the very Medtronic division that sells and markets INFUSE Bone Graft. Moreover, as a result of the CIA, Collins, Ellis and Hawkins each had actual knowledge of the heightened risks associated with any illegal, improper and/or unethical promotional conduct at the Company's Spinal division.

164. Defendants Collins, Ellis and Hawkins, based on their positions in the Company, were assigned specific monitoring and compliance responsibilities pursuant to the CIA, including reviewing quarterly reports regarding compliance matters at Medtronic's Spinal division. The obligations imposed by the CIA were meant to ensure that Defendants Collins, Ellis, and Hawkins would be regularly informed of the promotional activities at Medtronic's Spinal division, including the consulting arrangements that Medtronic used to promote INFUSE Bone Graft for off-label purposes.

165. The Individual Defendants, including Defendants Collins, Hawkins, and Ellis, also knew the extraordinarily high extent to which sales of INFUSE Bone Graft were dependent upon off-label use and/or were personally involved in approving sales quotas that contemplated and, in fact, necessitated an increase in the number of off-label procedures. In setting sales projections for INFUSE Bone Graft, CW 2 stated that Medtronic's marketing department took into account the scope and number of procedures including trends showing the specific numbers

of off-label procedures, such as PLIFs and TLIFs, to predict sales projections. This analysis, according to CW 2, was based in part on data purchased from market research companies that provided detail on the number of procedures involving different areas of the spine, e.g., lumbar (on-label) versus cervical (off-label). Once Medtronic determined its sales projections, these figures were incorporated into a budget reviewed by former President of Medtronic Spinal and Biologics Wehrly, who reported directly to Defendant Hawkins during the Class Period, and presented the budget and sales projections to Medtronic's senior management. According to CW 2, Medtronic's senior management would then engage in a process of negotiating the budgets and sales projections, often taking three months before settling on a plan. Ultimately, however, the final sales quotas for INFUSE Bone Graft were dictated by Medtronic senior management and were far in excess of what Medtronic's Spinal division's projections indicated or could be achievable without promotion of the product for off-label uses. According to CW 2, "when the numbers came back down, they never reflected the projections. They were much larger."

166. Numerous confidential witnesses, including CWs 1, 9, 12 and CW 14 (a senior manager for Medtronic Spinal and Biologics from 2005 to 2008), confirm the intense pressure that Medtronic's management placed on Medtronic sales representatives to meet the sales quotas they set. Similar to CW 2, CW 14 explained that sales goals were set by a handful of Medtronic executives, including Defendant Ellis, and that they were "very, very, very aggressive." Likewise, CW 12 stated that there was a lot of pressure on Medtronic's Spinal and Biologics division to reach unreasonable sales targets.

167. As demonstrated above, by 2006-07, an astounding 85% of INFUSE Bone Graft sales were for off-label uses, a fact known to or recklessly disregarded by all Defendants, including Collins, Hawkins and Ellis, who reviewed marketing data and analyses and established

sales projections, including sales quotas for INFUSE Bone Graft. Despite their knowledge of the extraordinarily high extent to which revenue of INFUSE Bone Graft was generated by off-label applications of the product, the Individual Defendants, including Defendants Collins, Hawkins and Ellis, agreed upon and established sales quotas for the Spinal division and for INFUSE Bone Graft that required sales to grow 20% year-over-year, with the knowledge that such increases could not be achieved without substantial off-label sales, and that the setting of such aggressive targets would encourage off-label promotion. As one industry consultant quoted in *Medical Marketing & Media* stated, "Let's say the sales goal [for a device] is larger than if every patient over 60 is already on it. Divide that down to territories, and everybody has to meet it. ***The message is, sell off-label***." (Emphasis added.)

168. Not only did the Defendants encourage such off-label promotion through their constantly increasing sales quotas, they also had actual knowledge of, and control over, the surreptitious efforts to promote off-label use of INFUSE Bone Graft through doctors who received undisclosed consulting payments in return for publishing medical journal articles and delivering presentations that addressed and endorsed off-label applications of the product. As discussed above, all of the Individual Defendants occupied senior positions at Medtronic when the Company settled the two whistleblower lawsuits alleging illegal marketing practices in the Spinal division, and were therefore fully aware of the allegations that Medtronic used consulting fees paid to surgeons as compensation for their off-label promotion of the Company's products. The CIA that resulted from this settlement specifically tasks Medtronic's senior management to monitor the Company's compliance with off-label marketing rules and regulations, particularly with regard to payments to doctors. Despite this, the Company continued its practice of providing lucrative consulting fees to surgeons who actively promoted off-label use of INFUSE

Bone Graft, such as Dr. Kuklo, Dr. Polly, Dr. Zdeblick, and numerous others (amounting to millions of dollars per year), often with direct involvement from the senior management of Medtronic. For example, as detailed in ¶ 127, *supra*, Dr. Polly had frequent meetings, telephone calls, and email discussions directly with Defendant Hawkins and other senior executives during the time he was engaged in off-label promotion of INFUSE Bone Graft, as indicated by the billing reports he submitted and which were approved by the Company.

169. These Defendants encouraged the off-label promotion of INFUSE Bone Graft notwithstanding their knowledge of the serious adverse events that patients could suffer as a result of off-label use of the product, which have often resulted in the need for additional surgery, emergency intervention, and in at least one case, death. Not only was Medtronic aware of these complications, as indicated by the statements of CW 2 discussed *supra* at ¶ 146, the Company itself informed doctors as early as 2004 of complications associated with anterior cervical fusions using INFUSE Bone Graft.

170. Indeed, Medtronic submitted many of the adverse event reports associated with the off-label use of INFUSE Bone Graft to the FDA, maintained its own monitoring procedures to track reports of complaints and adverse events (as it is required to do by federal regulations), and even instituted an internal study, or Preventative Action, dated April 21, 2006, to examine INFUSE Bone Graft-related complications, that was prompted by "trended complaint and [Medical Device Reporting] information" monitored by the Company. According to CW 15, a Senior Vice President who worked at Medtronic for numerous years until 2006, a "Quality Group" at Medtronic's Spine division was responsible for addressing adverse events. According to CW 15, former COO Michael DeMane, former President of Medtronic Spinal and Biologics Wehrly and former Worldwide Vice President and General Manager, Biologics, Jon Serbousek,

were aware of the adverse events related to INFUSE Bone Graft, and CW 15 would discuss the complaints related to INFUSE Bone Graft at meetings with these individuals and members of the Quality Group to decide whether or not certain adverse events should be reported to the FDA. In addition, CW 15 stated that the Spinal division used the same complaint reporting system as Medtronic corporate, and that this gave Medtronic's executive officers access to a database containing details of every complaint Medtronic received relating to INFUSE Bone Graft.

171. Promotion of high off-label use of INFUSE Bone Graft also was known to or recklessly disregard by these Defendants and the Company given their monitoring of sales of INFUSE Bone Graft's rhBMP-2 component separately from the required LT-CAGE component, and from their above described efforts to educate doctors on the proper dosage to be used in the cervical spine, an off-label procedure, particularly by advising them through sales representative training programs to use half the dosage in the cervical spine. In addition, Medtronic sales personnel were often present in the operating room at the time of these off-label surgeries.

172. Thus, notwithstanding the extraordinarily high off-label usage of INFUSE Bone Graft, the growing adverse events associated with the product, the Company's claimed compliance systems and CIA obligations, and continuing massive consulting fees to doctors, Defendants repeatedly highlighted growing INFUSE Bone Graft sales throughout the Class Period without ever disclosing the very high off-label use of the product and the fact that this use was driven by its undisclosed off-label marketing campaign, which created the material risk of another adverse regulatory action.

173. Each of the Individual Defendants also personally made repeated statements regarding increased sales growth and acceptance of INFUSE Bone Graft, one of the Company's

core flagship products, as well as regarding the Company's 2006 DOJ settlement and Corporate Integrity Agreement, without ever disclosing the true facts as set forth below.

H. DEFENDANTS' FALSE AND MISLEADING STATEMENTS DURING THE CLASS PERIOD

174. As set forth herein, Defendants each made numerous statements throughout the Class Period regarding INFUSE Bone Graft sales and the CIA that were materially incomplete, false and misleading when made given Defendants' failure to disclose Medtronic's surreptitious off-label marketing and promotion practices and the material risks those practices exposed the Company to in terms of another adverse regulatory action. Defendants made these statements in Medtronic's filings with the SEC, conference calls with analysts, press releases, and other public statements. In particular, Defendants' materially incomplete, false and misleading statements did not disclose: (a) that INFUSE Bone Graft sales were primarily dependent on off-label use of the product; (b) the large sums Medtronic continued to pay Key Opinion Leaders and other "consultants" to promote off-label use of INFUSE Bone Graft throughout the Class Period; and (c) that Medtronic's sales force was actively marketing INFUSE Bone Graft for off-label use, therefore the Company was risking the very regulatory actions, investigations, lawsuits, and declining sales that eventually resulted.

175. Throughout the Class Period, Defendants claimed to strictly adhere to the highest ethical standards and affirmatively stated that Medtronic complied with all applicable healthcare laws and regulations, including prohibitions on off-label promotion. Indeed, Medtronic repeatedly invited investors to its website throughout the Class Period, where the Company described in detail the practices and policies it purportedly implemented and followed to ensure Medtronic conducted its business in an ethical and legal manner.

176. For example, the introduction to a booklet entitled "U.S. Business Conduct Standards 2006," which was published in 2006 and featured prominently on Medtronic's website during the Class Period, states that "[c]ompliance with the law and with the highest ethical standards is critical to Medtronic's continued collaboration with its physician customers." The document mandates that all Medtronic employees comply with the Company's standards, as well as "applicable law, including . . . FDA [] laws." The Company's standards specifically state that consulting arrangements are not to be used as vehicles for promoting Medtronic products off-label, and that "[c]onsultants may not be paid to endorse or otherwise recommend the sale, lease or use of Medtronic products." Moreover, this document states that, "[s]ubject to these limitations, ***and to any FDA restrictions on off-label promotion***, Medtronic may retain Consultants to speak, write and provide Training and Education to audiences, including to healthcare professionals, on topics related to Medtronic products and therapies and related disease states." (Emphasis added.)

177. Defendants' statements regarding Medtronic's compliance with health care laws, including the Company's purported adherence to regulations regarding off-label promotion, were knowingly or recklessly materially incomplete, false and misleading when made because Defendants in fact engaged in an undisclosed campaign to market and encourage off-label use of the INFUSE Bone Graft throughout the Class Period, as detailed in the accounts provided by numerous confidential witnesses above, and because members of Medtronic's senior management, including Defendants Hawkins, Ellis and Collins, established sales quotas and projections that encouraged and in fact expected that the Company's sales force would promote the product for off-label uses. Defendants' materially incomplete, false and misleading Class

Period press releases, SEC filings, and other statements are set forth herein in chronological order.

Second Quarter FY 2007 Financial Results Press Release, Earnings and Other Conference Calls, and Form 10-Q

178. On November 20, 2006, the first day of the Class Period, Defendants reported Medtronic's financial results for the second quarter (ended October 27, 2006) of its 2007 fiscal year in a press release filed with the SEC as an attachment to Form 8-K (the "2Q 2007 8-K"), which was signed by Defendant Ellis. In this first full quarter of sales after Medtronic signed the CIA with the DOJ to settle whistleblower suits regarding promotional and marketing practices in its Spinal division, the Company recorded revenue of $3.075 billion and net earnings for the quarter of $681 million, or $0.59 per diluted share. The press release stated that Spinal revenue increased 16% and noted that the Biologics line, which included INFUSE Bone Graft, contributed significantly through 33% growth. In fact, the press release specifically listed expanded use of INFUSE Bone Graft as a Spinal quarterly highlight:

> ***Worldwide INFUSE® Bone Graft revenue grew 36 percent, driven by expanded surgeon adoption***. On November 9, a Food and Drug Administration (FDA) advisory panel recommended approval of INFUSE Bone Graft for use in oral maxillofacial procedures. [Emphasis added.]

179. On the same day, Defendants conducted a conference call with analysts to discuss Medtronic's second quarter earnings. During this conference call, Defendant Hawkins stated that the Company had "achieved double-digit growth in Spinal and Navigation," and provided additional detail about Medtronic's Spinal business and INFUSE Bone Graft as follows:

> Now let me turn to our Spinal business, one of our consistent performers and most attractive growth platforms. Spinal and Navigation's second quarter revenue increased 16%, with spinal revenue increasing 16% as well. Spinal instrumentation sales increased 10%, but growth was constrained by limited commercial availability of allograft tissue. Spinal biologics sales grew 33%.
>
> ...

> On November 9, an FDA Advisory Panel recommended approval of INFUSE Bone Graft for use in the oral maxillofacial market, which signals an important step in the expansion of indications for INFUSE.

180. Similarly, at a Medtronic conference call at the Lazard Life Sciences Conference on November 29, 2006, a Medtronic representative discussed the tremendous growth of the Company's Spinal division and the importance of INFUSE Bone Graft sales to that business:

> Turning to our spinal business—this has absolutely been a stellar business for Medtronic with gravity defying growth rates that have been in the 20% range consistently for years. . . . ***INFUSE is our biologics, our bone morphogenetic protein which has also been—it's the only bone morphogenetic protein on the market and we have a number of indications—or actually a couple of indications right now in trauma and single level fusions***, but we have recently had a favorable panel recommendation, an FDA panel recommendation for the oral maxillofacial indication. [Emphasis added.]

181. In a Medtronic conference call at a Piper Jaffray Health Care Conference on December 1, 2006, Defendant Collins stated that "***INFUSE, which is our recombinant human bone morphogenic protein used initially in spinal fusion, but historically we received an FDA indication for acute tibial fractures, and just recently picked up an indication for oral maxofacial [sic] indications. It is growing very well. It was up 33% last quarter, and that is without the new indication.***" (Emphasis added.)

182. On December 5, 2006, Defendants filed Medtronic's Quarterly Report for the second quarter of its 2007 fiscal year with the SEC on Form 10-Q (the "2Q 2007 10-Q"). The 2Q 2007 10-Q, which was signed by Defendants Collins and Ellis, reported the same financial results set forth in the 2Q 2007 8-K, and provided additional detail about Medtronic's Spinal business and INFUSE Bone Graft:

> Spinal and Navigation net sales for the three and six months ended October 27, 2006 were $625 million and $1.224 billion, an increase of 16% and 15%, respectively, over the same periods of the prior year.
>
> ...

> The net sales increase for the three and six months ended October 27, 2006 in the operating segment were driven primarily by our Spinal business, which grew 16% and 15%, respectively, over the same periods of the prior fiscal year. . . . Spinal Biologics net sales for the three and six months ended October 27, 2006 were $178 million and $341 million, an increase of 33% and 30%, respectively, over the same periods of the prior year. ***The Spinal sales increase reflects solid growth across our portfolio of product offerings including expanded surgeon adoption of INFUSE Bone Graft***. . . . [Emphasis added.]

183. The 2Q 2007 10-Q also addressed the CIA Medtronic signed as part of the settlement that the Company reached with the DOJ, stating:

> During the six months ended October 27, 2006, the Company reached a settlement agreement with the United States Department of Justice which requires the government to obtain dismissal of the two qui tam civil suits and is conditional upon such dismissal being obtained. To resolve the matter, Medtronic has entered into a five-year agreement that ***further strengthens its employee training and compliance systems surrounding sales and marketing practices. The settlement agreement also reflects Medtronic's assertion that the Company and its current employees had not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

184. In addition, the Company's 2Q 2007 10-Q also contained certifications required by the Sarbanes-Oxley Act of 2002, signed by Defendants Collins and Ellis, who each certified (among other things) that the filing did "not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading." These Defendants also certified that they had "[d]esigned such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to [Medtronic] . . . is made known to us" and that the "information contained in this report fairly presents, in all material respects, the financial condition and results of operations of Medtronic, Inc." Defendants Hawkins and Collins, during their respective terms as CEO of Medtronic, and Defendant Ellis, as CFO, signed the same or substantially similar certifications in each Form 10-Q and Form 10-K filed throughout the Class Period.

185. These statements, which were made following the first full quarter after Medtronic signed the CIA with the DOJ, in which the Defendants purported to ensure "top-level attention to corporate compliance measures" regarding the Company's marketing and promotion activities, were knowingly or recklessly materially incomplete, false and misleading when made because they did not disclose the extraordinarily high extent to which strong revenues from sales of INFUSE Bone Graft depended on off-label applications of the product that were outside the FDA-approved indications, rather than on the factors indicated by management such as increased "surgeon adoption" or expansion of the product's use into new FDA-approved indications, nor did they disclose that the extraordinarily high extent of off-label usage of INFUSE Bone Graft resulted from Defendants' undisclosed campaign to market and encourage off-label use of the product.

186. Furthermore, Defendants' statements in the 2Q 2007 10-Q regarding the CIA entered into with the DOJ were knowingly or recklessly materially incomplete, false and misleading because, although Defendants described further strengthening of Medtronic's employee training and compliance systems, in fact, they continued to engage in a surreptitious campaign to market and encourage off-label use of INFUSE Bone Graft throughout the Class Period and also encouraged and expected the Company's sales force to promote the product for off-label uses, despite the concerns of the FDA Advisory Committee and the serious medical risks associated with off-label application of INFUSE Bone Graft.

Third Quarter FY 2007 Financial Results Press Release, Earnings and Other Conference Calls, and Form 10-Q

187. On February 20, 2007, Defendants reported Medtronic's financial results for the third quarter (ended January 26, 2007) of its 2007 fiscal year in a press release filed with the SEC as an attachment to Form 8-K (the "3Q 2007 8-K"), which was signed by Defendant Ellis.

The Company recorded revenue of $3.048 billion and net earnings for the quarter of $710 million, or $0.61 per diluted share. The press release also reported:

> Spinal and Navigation revenue of $629 million grew 12 percent. Spinal revenue increased 12 percent and Navigation revenue increased 7 percent. Worldwide Spinal revenue was driven by the Biologics product line and the CD Horizon® LEGACY™ family of products, which includes the new PEEK ROD.

188. That same day, Defendants held a conference call with analysts to discuss Medtronic's third quarter earnings. During the call, Defendant Collins reiterated the results announced in the 3Q 2007 8-K:

> Compared to the third quarter of last fiscal year, revenue of $3.048 billion increased 10%, including a $55 million positive impact of foreign currency translation. Net earnings for the third quarter of $710 million translated into diluted earnings per share of $0.61. That was $0.03 above the consensus estimate.

189. Also during this call, Defendant Hawkins added additional detail about the Company's Spinal business and INFUSE Bone Graft:

> So turning to our Spinal and Navigation business, third-quarter revenue increased 12%. Growth in our Spinal business was fairly balanced, with spinal instrumentation sales increasing 11% and spinal biologics growing 15%....
>
> ***Spinal results were largely driven by*** the continued growth of the legacy family, ***INFUSE bone graft***, the CD HORIZON SEXTANT system, and the DIAM system internationally. [Emphasis added.]

190. Significantly, despite these strong results, Defendant Hawkins highlighted increasing competition in the Company's Spinal division, which he attributed to aggressive sales practices of smaller, surgeon-owned companies. Noting that revenue attributable to 60 of the smaller companies had doubled in the last calendar year, Defendant Hawkins stated that their success was in part, based on "business practices" which, according to Defendant Hawkins, could "***come under increasing regulatory and public scrutiny***." (Emphasis added.)

191. Furthermore, Defendant Hawkins reiterated that the Company's business strategy was to continue to develop products that required a stricter regulatory review and approval process—"a PMA rather than a 510(k) regulatory review"—and specifically noted that expanding the indications for INFUSE Bone Graft was part of that strategy: "Another effort of ours is in the area of oral maxillofacial bone grafting, which is an important step in the expansion of indications for INFUSE. This indication for INFUSE, also requiring a PMA, received a favorable FDA advisory panel recommendation last November." In other words, Defendant Hawkins contrasted Medtronic's business practices and strategy—which investors were led to believe were based on following the proper FDA approval process—with those of other smaller spinal companies, which, unlike Medtronic, Defendant Hawkins suggested, faced the threat of "increasing regulatory and public scrutiny."

192. Later during the call, in response to a question from Citigroup analyst Matthew Dodds, Defendants Hawkins and Collins emphasized the importance of INFUSE Bone Graft to Medtronic's Biologics business:

> **Dodds**: Okay, and one last question – on the biologics, Bill, did that also slow down a little bit? Is that an anomaly there, or is it just starting to mature in the core market of spine?
>
> **Hawkins**: No, the law of big numbers – ***that's a business continues to do well***. And as you know, with the expansion we're going to get with the OMF indication and as we get amplified – I mean we think there's lots of legs for sustainable growth in that business.
>
> **Collins**: ***The INFUSE still grew 15%.*** And obviously some of the comps were a little bit more difficult. ***But as Bill said, one of the biggest opportunities we have is continuing to expand the indication***. [Emphasis added.]

193. On March 6, 2007, Defendants filed Medtronic's Quarterly Report for the third quarter of its 2007 fiscal year with the SEC on Form 10-Q (the "3Q 2007 10-Q"). The 3Q 2007 10-Q, which was signed by Defendants Collins and Ellis, reported the same financial results set

forth in the 3Q 2007 8-K and discussed on the conference call, and specifically noted that the "increase in net sales for the three and nine month periods was driven by strong performances in our Spinal and Navigation, Vascular, Neurological and Diabetes operating segments." The 3Q 2007 10-Q also supplied additional detail about the Company's Spinal business and the INFUSE Bone Graft:

> Spinal and Navigation net sales for the three and nine months ended January 26, 2007 were $629 million and $1.854 billion, an increase of 12% and 14%, respectively, over the same periods of the prior year. Foreign currency translation had a favorable impact on net sales for the three and nine months ended January 26, 2007 of approximately $3 million and $6 million, respectively, when compared to the same periods of the prior year. The net sales increase for the three and nine months ended January 26, 2007 in this operating segment were driven primarily by our Spinal business, which grew 12% and 14%, respectively, over the same periods of the prior fiscal year. Spinal instrumentation net sales for the three and nine months ended January 26, 2007 were $429 million and $1.265 billion, an increase of 11% and 10%, respectively, as compared to the same periods of the prior year. Spinal Biologics net sales for the three and nine months ended January 26, 2007 were $169 million and $509 million, an increase of 15% and 25%, respectively, over the same periods of the prior year. ***The Spinal sales increase reflects solid growth across our portfolio of product offerings including expanded surgeon adoption of INFUSE Bone Graft*** and growth of the CD HORIZON LEGACY family of products, which includes our new PEEK ROD. [Emphasis added.]

194. The 3Q 2007 10-Q also addressed the CIA Medtronic signed as part of the settlement, discussed *supra* at Section D, that the Company reached with the DOJ, stating:

> To resolve the matter, Medtronic has entered into a five-year corporate integrity agreement effective upon dismissal of the two suits that ***further strengthens its employee training and compliance systems surrounding sales and marketing practices. The settlement agreement also reflects Medtronic's assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

195. On March 13, 2007, following the release of the Company's 3Q 2007 10-Q, Defendant Hawkins, who had recently been named as successor to Defendant Collins as Medtronic's CEO, participated in a Cowen and Company Annual Health Care Conference in which he announced the approval of INFUSE Bone Graft for oral maxillofacial procedures and

reiterated the impressive sales of INFUSE Bone Graft and the Company's strategy on expanding FDA-approved indications to drive growth:

> Now some good news—you're the first to hear this, but we just recently received expanded indication for INFUSE, for the OMF indication. We are—this is something we have been working on for quite some time. It now gives us one more indication for INFUSE. This is a distinct market from where we have operated in the past.

196. Defendant Hawkins also reiterated the Company's stated business strategy of obtaining FDA approval for new indications for Medtronic's existing products to drive growth, explaining that "One of the things that we think [] will drive growth is, in our ability to expand indications—take existing technologies and then do clinical trials to basically expand the market that we're already in," noting that one such new indication was the approval "for the oral maxillofacial indication, for INFUSE."

197. Similarly, during a March 21, 2007 Lehman Global Healthcare Conference investor call, Defendant Collins reiterated the Company's purported strategy of seeking new indications to drive INFUSE Bone Graft sales, noting the recent approval for oral maxillofacial indications for INFUSE Bone Graft and stating that "We will enter new markets in terms of ageing spine and trauma and we'll continue to build on Infuse applications."

198. These statements were knowingly or recklessly materially incomplete, false and misleading when made because they did not disclose the extraordinarily high extent to which strong revenues from sales of INFUSE Bone Graft depended on off-label applications of the product rather than on the factors indicated by management such as increased "surgeon adoption" or expansion of the product's use into new FDA-approved indications, nor did they disclose that the extraordinarily high extent of off-label usage of INFUSE Bone Graft resulted from Defendants' undisclosed campaign to market and encourage off-label use of the product.

199. Furthermore, Defendants' statements regarding Medtronic's smaller competitors and in the 3Q 2007 10-Q regarding the CIA entered into with the DOJ were knowingly or recklessly materially incomplete, false and misleading because although Defendants contrasted the alleged practices of Medtronic's smaller competitors and described further strengthening of Medtronic's employee training and compliance systems, in fact, they continued to engage in a surreptitious campaign to market and encourage off-label use of INFUSE Bone Graft throughout the Class Period and also encouraged and expected the Company's sales force to promote the product for off-label uses, despite the concerns of the FDA Advisory Committee and the serious medical risks associated with off-label application of INFUSE Bone Graft.

Fourth Quarter FY 2007 Financial Results Press Release, Earnings and Other Conference Calls, and FY 2007 Annual Reports

200. On May 22, 2007, Defendants announced Medtronic's financial results for the fourth quarter (ended April 27, 2007) of its 2007 fiscal year in a press release filed with the SEC as an attachment to Form 8-K (the "4Q 2007 8-K"), which was signed by Defendant Ellis. The Company recorded fiscal year 2007 revenue of $12.299 billion, and fiscal year 2007 net earnings of $2.80 billion, or $2.41 per diluted share. The press release also reported specific revenue numbers for Medtronic's Spinal business and commented on the importance of INFUSE Bone Graft:

> Spinal and Navigation annual revenue of $2.544 billion and fourth quarter revenue of $690 million grew 13 and 11 percent, respectively. Spinal annual revenue of $2.417 billion increased 13 percent for the year and quarterly revenue increased 10 percent. ***Spinal revenue was driven by the continued market acceptance of the InFuse product line***, the CD HORIZON LEGACY Peek Rod System and the Verte-Stack Crescent Vertebral Body Spacer. [Emphasis added.]

201. That same day, Defendants conducted a conference call with analysts to discuss Medtronic's second quarter earnings. On that call, Defendants Collins and Hawkins reiterated the earnings numbers announced in the 4Q 2007 8-K:

> **Collins**: While generating $12.3 billion in revenue this past year, we were able to post a 15% annual increase in diluted earnings per share even though the year-over-year downturn in the U.S. ICD market negatively affected our performance throughout the fiscal year. As you will note, annual results exceeded the upper end of our most recent EPS—EPS guidance.
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> ...
>
> **Hawkins**: During the fourth quarter four of our business segments saw double-digit revenue growth. Vascular and diabetes each grew 22%. Neurological grew 15%. And spinal and navigation grew 11%.

202. Echoing his earlier statements in the February 20, 2007 earnings conference call, Defendant Hawkins noted that Medtronic was losing spine treatment market share to smaller competitors that, he suggested, were engaging in business practices that exposed them to potential regulatory action:

> Well, in terms of the spine, actually we lost a little bit of share in the overall spine market, and primarily due to the plethora of small surgeon-owned spine companies, which we are addressing, one, by bringing out PMA type of products, the new cervical disk, the new products like Peek Rod and Agile, so we have a clear strategy as to how to compete with those companies. And there are other things that could happen that may make it difficult for those companies going forward.

203. Analysts picked up on Defendant Hawkins' statements regarding Medtronic's competitors' sales tactics. For example, in a May 22, 2007, report, Deutsche Bank wrote that "Management noted once again that competition in the spinal implant market continues to intensify owing to market share gains of smaller players (particularly surgeon-owned companies) in light of their ***aggressive sales practices with spine surgeons***." (Emphasis added.) In other words, Defendant Hawkins' statements conveyed the false impression—which was believed by the investor community—that the Company engaged in ethical and legal conduct, when, in fact, Medtronic had embarked on an undisclosed campaign to market INFUSE Bone Graft for off-label uses that eventually brought about the very regulatory action he claimed would befall the Company's competitors.

204. The following day, at a May 23, 2007 Citigroup Healthcare Conference, Defendant Ellis reiterated the strong growth potential for INFUSE Bone Graft, which Defendant Ellis described as dependent on expanding FDA-approved indications for the product, and explained that the Company's growth strategy was driven by increasing sales of products for FDA-approved indications. At the presentation, Defendant Ellis explained that "we still are operating in significantly underpenetrated markets. These graphs highlight the penetration, the people—basically, the people who are indicated for are who is getting it and the percentage of those people that are getting it. And you'll see in many of our therapies, it is very low, under 40% penetration. . . . So again, people that are currently indicated that are actually receiving the appropriate therapy is very low, which means we have significant potential for the markets to continue to grow." Indeed, driving sales of INFUSE Bone Graft for FDA-approved indications, according to Defendant Ellis, was Medtronic's strategy for increasing sales of the product, stating that "our bone morphogenetic protein, InFuse, this received FDA approval for expanded OMF indications, which we think will help grow that business going forward on the biologic side."

205. Likewise, on a May 31, 2007 conference call hosted at the Bank of America Health Care Conference, Defendant Ellis discussed Medtronic's business opportunities in the U.S., where there was significant underpenetration in many of Medtronic's markets, "which gives us more confidence that the market growth will continue to be very, very strong across those businesses." Defendant Ellis also noted that the recent FDA approval for use of INFUSE Bone Graft in oral maxillofacial procedures "will really help reaccelerate even the biologics growth as we go into '08 and '09."

206. At a May 31, 2007 conference call hosted at the Sanford Bernstein 23rd Annual Strategic Decisions Conference 2007, Defendant Hawkins again stressed the importance of INFUSE Bone Graft to Medtronic's business, stating that "One of the key products for us has been a biologic. We licensed a bone morphogenetic protein from Wyeth Corporation and we have been distributing that product. It has now annualizing close to I believe $600 million in sales. It's a very important product and been growing at 15% per annum." Defendant Hawkins also noted that future increases in INFUSE Bone Graft sales would be driven by obtaining FDA approval for additional applications of the product, explaining that "We're continuing to expand the InFuse by doing clinical studies to expand the indications. . . ." Defendant Hawkins also noted the recently-approved indication for use of INFUSE Bone Graft for oral maxillofacial procedures, stating that "We're excited about entering [the dental market] with our oromaxillofacial [sic] indications with the InFuse and we are building a direct sales organization."

207. Similarly, at a June 13, 2007 teleconference call held as part of the Goldman Sachs 28th Annual Global Healthcare Conference, Defendant Ellis reiterated that INFUSE Bone Graft sales would be driven by sales for FDA-approved indications, stating that "INFUSE is our new—one of our big growth platforms over the last several years. We still see significant opportunity there with the expansion into [OMF] indication with INFUSE. And we see increased indications with INFUSE in the future." Defendant Ellis explained that the Spinal division would capitalize on underpenetrated markets and suggested that the Company would work to increase sales for FDA-approved applications, contrasting the opportunities in the Spinal division with other markets, such as pacemakers, which, "based on current indications, is closer to being fully penetrated." By contrast, "the majority of our markets, whether it is spine, diabetes, ICDs,

are still not fully penetrated at all. In fact, in most cases, there are 30, 35% or even less penetration in most of those marketplaces."

208. Likewise, at a Medtronic Investor and Analyst Meeting on June 20, 2007, Medtronic's Spinal Divisions Vice President for Clinical Affairs explained that the Company's strategy for driving sales was based on obtaining FDA approval for additional applications of the Company's spinal products. Specifically, the Medtronic representative stated that:

> We know that Spine market growth over the next several years will be fueled by expanded indications and new procedural therapy. . . . New procedures as well as expanded indications must be supported by new innovative technologies that require rigorous clinical research to secure PMA approval.

209. The Medtronic representative specifically identified several clinical trials that the Company was sponsoring to obtain additional FDA approvals for INFUSE Bone Graft, including an ongoing IDE trial examining the use of INFUSE Bone Graft in off-label Posterolateral Fusions and another recently-approved IDE study involving the use of INFUSE Bone Graft in the cervical spine. Stressing the Company's high scientific standards and its appreciation of the FDA's approval requirements, the Medtronic representative said the Company's unwillingness to "cut corners" ensured that its exposure to regulatory risk was minimized:

> We do not cut corners in clinical research, rather we do employ consistently the highest scientific standards. It allows us to reduce our regulatory risk and to generate the additional evidence required for the adoption of our devices. Our research incorporates a keen understanding of the FDA requirements and other post-approval consideration. We understand the importance of health technology assessments again worldwide and the concerns expressed by our hospital customers, payers and health policymakers.

210. On June 25, 2007, Defendants filed Medtronic's Annual Report for its 2007 fiscal year with the SEC on Form 10-K (the "2007 10-K"). The 2007 10-K, which was signed by Defendants Collins, Hawkins and Ellis, reiterated the financial results set forth in the 4Q 2007 8-K. The 2007 10-K also contained additional detail concerning the INFUSE Bone Graft, and its

material and increasingly important role within the Company's operations and financial condition:

> In March 2007, we received Food and Drug Administration (FDA) approval to begin marketing 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 pre-market approval (PMA) with the FDA for a posterolateral spinal indication for INFUSE Bone Graft.
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> ...
>
> Spinal and Navigation net sales increased 13 percent over the prior fiscal year to $2.544 billion. ***The increase reflects strong growth across our portfolio of spinal surgery products including the INFUSE Bone Graft,*** the CD HORIZON LEGACY Spinal System family of products for thoracolumbar stabilization, our Minimal Access Spinal Technologies (MAST) family of products, and increased acceptance of the CAPSTONE and CRESCENT Vertebral Body Spacers. Vascular net sales increased 28 percent over the prior fiscal year to $1.205 billion. Vascular growth was driven by Coronary Vascular net sales which grew 31 percent, and by Endovascular/Peripheral sales which grew 20 percent over fiscal year 2006. [Emphasis added.]

211. The 2007 10-K further elaborated on Medtronic's fiscal year 2007 performance in Biologics and added additional detail about the INFUSE Bone Graft:

> Spinal and Navigation net sales for fiscal year 2007 increased by 13 percent from the prior fiscal year to $2.544 billion. Foreign currency translation of $9 million had a favorable impact on net sales when compared to the prior fiscal year. Spinal net sales for fiscal year 2007 increased 13 percent from the prior fiscal year to $2.417 billion driven by solid growth across our entire portfolio of product offerings.
>
> ...
>
> Biologics net sales were $696 million in fiscal year 2007, a 22 percent increase over the prior year, ***based on continued strong acceptance of INFUSE Bone Graft***. 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.
>
> ...
>
> Spinal and Navigation net sales for fiscal year 2006 increased by 19 percent from the prior fiscal year to $2.244 billion. Foreign currency translation had an

> unfavorable impact on net sales of $11 million when compared to the prior fiscal year. Spinal net sales for fiscal year 2006 increased 20 percent from the prior fiscal year to $2.136 billion. While this increase reflected solid growth across our portfolio of product offerings, ***Biologics net sales were $570 million, a* 38 *percent increase over the prior year, based on continued acceptance of INFUSE Bone Graft***. [Emphasis added.]

212. Finally, the 2007 10-K addressed the CIA Medtronic signed as part of the settlement, discussed *supra* at Section D, that the Company reached with the DOJ, stating:.

> To resolve the matter, Medtronic has entered into a five-year corporate integrity agreement effective upon dismissal of the two suits that ***further strengthens its employee training and compliance systems surrounding sales and marketing practices. The settlement agreement also reflects Medtronic's assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

213. The Defendants reiterated the fiscal year 2007 financial results in Medtronic's 2007 Annual Report to shareholders. The Annual Report, which was signed by Defendants Collins and Ellis, stated the following with regard to Medtronic's financial results and the impact of INFUSE Bone Graft on the Company's operations and financial condition:

> Spinal and Navigation net sales increased 13 percent over the prior fiscal year to $2.544 billion. ***The increase reflects strong growth across our portfolio of spinal surgery products including the INFUSE Bone Graft***. . . .
>
> ...
>
> Biologics net sales were $696 million in fiscal year 2007, a 22 percent increase over the prior year, ***based on continued strong acceptance of INFUSE Bone Graft***. [Emphasis added.]

214. The 2007 Annual Report also addressed the CIA Medtronic signed as part of the settlement reached with the DOJ, reiterating that the "agreement reflects our assertion that ***the Company and its current employees have not engaged in any wrongdoing or illegal activity***." (Emphasis added.)

215. These statements were knowingly or recklessly materially incomplete, false and misleading when made because they did not disclose the extraordinarily high extent to which

strong revenues from sales of INFUSE Bone Graft depended on off-label applications of the product rather than on the factors indicated by management, such as "continued market acceptance" of INFUSE Bone Graft or expansion of the product's use into new FDA-approved indications, nor did they disclose that the extraordinarily high extent of off-label usage of INFUSE Bone Graft resulted from Defendants' undisclosed campaign to market and encourage off-label use of the product. Notably, the 2007 10-K stated that Medtronic has submitted a PMA with the FDA for a Posterolateral spinal indication for the INFUSE Bone Graft, but failed to disclose the extent to which the sales of the product were already dependent on such off-label applications. Moreover, in direct contrast to the Company's representations during the June 20, 2007 investor meeting, Medtronic actively promoted INFUSE Bone Graft for uses outside its labeled application, circumventing the very clinical and scientific evaluation required by the FDA's pre-market approval process.

216. Furthermore, Defendants' statements regarding Medtronic's smaller competitors and in the 2007 10-K and 2007 Annual Report to shareholders regarding the CIA entered into with the DOJ were knowingly or recklessly materially incomplete, false and misleading because, although Defendants contrasted the alleged sales practices of Medtronic's smaller competitors and described further strengthening of Medtronic's employee training and compliance systems, in fact, they continued to engage in a surreptitious campaign to market and encourage off-label use of INFUSE Bone Graft throughout the Class Period and also encouraged and expected the Company's sales force to promote the product for off-label uses despite the concerns of the FDA Advisory Committee and the serious medical risks associated with off-label application of INFUSE Bone Graft.

First Quarter FY 2008 Financial Results Press Release, Earnings Conference Call, and Form 10-Q, and Statements Responding to Reports of Congressional Inquiries

217. On August 21, 2007, Defendants reported Medtronic's financial results for the first quarter (ended July 27, 2007) of its 2008 fiscal year in a press release filed with the SEC as an attachment to Form 8-K (the "1Q 2008 8-K"), which was signed by Defendant Ellis. The Company recorded revenue of $3.127 billion and net earnings of $675 million, or $0.59 per diluted share. The press release specifically noted the importance of INFUSE Bone Graft to the Spinal division's revenues:

> Spinal revenue of $644 million grew 12 percent. ***Worldwide Spinal revenue was driven by sales of INFUSE® Bone Graft in the Biologics product line***, CRESCENT™ Vertebral Body Spacers and the LEGACY® family of products, which includes a new PEEK Rod System. [Emphasis added.]

218. On the same day, Defendants held a conference call with analysts to discuss Medtronic's first quarter results. During that call, Defendant Collins reiterated the financial results announced in the 1Q 2008 8-K:

> By now, most of you should have seen the press release discussing our fiscal 2008 first-quarter financial results. Compared to the first quarter of last fiscal year, revenue of $3.127 billion increased 8%. . . . Net earnings for the first quarter of $675 million resulted in a diluted earnings per share of $0.59, which grew 16% over the first quarter a year ago.

219. On September 5, 2007, Medtronic filed its Quarterly Report for the first quarter of its 2008 fiscal year with the SEC on Form 10-Q (the "1Q 2008 10-Q"). The 1Q 2008 10-Q, which was signed by Defendants Hawkins and Ellis, reported the same financial results that were included in the 1Q 2008 8-K and discussed on the August 21, 2007 analyst call and stated that the "Spinal business experienced strong net sales growth in the United States." The 1Q 2008 10-Q also provided additional details regarding the significance of INFUSE Bone Graft to the continued success of the Spinal segment:

> ***Spinal Biologics net sales were $190 million for the three months ended July 27, 2007, a 17 percent increase over the same period in the prior fiscal year, based on continued strong acceptance of INFUSE Bone Graft***. . . . Late in fiscal year 2007 we received FDA approval for the use of INFUSE Bone Graft for certain oral maxillofacial and dental regenerative bone grafting procedures. [Emphasis added.]

220. The 1Q 2008 10-Q also addressed the CIA Medtronic signed as part of the settlement, discussed *supra* at Section D, that the Company reached with the DOJ, stating:

> To resolve the matter, Medtronic has entered into a five-year corporate integrity agreement effective upon dismissal of the two suits that ***further strengthens its employee training and compliance systems surrounding sales and marketing practices. The settlement agreement also reflects Medtronic's assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

221. Several weeks later, on September 27, 2007, articles in the *Wall Street Journal* and *The New York Times* reported on a letter Senator Grassley sent to Defendant Hawkins requesting a briefing from the Company and documents related to Medtronic's physician payments, an inquiry that was prompted by allegations in the whistleblower action that settled just before the start of the Class Period and news reports that indicated the Company's physician consultants had sometimes promoted off-label use of Medtronic products. The *New York Times* article stated that "Medtronic's payments to surgeons appear to have continued for at least several months after the settlement [with the DOJ] was reached in July 2006," which itself demonstrates that the investor community had accepted Medtronic's misleading statements indicating that the Company had curbed the activities that formed the basis of the whistleblower suits. In an attempt to quell the serious concerns raised by these reports, and to continue misleading investors regarding the true facts as set forth herein, in a September 28, 2007 article in the Minneapolis-St. Paul *Business Journal*, a Medtronic spokesman stated that Medtronic's payments to doctors had been "***fully compliant with the law and industry standards***." (Emphasis added.)

222. These statements were knowingly or recklessly materially incomplete, false and misleading when made because they did not disclose the extraordinarily high extent to which strong revenues from sales of INFUSE Bone Graft depended on off-label applications of the product rather than on the factors indicated by management such as "continued strong acceptance" of INFUSE Bone Graft, nor did they disclose that the extraordinarily high extent of off-label usage of INFUSE Bone Graft resulted from Defendants' undisclosed campaign to market and encourage off-label use of the product. In fact, when questions regarding off-label promotion and questionable payments to doctors were raised by Senator Grassley and publicized in the news media, Medtronic officials publicly denied they had engaged in any wrongdoing, in flat contradiction to the accounts of numerous confidential witnesses that detail the Company's deliberate scheme to promote INFUSE for off-label uses.

223. Furthermore, Defendants' statements in the 1Q 2008 10-Q regarding the CIA entered into with the DOJ were knowingly or recklessly materially incomplete, false and misleading because, although Defendants described further strengthening of Medtronic's employee training and compliance systems, in fact, they continued to engage in a surreptitious campaign to market and encourage off-label use of INFUSE Bone Graft throughout the Class Period, and also encouraged and expected the Company's sales force would promote the product for off-label uses, despite the concerns of the FDA Advisory Committee and the serious medical risks associated with off-label application of INFUSE Bone Graft.

Second Quarter FY 2008 Financial Results Press Release, Earnings Conference Call, and Form 10-Q

224. On November 19, 2007, Defendants reported Medtronic's financial results for the second quarter (ended October 26, 2007) of its 2008 fiscal year in a press release filed with the SEC as an attachment to Form 8-K (the "2Q 2008 8-K"), which was signed by Defendant Ellis.

The Company recorded revenue of $3.124 billion and net earnings for the quarter of $666 million, or $0.58 per diluted share. The press release noted strong results in the Company's Spinal Biologics business, stating that "Spinal revenue of $660 million grew 10 percent, ***driven by sales of the biologics product line***." (Emphasis added.)

225. On the same day, Defendants conducted a conference call with analysts to discuss Medtronic's second quarter earnings. During this conference call, Defendant Hawkins again emphasized the strong sales in the Company's Biologics business and the importance of Biologics to the Company's Spinal division: "So, turning to our spine business, we saw 10% growth in the quarter, driven by sales of biologics and strong growth outside the US."

226. On December 4, 2007, Defendants filed Medtronic's Quarterly Report for the second quarter of its 2008 fiscal year with the SEC on Form 10-Q (the "2Q 2008 10-Q"). The 2Q 2008 10-Q, which was signed by Defendants Hawkins and Ellis, reported the same financial results set forth in the 2Q 2008 8-K, and contained additional detail concerning the Spinal segment and the significant role that INFUSE Bone Graft 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.*** [Emphasis added.]

227. The 2Q 2008 10-Q also addressed the CIA Medtronic signed as part of the settlement, discussed *supra* at Section D, that the Company reached with the DOJ, stating:

> To resolve the matter, we have entered into a five-year corporate integrity agreement effective which will become effective when any appeals regarding those dismissals to the U.S. Court of Appeals for the Sixth Circuit become final. ***The corporate integrity agreement further strengthens our employee training and compliance systems surrounding sales and marketing practices. The settlement agreement reflects our assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

228. These statements were knowingly or recklessly materially incomplete, false and misleading when made because they did not disclose the extraordinarily high extent to which strong revenues from sales of INFUSE Bone Graft depended on off-label applications of the product rather than the factors indicated by management, such as "continued strong acceptance" of INFUSE Bone Graft, nor did they disclose that the extraordinarily high extent of off-label usage of INFUSE Bone Graft resulted from Defendants' undisclosed campaign to market and encourage off-label use of the product.

229. Furthermore, Defendants' statements in the 2Q 2008 10-Q regarding the CIA entered into with the DOJ were knowingly or recklessly materially false and misleading because although Defendants described further strengthening of Medtronic's employee training and compliance systems, in fact, they continued to engage in a surreptitious campaign to market and encourage off-label use of INFUSE Bone Graft throughout the Class Period and also encouraged and expected the Company's sales force would promote the product for off-label uses, despite the concerns of the FDA Advisory Committee and the serious medical risks associated with off-label application of INFUSE Bone Graft.

Third Quarter FY 2008 Financial Results Press Release, Earnings Conference Call, and Form 10-Q

230. On February 19, 2008, Defendants reported Medtronic's financial results for the third quarter (ended January 25, 2008) of its 2008 fiscal year in a press release filed with the SEC as an attachment to Form 8-K (the "3Q 2008 8-K"), which was signed by Defendant Ellis.

The Company recorded revenue of $3.405 billion and net earnings for the quarter of $77 million, or $0.07 per diluted share. The press release 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.

231. On the same day, Defendants conducted a conference call with analysts to discuss Medtronic's 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 Spinal 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.

232. On March 4, 2008, Defendants filed Medtronic's Quarterly Report for the third quarter of its 2008 fiscal year with the SEC on Form 10-Q (the "3Q 2008 10-Q"). The 3Q 2008 10-Q, which was signed by Defendants Hawkins and Ellis, reiterated the financial results set forth in the 3Q 2008 8-K, and also contained additional detail concerning the Spinal segment, highlighting the fact that INFUSE Bone Graft continued to be a primary driver of net sales increases in the Biologics division:

> 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.*** [Emphasis added.]

233. The 3Q 2008 10-Q also addressed the CIA Medtronic signed as part of the settlement, discussed *supra* at Section D, that the Company reached with the DOJ, stating:.

> The two suits were based upon allegations about certain sales and marketing practices in the Spinal business. To resolve the matter, we have entered into a five-year corporate integrity agreement which will become effective when any appeals regarding those dismissals to the U.S. Court of Appeals for the Sixth Circuit become final. ***The corporate integrity agreement further strengthens our employee training and compliance systems surrounding sales and marketing practices. The settlement agreement reflects our assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

234. These statements were knowingly or recklessly materially incomplete, false and misleading when made because they did not disclose the extraordinarily high extent to which strong revenues from sales of INFUSE Bone Graft depended on off-label applications of the product rather than the factors indicated by management such as "continued strong acceptance" of INFUSE Bone Graft, nor did they disclose that the extraordinarily high extent of off-label usage of INFUSE Bone Graft resulted from Defendants' undisclosed campaign to market and encourage off-label use of the product.

235. Furthermore, Defendants' statements in the 3Q 2008 10-Q regarding the CIA entered into with the DOJ were knowingly or recklessly materially false and misleading because although Defendants described further strengthening of Medtronic's employee training and compliance systems, in fact, they continued to engage in a surreptitious campaign to market and encourage off-label use of the INFUSE Bone Graft throughout the Class Period despite the concerns of the FDA Advisory Committee and the serious medical risks associated with off-label application of INFUSE Bone Graft.

Fourth Quarter FY 2008 Financial Results Press Release, Earnings Conference Call, and Annual Reports, and the April 2008 INFUSE Bone Graft Press Release

236. On April 29, 2008, Defendants issued a press release which announced that Medtronic had received FDA approval to market smaller kit sizes of INFUSE Bone Graft, XX Small (0.7 cc) and X Small (1.4cc) for FDA-approved applications. The press release further stated:

> Since its initial market introduction, INFUSE Bone Graft has enabled advances in surgical procedures and been used successfully in treating over 500,000 patients. ***Expanding the portfolio increases the availability to a broader number of patients and represents Medtronic's continued commitment to innovation in the science of bone regeneration and advancing surgical technology.*** [Emphasis added.]

237. On May 20, 2008, Defendants reported Medtronic's fourth-quarter and full-year financial results for the 2008 fiscal year (ended April 25, 2008) in a press release filed with the SEC as an attachment to Form 8-K (the "4Q 2008 8-K"), which was signed by Defendant Ellis. The Company reported 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.

238. The press release further 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.

239. On the same day, Defendants held an analyst conference call to discuss Medtronic's 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.

240. At a Medtronic Institutional Investor and Analyst Meeting held June 2, 2008, a Medtronic representative discussed the importance of expanding FDA approvals for new indications to the growth of INFUSE Bone Graft sales, stating that "Biologics is another big area and just recently a couple of weeks ago we received our product clearance, our label approval for claims in the – I'm sorry, for the two different small kid [sic] sizes that allow us to support our claims in the OMF area. Right now there's obviously an A-List procedure—a tibia area for trauma, and then of course this recent release in the OMF area which gives us a chance for we think tremendous growth in a space that we've not played in significantly in the past."

241. On June 24, 2008, Defendants filed Medtronic's Annual Report for its 2008 fiscal year with the SEC on Form 10-K (the "2008 10-K"), which was signed by Defendants Hawkins and Ellis. The 2008 10-K reiterated the same financial results set forth in the 4Q 2008 8-K, and provided additional detail concerning the Spinal segment, particularly the INFUSE Bone Graft and its material and increasingly important role within the company's operations and financial condition.

242. In the overview of the business set forth in the 2008 10-K, Defendants stated as follows with respect to INFUSE Bone Graft:

> 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 pre-market approval (PMA) with the FDA for a posterolateral spinal indication for INFUSE Bone Graft.

243. The 2008 10-K also discussed the material role that INFUSE Bone Graft 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.
>
> ...
>
> 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.
>
> ...
>
> Biologics net sales were $704 million in fiscal year 2007, a 24 percent increase over the prior year, based on continued strong acceptance of INFUSE Bone Graft. [Emphasis added.]

244. Finally, the 2008 10-K addressed the CIA Medtronic signed as part of the settlement, discussed *supra* at Section D, that the Company reached with the DOJ, stating:

> To resolve the matter, Medtronic has entered into a five-year corporate integrity agreement effective upon dismissal of the two suits that ***further strengthens its employee training and compliance systems surrounding sales and marketing practices. The settlement agreement also reflects Medtronic's assertion that the Company and its current employees have not engaged in any wrongdoing or illegal activity.*** [Emphasis added.]

245. Defendants reiterated the fiscal year 2008 financial results in Medtronic's 2008 Annual Report to shareholders. The 2008 Annual Report, which was signed by Defendants

Hawkins and Ellis, stated the following with regard to Medtronic's financial results, and the impact of INFUSE Bone Graft on the Company's operations and financial condition:

> Spinal net sales for fiscal year 2008 increased by 23 percent from the prior fiscal year to $2.982 billion.
>
> ...
>
> 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.*** [Emphasis added.]

246. The 2008 Annual Report also addressed the CIA Medtronic signed as part of the settlement reached with the DOJ, reiterating that the "agreement reflects our assertion that ***the Company and its current employees have not engaged in any wrongdoing or illegal activity***." (Emphasis added.)

247. These statements were knowingly or recklessly materially incomplete, false and misleading because they did not disclose the extraordinarily high extent to which strong revenues from sales of INFUSE Bone Graft depended on off-label applications of the product rather than on the factors indicated by management such as the increased tibial and oral maxillofacial usage, nor did they disclose that the extraordinarily high extent of off-label usage of INFUSE Bone Graft resulted from Defendants' undisclosed campaign to market and encourage off-label use of the product. Notably, the 2008 10-K also stated that Medtronic had submitted a PMA with the FDA for a Posterolateral spinal indication for the INFUSE Bone Graft, but failed to disclose the extent to which the sales of the product already were dependent on such off-label applications. Similarly, Defendants' April 29, 2008 press release announced the availability of smaller INFUSE Bone Graft kits without disclosing that they were primarily being made available in those smaller sizes not for the procedures they described, which had been approved by the FDA, but for off-label use, particularly in the cervical spine.

248. Furthermore, Defendants' statements in the 2008 10-K and 2008 Annual Report regarding the CIA entered into with the DOJ were knowingly or recklessly materially false and misleading because although Defendants described further strengthening of Medtronic's employee training and compliance systems, in fact, they continued to engage in a surreptitious campaign to market and encourage off-label use of the INFUSE Bone Graft throughout the Class Period despite the concerns of the FDA Advisory Committee and the serious medical risks associated with off-label application of INFUSE Bone Graft.

First Quarter FY 2009 Financial Results Press Release, Earnings Conference Call, and Form 10-Q

249. On August 19, 2008, Defendants reported Medtronic's 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 2009 8-K"), which was signed by Defendant Ellis. The Company recorded revenue of $3.706 billion and net earnings for the quarter of $747 million, or $0.66 per diluted share. The press release 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.

250. On the same day, Defendants held an analyst conference call to discuss Medtronic's first quarter earnings. During this conference call, Defendant Hawkins reiterated the results described in the 1Q 2009 8-K, and 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.***
>
> ...
>
> 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.]

251. Defendant Hawkins went on to discuss expanded indications of the INFUSE Bone Graft (without disclosing that approximately 85% of INFUSE Bone Graft sales at that time were already for off-label applications):

> 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.*** [Emphasis added.]

252. Defendant Hawkins later emphasized the strength and significance of the Spinal division:

> So I mean, we are all over the Spine business right now, I can tell you. And I am confident that this business is going to be a strong business for Medtronic. And by the way, as I mentioned, the ***Biologics continues to do very well with the two new small kit sizes. You know, we have got a dedicated sales force going after the OMF marketplace, and we are beginning to see some traction there.*** So, look, I am optimistic and very confident in the Spine business. [Emphasis added.]

253. On September 3, 2008, Defendants filed Medtronic's Quarterly Report for the first quarter of its 2009 fiscal year with the SEC on Form 10-Q (the "1Q 2009 10-Q"). The 1Q 2009 10-Q, which was signed by Defendants Hawkins and Ellis, reiterated the same financial results set forth in the 1Q 2009 8-K, and also contained additional detail concerning the Spinal

segment, highlighting the material role played by INFUSE Bone Graft 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.*** [Emphasis added.]

254. These statements were knowingly or recklessly materially incomplete, false and misleading when made because they did not disclose the extraordinarily high extent to which strong revenues from sales of INFUSE Bone Graft depended on off-label applications of the product rather than on the factors indicated by management such as the expanded oral maxillofacial indication, nor did they disclose that the extraordinarily high extent of off-label usage of INFUSE Bone Graft resulted from Defendants' undisclosed campaign to market and encourage off-label use of the product. Furthermore, Defendants described the success of the smaller size INFUSE Bone Graft kits without disclosing that they were primarily being made available in these smaller sizes not for the procedure they described, which had been approved by the FDA, but for off-label use, particularly in the cervical spine.

Defendants' Statements in Response to Reports of Off-Label Complications and Marketing

255. On September 5, 2008, the day after the *Wall Street Journal* published articles about complications suffered by many patients who received the INFUSE Bone Graft in off-label applications, the Minneapolis-St. Paul *Star Tribune* quoted a Medtronic spokesperson as saying,

"Infuse is a revolutionary and safe product, when used within its current product labeling," and "***Medtronic does not promote off-label use***." (Emphasis added.)

256. On September 25, 2008, in response to a *Wall Street Journal* article published the same day regarding the whistleblower suits alleging improper financial relationships between Medtronic and doctors who use the INFUSE Bone Graft discussed in Section D *supra*, the Company issued a press release stating:

> ***Behaviors like those described in the article are inconsistent with Medtronic's ethical standards.***
>
> ***Since the* qui tam *lawsuit, the company has put more rigorous systems and processes in place to assure alignment with these standards, identify any break from standards, and address behavior that is in violation.***
>
> Employees must follow rigorous compliance processes in connection with all arrangements with physicians, including consulting and service agreements and appropriate travel and entertainment.
>
> ...
>
> Because these goals are so central to the ability of our company and our industry to steadily improve patient outcomes, we are committed to continuous improvement and will continue to take whatever actions are required, at any point in time, to remediate unacceptable conduct when it occurs, and to prevent it from occurring in the future. [Emphasis added.]

257. These statements were knowingly or recklessly materially incomplete, false and misleading because they asserted that Medtronic was not engaging in off-label promotion of the INFUSE Bone Graft, notwithstanding the fact that Defendants were engaged in an undisclosed campaign to market and encourage off-label use of the product throughout the Class Period. Furthermore, Defendants' statement that "Infuse is a revolutionary and safe product, when used within its current product labeling" was materially incomplete and misleading as it failed to disclose the significant risk and incidences of adverse events in patients undergoing off-label

procedures using INFUSE Bone Graft and the fact that approximately 85% of INFUSE Bone Graft sales at the time of the statement were for off-label applications.

I. THE PRICE OF MEDTRONIC COMMON STOCK DECLINES AS INFUSE BONE GRAFT SALES ARE DRIVEN DOWN FOLLOWING THE STRONG FDA NOTIFICATION AND DOJ SUBPOENA

258. Throughout the Class Period, the trading price of Medtronic's common stock was artificially inflated as a result of the foregoing materially incomplete, false and misleading statements. The price of Medtronic shares immediately declined in a statistically significant amount after J.P. Morgan issued the results of its proprietary spine surgery survey on November 12, 2008, after another analyst from William Blair & Company also expressed concerns about INFUSE Bone Graft sales on November 14, 2008, and then again, on November 18, 2008, immediately after the last day of the Class Period, when the Company disclosed that INFUSE Bone Graft sales had, in fact, declined as a result of the strong FDA Notification and that Medtronic had received a subpoena from the DOJ.

259. On November 12, 2008, J.P. Morgan issued a report, entitled "InFuse at Risk: Proprietary JPM Spine Survey and F2Q Preview," which noted the results of a proprietary survey of fifty U.S. spine surgeons to gauge their expected use of INFUSE Bone Graft going forward "in the wake of [a July 1, 2008] FDA warning letter on off-label use in the cervical spine, a whistleblower suit targeting leading InFuse surgeons, and a resulting increase in reimbursement scrutiny tied to off-label use." In its report, J.P. Morgan concluded that although INFUSE Bone Graft had been a significant driver of growth for Medtronic in the past and one of the Company's most consistent products, it expected sales of INFUSE Bone Graft "to decline considerably" and that it found that "[o]ne third of surgeons said they expect to reduce InFuse use in the wake of these events, forecasting a 57% reduction in cervical applications and 24% decline in lumbar." J.P. Morgan further noted that the surgeons as a whole had forecast a 6%

decline in INFUSE Bone Graft use in the coming year, which was a significant reversal for a product that grew 16.9% over the previous year.

260. Investors reacted sharply to the J.P. Morgan report, as the price of Medtronic common stock immediately declined in a statistically significant manner from a close of $40.08 on November 11, 2008, to a closing price of $37.72 on November 12, 2008, a drop of 5.89%.

261. On November 14, 2008, William Blair & Company issued a report that provided additional discussion of the concerns expressed in the J.P. Morgan report, specifically regarding the effect that the FDA Notification would have on INFUSE Bone Graft sales. The analyst noted that "InFuse had remained a bright spot with midteens growth, but ***a recent FDA warning letter likely has chilled the widespread off-label use of the product in the cervical spine***, suggesting the company will miss our target this quarter." (Emphasis added.)

262. In response to the William Blair & Company report, the price of Medtronic common stock immediately declined in a statistically significant manner from a close of $39.93 on November 13, 2008, to a closing price of $37.45 on November 14, 2008, a drop of 6.21%.

263. Medtronic's financial results for the second quarter of the 2009 fiscal year (ended October 24, 2008), reported in a press release filed with the SEC as an attachment to a November 18, 2008 Form 8-K (the "November 18th 8-K"), further revealed the true adverse facts. Medtronic reported that revenue from the Spinal segment had declined to $829 million for the quarter, down $30 million from the previous quarter. The decreased sales in the Spinal segment stemmed from a significant decline in INFUSE Bone Graft sales and were a sharp deviation from the Company's reports of repeated double-digit growth in the Spinal segment in previous quarters. Revenue from INFUSE Bone Graft alone had declined to $198 million, down from $221 million the previous quarter.

264. During the Company's quarterly earnings conference call, conducted the morning of November 18, 2008, Defendant Hawkins discussed the problems with INFUSE Bone Graft and stated that the "**[*p*]*ublic health notice issued on the use of bone morphogenetic protein and the cervical setting, along with the related negative press coverage and payer pushback created some significant new hurdles***." (Emphasis added.) Defendant Hawkins then went on to describe the problems with INFUSE Bone Graft in more detail and added that Medtronic had received a subpoena from the DOJ looking into off-label use of INFUSE Bone Graft:

> 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 [sic] 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.]

265. In response to an analyst's question, Defendant Hawkins referred to these problems as "kind of the perfect storm," yet this storm was of Defendants' own making. Indeed the strong FDA Notification and a subpoena from the DOJ and the numerous other negative developments noted by Defendant Hawkins were precisely the undisclosed risks that Medtronic had been taking by engaging in its surreptitious off-label promotional practices.

266. The analyst community reacted sharply to news of the INFUSE Bone Graft sales decline and the new disclosure regarding the DOJ subpoena. Following on its previous week's warning regarding INFUSE Bone Graft, J.P. Morgan's Medtronic analyst wrote prior to the earnings conference call that "***Spine was particularly light, and even worse than we previewed last week when we sounded the alarm on InFuse with survey. For the quarter, InFuse came in flat* [*year-over-year*]*, missing Street consensus by a shocking $28M.***" (Emphasis added.) Collins Stewart's Medtronic analyst also noted the significant impact that weak INFUSE Bone

Graft sales had on Medtronic's financial results, stating "[s]pine sales continue to be disappointing…. ***INFUSE is the latest red flag. Sales growth in the quarter was flat, reflecting increasing concerns by surgeons to use the product off label***." (Emphasis added.) The Medtronic analyst from Morgan Stanley summarized the negative developments regarding INFUSE Bone Graft in detail, stating:

> ***Infuse sales were flat at $198 million, missing our estimate of $220 million.*** This shortfall resulted from several factors including the FDA public health notice regarding the cervical use of BMP, several negative news stories from the media regarding off-label use for the cervical indication, and a whistleblower suit filed against a number of spine surgeons. Medtronic also disclosed that it recently received a subpoena from the Department of Justice seeking information into off-label use of Infuse…. ***It will be difficult for Medtronic to combat each of these threats to its spine franchise and sales in this division will continue to struggle.*** [Emphasis added.]

267. Other analysts covering Medtronic echoed Morgan Stanley in predicting that the newly-disclosed problems with the INFUSE Bone Graft would continue to plague Medtronic's sales in the near future. In a report issued following the conference call, Credit Suisse, after discussing the various problems with INFUSE Bone Graft, predicted that "[w]e don't think things get better from here; in fact there is a real risk things get worse." Collins Stewart noted that "[u]nderperformance in Spine is likely to continue with reduced sales from off-label use of INFUSE in cervical spine procedures." And in a report issued after the earnings conference call, J.P. Morgan's Medtronic analyst noted that "[w]e are further reducing our Biologics forecast today, now estimating a 10% decline in Infuse sales in the back half of the year and a further 3% contraction in FY10. Medtronic also announced today that it has received a subpoena from the US Department of Justice (DOJ), which will take some time to resolve and is likely in our view to put further pressure on off-label usage."

268. As a result of these adverse revelations, the price of Medtronic common stock price immediately declined sharply in a statistically significant manner from a closing price of

$36.42 on November 17, 2008, to a closing price of $31.60 on November 18, 2008, or a 13.23% decline.

J. ADDITIONAL ADVERSE POST-CLASS PERIOD DISCLOSURES FOLLOW

269. After the end of the Class Period, a series of negative news stories and revelations resulting from Congress' investigation into Medtronic's financial arrangements with spinal surgeons and their involvement with and promotion of INFUSE Bone Graft, as well as the conflicts of interest and risks to patient safety posed by those relationships, continued to hamper sales of INFUSE Bone Graft, as Defendants themselves repeatedly admitted. These disclosures further confirm Lead Plaintiffs' allegations and the material risks presented by Medtronic's improper marketing of INFUSE Bone Graft that were known and concealed by the Defendants throughout the Class Period.

270. For example, a December 12, 2008 Minneapolis-St. Paul *Star Tribune* article reported on Medtronic's financial relationship with several surgeons at Twin Cities Spine Center, one of the world's largest spine practices. As noted in the article, documents filed in the Boston whistleblower action earlier that week included a July 2002 letter to Defendant Collins from one Twin Cities Spine surgeon, Dr. Ensor Transfeldt, inviting Defendant Collins to view an off-label procedure involving INFUSE Bone Graft scheduled just days after the FDA's approval of the product. The article also discussed two other documents filed in the litigation—a 2002 draft consulting agreement providing for payments to several Twin Cities Spine surgeons of $4,000 per day not to exceed a total of $80,000 per year, for a total of $240,000 for the three-year contract term and a proposed royalty agreement for six Twin Cities Spine doctors that would provide payments of 5 percent of net sales of "royalty products" sold in the United States to compensate the doctors for their work in helping to develop or contribute to these future

"inventions"—that hinted at the lucrative opportunities for surgeons who worked for the Company.

271. Subsequently, on January 16, 2009, *The Wall Street Journal* reported on a letter sent by Senator Grassley to Kevin P. Reilly, President at the University of Wisconsin, regarding the consulting and royalty payments received by Dr. Zdeblick, the Chair of the university medical school's Department of Orthopedics & Rehabilitation and one of the surgeons who authored some of the preliminary studies that led to the FDA's approval of INFUSE Bone Graft. Although the university is required to monitor its researchers' financial conflicts of interest, according to information requested from Medtronic by Senator Grassley that he disclosed in his January 16, 2009 letter, the amounts Medtronic paid Dr. Zdeblick far exceeded those he reported to the university. Specifically, while Dr. Zdeblick was only required to disclose annual amounts in excess of $20,000 per year, and in one year reported payments in excess of $40,000, Dr. Zdeblick actually received between $2.6 million and $4.6 million per year from Medtronic, for a total of $19 million in payments, from 2003 through 2007. Similarly, Senator Grassley's inquiry into Medtronic's consulting arrangements uncovered that Dr. Jeffrey Wang of UCLA failed to disclose payments received by the Company, resulting in a university probe of his research and his removal as co-executive director of the UCLA Comprehensive Spine Center.

272. Then, on May 13, 2009, *The New York Times* disclosed that the U.S. Army's investigation into a study authored by Dr. Kuklo concluded that the doctor made false claims that overstated the benefits of INFUSE Bone Graft in treating wounded soldiers injured in Iraq. As reported in *The New York Times* and detailed in the Army's findings, Dr. Kuklo, a former Army surgeon who was then a professor at Washington University in St. Louis, falsified data that exaggerated the benefits of INFUSE Bone Graft in a prominent medical journal, conduct that

Col. J. Edwin Atwood, an Army doctor who led the Army's inquiry, described as "the ultimate tragedy and catastrophe in academic medicine."

273. As disclosed in a series of articles in *The New York Times* and *The Wall Street Journal*, the true facts regarding Dr. Kuklo's study were only uncovered when one of the study's supposed "co-authors," Lt. Col. Romney C. Andersen, was congratulated on its publication by a colleague. After this discovery, Andersen alerted Army investigators who found that:

- Dr. Kuklo listed four other Army surgeons as "co-authors" without their knowledge, and these four doctors did not participate in or review the article's preparation or submission for publication;
- The signatures of the four doctors listed as co-authors on the copyright release forms submitted to *The Journal of Bone and Joint Surgery* were forged by Dr. Kuklo;
- The number of cases cited by Dr. Kuklo in the article differed from the number of cases contained in the Wartime casualty database, with no explanation for the discrepancies in the article;
- Contrary to Army policy, Dr. Kuklo did not obtain publication review or clearance from Walter Reed prior to submitting the article for publication; and
- The published results of the article suggested a much higher efficacy rate for the INFUSE Bone Graft than is supported by the experience of the purported co-authors.

274. According to one of the Army's investigators, Colonel Norvell V. Coots, the study cited higher numbers of patients and injuries than the hospital could account for. "It's like a ghost population that were reported in the article as having been treated that we have no record

of ever having existed," Colonel Coots said. "So this really was all falsified information." *The Journal of Bone and Joint Surgery* formally retracted the article and banned Dr. Kuklo from submitting further papers to the Journal in March 2009 after receiving correspondence from Walter Reed dated November 6, 2008 stating that its investigation concluded that Dr. Kuklo did not follow Army regulations in submitting the article, that the signatures of the purported co-authors had been forged and that the article's purported co-authors had questioned the study's findings.

275. As noted in a May 19, 2009 follow-up article in *The New York Times*, when questioned about its ties to Dr. Kuklo, Medtronic repeatedly declined to disclose when it began its financial relationship with the former Army surgeon or the extent of funding it provided. Senator Grassley, who had been leading a Congressional investigation into Medtronic's promotion of INFUSE Bone Graft, stated that Dr. Kuklo's name did not appear on a list of paid consultants for INFUSE Bone Graft provided by the Company that the Senator had requested in a September 30, 2008 letter to Defendant Hawkins. Senator Grassley disclosed the list Medtronic provided—which included 22 doctors who were paid a total of $943,000 from 2005 to 2008—in a May 18, 2009 letter to Defendant Hawkins that was published in the *Congressional Record* the following day. According to the May 18, 2009 letter, Senator Grassley was "concerned" that Medtronic did not provide Dr. Kuklo's name in response to his inquiry that specifically requested information regarding consultants who work on INFUSE Bone Graft, as it was "clear that Dr. Kuklo had some sort of consulting agreement" and was named in *The New York Times* as a consultant on INFUSE Bone Graft. Indeed, Dr. Kuklo has given numerous presentations for Medtronic about the bone-growth product over the past several years.

276. The list provided to Senator Grassley also omitted names of other Medtronic consultants who have spoken about INFUSE Bone Graft, such as Dr. Polly, another former Walter Reed surgeon. Frustrated with the Company's omissions, Senator Grassley stated in his May 18 letter that "[i]n the future, I hope that instead of not providing me with the name of the physician involved in Infuse, or any other matter that I am looking into, that Medtronic contact me to avoid the situation in which we find ourselves." A May 19, 2009 *New York Times* article reported that Medtronic also faced a DOJ inquiry as to whether it illegally promoted uses of INFUSE Bone Graft that were not approved by the FDA by paying doctors, among other alleged measures.

277. However, it was not until approximately one month later, on June 18, 2009, that Medtronic disclosed to *The Wall Street Journal* that Dr. Kuklo had received almost $850,000 in payments from the Company over the past 10 years, the majority of which—nearly $800,000—were made in the past three years when Dr. Kuklo was shopping his study to medical journals. Specifically, the Company paid Dr. Kuklo $356,242 in 2007, the year Dr. Kuklo sought publication of the study in two medical journals, and $249,772 in 2008, the year the study was published. Medtronic made both of these payments during the Class Period and after the Company announced the settlement with the DOJ in July 2006. *The Wall Street Journal* subsequently reported on June 24, 2009 that Medtronic had received a subpoena from federal prosecutors about its payments to Dr. Kuklo.

278. In July 2009, Senator Grassley also publicly disclosed information demonstrating that Dr. Kuklo hid his financial relationship from Washington University and failed to disclose his financial ties in conflict of interest disclosure forms while he was conducting research related to INFUSE Bone Graft. As revealed in documents provided by Washington University and

reported in *The New York Times* and *The Wall Street Journal*, the Company financed two separate, unpublished studies that also examined the use of INFUSE Bone Graft on Walter Reed patients with combat-related leg injuries while Dr. Kuklo was supposedly conducting research for the falsified study. At the time Washington University approved the study protocols, Dr. Kuklo indicated on disclosure forms that he did not receive any payments from Medtronic when, in fact, Dr. Kuklo signed a contract with the Company shortly after joining the university faculty and had received payments from Medtronic for almost a year into his research. In mid-2007, after Dr. Kuklo disclosed to Washington University that he had received funding from Medtronic, the university's internal disclosure review board re-reviewed Dr. Kuklo's involvement in the Medtronic-sponsored studies and informed him he would have to reduce his personal financial interest with Medtronic to less than $10,000 per year or discontinue his involvement with the research. Dr. Kuklo opted to stop the two studies, which were closed in February 2008.

279. Dr. Kuklo was not the only Medtronic-funded surgeon at Washington University who failed to disclose the full extent of his financial ties to Medtronic under the university's conflicts of interest policies. A June 4, 2009 article published in the *St. Louis Beacon* revealed that university surgeon Dr. Daniel Riew, a Medtronic consultant who had earlier publicly defended Dr. Kuklo in an article in the *St. Louis Post Dispatch* when reports of the falsified Army study first surfaced, also failed to properly report significant payments from the Company. The article quoted a May 21, 2009 letter from Senator Grassley—who had requested information regarding consulting payments from both Medtronic and the university as part of the congressional inquiry into conflicts of interest in the medical device industry—which noted that the consulting payment amounts that Medtronic submitted to the Senator did not match those that

Dr. Riew reported to the university. For example, according to Senator Grassley, while Dr. Riew reported to the university that he received less than $10,000 in 2006, "[i]n fact, Medtronic reported to me that there was not a single year from 2003 to 2007 for which Dr. Riew received less than $10,000. In fact, he received well over $10,000 in each of those years."

280. On June 20, 2009, the *Milwaukee Journal Sentinel* reported that in 2008, Medtronic paid Dr. Zdeblick $2 million in royalty payments and for eight days of consulting work, and Dr. Paul Anderson received $150,000 in Medtronic consulting fees for working just eight days—figures that were only recently disclosed under the University of Wisconsin's new conflict-of-interest disclosure rules.

281. On July 22, 2009, the *Wall Street Journal* reported that Dr. Jeffrey Wang lost his position as co-executive director of UCLA's Comprehensive Spine Center for failing to disclose that he was receiving consulting fees from, *inter alia*, Medtronic.

282. On July 29, 2009, the *Wall Street Journal* reported that Dr. Polly also failed to disclose payments he had received from Medtronic in connection with testimony before a Senate committee in 2006, as discussed, *supra*, at ¶ 126.

283. On August 19, 2009, the *Wall Street Journal* reported that Dr. Kuklo had "agreed to voluntary resign" from Washington University's Medical School as a result of the Army investigation that concluded that he had falsified data in the *Journal of Bone and Joint Surgery*.

284. The congressional inquiry and other negative publicity surrounding Medtronic's financial ties with surgeons involved with INFUSE Bone Graft has also been accompanied by federal and state regulatory action. As the Company has admitted, the July 2008 FDA health warning, DOJ scrutiny and negative publicity surrounding INFUSE Bone Graft have all contributed to declining sales of the product.

285. In Medtronic's Third Quarter 2009 financial results (the "3Q 2009 10-Q") filed with the SEC on March 4, 2009, the Company also disclosed that it had received a civil investigative demand from the Massachusetts Attorney General's Office requesting production of documents related to INFUSE Bone Graft.

286. In addition to this new inquiry, the 3Q 2009 10-Q indicated that sales of INFUSE Bone Graft continued to lag as a result of "***a public health notice from the FDA regarding the off-label use of recombinant human bone morphogenic protein in the cervical spine that was issued in July 2008, a previously disclosed government investigation, negative newspaper stories, and a whistleblower lawsuit filed against a number of spine surgeons and distributors of INFUSE bone graft***." (Emphasis added.) Furthermore, the Company specifically noted that the slight increase in overall growth in INFUSE Bone Graft sales for the nine-month period ended January 23, 2009 was entirely "driven from net sales in the three months ended July 25, 2008"—i.e., from sales that occurred ***before*** the end of the Class Period and prior to the materialization of the risks presented by Medtronic's undisclosed off-label marketing campaign.

287. Likewise, Medtronic disclosed in its fourth-quarter and full-year financial results for the 2009 fiscal year (ended April 24, 2009) filed with the SEC on June 23, 2009 (the "2009 10-K"), that sales of INFUSE Bone Graft continued to suffer as a result of the negative publicity surrounding Medtronic's business practices, the risks to patient safety, and the governmental investigations into the Company's off-label promotion of INFUSE:

> Biologics net sales for fiscal year 2009 were $840 million, an increase of 3 percent when compared to the prior fiscal year. This increase was primarily driven by worldwide net sales growth of INFUSE Bone Graft in the first quarter of fiscal year 2009. ***Net sales of INFUSE Bone Graft during the remainder of fiscal year 2009 were flat because of the negative impact of several external factors including: a public health notice from the FDA regarding off-label use of recombinant human bone morphogenic protein in the cervical spine that was issued in July 2008, a previously disclosed government investigation, negative***

newspaper stories and a whistleblower lawsuit filed against a number of spine surgeons and distributors of INFUSE Bone Graft. [Emphasis added.]

288. In the 2009 10-K, the Company further admitted that "[d]uring fiscal year 2009, the FDA issued a public health notice regarding use of bone morphogenetic protein in cervical procedures, which was received negatively by both physicians and payors. As a result, this negatively impacted the sales of our INFUSE Bone Graft in fiscal year 2009."

289. The filing also disclosed additional governmental investigations into INFUSE. Specifically, the Company stated that it received a subpoena on May 21, 2009 from the United States Attorney's Office for the District of Massachusetts seeking documents related to Dr. Kuklo's falsified study and "contracts, research grants, speaking and education programs, and payments for certain named physicians," and revealed that it received an administrative subpoena from the New Jersey Attorney General requesting "production of documents relating to the Company's clinical studies, its financial arrangements with certain physicians and health care providers, and clinical research done by certain physicians and health care providers."

290. The use of INFUSE Bone Graft in off-label procedures was further scrutinized in a study published in the July 1, 2009 issue of JAMA that documented the health risks associated with off-label use of INFUSE Bone Graft and, contrary to previous studies conducted by Medtronic-funded physicians, cast doubt on the cost-effectiveness of the product. According to the Minneapolis-St. Paul *Star Tribune*, "JAMA's findings loom large for Medtronic, which sells the bioengineered product called INFUSE used in spine fusion procedures."

291. The study, entitled "Prevalence, Complications, and Hospital Charges Associated With Use of Bone-Morphogenetic Proteins in Spinal Fusion Procedures," analyzed the integration of BMP into spinal surgeries since 2002, and the association between its use and postoperative complications, length of hospital stays, and hospital charges. Significantly, the

study's authors determined that use of bone morphogenetic proteins is associated with a substantially higher rate of complications in anterior cervical fusion procedures, which has resulted in an approximate 41% increase in hospital charges for these procedures. The authors of this study used a similar methodology in analyzing the use of bone morphogenetic protein as did Lead Counsel, using ICD-9-CM codes to estimate the extent of off-label usage of INFUSE Bone Graft by identifying the type of spine surgery conducted, whether or not BMP was used in the surgery, and whether any complications resulted from the procedure. Notably, the study only considered complications that occurred during the postoperative inpatient hospitalization immediately following the surgical procedure, and did not consider hospital readmissions due to complications, and therefore "does not include delayed complications in the outpatient setting."

292. This shortcoming likely resulted in a significant understatement of the extent of complications resulting from use of bone morphogenetic proteins because, as an FDA Public Health Notification regarding complications from use of BMP in the cervical spine indicated, "[m]ost complications occurred between 2 and 14 days post-operatively with only a few events occurring prior to day 2." Indeed, acknowledging this fact, Dr. Kevin S. Cahill, who led the study, publicly commented, "ours is probably a bottom estimate." Notwithstanding this potential understatement of complications, the study found that the rate of complications in anterior cervical fusions was 51.4% higher when using bone morphogenetic protein than in similar cases when bone morphogenetic protein was not used. These complications included increased rates of voice and swallowing-related problems, and swelling of the neck. The study's authors noted a "significantly greater" rate of complications when using bone morphogenetic proteins in these surgeries, even after considering and compensating for numerous other variables that could affect complications rates, such as age, sex, etc.

THE STATUTORY SAFE HARBOR PROVISIONS DO NOT APPLY

293. The federal statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not "forward looking statements" when made. To the extent there were any forward-looking statements, there was no meaningful cautionary statement identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, to the extent that the statutory safe harbor does apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the forward-looking statement was incomplete, false or misleading, and/or the forward-looking statement was authorized and/or approved by an executive officer of Medtronic who knew that those statements were incomplete, false or misleading when made given Defendants' failure to disclose the very extensive amount of off-label use of INFUSE Bone Graft and Medtronic's undisclosed off-label promotion of that product. Moreover, to the extent that Defendants issued any disclosures designed to "warn" or "caution" investors of certain "risks," those disclosures were also false and misleading since they did not disclose that Defendants were actually engaging in the very actions about which they purportedly warned and/or had actual knowledge of undisclosed material adverse facts that rendered such "cautionary" disclosures false and misleading.

PRESUMPTION OF RELIANCE

294. At all relevant times, the market for Medtronic's publicly traded securities was an efficient market for the following reasons, among others:

(a) Medtronic common stock met the requirements for listing, and was listed and actively traded on the New York Stock Exchange, a highly efficient and automated market;

(b) As a regulated issuer, Medtronic filed periodic public reports with the SEC;

(c) Medtronic regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Medtronic was followed by well over a dozen securities analysts employed by major brokerage firms throughout the Class Period who wrote reports that were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

295. As a result, the market for Medtronic's publicly traded common stock promptly digested current information regarding Medtronic from all publicly-available sources and reflected such information in Medtronic's stock prices. Under these circumstances, all purchasers of Medtronic's common stock during the Class Period suffered similar injury through their purchase of Medtronic's common stock at artificially inflated prices, and a presumption of reliance applies.

COUNT I

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against Medtronic, Inc., Arthur D. Collins, Jr., William A. Hawkins and Gary L. Ellis)

296. Lead Plaintiffs repeat and allege every allegation set forth above as if fully set forth herein.

297. This Count is brought pursuant to Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder, on behalf of Lead Plaintiffs and all other members of the Class, against Defendants Medtronic, Collins, Hawkins and Ellis.

298. Throughout the Class Period, Defendants, individually and in concert, directly and indirectly, by use of the means and instrumentalities of interstate commerce, made untrue statements of material fact and/or omitted to state material facts necessary to make the statements made not misleading, in order to maintain artificially high market prices for Medtronic's common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5(b) promulgated thereunder.

299. Defendants' materially incomplete, 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 Lead Plaintiffs and the other members of the Class; (ii) artificially create, inflate, and maintain the market for and market price of Medtronic common stock; and (iii) cause Lead Plaintiffs and the other members of the Class to purchase Medtronic common stock at inflated prices.

300. By knowingly or recklessly making affirmative statements concerning INFUSE Bone Graft while failing to inform the market of the true facts, as alleged herein, 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 common stock throughout the Class Period until the true state of affairs was revealed.

301. 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 by making direct statements to the investing public on the conference calls detailed herein. 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.

302. The Individual Defendants, as senior officers and/or directors of Medtronic, occupied senior executive-level positions at the Company and were privy to non-public information concerning the Company and the INFUSE Bone Graft. Each of them knew or recklessly disregarded the adverse facts specified herein and omitted to disclose these facts.

303. As described herein, Defendants made the materially false statements and omissions knowingly, or in such an extremely reckless manner as to constitute willful deceit and fraud upon Lead Plaintiffs and other members of the Class who purchased Medtronic securities during the Class Period.

304. As a result of the Defendants' materially incomplete, false and misleading statements and omissions described herein, the price of Medtronic's common stock was artificially inflated during the Class Period. 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, Lead Plaintiffs and the other members of the Class purchased Medtronic common

stock at these artificially inflated prices during the Class Period. But for the fraud, they would not have purchased Medtronic common stock at artificially inflated prices.

305. The market price for Medtronic common stock declined materially as the consequence of the facts that had previously been misrepresented or omitted by the Defendants materialized in reduced sales of INFUSE Bone Graft, as described herein.

306. As a direct and proximate result of the Defendants' wrongful conduct, and their materially incomplete, false and misleading statements and omissions, Lead Plaintiffs and the other members of the Class suffered damages in connection with their purchases of Medtronic common stock, for which the Defendants named in this Count are jointly and severally liable.

307. This claim is 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.

COUNT II
Violation of Section 20(a) of the Exchange Act
(Against Arthur D. Collins, Jr., William A. Hawkins and Gary L. Ellis)

308. Lead Plaintiffs repeat and allege every allegation set forth above as if fully set forth herein.

309. This Count is brought pursuant to Section 20(a) of the Exchange Act on behalf of Lead Plaintiffs and all other members of the Class, against Defendants Collins, Hawkins and Ellis.

310. As alleged herein, Medtronic committed primary violations of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by virtue of its false and misleading statements and omissions.

311. Throughout the Class Period, the Individual Defendants were controlling persons of Medtronic within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their executive positions and memberships on Medtronic's Board of Directors, and their

direct involvement in the day-to-day operations of the Company, the Individual Defendants had the power to influence and control, and did influence and control, directly or indirectly, the decisionmaking of Medtronic. The Individual Defendants were provided with, or had unlimited access to, copies of internal documents, reports, press releases, public filings, and other statements alleged by Lead Plaintiffs to be misleading, and had the ability to prevent the issuance of the false and misleading statements or to cause the statements to be corrected.

312. By virtue of their positions as controlling persons of Medtronic, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiffs and the members of the Class suffered damages in connection with their purchases of Medtronic common stock, for which the Defendants named in this Count are jointly and severally liable.

313. 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.

WHEREFORE, Lead Plaintiffs pray 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 Lead Plaintiffs and the members of the Class compensatory damages against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial;

C. Awarding Lead Plaintiffs and the members of the Class pre-judgment and post-judgment interest, as well as reasonable attorneys' fees, expert witness fees, and other costs and expenses incurred in this action; and

D. Awarding such other relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Lead Plaintiffs hereby demand a trial by jury in this action for all issues so triable.

Dated: August 21, 2009
CHESTNUT & CAMBRONNE

s/ Karl L. Cambronne

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