UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF MISSISSIPPI

SOUTHERN DIVISION

GERARD E. LEDET and SHARONDA J. LEDET,

Plaintiffs,

vs.

MEDTRONIC, INC., a Minnesota corporation; MEDTRONIC SOFAMOR DANEK, USA, INC.,

Defendants.

Case No. 1:13cv200LG-JMR

COMPLAINT FOR DAMAGES

(1) Fraudulent Concealment and Fraud in the Inducement
(2) Strict Liability – Failure to Warn
(3) Constructive Fraud
(4) Strict Liability – Design Defect
(5) Negligence
(6) Negligent Misrepresentation
(7) Breach of Express Warranty
(8) Breach of Implied Warranties
(9) Loss of Consortium

DEMAND FOR JURY TRIAL

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Plaintiffs Gerard E. Ledet and Sharonda J. Ledet ("Plaintiffs")[1] by and through their counsel Reeves & Mestayer, PLLC and Lieff Cabraser Heimann & Bernstein, LLP allege as follows:

INTRODUCTION

1. This case involves a spinal surgery in which a bio-engineered bone graft device known as the Infuse® Bone Graft ("Infuse®") was implanted in Plaintiff GERARD E. LEDET in an off-label manner.

2. Infuse® is a bio-engineered liquid bone graft product classified by the FDA as a medical device. It was developed, designed, manufactured, marketed, and distributed by a division of Medtronic, Inc. known as Medtronic Sofamor Danek USA, Inc. (collectively "MEDTRONIC" or "MEDTRONIC Defendants"). Infuse® is used in spinal fusion surgeries, its purpose is to accomplish the foster fusion between the vertebrae without implanting a patient's own bone or cadaver bone between the vertebrae in the spine, obviating the necessity of harvesting bone from the patient's own hip or risking rejection of cadaver bone.

3. This case involves a spinal fusion surgery in which Infuse® was used in an *off-label* manner (i.e. in a way that was not approved by the FDA) in a lumbar spine fusion surgery. Infuse® is approved by the FDA and is indicated *only*: (1) for lumbar surgery that is performed through the abdomen (anterior approach); (2) some tibia fractures; and (3) some specific dental surgeries not relevant to this case. Further, Infuse® is only approved by the FDA for lumbar surgery that is performed through the abdomen (anterior approach) when it is used *in combination with* an "LT-Cage™," a hollow metal cylinder that is used to insert the Infuse® into the spine. Infuse® is *not* approved by the FDA for use in cervical spine surgery, or for any

[1] When "Plaintiff" is used in its singular form, it refers to Plaintiff GERARD E. LEDET unless

lumbar surgery performed through the back or side of the body (posterior approaches). All cervical spine surgeries, many lumbar surgeries if the approach is not through the abdomen, and all Infuse® back surgeries that do not use an LT-Cage™ are considered off-label uses.

4. Despite this lack of FDA approval, and the FDA's explicit concerns about the dangers to patients of off-label uses, Infuse® was improperly promoted by MEDTRONIC to be used off-label for posterior approach lumbar spine fusions, cervical spine fusions, and without an LT-Cage™.

5. Patients' spine surgeons, including Plaintiff's surgeon, were persuaded by MEDTRONIC and by MEDTRONIC's consultant "opinion leaders," who are paid physician promoters, to expand their use of Infuse® for off-label uses such as posterior approach lumbar fusions and cervical spine fusions.

6. When Infuse® is used off-label, it can cause severe injuries to the patient, including Infuse®-induced bone overgrowth and other complications that often necessitate risky, painful, and costly revision surgeries, which may not cure the problems caused by Infuse®.

7. This uncontrolled bone growth (also known as "ectopic" or "exuberant" bone growth) can result in severe damage to or compression of the surrounding neurologic structures in the spine, and bone can grow onto or around the spinal cord or the spinal nerve roots. When nerves are compressed by excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms, and may need revision surgery.

8. When Infuse® is used off-label, it can cause or contribute to other serious injuries and complications, including extreme inflammatory reactions, chronic radiculitis, retrograde

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otherwise stated.

ejaculation, sterility, osteolysis (bone resorption), displacement or migration of the spacer cage, pseudoarthrosis, and worse overall outcomes.

9. Notwithstanding overwhelming and substantial evidence (including MEDTRONIC-sponsored studies) demonstrating these increased risks of adverse reactions from off-label use of Infuse®, MEDTRONIC recklessly and/or intentionally misrepresented, minimized, downplayed, disregarded, and/or completely omitted these off-label risks while promoting Infuse® to spine surgeons for off-label uses. In fact, MEDTRONIC promoted to spine surgeons and patients the use of the product in dangerous off-label procedures, thereby demonstrating a conscious disregard for the health and safety of spinal fusion patients such as the Plaintiff.

10. Moreover, the actual rate of incidence of serious side effects from off-label use of Infuse® is, in fact, much greater than that disclosed by MEDTRONIC to spine surgeons and patients. With respect to the off-label approaches, MEDTRONIC failed to accurately disclose the significant off-label risks of which it knew of or should have known.

11. Because of MEDTRONIC's wrongful conduct in actively and illegally promoting the off-label use of Infuse® and because of MEDTRONIC's additional wrongful conduct in minimizing, concealing, and downplaying the true risks of these non-FDA approved off-label uses of its product Infuse®, thousands of spine patients, including Plaintiff, underwent surgeries without knowing the true risks inherent in the off-label use of Infuse®.

12. These patients and their physicians relied on MEDTRONIC's false and misleading statements of material fact including statements and publications by MEDTRONIC's "opinion leaders," or "thought leaders," and sales representatives. MEDTRONIC orchestrated a marketing campaign from at least 2002 to the present to persuade spine surgeons to use Infuse®

in dangerous off-label uses in the spine. Indeed, absent MEDTRONIC's extensive off-label promotion campaign, physicians, such as the Plaintiff's spine surgeon, would never have performed these risky off-label procedures.

13. As a result of off-label Infuse® surgery using off-label procedures and/or components, Plaintiffs suffered the bodily injuries and damages as described herein

PARTIES

14. Plaintiffs GERARD E. LEDET and SHARONDA J. LEDET are individuals who are citizens and residents of Ocean Springs, Mississippi. They are married to one another and were married at all times relevant to this action.

15. Defendant MEDTRONIC, INC. is a Minnesota corporation, with its principal place of business at 710 Medtronic Parkway, Minneapolis, Minnesota 55432.

16. Defendant MEDTRONIC SOFAMOR DANEK USA, INC. is a Tennessee corporation, with its principal place of business at 1800 Pyramid Place, Memphis, Tennessee 38132.

JURISDICTION AND VENUE

17. This court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because there is complete diversity of citizenship between Plaintiffs and the Defendants, and because Plaintiffs allege an amount in controversy in excess of $75,000, exclusive of interest and costs.

18. The court has personal jurisdiction over Defendants because at all relevant times they have engaged in substantial business activities in the State of Mississippi. At all relevant times the MEDTRONIC Defendants transacted, solicited, and conducted business in Mississippi through their employees, agents, and/or sales representatives, and derived substantial revenue from such business in Mississippi.

19. Venue is proper in this district pursuant to 28 U.S.C. § 1391(a) because a substantial portion of the wrongful acts upon which this lawsuit is based occurred in this District. Venue is also proper pursuant to 28 U.S.C. § 1391(c) because Defendants are all corporations that have substantial, systematic, and continuous contacts in the State of Mississippi and they are all subject to personal jurisdiction in this District.

BACKGROUND

A. Summary of Allegations.

1. Generally.

20. At all relevant times, Infuse® was researched, developed, manufactured, marketed, promoted, advertised, sold, and distributed by the MEDTRONIC Defendants.

21. Plaintiffs suffered grievous personal injuries as a direct and proximate result of Defendants' misconduct.

22. In off-label lumbar or cervical spine surgeries, Infuse® often leads to serious complications including, but not limited to, chronic permanent radiculitis and other nerve injuries, uncontrolled bone growth, osteolysis, and poorer overall outcomes.

2. MEDTRONIC's Representations.

23. At all relevant times, the MEDTRONIC Defendants negligently manufactured, marketed, advertised, promoted, sold and distributed Infuse® as a safe and effective device to be used for spinal fusion surgery. MEDTRONIC negligently, recklessly, and/or intentionally promoted Infuse® for off-label use to physicians and spine patients, including Plaintiff and Plaintiff's physicians, and downplayed to physicians and spine patients its dangerous effects, including but not limited to the downplaying of the dangerous effects of Infuse® in off-label spine surgeries such as that performed on Plaintiff.

24. At all relevant times, the MEDTRONIC Defendants misrepresented the safety of Infuse® to physicians and patients, and recklessly, willfully, and/or intentionally failed to alert physicians and patients of the significant danger to patients resulting from the off-label uses of Infuse®.

3. MEDTRONIC's Knowledge.

25. MEDTRONIC and its agents knew or should have known and/or recklessly disregarded the materially incomplete, false, and misleading nature of the information that they caused to be disseminated to the public and to spine surgeons regarding Infuse® and including MEDTRONIC's surreptitious campaign to promote the product for off-label uses (i.e. uses that had never been evaluated or approved by the FDA). The ongoing scheme described herein could not have been perpetrated over a substantial period of time, as has occurred, without the knowledge and complicity of personnel at the highest level of MEDTRONIC, including its corporate officers.

26. At all relevant times, MEDTRONIC knew, and/or had reason to know, that Infuse® was not safe for off-label uses in the spine because the device had never been approved for use in the spine, other than solely in anterior approach lumbar fusion surgeries with a LT-Cage™; and that use without a LT-Cage™ was known by MEDTRONIC to be unsafe and ineffective.

27. At all relevant times, MEDTRONIC knew, and/or had reason to know that Infuse® was not safe for off-label use because it had not been approved for off-label use; and its safety and efficacy for off-label use was either unknown, or was known by MEDTRONIC to be unsafe and ineffective.

28. MEDTRONIC's acts to promote off-label use of Infuse®, their knowledge of, but failure to disclose, the growing adverse events associated with the product, MEDTRONIC's

continued payments to certain spine surgeon "Opinion Leaders" to promote off-label uses, repeat FDA regulatory action against MEDTRONIC, two whistleblower lawsuits against MEDTRONIC, a Department of Justice ("DOJ") settlement and resulting Corporate Integrity Agreement, and a United States Senate finance Committee investigation culminating in a scathing report on MEDTRONIC's improper promotional activities on this product demonstrate a conscious and reckless disregard for the health and safety of spinal patients, including Plaintiff.

29. At all relevant times, MEDTRONIC knew, and/or had reason to know, that their representations and suggestions to physicians that Infuse® was safe and effective for off-label use were materially false and misleading and that physicians and patients would rely on such representations.

30. MEDTRONIC knew and/or had reason to know of the likelihood of serious injuries caused by the off-label use of Infuse® in the spine, but they concealed this information and did not warn Plaintiff or his physicians, preventing Plaintiff and his physicians from making informed choices in selecting other treatments or therapies prior to Plaintiff's implantation surgery and preventing them from timely discovering Plaintiff's injuries.

31. The prevailing best scientific and medical knowledge, as discussed supra, demonstrated prior to the date of Plaintiff's injury that off-label Infuse® was likely to cause the Plaintiffs' injuries as stated herein. This prevailing scientific and medical knowledge was known or knowable by MEDTRONIC for at least a year or more prior to Plaintiff's off-label Infuse® surgery.

4. <u>MEDTRONIC's Off-Label Promotion.</u>

32. MEDTRONIC had knowledge and information reflecting the true risks and dangers to spine patients of off-label Infuse®, the extent of the off-label use, and their reckless promotion of the off-label uses. Despite this knowledge, MEDTRONIC knowingly and

recklessly conducted an egregious off-label promotion campaign to the detriment of the spine patients, including Plaintiff.

33. MEDTRONIC and its agents encouraged the off-label promotion of Infuse® described throughout this Complaint, notwithstanding their knowledge of the serious adverse events that patients could, and did, suffer, which have often resulted in the need for additional surgery, emergency intervention, and, in at least one case, the death of a patient.

34. MEDTRONIC improperly promoted and marketed Infuse® to Plaintiff's implanting surgeon for off-label use in the spine, and this improper promotion and marketing improperly influenced Plaintiff's spine surgeon's decision to implant Infuse® in Plaintiff's spine using an off-label approach.

35. MEDTRONIC, as herein described, directly and indirectly promoted, trained, and encouraged Plaintiff's surgeon to perform Plaintiff's spinal fusion procedure utilizing Infuse® in a dangerous off-label manner.

36. MEDTRONIC recklessly and/or fraudulently promoted and marketed Infuse® to Plaintiff and Plaintiff's physicians for off-label use in the spine.

5. Failure to Warn.

37. At all relevant times, MEDTRONIC misrepresented the safety of Infuse® to physicians and spine patients, including to Plaintiff and Plaintiff's physicians, and recklessly, willfully, or intentionally failed to inform Plaintiff and/or Plaintiff's physicians of the significant dangers to patients resulting from the off-label use of Infuse®.

38. Any warnings MEDTRONIC may have issued concerning the dangers of off-label uses of Infuse® or regarding the specific risks of those uses were insufficient in light of MEDTRONIC's contradictory prior, contemporaneous and continuing illegal promotional efforts and promotion of Infuse® for non-FDA-approved off-label uses in the spine and

contemporaneous efforts to hide or downplay the true risks and dangers of the off-label uses of Infuse®.

6. Causation.

39. Plaintiff GERARD E. LEDET would not have consented to be treated with the off-label use of Infuse® had he known of or been informed by MEDTRONIC or by his spine surgeon of the true risks of the off-label use of Infuse®.

40. Plaintiff and Plaintiff's spine surgeon relied on MEDTRONIC's misrepresentations regarding the safety and efficacy of Infuse® in Plaintiff's spine surgery. Plaintiff and Plaintiff's spine surgeon did not know of the specific risks, and/or were misled by MEDTRONIC, who knew or should have known of the true risks but consciously chose not to inform Plaintiff or his spine surgeon of those risks and to actively misrepresent those risks to the Plaintiff and Plaintiff's physician.

41. MEDTRONIC's off-label promotion and marketing caused Plaintiff's spine surgeon to decide to implant Infuse® in Plaintiff's spine using an off-label approach.

42. Plaintiff's spine surgeon received and relied on MEDTRONIC's improper promotion of the off-label uses, and MEDTRONIC'S inadequate warnings which hid or downplayed the risks of off-label use of Infuse®. Plaintiff's spine surgeon would not have done the procedure using off-label Infuse® (or using Infuse® at all) in the absence of MEDTRONIC's false and misleading promotion of the off-label uses.

7. Alter Ego.

43. At all times herein mentioned, each of the defendants was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of each of the other defendants named herein and was at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture and rendered

substantial assistance and encouragement to the other defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiffs.

44. At all times herein mentioned, Defendants were fully informed of the actions of their agents and employees, and thereafter no officer, director or managing agent of Defendants repudiated those actions, which failure to repudiate constituted adoption and approval of said actions and all Defendants and each of them, thereby ratified those actions.

45. There exists and, at all times herein mentioned there existed, a unity of interest in ownership between certain Defendants and other certain Defendants, such that any individuality and separateness between the certain Defendants has ceased and these Defendants are the alter-ego of the other certain Defendants and exerted control over those Defendants. Adherence to the fiction of the separate existence of these certain Defendants as entities distinct from other certain Defendants will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

46. At all times herein mentioned, the MEDTRONIC Defendants, and each of them, were engaged in the business of, or were successors in interest to, entities engaged in the business of researching, designing, formulating, compounding, testing, manufacturing, producing, processing, assembling, inspecting, distributing, marketing, labeling, promoting, packaging, prescribing and/or advertising for sale, and selling products for use by the Plaintiff and Plaintiff's physicians. As such, each of the MEDTRONIC Defendants is individually, as well as jointly and severally, liable to the Plaintiffs for their damages.

47. The harm which has been caused to Plaintiffs resulted from the conduct of one or various combinations of the Defendants, and through no fault of the Plaintiffs. There may be uncertainty as to which one or which combination of Defendants caused the harm. Defendants

have superior knowledge and information on the subject of which one or which combination of the Defendants caused Plaintiffs' injuries.

48. Thus, the burden of proof should be upon each Defendant to prove that the Defendant has not caused the harms suffered by Plaintiffs.

B. The Infuse® Device and Spinal Fusion Surgery Generally.

49. MEDTRONIC designed and marketed Infuse® for lumbar spine fusion surgery, 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.

50. Spinal fusion is used 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 uses bone grafts to join vertebrae together and eliminate or reduce movement between vertebrae.

51. In a spinal fusion procedure, the graft — usually the patient's own harvested bone (i.e. autograft) or cadaver bone (i.e. allograft) — is placed in a spacer cage within the disc space between the vertebrae during the 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.

52. For years, autologous bone graft has been considered the "gold standard" in 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 or from the patient's own spine (from the parts of one or more vertebrae removed to gain access to the disc space to perform the fusion), and implants the bone graft in the site where fusion is

desired. Successful fusions occur at very high rates in autograft procedures, as the harvested bone exhibits all the properties necessary for bone growth (including osteogenic, osteoconductive and osteoinductive properties).

53. As an alternative to autograft, patients can undergo an "allograft" procedure using cadaver bone instead of autograft. Although healing and fusion is not as predictable when using allograft as when using autograft (the patient's own bone), an allograft eliminates the need for the harvest procedure required in an autograft.

54. A newer option to traditional bone graft procedures is bio-engineered and bio-manufactured bone-growth materials, including Infuse®. Infuse® and similar materials were thus (at least initially) appealing to many spine surgeons, since they can obviate the need for using autograft harvested from the patient's own body.

55. Infuse® is a genetically engineered material containing a bone morphogenetic protein ("rhBMP-2"), and is used as an alternative or supplement to autograft and allograft to help fuse the vertebrae in the spine as part of the spinal fusion surgery. The purpose of Infuse® is to accomplish the same clinical outcomes as grafting a patient's own bone into these locations but without the need to harvest bone from the patient's hip or spine.

56. MEDTRONIC's Infuse® product consists of (1) a metallic spinal fusion cage (the LT-Cage™); (2) the bone graft substitute which consists of liquid rhBMP-2 (derived from Chinese hamster cells); and (3) a sponge-like carrier or scaffold for the protein (manufactured from bovine collagen) that is placed inside the fusion cage.

57. The fusion cage component maintains the spacing and temporarily stabilizes the diseased region of the spine, while the Infuse® bone graft component is used to form bone, which is intended to permanently stabilize (fuse) this portion of the spine.

58. During surgery, the rhBMP-2 is soaked onto and is intended to bind with the absorbable collagen sponge that is designed to resorb, or disappear, over time. As the sponge dissolves, the rhBMP-2 stimulates the cells to produce new bone.

59. Certain bone morphogenetic proteins ("BMP"s) have been studied for decades because of their ability to heal bone and potentially decrease or eliminate the need for bone graft harvesting from other parts of the body.

60. Scientists isolated the gene for one protein (rhBMP-2) from bone tissue and used molecular biology techniques to create genetically engineered cells. These cells then produce large quantities of rhBMP-2. A similar process is used to manufacture other proteins, such as insulin.

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

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

63. In January of 1999, MEDTRONIC purchased Sofamor Danek for $3.6 billion. On July 2, 2002, the FDA approved Infuse®, a medical device containing an absorbable collagen sponge that is treated with rhBMP-2, for one limited and very specific spinal fusion procedure.

C. FDA Approval of Infuse®.

1. The Pre-Market-Approval Process.

64. 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 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. Finally, 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® is a Class III device.

65. Manufacturers such as the MEDTRONIC Defendants seeking to market a Class III device, such as Infuse®, 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 a process that 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").

66. 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." 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 whom the device is intended.

67. 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, the name and address of the manufacturer, as well as any prescription use restrictions, information for use (including indications, effects, routes, methods, 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. Approval of 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.

2. Infuse's® Limited FDA-Approved Uses.

68. In October of 1996, Sofamor Danek submitted an IDE to the FDA to study the use of rhBMP-2 as applied to an absorbable collagen sponge 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. This study marked the first time rhBMP-2 was used in patients undergoing spinal fusion. In this initial clinical trial, all 11 patients who had been implanted with rhBMP-2 achieved successful fusion within six months from the time of surgery.

69. 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 (ALIF) procedure and 135 control patients who underwent the same procedure using autologous bone graft instead of rhBMP-2.

70. After acquiring Sofamor Danek in 1999, MEDTRONIC filed the Infuse® PMA on January 12, 2001, and was granted expedited review status by the FDA.

71. As presented in MEDTRONIC's original PMA (eventually approved by the FDA in July 2002), the initially-approved Infuse® product consisted of two components:

a. A specific type of spacer (the LT-Cage™ Lumbar Tapered Fusion Device) component, which is 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

b. The Infuse® Bone Graft Component, which includes a collagen sponge that acts as a carrier and scaffold for the active ingredient in Infuse®, and rhBMP-2, the actual active ingredient that is reconstituted in sterile water and applied to the collagen sponge before it is placed inside the spacer cage.

72. According to the label sought by MEDTRONIC in the PMA and subsequently approved by the FDA, Infuse® 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.

73. On July 2, 2002, the FDA approved Infuse® to treat degenerative disc disease, but only by means of one specific procedure, namely, anterior approach lumbar interbody fixation (ALIF) surgeries, and only in one-level procedures at lumbar spine levels L4 through S1.

74. Importantly, the initial approved labeling for the product indicates in bold underlined formatting: **"These components must be used as a system. The Infuse® Bone Graft component must not be used without the LT-Cage™ Lumbar Tapered Fusion Device component."** The labeling also directs the specific manner in which both components are to be used in a fusion procedure.

75. Despite the fact that the FDA only approved rhBMP-2 for use in the spine in combination with use of the LT-Cage™, MEDTRONIC sells Infuse® separately from the LT-Cage™ and has done so continuously since the approval in 2002.

76. Infuse® has never been approved by the FDA for use in other parts of the body or for use in any other type of procedure, other than two non-spinal uses as noted in footnote 1. Any such uses are thus, by definition, "off-label" experimental uses not approved by the FDA.

77. There are numerous lumbar and cervical spine surgical procedures for which Infuse® was not initially approved, and for which it has never subsequently been approved. No

[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. Infuse® has been approved by the FDA for only two other uses: certain oral maxillofacial surgeries and repair of tibial fractures that have already been stabilized with IM nail fixation after appropriate wound management. Infuse® was approved by the FDA on March 9, 2007, for certain oral maxillofacial uses. While Infuse® has also been approved for treatment of certain tibial fractures and certain oral maxillofacial uses, these uses represent a very minor percentage of the product's overall sales.

cervical fusion procedure, whatsoever, using Infuse® has ever been approved by FDA, regardless of the approach or procedure. The non-approved lumbar procedures include:

a. 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 delicate surgical approach in some respects because the spinal canal and nerves are posterior to 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;

b. Posterolateral Fusion ("PLF") which 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; and

c. Transforaminal Lumbar Interbody Fusion ("TLIF"), which is also similar to the PLIF procedure, and is a technique utilized when an inter-body fusion is performed via a posterior approach. TLIF 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.

D. Off-Label Use of Infuse, Risks Associated with Off-Label Uses, and MEDTRONIC's Knowledge of Such Risks.

1. Generally

78. Physicians may use FDA-approved medical devices in any way they see fit — either on-label or off-label, but medical device companies are prohibited by federal law to promote off-label uses for their medical devices or to pay doctors inducements or kickbacks to

promote off-label uses, or to perform procedures using the devices off-label. When a physician wishes to use a medical device in an off-label manner, he or she must inform the patient of the off-label nature of the surgery and the expected risks and benefits of such off-label use, and obtain the patient's informed consent to such use.

2. FDA's Initial Concerns with Infuse's® Off-Label Uses.

79. The FDA's approval of Infuse® was limited to one specific lumbar procedure (the ALIF procedure) due to FDA's concerns about potential adverse events in posterior uses that had already been reported at the time of the product's approval. As a result, the FDA approved Infuse® for the small percentage of overall spinal fusion surgeries which are ALIF procedures, with the device label specifying this limited surgical application.

80. FDA approval of Infuse® was limited to ALIF only because of adverse events resulting from the use of rhBMP-2 in off-label applications. In particular, a MEDTRONIC-sponsored trial examining the application of rhBMP-2 in off-label PLIF (Posterior Lumbar Interbody Fixation) procedures was halted in December 1999 when uncontrolled bone growth developed in a number of the patients. Indeed, the study reported that one patient required two additional surgeries to remove excessive bone growth from the spinal canal. Such bone overgrowth observed in this PLIF trial was particularly alarming because it could, and did in many patients, result in worsening the very pain that the fusion procedure was designed to eliminate, and in some cases necessitating difficult revision surgeries to remove the bone overgrowth.

81. Moreover, the 1999 PLIF trial demonstrated that bone overgrowth complications from Infuse® result from the product's very mechanism of action; i.e., rhBMP-2 stimulates the growth of new bone. Thus adverse events can result when the rhBMP-2 leaks out of the area in which bone growth is desired and/or when too much rhBMP-2 is used. In such cases, Infuse®

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, compression of nerves, and associated additional or new pain. Such unintended bone growth and swelling can be especially problematic in spinal surgeries because of the proximity to sensitive neurological structures in which Infuse® is used; i.e., the spinal cord and the exiting nerve roots.

82. During the FDA Advisory Committee Panel ("FDA Panel") hearing dated January 10, 2002 concerning potential FDA approval of Infuse®, panel members voiced concerns regarding potential off-label use of the product, and asked MEDTRONIC to describe its efforts to guard against off-label use of the product.

83. In response to FDA concerns of off-label applications, one MEDTRONIC consultant, who is alleged to have received hundreds of thousands of dollars in the form of kickbacks from consulting agreements promoting Infuse®, dismissed the FDA Panel's concerns of off-label use, stating: "this specific application before the panel today is through an anterior approach," and accordingly, "seems to me to be outside the scope of what we ought to be focusing on today."

84. Reiterating its concerns of off-label use, the FDA Panel cautioned MEDTRONIC to guard against procedures outside the specifically approved ALIF procedure provided in the labeled application. The FDA Panel's admonishment included concerns voiced by panel member Dr. John Kirkpatrick that off- label use could result in harm to patients. More specifically, 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 [PLIF] perspective." In other words, the FDA explicitly warned MEDTRONIC against

promoting Infuse® for use in off-label PLIF procedures because, according to the statements of the FDA Panel, such use could endanger patients.

85. At this 2002 FDA Advisory Committee Panel hearing, the panel members stressed concerns regarding potential off-label use of the product and repeatedly asked the MEDTRONIC presenters questions about how MEDTRONIC would seek to guard against off-label applications of the product.

86. At the conclusion of the hearing, the FDA Advisory Panel again reiterated concerns regarding the potential for off-label use, specifically admonishing the MEDTRONIC Defendants to guard against procedures other than the specific ALIF (anterior lumbar interbody fusion) procedure approved by the FDA.

E. Off-Label Use of Infuse® is Dangerous and Causes Adverse Side Effects.

87. The off-label use of Infuse® in the spine frequently causes serious adverse events. This has been known to MEDTRONIC and its key "opinion leaders" for many years.

88. The FDA Panel's initial fears in 2002 concerning the dangers of off-label use of this product were confirmed by subsequent medical studies which demonstrate that off-label use of Infuse® may present severe risks and dangers to patient safety.

89. For example, an early study sponsored and funded by MEDTRONIC in 1999 demonstrated an approximately 70% rate of ectopic bone growth — meaning bone overgrowth where such growth is not desired. Only a few months into this clinical trial of Infuse®, CT scans showed unwanted bone had already formed in the spinal canals of 70% of the patients treated with Infuse®. This clinical trial, intended to include hundreds of people with degenerative disc disease, was halted after only 34 patients received Infuse®.

90. A spine surgeon who participated in this PLIF with Infuse® study reported that one of the patients he treated required two extra surgeries to clear the excessive bone growth

from the patient's spinal canal. The complications observed in this 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 is intended to eliminate.

91. This bone overgrowth results from Infuse®'s very mechanism of action. In such cases, Infuse® can stimulate bone growth where new bone is not desired and can lead to excessive bone growth into areas where bone should not be growing — *i.e.*, into or against the spinal cord or other spinal nerves.

92. There is insufficient scientific evidence concerning the proper dosages of rhBMP-2 for use in the off-label procedures such as PLIF, TLIF, PLF and cervical fusions. The expected responses to the protein in different biological environments. Many adverse events associated with the use of Infuse® result from off-label use of the product by surgeons who do not fully understand the highly potent nature of this molecule.

93. A study entitled, "Prevalence, Complications, and Hospital Charges Associated with Use of Bone-Morphogenetic Proteins in Spinal Fusion Procedures," Cahill, et al., *JAMA*, 2009 Jul 1;302(1):58-66, 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 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. Notably, the study only considered complications that occurred during postoperative inpatient hospitalization immediately following the surgical procedure, and did "not include

delayed complications in the outpatient setting," such as hospital readmission-related complications.

94. Such a 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."

95. Aside from 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.

96. Astonishingly, it was not until 2004 that a paper about the disastrous 1999 PLIF trial by spine surgeons with financial ties to MEDTRONIC was finally published in a medical journal. This article inaccurately maintained that these patients were not harmed by Infuse®. The paper (Haid, et al., *Posterior lumbar interbody fusion using recombinant human bone morphogenetic protein type 2 with cylindrical interbody cages, The Spine Journal*, 4(5):527-538, September 2004) downplayed the bone overgrowth complications claiming that while it showed

up on CT scans, patients did not suffer ill effects. This claim was false and misleading and further encouraged dangerous off-label uses of Infuse.

97. In fact, David Malone, M.D., a Tulsa, Oklahoma spine surgeon involved in this 1999 PLIF clinical trial with Infuse, told the *Milwaukee Journal Sentinel* that two of his patients had to undergo additional surgeries because the BMP-induced bone overgrowth was painfully impinging on their nerve roots. One of the patients, a man who was in his 50s at the time, needed three operations - one for the implant, a second to remove the unwanted bone formation, and then a third when the additional bone grew back yet again.[3]

98. "It was a pretty amazing biological response," Dr. Malone said in an interview. "It grew back even larger than the first time. It got to the point that secretaries in our clinic could look at X-rays and tell who got the BMP (Infuse) and who did not. You could see that much bone growth."[4]

99. 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, "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." [5]

100. Again, in a November 2006 issue of *Spine*, several authors noted a significantly increased risk of swelling from off-label use of Infuse® in cervical spine fusions compared to

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[3] *See, e.g.*, "Infuse® Cited in Patients' Painful Bone Overgrowth: More Surgery Needed After Use, Surgeon Says," by John Fauber, *Milwaukee Journal Sentinel*, June 27, 2011.

[4] *Id.*

[5] Patel, et al., *Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic*

traditional fusion surgeries. Of the 234 patients studied, 27.5% of those patients treated with Infuse® had significant swelling after the surgery, while only 3.6% of those patients not treated with Infuse® experienced such a complication. Further analysis demonstrated that "patients receiving rhBMP-2 were ***10.1 times more likely*** to have a swelling complication versus those who did not receive rhBMP-2." (Emphasis added.)[6]

101. A March 2007 article in *The Spine Journal* highlighted the severity of the complications associated with off-label use of Infuse®. According to this article, five days after Infuse® was implanted off-label in a cervical spine fusion surgery, the implanted patient experienced severe swelling of the neck and difficulty swallowing which required emergency medical treatment such as an exploratory surgery and implantation of a breathing tube.[7]

102. A *European Spine Journal* article in August 2007 found that use of Infuse® in certain cervical spine fusions resulted in 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 evaluated, 85% of those treated with Infuse® reported difficulty swallowing after the surgery; a complication that was far less

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Protein-Stimulated Bone Growth Using Fibrin Glue, Spine, 31(11): 1201-1206, May 2006.

[6] Smucker, et al., *Increased Swelling Complications Associated with Off-Label Usage of rhBMP-2 in the Anterior Cervical Spine, Spine,* 31(24): 2813-2819, November 2006.

[7] Perri, et al., *Adverse Swelling Associated with Use of rh-BMP-2 in Anterior Cervical Discectomy and Fusion: A Case Study, The Spine Journal,* 7(2): 235-239, March 2007.

severe in those not treated with Infuse®. Indeed, one patient required a feeding tube for six weeks after the surgery as a result of the complication. [8]

103. 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"), which strongly warned medical professionals who used Infuse® and other BMP products of serious complications that had occurred from the off-label use of these products in the cervical spine.[9]

104. The FDA Notification stated that the agency had 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."

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[8] Vaidya, et al., *Complications of Anterior Cervical Discectomy and Fusion Using Recombinant Human Bone Morphogenetic Protein-2, European Spine Journal,* 16(8): 1257-1265, March 2007.

[9] FDA Public Health Notification: Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion, July 1, 2008, http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/PublicHealthNotifications/ucm062000.htm

105. On September 4, 2008, *The Wall Street Journal* published a front-page article entitled "MEDTRONIC Product Linked to Surgery Problems."[10] This article noted both the complications resulting from the use of Infuse® in the cervical spine already disclosed in the FDA Notification and additional complications resulting from other off-label applications of the product, stating:

> 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, or 75%, of the adverse events reported to the FDA involved off-label use of Infuse®. Of course, this news had serious implications for MEDTRONIC because off-label use of Infuse® accounted for the majority of all Infuse® sales.

106. A September 2008 article in *The Spine Journal* also observed that the use of Infuse® in the cervical spine "has been associated with reports of serious adverse events.[11] 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 observed in this patient study group, 17% occurred in patients treated with traditional techniques, while 83% occurred in patients treated off-label with Infuse®. The authors concluded that the "cervical spine has proven much less forgiving with the

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[10] "Medtronic Product Linked to Surgery Problems," by David Armstrong and Thomas M. Burton, *Wall Street Journal*, September 4, 2008.

[11] Jarosz, et al., *Complications of BMP Use in Cervical Spine Surgery, The Spine Journal,* 8(5): 23S-24S, September 2008.

institution of rhBMP-2 use. Complications induced by . . . rhBMP-2 were clearly evident in our review."

107. 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, clearly stemming from a significant decline in Infuse® sales, were a sharp deviation from MEDTRONIC's reports of repeated, double-digit, growth in the Spinal segment in previous quarters. Moreover, MEDTRONIC disclosed, for the first time, that it "recently received a subpoena from the Department of Justice looking into off-label use of Infuse®."

108. Thereafter, MEDTRONIC continued to report lower sales of Infuse®, which it admittedly linked to (a) 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; (b) a previously disclosed government investigation, negative newspaper stories; and (c) a whistleblower lawsuit filed by two former MEDTRONIC employees against MEDTRONIC and a number of spine surgeons and distributors of the Infuse® bone graft.

109. The use of Infuse® 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® and, contrary to previous studies conducted by MEDTRONIC-funded physicians, cast doubt on the cost-effectiveness of the product.[12]

110. At least 1,200 reports of adverse events involving Infuse® have been made to the FDA from 2002 to 2011. In 2011, for example, 278 Infuse-related adverse events were reported;

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[12] Cahill, et al., *Prevalence, Complications, and Hospital Charges Associated with Use of Bone-*

in 2010, 362 adverse events were reported; and in 2009, 244 adverse events were reported. The vast majority of these adverse event reports involve off-label use of Infuse®.

111. In fact, in a 2012 article published in The Spine Journal, FDA researcher Emily Woo, M.P.H. concluded on-label use of Infuse® accounts for only a tiny percentage (0.5%) of adverse events. Off-label use of Infuse® accounts for 99.5% of adverse events.[13]

112. The number of Infuse-related adverse events is growing steadily over the years. The proportion of off-label adverse events increases as a direct result of the MEDTRONIC Defendants' long-standing campaign of improper off-label promotion of the more dangerous off-label uses of Infuse® which were never approved by the FDA. At all relevant times, the extent of these adverse events was hidden or downplayed by MEDTRONIC and its paid consultants.

F. MEDTRONIC's Prior Knowledge and Concealment of the Dangers of Off-Label Infuse® Uses.

113. Even at the time of FDA approval, MEDTRONIC and its senior management and its paid consultant "opinion leaders," were well aware of the concerns regarding off-label uses of Infuse® and the serious dangers to patients posed by those off-label uses.

114. Notwithstanding the original FDA Panel's well-founded concerns regarding off-label use, as well as the medical literature's corroboration of the same, both of which MEDTRONIC had knowledge, MEDTRONIC intentionally, negligently and recklessly concealed these dangers from the general public, including the Plaintiff and Plaintiff's physicians.

Morphogenetic Proteins in Spinal Fusion Procedures, JAMA, 302(1): 58-66, July 2009.

[13] Emily Jane Woo, *Recombinant Human Bone Morphogenetic Protein 2: Adverse Events Reported to the Manufacturer and User Facility Device Experience Database, The Spine*

115. MEDTRONIC had actual knowledge of the Advisory Committee's concerns regarding off-label use of the product, and the dangers posed by off-label use. Indeed, Defendants were on actual notice at this time of the Advisory Committee's warnings that MEDTRONIC should guard against off-label uses of this potent genetically-engineered liquid bone protein. Thus, even *prior* to FDA approval, Defendants were on actual notice of the dangers that off-label use of Infuse® posed to patients, such as the Plaintiff.

116. Further, as described immediately *infra*, the MEDTRONIC-funded studies on Infuse® from 1999 until at least 2007 failed to accurately describe the adverse effects that were observed in the earliest trials of Infuse®, such as severe uncontrolled or ectopic bone growth, severe inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation in men, urinary retention, bone resorption, and implant displacement. These MEDTRONIC-funded articles also omitted any mention of the risks of sterility and cancer associated with rhBMP-2 use, as reported in FDA documents and hearings. MEDTRONIC discouraged the publication of these adverse events in the medical journal literature, thereby hiding significant side effects from spine surgeons and patients.

117. Further, Confidential Witness #2 ("CW 2") in a shareholder derivative lawsuit filed against MEDTRONIC, more fully discussed *supra*, stated that MEDTRONIC was aware of adverse events resulting from off-label use of Infuse® in the cervical spine, including swallowing, and breathing problems.

118. In response to these reports of adverse events, CW 2 stated that MEDTRONIC attempted to disseminate information to the medical community regarding what it considered to

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Journal, 12(10): 894-899, October 2012.

be the proper dose of Infuse® for this off-label application. MEDTRONIC also issued a "Safety Alert" letter to surgeons on September 14, 2004, informing them that MEDTRONIC had received reports of complications associated with off-label use of Infuse® in anterior cervical fusion procedures. MEDTRONIC wrote, "***[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.)

119. These adverse events were not isolated incidents, as described above. These adverse event reports from off-label uses of Infuse® indicate the very same complications as those noted in the studies discussed above, including, swelling, difficulty swallowing and breathing, excessive bone growth resulting in dangerous and painful spinal nerve compression and corresponding injuries, etc., and often require emergency medical intervention or a second surgery.

120. For example, a December 12, 2005 report indicates that four or five days after an off-label PLIF procedure using Infuse®, the 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® found on the MAUDE Database.

121. 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®. As a result, this patient had to undergo another surgery four days after the initial fusion.

122. 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 with Infuse®.

123. 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 (or should be) in a database. MEDTRONIC is required by federal regulation to "establish and maintain" such an adverse event database. *See* 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, revealed 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."

124. According to Confidential Witness #15 ("CW 15") in the *Minneapolis Firefighters* lawsuit filed against MEDTRONIC, more fully discussed *supra*, a Senior Vice President who worked at MEDTRONIC for numerous years until 2006 and a "Quality Group" at MEDTRONIC's Spine division were responsible for addressing adverse events. According to CW 15, former COO Michael DeMane, former President of MEDTRONIC Spinal and Biologics Mr. Wehrly, and former Worldwide Vice President and General Manager, Biologics, Jon Serbousek, were all aware of the adverse events related to Infuse®. As a part of his employment with Defendants, CW 15 discussed the complaints related to Infuse® 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. Moreover, MEDTRONIC's Spinal division used the very same

complaint/adverse event reporting system as MEDTRONIC corporate, which provided MEDTRONIC's executive officers access to a database containing details of every complaint/adverse event MEDTRONIC received relating to Infuse®.

125. MEDTRONIC was further clearly aware of its settlement with the Department of Justice ("DOJ") and entry into a Corporate Integrity Agreement, discussed *supra*, in July of 2006. As a result, MEDTRONIC had actual knowledge of the heightened risks to spine patients associated with MEDTRONIC's illegal, improper, and unethical promotion of off-label use of Infuse® by MEDTRONIC's Spinal or Biologics Divisions.

II. Infuse® is Profitable and thus MEDTRONIC had an Economic Motive to Promote Infuse® Off-label.

126. Infuse® has become a best seller for MEDTRONIC. MEDTRONIC's Infuse® sales have exceeded $3.6 billion since the launch of the Infuse® Bone Graft in July 2002. As a J.P. Morgan research analyst covering MEDTRONIC noted in a report dated November 12, 2008:

> 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.

127. MEDTRONIC has depended heavily on Infuse® sales because so many of its other products, such as cardiac defibrillators, have slowed as the result of recalls of those defective defibrillators in the past several years.

128. Revenue generated by sales of Infuse® was approximately $800 million for the 2011 fiscal year, and the vast majority of these sales were attributable to off-label use of the product. Off-label uses of Infuse® account for 85% to 90% of all spine surgeries involving Infuse®.

129. Plaintiff is informed and believes and based thereon alleges that, as a result of MEDTRONIC's illegal and improper off-label promotion, sales of Infuse® have soared and have totaled more than 4 billion of dollars from 2002 to 2011.

130. MEDTRONIC has consistently sought to expand the use of Infuse® by, among other things, illegally and improperly promoting dangerous and/or insufficiently studied off-label uses for Infuse® in various parts of the spine for various types of spine surgeries, as discussed throughout this Complaint.

III. MEDTRONIC Improperly Promoted Off-Label Uses of Infuse.

A. Generally

131. In spite of the very specific and limited FDA approval of Infuse® (for ALIF procedures only), the overwhelming majority of MEDTRONIC's Infuse® sales have been driven by non-FDA approved, or "off-label," uses, such as that used on the Plaintiff in this civil action. Until recently, MEDTRONIC was very successful (and profitable) in driving off-label sales of Infuse® through undisclosed "consulting" and royalty agreements with physicians who, in exchange for handsome sums of money from MEDTRONIC or lavish trips paid for by MEDTRONIC, those physicians would push off-label usage in a number of ways, including by authoring scientific and medical literature promoting such uses, and by direct advocacy to other spine surgeons.

132. MEDTRONIC also directed its own sales representatives to promote off-label uses of the product, many of whom went so far as to recommend dosages of this potent molecule in risky off-label procedures, and guide surgeons through off-label uses of the product during surgery. Indeed, MEDTRONIC's unlawful off-label promotion campaign was so extensive that it caught the attention of, among others, the FDA (on numerous occasions), the United States DOJ,

Congress, the United States Army, several major universities, multiple medical journals, numerous major newspapers, independent physicians, and investors.

133. Moreover, MEDTRONIC's unlawful off-label campaign has resulted in, among other actions, two whistleblower lawsuits (resulting in a multi-million dollar settlement with the DOJ, which included a Corporate Integrity Agreement), a shareholder derivative lawsuit that was recently settled for $85 million, several adverse regulatory actions by the FDA, and a congressional investigation (led by the United States Senate Committee on Finance).

134. Indeed, even following MEDTRONIC's settlement with the DOJ in 2006 for unlawful kickbacks to physicians to use and promote its products, and corresponding entry into a Corporate Integrity Agreement ("CIA"), discussed *supra*, MEDTRONIC failed to disclose its continued reliance on kick-backs, royalties, and other undisclosed payments to physicians to drive Infuse® sales, primarily for off-label use.

135. Off-label use of Infuse® was and remains particularly concerning due to the known adverse (and in at least one case deadly) side effects known to MEDTRONIC at the time of the product's original FDA approval in 2002. Nonetheless, off-label use of Infuse® 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 accounted for an astounding 85% to 90% of all Infuse® sales.

136. Although undisclosed by MEDTRONIC, the first-hand accounts of its former employees demonstrate that this extraordinarily high off-label use was driven by MEDTRONIC's sales force. Specifically, MEDTRONIC's marketing and sales employees directed spine surgeons to MEDTRONIC-compensated consultants or "Opinion Leaders" or "Thought Leaders" – other spine surgeons paid by enormous sums of money by MEDTRONIC –

the sole purpose of which was to promote off-label uses of Infuse®. Through these and other illegal and improper practices, MEDTRONIC was able to increase Infuse® sales year after year while continuing to hide and downplay the product's dangerous side effects when used off-label in the spine.

137. MEDTRONIC actively promoted off-label use of Infuse® through its sales representatives and massive payments to its "Opinion Leader" spine surgeon consultants, which included sponsoring presentations at continuing medical education courses, and appearances at consulting engagements promoting off-label applications of Infuse®. In turn, MEDTRONIC's sales force directed other physicians to these consultants and "Opinion Leaders" or to their written work (paid for by MEDTRONIC) to further drive off-label sales of Infuse®. Indeed, MEDTRONIC engaged in such conduct even after its settlement of the whistleblower action with the DOJ in which it agreed to employ stricter compliance controls regarding the sale and marketing of its spine products.

138. MEDTRONIC, while providing spine surgeons with MEDTRONIC-funded studies and published articles purporting to support the efficacy and safety of the off-label uses, simultaneously and systematically concealed or downplayed other non-MEDTRONIC-funded studies and articles demonstrating serious and frequent adverse events caused by the same off-label uses.

139. Several spine surgeons have already testified under oath at depositions that MEDTRONIC sales personnel overtly and directly promoted to them the off-label uses of Infuse® in the spine, and Plaintiffs are thus informed and believe that MEDTRONIC engaged in a scheme at all relevant times to expand its market share of this product by improperly encouraging such off-label uses.

140. In this particular case, MEDTRONIC actively promoted the off-label procedures to Plaintiff's spine surgeon. Plaintiff's spine surgeon would not have performed the off-label Infuse® procedure in the absence of such promotion. MEDTRONIC's off-label promotion of Infuse® to Plaintiff's surgeon was false and misleading, because it overemphasized the purported benefits of the off-label use, and hid, minimized, or downplayed the true risks and dangers of the off-label use, all of which were known to MEDTRONIC at all relevant times.

B. Off-label Promotion of Infuse® Violates the Food, Drug, and Cosmetic Act.

141. The Food, Drug, and Cosmetic Act ("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," and physicians are free to prescribe or use medical devices in any manner they deem medically appropriate. 21 U.S.C. § 396.

142. Importantly, however, medical device 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 inconsistent with a product's labeling. Severe penalties for off-label promotion, such as 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 a product's suitability for public consumption is not undermined by manufacturers seeking to circumvent that process. The MEDTRONIC Defendants are medical device companies, not physicians, and they were thus prohibited by federal law including the relevant FDA regulations, at all relevant times, from promoting to physicians or patients any off-label use of Infuse®.

143. Under the FDCA and its accompanying regulations, a device manufacturer must include all intended uses in the label, otherwise the device is misbranded. 21 C.F.R. §801.4. Under the FDCA, device manufacturers can be held liable for off-label promotion when their products are deemed "misbranded" under the statute. 21 U.S.C. § 331(b).

144. 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. *See* 21 C.F.R. §801.4. Further, a device's intended uses are evidenced by the manufacturers' conduct, not by reference to what the FDA has approved. *Id.* 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 can be liable under the FDCA if its conduct demonstrates intent to encourage product use inconsistent with or outside the scope of the product's approved label. *Id.*

145. The FDCA's accompanying regulations require that medical devices sold by manufacturers have adequate directions for use, 21 C.F.R. §801.5, and failure to have adequate instructions for use is considered "misbranding," 21 U.S.C. § 352(f), which is prohibited. 21 U.S.C. § 331(b).

146. The FDCA requires medical device manufacturers to disclose all material facts in advertising and labeling,[14] 21 U.S.C. §321(n), and false or misleading labeling is considered "misbranding," 21 U.S.C. § 352(a), (q)(1), which is prohibited. 21 U.S.C. § 331(b).

147. Further, the FDCA requires medical device manufacturers to maintain and submit information as required by regulation, 21 U.S.C. § 360i, including submitting adverse event

[14] 21 U.S.C. §321(m) defines the scope of medical device labeling.

reports, 21 C.F.R. § 803.50, and establishing internal procedures for reviewing complaints and event reports. 21 C.F.R. § 820.198(a).

148. MEDTRONIC violated these FDCA statutes and accompany regulations by promoting Infuse® for off-label uses, and by failing to account for adverse events and update its labeling, directions for use, and advertising to account for the adverse events resulting from these off-label uses.

149. MEDTRONIC's violation of these FDCA statutes and accompany regulations, as discussed above, constitutes violation of the state law tort causes of action alleged in this Complaint, as set forth below.

150. MEDTRONIC's violation of the FDCA statutes and accompany regulations, as discussed above, directly caused or significantly contributed to the off-label use of Infuse® generally, and directly caused or significantly contributed to the off-label use of Infuse® in this particular Plaintiff, and MEDTRONIC's misconduct in this regard thus caused or contributed to Plaintiffs' injuries and damages.

C. MEDTRONIC Settles Whistleblower Litigation with the DOJ and Agrees to Enter into a Corporate Integrity Agreement

151. MEDTRONIC was named as a defendant in two qui tam actions, United States ex rel. (UNDER SEAL) v. MEDTRONIC. Inc., et al., Civil Action No. 02-2709 (W. D. Tenn. 2002) (hereinafter "[Under Seal]"), and United States ex rel. Poteet v. MEDTRONIC, Inc., et al., Civil Action No. 03-2979 (W. D. Tenn. 2003) (hereinafter "Poteet I"), (collectively the "qui tam lawsuits"). Both lawsuits alleged that MEDTRONIC violated the False Claims Act, 31 U.S.C. § 3729, et seq., by paying illegal kickbacks to physicians in connection with promoting the off-label use of Infuse® in the spine, which resulted in the submission of false or fraudulent claims to federal health care programs.

152. Based on its investigation, the DOJ contended that certain of the payments, services, and remuneration mentioned above were improper and resulted in the submission of false or fraudulent claims in violation of 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. Both *[Under Seal]* and *Poteet I* were brought by MEDTRONIC's former employees who made these allegations.

153. In these lawsuits, the DOJ contended that between January 1, 1998 and April 30, 2003, MEDTRONIC made payments and provided other remuneration to a number of physicians and entities in connection with its spinal products in the form of (1) payments and other remuneration for physicians' attendance and expenses at medical education events, "think tanks," VIP/opinion leader events, and meetings at resort locations; (2) services and payments for services to physicians through MEDTRONIC's Healthcare Economic Services and eBusiness Departments; and (3) payments made pursuant to consulting, royalty, fellowship and research agreements with various physicians and entities.

154. Specifically, *[Under Seal]* was brought by a former MEDTRONIC in-house counsel, who alleged that MEDTRONIC's "aggressive and illegal" sales and marketing efforts were intended by MEDTRONIC to improperly induce physicians to use MEDTRONIC's Spinal products, including Infuse®. 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 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."

155. 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."

156. *Poteet I* was brought by a former MEDTRONIC employee who was tasked by MEDTRONIC to arrange travel (including expense reimbursement) for numerous spinal surgeons to attend MEDTRONIC-sponsored events and other professional meetings. This former employee 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 physicians 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. These 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.

157. On July 18, 2006, MEDTRONIC agreed to pay $40 million to the United States of America to settle these lawsuits under the False Claims Act, 31 U.S.C. §§ 3729-3733, the

Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-12.

158. 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 MEDTRONIC's Chief Compliance Officer.

159. Moreover, the CIA required MEDTRONIC to implement internal policies and procedures to ensure stricter regulatory compliance, which obligated MEDTRONIC to institute a number of changes to improve oversight of its Spinal division.

160. Significantly, the CIA required MEDTRONIC to adopt procedures to ensure that any "arrangements"—a term intended to cover physician 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., physicians]"—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.

161. The CIA and the previous whistleblower and wrongful termination litigation, placed MEDTRONIC and its agents on actual notice that its practice of marketing, and promoting Infuse® for off-label uses was improper and required wholesale change to avoid further adverse regulatory action or other liability.

162. As a result of this settlement, MEDTRONIC agreed to negotiate with representatives of the National Association of Medicaid Fraud Control Units to reach an agreement that provides for distribution of certain sums to the several states with which MEDTRONIC agreed to a settlement concerning the conduct at issue in the False Claims lawsuits.

163. Nonetheless, MEDTRONIC's unlawful practices continued, as did MEDTRONIC's aggressive efforts to drive Infuse® sales by promoting off-label applications, such as precisely those used on the Plaintiff. MEDTRONIC has continued to improperly and illegally promote the off-label use of Infuse® for non-FDA-approved uses of the product. Indeed, they were motivated to do so knowing that, absent off-label use, sales of Infuse® would dramatically decline. In order to obviate a decline in sales revenue, MEDTRONIC continued to covertly employ the same lucrative "consulting" arrangements and other unlawful conduct to promote off-label uses of Infuse®.

164. As a result of MEDTRONIC's undisclosed misconduct, the percentage of off-label Infuse® usage increased over time, including after the DOJ settlement on July 14, 2006.

By 2011, off-label use of Infuse® constituted more than 90% of the total use of Infuse® in spinal fusion procedures.

165. Indeed, MEDTRONIC's unlawful marketing and promotion was so effective that a MEDTRONIC analyst from Bernstein Research noted in a November 21, 2006 report 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 public at large did not know was that, despite the limited FDA-approved applications of Infuse®, MEDTRONIC continued to drive sales solely through off-label indications. And MEDTRONIC persisted in doing so despite the CIA, the material risk of further regulatory action or other liability, and in conscious disregard for the health and welfare of spine patients such as the Plaintiff.

D. Testimony of Former Medtronic Employees Regarding Off-label Promotion of Infuse® in a Shareholder Derivative Action Against Medtronic.

166. A federal securities lawsuit filed on behalf of the Minneapolis Firefighters' Relief Association against MEDTRONIC, *Minneapolis Firefighters' Relief Assoc. vs. MEDTRONIC, Inc.*, Civil No. 08-6324 (PAM/AJB) (D.Minn., 2009), also alleged evidence of MEDTRONIC's egregious campaign of off-label promotion of Infuse®, even after the entry of the CIA. MEDTRONIC's actions, described by the "Confidential Witnesses" ("CW"), included:

a. MEDTRONIC-sponsored physician meetings, during which MEDTRONIC would employ paid consultants – typically surgeons hand selected by MEDTRONIC – to present off-label presentations to local physicians. CW1, Consolidated Class Action Complaint dated August 21, 2009, at ¶ 93.

b. MEDTRONIC's instructions to its sales representatives regarding various off-label uses of Infuse®, including how much of the biologic to use with off-label cervical

fusions, the purpose of which was to instruct physicians regarding off- label uses. CW1, *Id.* at ¶ 94.

c. MEDTRONIC's directions to its sales representatives that they be present during off-label Infuse® surgeries "to assist and direct and give advice when asked." CW1, *Id.* at ¶ 95; CW2, *Id.* at ¶ 97; CW5, *Id.* at ¶ 101; CW6, *Id.* at ¶ 102.

d. MEDTRONIC's creation of sales quotas that were described by the CWs as impossible to reach without pushing off-label use. CW1, *Id.* at ¶ 95; CW9, *Id.* at ¶ 105; CW11, *Id.* at ¶ 107; CW12, *Id.* at ¶ 108.

e. MEDTRONIC's sales representatives' references to data from published literature (presumably funded by MEDTRONIC) when questioned by surgeons, the purpose of which was to provide surgeons with information regarding proffered techniques for off-label procedures and to educate them regarding off-label uses. CW2, *Id.* at ¶ 96.

f. MEDTRONIC's development of smaller-sized bone graft kits under the guise of selling them for FDA-approved uses, when, in actuality, MEDTRONIC had designed each kit to be used in an off –label cervical fusion surgery. CW2, *Id.* at ¶ 97; CW7, *Id.* at ¶ 103.

g. Moreover, by comparing the number of units of rhBMP-2 with the sales of the LT-Cage™ component – which were packaged and sold separately – CW2, 11, and 12 determined that the driving force behind MEDTRONICs $750 million in sales of Infuse® was solely attributable to off-label uses. Although the FDA required the rhBMP-2 and LT-Cage™ to be used together, sales of the rhBMP-2 component greatly outpaced those of the LT-Cage™ component. CW2, *Id.* at ¶ 98; CW11, *Id.* at ¶ 107; CW12, *Id.* at ¶ 108.

h. When questioned by a physician about how to use Infuse® off-label, MEDTRONIC sales representatives directed physicians to other surgeons who used the product

off-label and also would demonstrate or explain how to do so. CW3, *Id.* at ¶ 99; CW5, *Id.* at ¶ 101; CW6, *Id.* at ¶ 102; CW10, *Id.* at ¶ 106; CW11, *Id.* at ¶ 107.

i. MEDTRONIC held quarterly meetings in at least one sales region, during which a national biologics specialist would attend to explain how to conduct off-label applications of Infuse®. CW3, *Id.* at ¶ 99.

j. MEDTRONIC directed its sales representatives to instruct physicians to use half the dose of rhBMP-2 during cervical fusion, and MEDTRONIC, aware of adverse events, instructed the representatives to tell physicians to use steroids to combat potential inflammation. CW4, *Id.* at ¶ 100; CW5, *Id.* at ¶ 101.

k. MEDTRONIC directed physicians using the product in cervical spine fusion to throw away a large portion, sometimes up to half, of the rhBMP-2 dosage. CW6, *Id.* at ¶ 102.

l. MEDTRONIC gave to physicians a small book containing no reference to MEDTRONIC, which contained information regarding the volume or dosage of rhBMP-2 that should be used for off-label applications of Infuse®. CW7, *Id.* at ¶ 103; CW8, *Id.* at ¶ 104; CW9, *Id.* at ¶ 105.

m. MEDTRONIC instructed CW8 and others during sales presentations regarding how to "get around" restrictions on off-label promotion. CW8, *Id.* at ¶ 104.

n. CW 13 was brought into MEDTRONIC to develop a marketing plan; which included: a) development of a "referral marketing" campaign designed to promote the product for off-label uses via a physician referral network; b) identifying which surgeons who should be targeted as part of MEDTRONIC's off-label campaign and what claims MEDTRONIC would make about the product; c) development of a "cookie- cutter" CD series that outlined

MEDTRONIC's off-label 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® among practitioners. CW 13 also stated that MEDTRONIC used a physician training program involving cadaver labs as a means to instruct surgeons regarding off-label applications. CW13, *Id.* at ¶ 109.

o. CW 13 was rebuffed for raising concerns about off-label promotion, and was told "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." CW13, *Id.* at ¶ 110.

p. A sales representative was present in the operating room during an off-label cervical procedure which led to the patient's death. The patient's family subsequently initiated civil litigation against MEDTRONIC and the sales representative who was allegedly encouraging the off-label procedure at MEDTRONIC's behest. *Id.* at ¶ 111.

q. Although MEDTRONIC is under an obligation to report all serious adverse events associated with Infuse®, MEDTRONIC failed to report the death of this patient 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 event. While the company filed an adverse event report with the FDA in which it noted the complications immediately following the procedure, MEDTRONIC did not inform the agency of her death until after a lawsuit was filed by the patient's family and reported in *The Wall Street Journal*. *Id.* at ¶ 112.

r. In a separate civil suit against MEDTRONIC, a physician admitted to attending numerous national spine meetings during which off-label uses of rhBMP-2 in the

cervical spine were promoted. A MEDTRONIC sales representative was in the operating room a lot when he was performing off-label uses. He admitted to doing over 100 cervical procedures, insinuating that the MEDTRONIC sales representative was in the room for a fair number of these procedures. *Id.* at ¶ 113.

167. The plaintiffs in the Minneapolis Firefighters plaintiffs also discovered the growing percentage of off-label Infuse® usage from 2003-2007 by analyzing surgical procedural codes used by hospitals.[15] The results of this analysis demonstrate that off-label usage of Infuse® was high, even from the inception of FDA approval, and increased by an astonishing 10% over the next 4 years; to wit:

[redacted]	25.7%	74.3%
	20.6%	79.4%
	15.8%	84.2%
	15.3%	84.7%
	14.8%	85.2%

168. Moreover, the data further demonstrate that off-label use of Infuse® in the cervical spine grew to as much as 18% of overall Infuse® use as of 2007, despite the known increased medical risks associated with that application.

169. Indeed, to set sales projections for Infuse®, CW 2 stated that MEDTRONIC's marketing department accounted for the scope and number of procedures performed, including the numbers of off-label procedures, such as PLIFs and TLIFs, to predict sales projections. This analysis was based, in part, on data purchased from market research companies demonstrating the number of procedures involving different areas of the spine, e.g., certain lumbar (on- or off-

[15] The methodology employed was consistent with a July 1, 2009 report in the JAMA that conducted a retrospective cohort study of 328,468 patients undergoing spinal fusion procedures from 2002-2006, using the same codes from the NIS database.

label) versus cervical (off-label). Once MEDTRONIC determined its sales projections, these figures were incorporated into a budget presented to MEDTRONIC's senior management. Importantly, the final sales quotas for Infuse® were dictated by MEDTRONIC senior management, and were far in excess of what MEDTRONIC's Spinal Division's had projected, or could be achievable absent 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."

170. Numerous confidential witnesses, including CWs 1, 9, 12 and CW 14 (a senior manager for MEDTRONIC's Spinal and Biologics division from 2005 to 2008), confirm the intense pressure MEDTRONIC's management placed on its sales representatives to meet the sales quotas the company set. Like CW 2, CW 14 explained that sales goals were set by a handful of MEDTRONIC executives, 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.

171. As demonstrated, by years 2006-07, off-label uses accounted for an astounding 85% of Infuse® sales; a fact known or recklessly disregarded by all employees, who reviewed marketing data and analyses to set sales quotas for Infuse®. Indeed, sales quotas for Infuse® required sales to grow 20% year-over-year, and MEDTRONIC knew that such increases could not be achieved without substantial off-label sales. Therefore, aggressive sales targets would encourage off-label promotion by its employees and representatives.

E. MEDTRONIC's Payments to Opinion Leaders.

1. Generally.

172. In addition to encouraging its sales representatives to promote off-label use of Infuse®, MEDTRONIC also promoted the off-label use of the product through its outside

physician "Opinion Leaders" to whom MEDTRONIC paid undisclosed sums in return for publishing medical journal articles and delivering presentations explaining, endorsing, and promoting off-label applications of the product. Indeed, even after the settlement with the DOJ and entry into the CIA as a result of this very same activity, MEDTRONIC continued its practice of providing lucrative consulting fees (amounting to millions of dollars per year) to surgeons who actively promoted off-label use of Infuse®, often with direct involvement by MEDTRONIC's senior management.

173. MEDTRONIC sought to expand the off-label uses (and has succeeded in doing so) by paying large amounts of money to key "Opinion Leader" spine surgeons around the country, many of whom then published studies and articles advocating the off-label use of Infuse® and minimizing the risks or dangers to patients of these uses.

174. Medical device companies look for surgeons who are known as "Opinion Leaders" and who will not only use a high volume of their products, but who can and will persuade other surgeons to use a particular device. Opinion leaders are physicians whose opinions on medical procedures and medical devices are held in high regard by other surgeons. If these influential physicians are willing to promote the use of a certain device, then other surgeons are likely to follow suit and use that device, sometimes including off-label uses which are illegal for the company itself to promote.

175. Many medical device companies, including MEDTRONIC, cultivate relationships with these "Opinion Leaders," paying them handsome (and in the case of Infuse®, sometimes seven-figure) consulting fees, travel expenses for seminars, sham or exaggerated royalty payments, and numerous other perks, to encourage these physicians to promote the use of a particular medical device.

176. Prior to the date of Plaintiff's spine surgery which involved off-label Infuse®, MEDTRONIC provided millions of dollars in undisclosed payments to certain spine surgeon "Opinion Leaders" who published articles in medical journals, delivered presentations at continuing medical education courses, and appeared at consulting engagements to promote off-label applications of Infuse® in the spine. In turn, MEDTRONIC's sales force would direct other physicians to these "Opinion Leaders" or to their written work to further drive off-label sales of the Infuse®. In this way, MEDTRONIC consciously and deliberately orchestrated a campaign to end-run the FDA's 2002 approval of and labeling for the Infuse® device.

177. MEDTRONIC, for example, paid more than $45 million to the 12 spine surgeons who authored the first 13 studies sponsored by MEDTRONIC on Infuse®. Additionally, "Medtronic paid a total of approximately $210 million to physician authors of Medtronic-sponsored studies from November 1996 through December 2010 for consulting, royalty, and other miscellaneous arrangements." *Staff Report on Medtronic's Influence on Infuse Clinical Studies*, U.S. Senate Committee on Finance, October 25, 2012.

2. Walter Reed "Opinion Leaders:" Timothy Kuklo, M.D., Rick Sasso, M.D., and David Polly, M.D.

178. Just one of MEDTRONIC's highly compensated "consultants"—Dr. Timothy Kuklo, a former Army physician 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, *The Wall Street Journal* and *New York Times* reported in 2009 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. MEDTRONIC 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. MEDTRONIC confirmed that Dr. Kuklo was a paid consultant for MEDTRONIC and that the company has paid him more than $800,000 over an eight year period.

179. While it is not inherently illegal or unethical for physicians to perform paid consulting work for medical device companies, the history of the growing Infuse® scandal demonstrates an egregious pattern of both MEDTRONIC and its "Opinion Leaders" overstepping ethical lines while recklessly promoting dangerous off-label uses of this product. Dr. Kuklo, for example, worked closely with MEDTRONIC as an active promoter of off-label uses of Infuse®; that is, until a U.S. Army investigation into a falsified study touting the benefits of Infuse® uncovered shocking misconduct by this former Army surgeon. 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 Ellis and Peter Wehrly ("Wehrly"), MEDTRONIC Spinal Division Senior Vice President. 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 such off-label use 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." For his part, Dr. Kuklo responded that the question "was well answered as far as appropriate dosage. I think it's really the bottom line."

180. Although Dr. Kuklo's and Dr. Sasso's rendition of the medical literature may not have been entirely accurate—in fact they baldly misrepresented the seriousness of the adverse events that Defendants knew were occurring in the cervical spine—their misrepresentations only hinted at the influence of MEDTRONIC's payments on its consultants' medical judgment. Indeed, an Army investigation later revealed that Dr. Kuklo deliberately falsified data by exaggerating the benefits of off-label use of Infuse® in a study published in the August 2008 issue of *The Journal of Bone and Joint Surgery*.

181. Dr. Kuklo's "study," which purported to compare fusion results of 67 patients who received an autogenous bone graft versus 62 that were treated with Infuse® to treat certain tibial (shin bone) fractures in injured soldiers (including certain off-label uses), reported that employing Infuse® resulted in "strikingly" better outcomes than a traditional (autogenous) bone graft. Specifically, Kuklo reported that those receiving autogenous bone grafts had successful fusions in 76% of procedures, while the union rate for the Infuse® group was significantly better at 92%; a claimed "striking finding."

182. According to Dr. Kuklo, not only were the reported union rates claimed better with Infuse® than with an autograft, but, according to this (falsified) study, patients who received Infuse® 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."

183. MEDTRONIC continued paying Dr. Kuklo as a consultant even after his article was discovered to be largely fabricated and thus retracted by *The Journal of Bone and Joint*

Surgery. Indeed, MEDTRONIC only placed Dr. Kuklo on "inactive status" after reports that he had falsified the study's data were published in *The New York Times*.

184. On May 13, 2009, *The New York Times* reported that the U.S. Army's investigation into a study authored by Dr. Kuklo concluded that he falsified an entire study touting the benefits of Infuse® to treat wounded soldiers injured in Iraq – conduct that Col. J. Edwin Atwood, an Army physician who led the Army's inquiry, described as "the ultimate tragedy and catastrophe in academic medicine."

185. Per *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, Lt. Col. Andersen alerted Army investigators who found that:

a. Dr. Kuklo listed four other Army surgeons as "co-authors" without their knowledge, and these four physicians did not participate in or review the article's preparation or submission for publication;

b. The signatures of the four physicians listed as co-authors on the copyright release forms submitted to *The Journal of Bone and Joint Surgery* were forged by Dr. Kuklo;

c. The number of cases cited by Dr. Kuklo in the article differed from the number of cases contained in the U.S. Army's wartime casualty database, with no explanation for the discrepancies in the article;

d. Contrary to Army policy, Dr. Kuklo did not obtain publication review or clearance from Walter Reed prior to submitting the article for publication; and

e. The published results of the article suggested a much higher efficacy rate for Infuse® than is supported by the experience of the purported co- authors.

186. According to one of the Army's investigators, Col. Norvell V. Coots, the study cited higher numbers of patients and injuries than the hospital could account for. According to Col. Coots, "[i]t's like a ghost population that were reported in the article as having been treated that we have no record of ever having existed ... this really was all falsified information."

187. After receiving correspondence from Walter Reed dated November 6, 2008 stating 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, *The Journal of Bone and Joint Surgery* formally retracted the article and banned Dr. Kuklo from submitting further papers to *The Journal of Bone and Joint Surgery*. 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 him or the extent of funding it provided.

188. As discussed in more detail *supra*, U.S. Senator Charles Grassley discovered that Dr. Kuklo's name did not appear on a list of paid consultants for Infuse® provided by MEDTRONIC that the Senator had requested in a September 30, 2008 letter to MEDTRONIC. Senator Grassley disclosed the list MEDTRONIC provided—which included 22 physicians who were paid a total of $943,000 from 2005 to 2008—in a May 18, 2009 letter to MEDTRONIC 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®, 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®. Indeed, by this time, Dr. Kuklo had given countless presentations on behalf of MEDTRONIC about off-label use of the product.

189. The list provided to Senator Grassley also omitted names of other MEDTRONIC consultants who had promoted off-label uses of Infuse®, such as David Polly, M.D., another former Walter Reed surgeon. Frustrated with MEDTRONIC's omissions, Senator Grassley stated 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 regarding its illegal promotion of Infuse®.

190. As a result, on June 18, 2009, MEDTRONIC disclosed to *The Wall Street Journal* that Dr. Kuklo had received almost $850,000 in payments from MEDTRONIC over the past 10 years, the majority of which—nearly $800,000— were made in the preceding three years when Dr. Kuklo was submitting his bogus fabricated study on Infuse® to medical journals for publication. Specifically, MEDTRONIC 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 in the *Journal of Bone and Joint Surgery*. MEDTRONIC made both of these payments after MEDTRONIC announced the settlement with the DOJ in July 2006.

191. 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®. In fact, MEDTRONIC financed two separate, unpublished studies that also examined the use of Infuse® 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

MEDTRONIC shortly after joining the University faculty and had received payments from MEDTRONIC for almost a year into his research.

192. 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.

193. Another highly compensated MEDTRONIC consultant involved in the promotion of off-label Infuse® use, Dr. Polly, a professor and Chief of the Spine Service at the University of Minnesota Department of Orthopaedic Surgery, received consulting fees from MEDTRONIC totaling $1.14 million from 2003 to 2007. 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 MEDTRONIC 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 stationed at Walter Reed in 2003. Dr. Polly attended these conferences to report on his research that purportedly demonstrated that Infuse® was more cost effective than traditional spinal fusion procedures.

194. 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 their article, published in the November 2004 issue of Minnesota Medicine, 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® 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."

195. Moreover, additional evidence demonstrates that, even before his and Dr. Polly's November 2004 article was published, MEDTRONIC reimbursed Dr. Kuklo for a meeting with MEDTRONIC representatives in Memphis, Tennessee, on April 20, 2004 regarding "Review of BMP Trauma and Spine Surgery."

196. 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® and antibiotics to treat traumatic and infected bone fractures. Dr. Polly represented that he was "speaking on behalf of the American Academy of Orthopedic Surgeons." However, according to information recently released by Senator Grassley, who, in conjunction with Senator Baucus, 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 MEDTRONIC, not the American Academy of Orthopedic Surgeons, as he had claimed. 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® research study.

197. The information released by Senator Grassley, discussed more fully *supra*, which includes billing reports submitted to MEDTRONIC by Dr. Polly and approved by MEDTRONIC, indicates that throughout this period, Dr. Polly had frequent meetings, telephone calls, and email correspondence with numerous MEDTRONIC senior executives, including former COO Michael DeMane ("DeMane"), and former President of MEDTRONIC Spinal and Biologics Wehrly, while speaking frequently regarding Infuse® at medical conferences and other events. For example, the records show meetings and other contacts between Dr. Polly and Hawkins on the following dates: 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 MEDTRONIC for a meeting with Hawkins on July 13, 2005 to discuss a "spine surgery advocacy effort."

3. Opinion Leader Dr. Graham A. Zdeblick.

198. Thomas A. Zdeblick, M.D., the Chairman of the Department of Orthopedics and Rehabilitation at the University of Wisconsin, received over $19 million from MEDTRONIC 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, he actually received between $2.6 and $4.6 million per year. In 2007 alone, Dr. Zdeblick received $2,641,000 in consulting 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 MEDTRONIC site in Memphis, Tennessee, and to participate in "workshops" for surgeons.

199. Dr. Zdeblick also has been a significant contributor to MEDTRONIC's promotion of Infuse®, 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 product. On a MEDTRONIC-owned website, "www.Back.com," Dr. Zdeblick describes the advantages of Infuse® and appears in an online video discussing the benefits of the product.

200. As discussed more fully *supra*, on January 16, 2009, *The Wall Street Journal* reported on a letter sent by Senator Charles Grassley to Kevin P. Reilly, President at the University of Wisconsin, regarding Defendants' consulting and royalty payments to Dr. Zdeblick, who co-authored preliminary studies that led to the FDA's approval of Infuse®. Although the University is required to monitor its researchers' financial conflicts-of-interest, the amounts MEDTRONIC paid Dr. Zdeblick far exceeded those he reported to the University. Specifically, Dr. Zdeblick was required to disclose annual amounts in excess of $20,000 per year, and in one year reported payments in excess of $40,000. In reality, Dr. Zdeblick received between $2.6 million and $4.6 million per year from MEDTRONIC, totaling an astonishing $19 million in payments, from 2003 through 2007.

201. As revealed in a June 20, 2009 article in the *Milwaukee Journal Sentinel*, 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. Dr. Anderson, along with MEDTRONIC consultants Drs. Boden, Keith H. Bridwell, and Jeffrey C. Wang, authored a July 2007 article in *Journal of Bone and Joint Surgery* article, titled "What's New in Spine Surgery." The article discussed, among other things, a study that examined the use of Infuse® in an off- label Posterolateral Fusion procedure. According to the authors, the study reported that Infuse® 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®] 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."

202. On June 20, 2009, the *Milwaukee Journal Sentinel* reported that, during calendar year 2008, MEDTRONIC paid Dr. Zdeblick $2 million in royalty payments for eight days of consulting work, and that Dr. Paul Anderson received $150,000 in MEDTRONIC consulting fees for working just eight days.

4. Norton Hospital Leatherman Spine Center Opinion Leaders.

203. Another set of highly compensated surgeons, those affiliated with the Norton Hospital Leatherman Spine Center in Louisville, Kentucky, collectively received more than one 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).

204. According to CW 1, several surgeons from the Leatherman Spine Center were requested by MEDTRONIC to speak at MEDTRONIC-sponsored physician talks attended by between 10 and 25 surgeons, including several "pretty high profile" physicians. At these physician talks a MEDTRONIC consultant, such as one of the surgeons at the Leatherman Spine Center, provided presentations covering off-label usage of Infuse®. According to CW 1, "[w]hat [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." Importantly, these physician talks were also attended by all MEDTRONIC sales representatives who worked in the area.

205. These same MEDTRONIC-funded surgeons associated with the Leatherman Spine Center have also written extensively on off-label uses of Infuse®. These surgeons have collectively authored at least 15 articles addressing the use of BMP, including many of the early

medical articles on the use of Infuse® in off-label posterolateral lumbar and anterior cervical fusion procedures. Specifically, Dr. Campbell has contributed to at least eight articles examining the use of BMP; Dr. Dimar has authored 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.

5. Other Various Opinion Leaders.

206. Several physicians who authored a May 2003 article describing positive results of Infuse® used in the cervical spine were paid tens of thousands of dollars in consulting fees by MEDTRONIC. The article, "New Technologies in Anterior Cervical Spine Fixation," published on SpineUniverse, a website intended for the general public that provides information regarding spinal disorders and treatment, described the physicians' use of Infuse® "in the cervical spine with very good results." According to the authors, "[p]reliminary results are promising and Infuse® may be especially appropriate in people undergoing multiple level fusions" (emphasis added)—i.e., for indications outside FDA limited approval to single-level fusion procedures.

207. 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. Another author, Dr. Gerard 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 ties to MEDTRONIC.

208. Dr. Haid was also the lead author of an article describing the results of the study of Infuse® in off-label PLIF procedures that was halted in December 1999 after several patients experienced adverse incidents of uncontrolled 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 rhBMP-2, including studies examining the use of Infuse® in off-label PLIF and anterior cervical procedures—received $416,775 in 2006 and similar amounts in the two preceding years.

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

210. 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."

211. Importantly, Dr. Kahanovitz also 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."

212. CW 1 stated that Drs. Lawrence "Larry" G. Lenke and Keith H. Bridwell, two surgeons from Washington University in St. Louis – where Dr. Kuklo worked as an associate professor until recently – similarly acted as "Opinion Leaders" 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 met 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®, including instruction in cadaver labs. According to CW1, who personally attended two such meetings, "[t]here 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." CW1 stated that MEDTRONIC chose which surgeons to invite to these corporate visits based, in part, upon the volume of Infuse® procedures they performed.

213. Another prominent MEDTRONIC consultant, Jeffrey Wang, M.D., 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®. Unsurprisingly, Senator Grassley recently discovered that Dr. Wang received $275,000 in royalty and consulting payments from MEDTRONIC from 2003 until 2008.

214. Furthermore, Dr. Wang failed to disclose his substantial financial relationship with MEDTRONIC while researching MEDTRONIC products, which violated UCLA's policy requiring him to do so. For example, 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, notwithstanding the fact that MEDTRONIC was, at that very moment, funding one of Dr. Wang's studies. In fact, Dr. Wang received $14,600 on January 4, 2007 for "lecture and teachings at spine meetings and universities in Korea for one week." As a result of his repeated failures to disclose payments received from MEDTRONIC, Dr. Wang lost his position as Executive Co-Director of UCLA's Comprehensive Spine Center.

215. As discussed more fully *supra*, Senator Grassley also discovered that, in addition to the compensation to MEDTRONIC consultants, MEDTRONIC collectively paid 22 other surgeons $943,000 from 2003 to 2008 to work on matters specific to Infuse®.

216. In June 2011, one of the leading journals on spine surgery, *The Spine Journal*, described more fully *supra*, devoted an entire issue to publishing various articles regarding the risks associated with Infuse®, including articles on MEDTRONIC's failure to accurately report the side effects from its clinical trials; MEDTRONIC's failure to report that many of the authors who studied and promoted Infuse® had significant financial ties to MEDTRONIC, with a median range of $12 to $16 million per study; that Infuse® can cause severe injuries to the spinal nerves and spinal cord; that off-label use of Infuse® can lead to other severe side effects; and that MEDTRONIC and its paid consultants/study authors downplayed the risks associated with Infuse®, over-emphasized its benefits and over-emphasized the risks associated with traditional non-Infuse® spine fusion procedures.

F. U.S. Senators' Letters to MEDTRONIC Regarding to the Promotion and Marketing of Infuse®.

1. September 30, 2008 Letter.

217. Despite the July 2006 Settlement with the DOJ, concerns regarding MEDTRONIC's off-label marketing activities and related payments to doctors continued.

218. On September 30, 2008, U.S. Senator Herb Kohl sent a letter to MEDTRONIC noting that earlier in 2008, MEDTRONIC's outside counsel provided to the Special Committee on Aging a written account of MEDTRONIC's efforts to comply with the July 2006 Settlement Agreement it reached with the DOJ concerning allegations that MEDTRONIC and its subsidiary improperly compensated surgeons and physicians in connection with the Infuse® device.

219. Senator Kohl's letter expressed several concerns, including the following:

> That account also addressed the corporate integrity agreement (CIA) that MEDTRONIC and its subsidiary entered into with the Office of the Inspector General of the United States Department of Health and Human Services stemming from those same allegations. In that same letter to the Committee, MEDTRONIC and its subsidiary both denied that "improper payments were made to physicians in the first place (MEDTRONIC's agreement with DOJ does not contain any admission of liability), much less that improper payments 'have continued.' Consequently, it was with concern that I read recent articles, in the *Wall Street Journal* and elsewhere, which outlined highly disturbing allegations of improper, if not illegal, payments by MEDTRONIC to surgeons and physicians.
>
> These continuing allegations are directly relevant to the Committee's oversight of inappropriate physician compensation practices within the medical device industry. All of the major orthopedic device companies that settled with DOJ over such allegations were required to publicly reveal information related to their payments to physicians. MEDTRONIC's response to the Committee's initial inquiry articulated no specific reasons as to why MEDTRONIC has yet to voluntarily make the same disclosures.

220. In this letter, Senator Kohl requested both documentation of MEDTRONIC's efforts to comply with the July 2006 Settlement Agreement and interviews with corporate witnesses and documents "given the ongoing, serious concerns publicly raised regarding the integrity and transparency of MEDTRONIC's physician compensation practices."

221. Senator Kohl also asked MEDTRONIC to explain "the circumstances that led MEDTRONIC's former counsel to file suit against the company [alleging improper payments to physicians] and how that matter was subsequently settled."

222. Also on September 30, 2008, U.S. Senator Charles Grassley sent a similar letter to MEDTRONIC pertaining to the marketing of Infuse® and allegations of related kickbacks to physicians regarding the sale of Infuse®, noting that:

> Last week, the *Wall Street Journal (WSJ)* reported on allegations of financial perks provided to doctors that included "entertainment at a Memphis strip club, trips to Alaska and patent royalties on inventions they played no part in."[16] I would appreciate your assistance in better understanding these allegations and would like to take this opportunity to lay out my specific concerns and questions.

223. Senator Grassley went on to express his concern over the *Wall Street Journal*'s reports "that one of the incentives MEDTRONIC provided physicians was to include them on patents for medical devices and reward them with royalties, even though the physicians may not have contributed to the development of the product."

224. This letter specifically addressed issues related to MEDTRONIC's marketing of Infuse®:

> Fourth, earlier this month the WSJ reported on problems with off-label use of MEDTRONIC's Infuse®. Infuse® is a bone graft replacement technology that uses a protein which creates bone. Specifically, it was reported that MEDTRONIC gave payments to physicians, in the form of consulting agreements, as a means of increasing sales of Infuse®. The allegations that MEDTRONIC has been disguising these consulting agreements as inducements or kickbacks for physicians to use Infuse® are equally troubling. Likewise, this is a practice that I would like to better understand and I would like to know what if anything has changed since these

[16] David Armstrong, "Lawsuit Says MEDTRONIC Gave Doctors Array of Perks," *Wall St. J.*, Sept. 25, 2008.

reported events.

225. Senator Grassley, in his September 30, 2008 letter, also questioned why several lawsuits against MEDTRONIC pertaining to Infuse® remained under seal, and indicated that he would like to "better understand the status of these lawsuits and the procedural process that has led to the current situation."

2. June 21, 2011 Letter.

226. The U.S. Senate Committee on Finance investigated whether MEDTRONIC has continued to misrepresent the adverse events that result from Infuse® and rhBMP-2, as well as the possibility that MEDTRONIC improperly influenced clinical trials and reporting regarding rhBMP-2.

227. On June 21, 2011, U.S. Senators Charles Grassley and Max Baucus sent another letter to MEDTRONIC on behalf of the Senate Committee on Finance requesting that MEDTRONIC produce documents and communications pertaining to "adverse postoperative events and/or medical complications" resulting from the use of rhBMP-2.[17] The letter also requests that MEDTRONIC provide "[a] detailed account of payments that MEDTRONIC made to all Infuse® clinical investigators."

228. In their June 21, 2011 letter, Senators Grassley and Baucus state: "[w]e are extremely troubled by press reports suggesting that doctors conducting clinical trials examining the safety and effectiveness of Infuse® on behalf of MEDTRONIC were aware that Infuse®, a treatment commonly used in spinal surgery, may cause medical complications, but failed to report this in the medical literature. This issue is compounded by the fact that some clinical investigators have substantial financial ties to MEDTRONIC."

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[17] Letter from Grassley and Baucus (June 21, 2011), *available at*, http://finance.senate.gov/newsroom/chairman/release.

229. The letter further states: "[w]e are also concerned that other severe side-effects of Infuse® and similar bone-growth products developed by MEDTRONIC may have been unreported or under-reported in clinical literature. Reports have linked Infuse® to potentially fatal swelling in the neck and throat, and radiating leg pain. Concerns have also been expressed about a potential link to cancer."

3. December 13, 2011 Letter.

230. Senators Herb Kohl, Charles Grassley, and Richard Blumenthal wrote to MEDTRONIC again in December 2011 demanding more information from the company over adverse events caused by on-label and off-label use of Infuse®. The letter noted that "your company has experienced safety issues, such as with your spine product Infuse®."

231. The letter also demanded that MEDTRONIC explain whether or not it requires physicians who receive funds from MEDTRONIC to disclose those payments to their patients before the patients receive one of MEDTRONIC's medical devices. And "[i]f not, why not?"

232. This new letter requires that MEDTRONIC produce this information to the U.S. Senate's Special Committee on Aging by no later than January 23, 2012.

233. On information and belief, this continued investigation by a U.S. Senate Committee suggests that MEDTRONIC has not changed its ways with regard to its illegal promotion of Infuse®, despite signing the CIA and paying a $40 million fine to DOJ in 2006.

G. June 1, 2011 Issue of *The Spine Journal.*

234. On June 1, 2011, *The Spine Journal*, a leading medical journal in the United States, published a special edition dedicated to addressing serious patient safety and ethical concerns related to the use of rhBMP-2 (Infuse®) in the spine.

235. This special edition reviewed thirteen peer-reviewed articles about rhBMP-2 by MEDTRONIC-sponsored authors, and concluded that these articles had inaccurately reported the safety of rhBMP-2 applications in the spine by underestimating its risks.

236. In an editorial summarizing the findings of this special issue, five prominent physicians, including spine surgeons at Stanford University Medical Center, wrote that the earlier industry-sponsored trials and reports were "remarkable for the complete absence of reported rhBMP-2-related clinical adverse events." For example, the industry-sponsored articles omitted mention of indications from the earliest trials of inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement. They also omitted mention of sterility and cancer risks associated with rhBMP-2, as reported in FDA documents and hearings. The trials and reports suffered from idiosyncratic trial design, reporting bias, and peer-review/publication shortfalls.

237. According to this editorial and several of the accompanying articles, the thirteen MEDTRONIC-funded articles reported only successful fusions and extremely low or nonexistent rates of complications with Infuse®, which led to the growth of "off-label" use of Infuse® in lumbar fusion procedures. According to the authors in *The Spine Journal*, the MEDTRONIC-funded articles "may have promoted widespread poorly considered on- and off-label use, eventual life-threatening complications and deaths."

238. Contrary to the conclusions of the earlier MEDTRONIC-sponsored trials and articles, an article in this special issue of the *Spine Journal* suggested "an estimate of adverse events associated with rhBMP-2 use in spine fusion ranging from 10% to 50% depending on approach."

> Anterior cervical fusion with rhBMP-2 has an estimated 40% greater risk of adverse events with rhBMP-2 in the early

> postoperative period, including life-threatening events. After anterior interbody lumbar fusion rates of implant displacement, subsidence, infection, urogenital events, and retrograde ejaculation were higher after using rhBMP-2 than controls. *Posterior lumbar interbody fusion was associated with radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes.* In posterolateral fusions, the risk of adverse effects associated with rhBMP-2 use was equivalent to or greater than that of iliac crest bone graft harvesting, and 15% to 20% of subjects reported early back pain and leg pain adverse events; higher doses of rhBMP-2 were also associated with a greater apparent risk of new malignancy."

Eugene J. Carragee, Eric L. Hurwitz & Bradley K. Weiner, *A Critical Review Of Recombinant Human Bone Morphogenetic Protein-2 Trials In Spinal Surgery: Emerging Safety Concerns And Lessons Learned*, *The Spine Journal* 11, 471-72 (2011) (emphasis added).

239. This article also reported that ten of the earlier industry-sponsored rhBMP-2 trials were funded in whole or in part by the manufacturer of rhBMP-2 (Infuse®), MEDTRONIC. Furthermore, in twelve of these earlier studies, the median-known financial association between the authors and MEDTRONIC Inc. was approximately $12,000,000-$16,000,000 per study (range, $560,000-$23,500,000). *Id.* at 475.

240. The following are some of the other significant conclusions in these articles in the June 1, 2011 Issue of *The Spine Journal*:

a. Many of the risks now accepted have been known since a publication by Poynton and Lane in 2002, which listed overgrown and uncontrolled bone formation, osteoclast activity (graft subsidence, migration, loss of fixation etc.), local safety (inflammation, edema, wound problems, and infection), potential negative effect of BMPs on exposed dura and nerves (neurologic events, retrograde ejaculation, persistent bladder retention, early back pain, leg pain, radiculitis, functional loss, carcinogenicity). *However, it appears that these risks were ultimately washed out and marginalized by the wealth of positive data from industry-sponsored studies.*

b. A 2-year rhBMP-2 follow-up published by Burkus, et al., reported no adverse events. However, in a 6-year follow-up publication using the same subjects, the authors contradict their earlier publication stating that there had been seven early adverse events associated with subsidence in the rhBMP-2 group, yet they were not reported in the two year follow-up.

c. In fact, on closer inspection of the Burkus studies, it was noted that all adverse events mentioned in the six-year follow-up had occurred within the first two years.

d. Furthermore, four of the adverse events required further surgery, and 22 additional surgeries for device failures occurred in the same rhBMP-2 group between 0-2 years after surgery according to the FDA summary, but were not specifically reported in the 2003 or 2004 studies, which were the same patients over the same time frame.

e. The estimates of rhBMP-2 safety from the original publications underestimated rhBMP-2-related adverse events of the product. In the small pilot studies, there were inadequate numbers to assess safety, but some suggestion of potential harm was seen in at least one study. In the larger trials, there is evidence in each trial that rhBMP-2 complications may be common and may be serious, but in each publication these were underreported.

f. The presence and magnitude of conflicts of interest and the potential for reporting bias were either not reported or were unclear in each of the original industry sponsored studies. Some of the conflicts-of-interest statements reported appeared to be vague, unintelligible, or were internally inconsistent.

g. The original estimates of ICBG (Iliac Crest Bone Graft, the pre-rhBMP-2 gold standard procedure for spinal fusion) harvesting morbidity were based on invalid

assumptions and methodology. This in turn may have exaggerated the benefit or underestimated the morbidity of rhBMP-2 in the clinical situations tested.

h. The control group methods and techniques, as selected for both posterior approach methods (PLIF and PLF) were potentially handicapped by significant design bias against the controls.

i. In those studies for which other data sources have been made available on the same patient sets (either FDA documents or subsequent reporting of follow-up data), serious contradictory findings have emerged. Major complications, additional surgeries, neurologic/urologic injury, and major back/leg pain events were apparently observed but not reported in the original articles.

j. By reporting perfect or near perfect safety, the original studies might have led others to widespread off-label use of the product with some potentially catastrophic outcomes. Revised estimates of adverse events are:

i. Posterior lumbar interbody fusion techniques: 25-50% risk of associated adverse events.

ii. Anterior lumbar interbody fusion: 10-15% risk of adverse events.

iii. Anterior cervical fusion: 40% greater risk of adverse events in the acute postoperative period including potentially life-threatening complications.

iv. Posterolateral fusions: equivalent or greater early postoperative risk of morbidity compared with ICBG harvesting for this dosage; 16-20% of rhBMP-2 subjects had adverse back and leg pain events, *a probable two to threefold increase in the first three months after surgery over control groups* (emphasis added).

H. October 25, 2012 U.S. Senate Committee on Finance Report on Medtronic's Manipulation of the Infuse® Studies and Close Financial Ties with Researchers

241. On October 25, 2012, Senate Finance Committee Chairman Max Baucus (D-Mont.) and senior member Chuck Grassley (R-Iowa) released the results of their 16-month investigation into MEDTRONIC, which revealed questionable ties between the company and its physician "Opinion Leader" consultants tasked with testing and reviewing Infuse®. Without public disclosure of their roles, MEDTRONIC employees collaborated with the physician authors to edit – and in some cases, write – segments of published studies on Infuse®. The studies may have inaccurately represented Infuse®'s risks and may have overemphasized the side effects of prior more traditional treatments. The Senate report found that MEDTRONIC also maintained significant, previously-undisclosed financial ties with the physicians who authored the early studies on Infuse®, making $210 million in payments to physicians over a 15-year period.

242. "Medtronic's actions violate the trust patients have in their medical care. Medical journal articles should convey an accurate picture of the risks and benefits of drugs and medical devices, but patients are at serious risk when companies distort the facts the way Medtronic has," Senator Baucus said. "Patients everywhere will be better served by a more open, honest system without this kind of collusion."

243. "These findings emphasize the value of the Grassley-Kohl Physician Payments Sunshine Act, which will result in public disclosure of industry payments to physicians starting next year. The findings also should prompt medical journals to take a very proactive approach to accounting for the content of the articles along with the authorship of the articles and studies they feature," Grassley said. "These publications are prestigious and influential, and their standing

rests on rigorous science and objectivity. It's in the interest of these journals to take action, and the public will benefit from more transparency and accountability on their part."

244. The report released on October 25, 2012 by Senators Baucus and Grassley on behalf of the U.S. Senate Finance Committee – which has sole jurisdiction over Medicare and Medicaid – was the product of an investigation they began in June 2011.[18] The major findings of the investigation include:

a. MEDTRONIC was involved in drafting, editing, and shaping the content of medical journal articles on Infuse® authored by its physician consultants who received significant amounts of money through royalties and consulting fees from MEDTRONIC. The company's significant role in authoring or substantively editing these articles was not disclosed in the published articles. Medical journals should ensure any industry role in drafting articles or contributions to authors be fully disclosed.

b. MEDTRONIC paid a total of approximately $210 million to physician authors of MEDTRONIC-sponsored studies from November 1996 through December 2010 for consulting, royalty and other arrangements.

c. An e-mail exchange shows that a MEDTRONIC employee recommended against publishing a complete list of adverse events, or side effects, possibly associated with Infuse® in a 2005 *Journal of Bone and Joint Surgery* article.

d. MEDTRONIC officials inserted language into studies that promoted Infuse® as a better technique than an alternative by emphasizing the pain associated with the alternative.

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[18] The Senate's full report is available online at: http://www.finance.senate.gov/newsroom/chairman/download/?id=e54db17c-a475-4948-bd81-69c8740c6aaf. In the interest of brevity, Plaintiff has not attached the full 2,315 page report.

I. Further Evidence of MEDTRONIC's Off-label Promotion.

245. MEDTRONIC's knowledge and promotion of off-label use of Infuse® is further evidenced by comparing sales of the rhBMP-2 component to the sales of the LT-Cage™ component (both components are required pursuant to FDA approval). On information and belief, MEDTRONIC sells the rhBMP-2 component separately from the LT-Cage™ in order to illegally and improperly promote off-label uses of Infuse® in the lumbar spine and in the cervical spine, procedures in which the LT-Cage™ is not used. As a result, sales of the rhBMP-2 component are and were at all relevant times far larger than sales of the LT-Cage™ component, despite FDA requirements that both be used according to the product's labeling; i.e. that the entire medical device (rhBMP-2 and the LT-Cage™) be used in the procedure.

246. As described in detail above and throughout this Complaint, therefore, MEDTRONIC's off-label promotion of Infuse® was not truthful. Instead, MEDTRONIC's off-label promotion of Infuse® was false and misleading. "Of course, off-label promotion that is false or misleading is not entitled to First Amendment protection." *United States v. Caronia*, No. 09-5006-cr, 2012 U.S. App. LEXIS 24831, at *39, n. 11 (2d Cir. Dec. 3, 2012).

247. MEDTRONIC's aggressive off-label promotion described above created the conditions for widespread acceptance by spine surgeons of the off-label uses of Infuse® after the 2002 PMA approval, and MEDTRONIC's violations of federal law described above (which parallel Plaintiff's state-law tort claims) directly caused or significantly contributed to the widespread off-label use of Infuse® generally, and also specifically with respect to Plaintiff. In particular, MEDTRONIC's off-label promotion activities and failure to report adverse events caused spine surgeons, including Plaintiff's surgeon to use Infuse® in dangerous off-label procedures.

J. Plaintiff GERARD E. LEDET's Lumbar Spine Surgery

248. On or about April 18, 2007, Plaintiff GERARD E. LEDET underwent an anterior lumbar interbody fusion at levels L4-S1 with a Cougar spacer cage device in which Infuse® was used off-label. The surgery was performed by Eric Graham, M.D. The use of Infuse® was off-label in this surgery because (1) it was implanted in multiple levels of the lumbar spine, and (2) the requisite LT-Cage™ was not used.

249. Prior to this surgery, MEDTRONIC did not inform Plaintiff GERARD E. LEDET that there were any risks specific to the use of Infuse® in the lumbar spine, and did not adequately inform his implanting surgeon, Dr. Graham, of the true incidence of ectopic or uncontrolled or unusual bone growth resulting from the use of Infuse® in off-label procedures, or of other risks or dangers or complications associated with the off-label use of Infuse® in the spine.

250. Plaintiff GERARD E. LEDET's post-operative period was marked by increasing back pain, shooting and burning pain down his left leg, and left foot numbness.

251. Post-operative imaging studies ultimately revealed that Plaintiff GERARD E. LEDET had developed uncontrolled bone growth ("bone overgrowth") and resulting radiculopathy related to bone overgrowth at or near where the Infuse® was implanted in the April 18, 2007 surgery. Indeed, these injuries and complications are the direct and proximate result of the use of off-label Infuse® in this surgery.

252. A June 2, 2009 lumbar spine CT revealed "... left posterior osteophyte(s) displacing the left ... nerve root(s)" at levels L4-S1. Shortly thereafter, on or about October 21, 2009, Mr. Ledet underwent a painful revision surgery performed by Dr. Graham to remove bone overgrowth in his spine.

253. Mr. Ledet's October 2009 revision surgery to remove bone overgrowth provided him only limited relief. His chronic pain symptoms eventually returned, as well as the bone overgrowth. An August 10, 2010 lumbar spine MRI revealed L4-S1 stenosis due to ". . . hypertrophic changes (and) prominent enhancing scar[ring] . . . ." An April 4, 2012 lumbar spine MRI confirmed ". . . residual left bone foraminal encroachment" at levels L4-S1.

254. On or about July 18, 2012, Mr. Ledet underwent a second painful revision surgery performed by Dr. Graham to remove bone overgrowth. In his operative notes, Dr. Graham observed Mr. Ledet "has recurrent stenosis over the foramina at [levels] 4-5 5-1. This is due to calcified disk and overgrowth of the posterolateral fusion . . ."

255. As a direct and proximate result of the use of Infuse® in this lumbar fusion surgery, Plaintiff GERARD E. LEDET now suffers from severe injuries and damages, including but not limited to bone overgrowth causing chronic radiculopathy, chronic pain, shooting and burning pain in his left leg, left foot numbness, and retrograde ejaculation.

256. As a direct and proximate result of the use of Infuse® in this lumbar fusion surgery, Mr. Ledet was forced to use accrued sick and vacation time for his numerous medical appointments and revision surgeries. Even after his revision surgeries, Mr. Ledet continues to experience significant pain. Mr. Ledet's job as a computer programmer requires him to sit for many hours on end. As a result of his ongoing chronic pain, Mr. Ledet is unable to sit and work for more than one hour without getting up from his desk.

257. As a direct and proximate result of the use of Infuse® in Plaintiff GERARD E. LEDET's lumbar fusion surgery, Plaintiff SHARONDA J. LEDET has suffered the loss of society, comfort and consortium of her beloved husband, Plaintiff GERARD E. LEDET.

258. The beginning of 2012 was the first time that Plaintiff GERARD E. LEDET had reason to suspect that his chronic pain was caused by Infuse®-induced bone overgrowth. In fact, it was not until approximately March 2012 that Plaintiff even learned that the Infuse®-induced bone overgrowth was causing his chronic pain.

259. Thus, Plaintiff did not know, and could not have known by the exercise of reasonable diligence, until March 2012 at the earliest that the off-label use of Infuse® caused his bone overgrowth injury and his chronic pain.

260. Before and after the implantation surgery using Infuse®, MEDTRONIC knowingly concealed from Plaintiff and his implanting surgeon, Dr. Graham, the significant rate of injuries and complications resulting from the off-label use of Infuse®. MEDTRONIC's improper promotion of Infuse® and MEDTRONIC's concealment from Dr. Graham of serious patient safety risks associated with off-label Infuse® were significant causes or contributing factors in Dr. Graham's decision to use off-label Infuse® in his patient GERARD E. LEDET.

261. MEDTRONIC's fraudulent concealment of the relevant facts tolled any relevant statutes of limitation.

262. As a result of the off-label use and failure to warn of the risks of off-label use of Infuse® as designed, manufactured, sold, supplied, and distributed by MEDTRONIC, and as a result of the negligence, callousness, and the other wrongdoing and misconduct of MEDTRONIC, as described herein:

263. Plaintiff GERARD E. LEDET has been injured and suffers injuries to his body and mind, the exact nature of which is not completely known to date.

264. Plaintiff GERARD E. LEDET has sustained economic losses, including loss of earnings and diminution of his earning capacity, the exact amount of which is presently unknown.

265. Plaintiff GERARD E. LEDET will be required to incur additional medical expenses in the future as a result of the injury and damages he has suffered.

266. Plaintiff SHARONDA J. LEDET has lost the society, comfort and consortium of her beloved husband.

267. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

268. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

FIRST CAUSE OF ACTION
Fraudulent Misrepresentation and Fraud in the Inducement
(By Plaintiff GERARD E. LEDET against the MEDTRONIC Defendants)

269. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further allege as follows:

270. In connection with their Infuse® products, MEDTRONIC fraudulently and intentionally misrepresented material and important health and safety product risk information from Plaintiff and Plaintiff GERARD E. LEDET's physicians; all as alleged in this Complaint. Plaintiff and Plaintiff's physicians would not have decided to use Infuse® without an LT-Cage™ or to implant it in multiple levels of the lumbar spine using cages other than an LT-Cage™ had they known of the safety risks related to Infuse®.

271. MEDTRONIC marketed their Infuse® product to and for the benefit of Plaintiff, and marketed it to Plaintiff's physicians. Defendants knew or had reason to know of the

unreasonable dangers and defects in their Infuse® product, and knew or had reason to know that Plaintiff and Plaintiff's physicians would use the product.

272. Any of the following is sufficient to independently establish MEDTRONIC's liability for fraudulent misrepresentation and/or fraud in the inducement:

a. MEDTRONIC fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label use of Infuse®;

b. MEDTRONIC fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physician, the off-label practice of using of Infuse® without an LT-Cage™ and placing it in multiple levels in the lumbar spine;

c. MEDTRONIC fraudulently concealed and misrepresented information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies.

273. MEDTRONIC knew, or should have known, that it was concealing and misrepresenting true information about the known comparative risks and benefits of the use of Infuse® and the relative benefits and availability of alternate products, treatments and/or therapies.

274. MEDTRONIC knew that Plaintiff and Plaintiff's physicians would regard the matters Defendants concealed and misrepresented to be important in determining the course of treatment for the Plaintiff, including Plaintiff and Plaintiff's physician's decision whether or not to use Infuse® without an LT-Cage™ or to place it in multiple levels in the lumbar spine in Plaintiff's lumbar spine fusion surgery.

275. MEDTRONIC intended to cause Plaintiff and Plaintiff's physicians to rely on their concealment of information and misrepresentations about the safety risks related to Infuse® to induce them to make off-label use of Infuse® for Plaintiff's lumbar spine fusion surgery.

276. Plaintiffs and Plaintiff's physicians were justified in relying, and did rely, on MEDTRONIC's concealment of information and misrepresentations about the safety risks related to Infuse® in deciding to use Infuse® in an off-label manner for Plaintiff's lumbar spine fusion surgery.

277. As the direct, proximate and legal cause and result of Defendants' fraudulent concealment and misrepresentations and suppression of material health and safety risks relating to Infuse® and Defendants' dangerous and irresponsible marketing and promotion practices, Plaintiffs have been injured and have incurred damages including, but not limited to, medical and hospital expenses, lost wages and lost earning capacity, physical and mental pain and suffering, loss of the enjoyment of life and loss of consortium.

278. Plaintiff GERARD E. LEDET has been injured and suffers injuries to his body and mind, the exact nature of which are not completely known to date;

279. Plaintiff GERARD E. LEDET has sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

280. Plaintiff GERARD E. LEDET will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff SHARONDA J. LEDET has lost the society, comfort and consortium of her beloved husband.

281. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

282. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

SECOND CAUSE OF ACTION
Strict Liability – Failure to Warn Pursuant to the Mississippi Product Liability Act (Miss. Code. Ann. § 11-1-63)
(By Plaintiff GERARD E. LEDET against the MEDTRONIC Defendants)

283. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further allege as follows:

284. MEDTRONIC had a duty to warn Plaintiff and Plaintiff's physicians about the dangers of Infuse® of which it knew, or in the exercise of ordinary care, should have known, at the time the Infuse® left MEDTRONIC's custody or control.

285. MEDTRONIC did know of these dangers of off-label use of Infuse®, and breached this duty by failing to warn Plaintiff and Plaintiff's physicians of the dangers of its off-label practice of using Infuse® without an LT-Cage™ and placing it in multiple levels in the lumbar spine in a lumbar spine fusion surgery.

286. Defendants, and each of them, knew that Infuse® would be purchased and used without inspection for defects in the design of the product.

287. The Infuse® used in Plaintiff was defective and unreasonably dangerous when it left the control of each of these Defendants due to its inadequate warnings.

288. Defendants knew or should have known of the substantial dangers involved in the reasonably foreseeable use of Infuse®, whose defective design, manufacturing, and lack of

sufficient warnings caused Infuse® to have an unreasonably dangerous propensity to cause catastrophic injuries.

289. The warnings accompanying the Infuse® product did not adequately warn Plaintiff and Plaintiff's physicians, in light of its scientific and medical knowledge at the time, of the dangers associated with Infuse® when used without an LT-Cage™ and when placed in multiple levels in the lumbar spine in a lumbar spine fusion surgery including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and worse global outcomes than alternative treatments currently available.

290. The warnings accompanying the Infuse® product failed to provide the level of information that an ordinary physician or consumer would expect when using the product in a manner reasonably foreseeable to the MEDTRONIC Defendants. The MEDTRONIC Defendants either recklessly or intentionally minimized and/or downplayed the risks of serious side effects related to the off-label use of Infuse®, including but not limited to the risk of ectopic or uncontrolled bone growth.

291. MEDTRONIC failed to provide adequate warnings, instructions, guidelines or admonitions to members of the consuming public, including Plaintiff and Plaintiff's physicians, of the problems with the off-label use of Infuse® which Defendants knew, or in the exercise of reasonable care should have known, to have existed with the off-label use of Infuse®.

292. Defendants knew that these substantial dangers are not readily recognizable to an ordinary consumer or physicians, and that consumers and physicians would purchase Infuse® without inspection.

293. At the time of Plaintiff's injury, Infuse® was being used in a manner promoted by Defendants and in a manner that was reasonably foreseeable by Defendants as involving substantial danger that was not readily apparent to its users.

294. Plaintiff's physician relied on the MEDTRONIC Defendants' inadequate warnings in deciding to use Infuse® in an off-label manner. Plaintiff and Plaintiff's physician would not have made off-label use of Infuse® without an LT-Cage™ and placement of it in multiple levels in the lumbar spine had they known of the true safety risks related to Infuse®.

295. As a direct and proximate result of one or more of the above-listed dangerous conditions and defects, and of MEDTRONIC's failure to provide adequate warnings about them, Plaintiff sustained serious injuries of a personal and pecuniary nature from approximately April 2007 to the present.

296. Plaintiff GERARD E. LEDET has been injured and suffers injuries to his body and mind, the exact nature of which are not completely known to date;

297. Plaintiff GERARD E. LEDET has sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

298. Plaintiff GERARD E. LEDET will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff SHARONDA J. LEDET has lost the society, comfort and consortium of her beloved husband.

299. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

300. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

THIRD CAUSE OF ACTION
Constructive Fraud
(By Plaintiff GERARD E. LEDET against the MEDTRONIC Defendants)

301. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

302. MEDTRONIC marketed their Infuse® product to and for the benefit of Plaintiff, and marketed it to Plaintiff's physicians, and Defendants knew or had reason to know of the unreasonable dangers and defects in their Infuse® product, and that Plaintiff and Plaintiff's physician would use the product.

303. Defendants owed Plaintiff duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge, and to produce and market Infuse® in as safe a manner and condition as possible.

304. Specific defects, as specified above in this Complaint, in the Infuse® product, rendered it defective and unreasonably dangerous.

305. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, Defendants breached their duties to Plaintiff. Such breach exhibited a reckless disregard for the safety of others and willful and wanton conduct.

306. By breaching their duties to Plaintiff, Defendants gain an advantage by profiting from the sale of Infuse® for off-label use.

307. Plaintiff and his physicians justifiably relied on Defendants' misrepresentations and concealment of the actual dangers of off-label use Infuse®.

308. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Plaintiff has suffered severe physical pain and pecuniary loss.

309. Plaintiff GERARD E. LEDET has been injured and suffers injuries to his body and mind, the exact nature of which are not completely known to date;

310. Plaintiff GERARD E. LEDET has sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

311. Plaintiff GERARD E. LEDET will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff SHARONDA J. LEDET has lost the society, comfort and consortium of her beloved husband.

312. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

313. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

FOURTH CAUSE OF ACTION
Strict Liability- Design Defect Pursuant to the Mississippi Product Liability Act (Miss. Code. Ann. § 11-1-63)
(By Plaintiff GERARD E. LEDET against the MEDTRONIC Defendants)

314. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further allege as follows:

315. Defendants' Infuse® device was defectively designed at the time that it left the Defendants' control and was placed into the stream of commerce in the State of Mississippi. The device reached Plaintiff without a substantial change in the condition in which it was sold.

316. Defendants' Infuse® device was defectively designed because the design was unsafe when used in the manner promoted by Defendants and/or in a manner reasonably foreseeable by Defendants. The Infuse® product failed to perform as safely as an ordinary consumer would expect when used, as it was promoted by MEDTRONIC for use off-label without an LT-Cage™ and placement in multiple levels in the lumbar spine in lumbar spine fusion surgeries.

317. Defendants' Infuse® device was defectively designed because the risks of danger in the design outweigh the benefits of the design.

318. At the time Infuse® left the Defendants' control and was placed into the stream of commerce in the State of Mississippi, there existed alternative designs that, if utilized by Defendants, were capable of preventing damage to Plaintiffs.

319. The Infuse® product was designed in a way that caused users to suffer injuries including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes than equally-effective, alternative designs and treatments.

320. The foreseeable risks of harm posed by using the Infuse® product in a manner promoted by Defendants could have been reduced or avoided by adopting a reasonably alternative design. Defendants did not adopt a design that would have rendered the Infuse® product reasonably safe.

321. Plaintiff and Plaintiff's physicians used Infuse® in a manner intended and reasonably foreseeable by Defendants.

322. Plaintiff was not aware of the aforementioned defects at any time prior to the injuries caused by the Infuse®.

323. As a legal and proximate result of the aforementioned defects of Infuse®, Plaintiff has sustained the injuries and damages set forth herein.

324. Plaintiff GERARD E. LEDET has been injured and suffers injuries to his body and mind, the exact nature of which are not completely known to date;

325. Plaintiff GERARD E. LEDET has sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

326. Plaintiff GERARD E. LEDET will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff SHARONDA J. LEDET has lost the society, comfort and consortium of her beloved husband.

327. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

328. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

FIFTH CAUSE OF ACTION
Negligence
(By Plaintiff GERARD E. LEDET against the MEDTRONIC Defendants)

329. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

330. MEDTRONIC marketed their Infuse® product to and for the benefit of Plaintiff, and additionally marketed it to his physicians, and these Defendants knew or should have known that Plaintiff and his physicians would use their product, including for off-label uses.

331. Defendants owed Plaintiff and his physicians duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

332. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, MEDTRONIC breached their duties to Plaintiff and to his physicians.

333. The following sub-paragraphs summarize, *inter alia*, these Defendants' breaches of duties to Plaintiff and his physicians and describe categories of acts or omissions constituting breaches of duty by these Defendants. Each and/or any of these acts or omissions establishes an independent basis for these Defendants' liability in negligence:

a. Unreasonable and improper promotion and marketing of Infuse® to physicians, including but not limited to the promotion and marketing of Infuse® for use off-label without an LT-Cage™ and placement in multiple levels in the lumbar spine in lumbar spine fusion surgeries;

b. Failure to warn physicians and Plaintiff of the dangers associated with Infuse® when used off-label without an LT-Cage™ and placement in multiple levels in the lumbar spine including, but not limited to, pain and weakness in limbs, radiculitis, ectopic bone formation, osteolysis, and poorer global outcomes.

c. Failure to exercise reasonable care by not complying with federal law and regulations applicable to the sale and marketing of Infuse®.

334. Defendants knew, or should have known, that, due to their failure to use reasonable care, Plaintiff and his physicians would use and did use Infuse®, to the detriment of Plaintiff's health, safety and well-being.

335. As the direct, producing, proximate and legal cause and result of the negligence of these Defendants, Plaintiff suffered severe physical pain and pecuniary loss.

336. Plaintiff GERARD E. LEDET has been injured and suffers injuries to his body and mind, the exact nature of which are not completely known to date;

337. Plaintiff GERARD E. LEDET has sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

338. Plaintiff GERARD E. LEDET will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff SHARONDA J. LEDET has lost the society, comfort and consortium of her beloved husband.

339. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

340. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

SIXTH CAUSE OF ACTION
Negligent Misrepresentation
(By Plaintiff GERARD E. LEDET against the MEDTRONIC Defendants)

341. Plaintiffs incorporate by reference all previous paragraphs of this Complaint as if fully set forth here and further allege as follows:

342. Specific defects in the Infuse® product, as specified above in this Complaint, rendered it defective and unreasonably dangerous.

343. MEDTRONIC marketed their Infuse® product to and for the benefit of Plaintiff, and marketed it to his physicians, to induce Plaintiff and his physicians to use the product.

344. Defendants also made untrue representations to Plaintiff and his physicians by sponsoring biased medical trials, reports, and articles that concluded that the dangers inherent is off-label use of Infuse® did not exist or were significantly less that the actual dangers.

345. Defendants knew or had reason to know of the actual, unreasonable dangers and defects in their Infuse® product.

346. Plaintiff and his physicians were justified in relying, and did rely, on the misrepresentations about the safety risks related to Infuse® in deciding to make off-label use of Infuse® without an LT-Cage™ and for placement in multiple levels in the lumbar spine.

347. As the direct, producing, proximate and legal cause and result of the Defendants' misrepresentations, Plaintiff has suffered severe physical pain, medical and hospital expenses, pain and suffering, and pecuniary loss.

348. Plaintiff GERARD E. LEDET has been injured and suffers injuries to his body and mind, the exact nature of which are not completely known to date;

349. Plaintiff GERARD E. LEDET has sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

350. Plaintiff GERARD E. LEDET will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff SHARONDA J. LEDET has lost the society, comfort and consortium of her beloved husband.

351. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

352. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

SEVENTH CAUSE OF ACTION
Breach of Express Warranty Pursuant to the Mississippi Product Liability Act (Miss. Code. Ann. § 11-1-63)
(By Plaintiff GERARD E. LEDET against the MEDTRONIC Defendants)

353. Plaintiffs incorporate by reference all previous and subsequent paragraphs of this Complaint as if fully set forth here and further allege as follows:

354. At all times herein mentioned, MEDTRONIC utilized journal articles, advertising media, sales representatives/consultants, and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of Infuse® Bone Graft and expressly warranted to physicians including Plaintiff's physician and other members of the general public and medical community that such off-label uses, including uses in lumbar fusion procedures, were safe and effective.

355. Defendants knew or, in the exercise of reasonable diligence, should have known that the off-label use of Infuse® had the serious side effects set forth earlier and throughout this Complaint.

356. Plaintiff is informed and believes and based thereon alleges that his treating surgeon relied on Defendants' express warranty representations regarding the safety and efficacy of off-label use of Infuse®, but such off-label uses, including uses in lumbar fusion procedures, were not effective, safe, and proper for the use as warranted in that Infuse® was dangerous when put to these promoted uses.

357. Defendants thus breached their express warranty which was a direct and proximate cause of Plaintiff's injuries and damages.

358. Plaintiff GERARD E. LEDET has been injured and suffers injuries to his body and mind, the exact nature of which are not completely known to date;

359. Plaintiff GERARD E. LEDET has sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

360. Plaintiff GERARD E. LEDET will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff SHARONDA J. LEDET has lost the society, comfort and consortium of her beloved husband.

361. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

362. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

EIGHTH CAUSE OF ACTION
Breach of Implied Warranties of Merchantability and Fitness for a Particular Purpose
(By Plaintiff GERARD E. LEDET against the MEDTRONIC Defendants)

363. Plaintiffs incorporate by reference all preceding paragraphs and allegations as set forth herein.

364. At all times herein mentioned, MEDTRONIC utilized journal articles, advertising media, sales representatives/consultants, and paid Key Opinion Leaders to urge the use, purchase, and utilization of the off-label use of Infuse® Bone Graft and impliedly warranted to physicians including Plaintiff's physician and other members of the general public and medical community that such off-label uses, including uses in lumbar fusion procedures, were safe and effective.

365. Defendants knew or, in the exercise of reasonable diligence, should have known that the off-label use of Infuse® had the serious side effects set forth earlier and throughout this Complaint.

366. Plaintiff is informed and believes and based thereon alleges that his treating surgeon relied on Defendants' implied warranty representations regarding the safety and efficacy of off-label use of Infuse®, but such off-label uses, including uses in lumbar fusion procedures, were not effective, safe, and proper for the use as warranted in that Infuse® was dangerous when put to these promoted uses.

367. Defendants thus breached their implied warranty which was a direct and proximate cause of Plaintiff's injuries and damages.

368. Plaintiff GERARD E. LEDET has been injured and suffers injuries to his body and mind, the exact nature of which are not completely known to date;

369. Plaintiff GERARD E. LEDET has sustained economic losses, including loss of earnings and diminution of the loss of earning capacity, the exact amount of which is presently unknown;

370. Plaintiff GERARD E. LEDET will be required to incur additional medical expenses in the future to care for himself as a result of the injury and damages he has suffered; and Plaintiff SHARONDA J. LEDET has lost the society, comfort and consortium of her beloved husband.

371. Plaintiffs are therefore entitled to damages in an amount to be proven at trial, together with interest thereon and costs.

372. Defendants' conduct as alleged above was malicious, intentional and outrageous and constitutes a willful and wanton disregard for the rights and safety of others. Such conduct was directed specifically at Plaintiffs and as such, warrants an imposition of punitive damages.

NINTH CAUSE OF ACTION
Loss Of Consortium
(By Plaintiff SHARONDA J. LEDET against the MEDTRONIC Defendants)

373. Plaintiff SHARONDA J. LEDET incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

374. Plaintiff SHARONDA J. LEDET was at all relevant times the lawful spouse of Plaintiff GERARD E. LEDET.

375. As a further legal and proximate result of the wrongful conduct and negligence of all Defendants, Plaintiff SHARONDA J. LEDET has suffered and continues to suffer the loss of the services, society, and consortium of her beloved husband, Plaintiff SHARONDA J. LEDET, as a result of her husband's injuries proximately caused by Defendants' misconduct.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request of this Court the following relief:

A. For general damages, in an amount to be proven at the time of trial;

B. For medical, incidental, hospital, psychological care, and other expenses, in an amount to be proven at the time of trial;

C. For loss of earnings and earning capacity, in an amount to be proven at the time of trial;

D. For an award of post-judgment interest as provided by law;

E. For an award of exemplary and/or punitive damages;

F. For consequential damages, in an amount to be proven at the time of trial;

F. For damages for loss of consortium;

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request of this Court the following relief:

A. For general damages, in an amount to be proven at the time of trial;

B. For medical, incidental, hospital, psychological care, and other expenses, in an amount to be proven at the time of trial;

C. For loss of earnings and earning capacity, in an amount to be proven at the time of trial;

D. For an award of post-judgment interest as provided by law;

E. For an award of exemplary and/or punitive damages;

F. For consequential damages, in an amount to be proven at the time of trial;

F. For damages for loss of consortium;

G. For an award providing for payment of costs of suit and attorneys' fees; and

I. For such other and further relief as this Court may deem just and proper.

Dated: April 24 2013

Respectfully submitted,

REEVES & MESTAYER, PLLC

By: _____
Jim Reeves

Jim Reeves
Matthew M. Mestayer
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Attorneys for Plaintiff Gerard E. Ledet and Sharonda J. Ledet

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues stated.

Dated: April 24, 2013

REEVES & MESTAYER, PLLC

By: _____
Jim Reeves

Jim Reeves
Matthew M. Mestayer
REEVES & MESTAYER, PLLC
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Attorneys for Plaintiff Gerard E. Ledet and Sharonda J. Ledet

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JS 44 (Rev. 12/12)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

1:13cv200 LG-JMR

I. (a) PLAINTIFFS

GERARD E. LEDET and SHARONDA J. LEDET

(b) County of Residence of First Listed Plaintiff Jackson County, MS
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
James R. Reeves, Jr., Reeves & Mestayer, PLLC, P. O. Drawer 1388, Biloxi, MS 39533, 228/374-5151

DEFENDANTS

MEDTRONIC, INC., a Minnesota corporation; MEDTRONIC SOFAMOR DANEK, USA, INC.

County of Residence of First Listed Defendant Hennepin Co., MN
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

SOUTHERN DISTRICT OF MISSISSIPPI
FILED
APR 24 2013
J T NOBLIN CLERK
BY _____ DEPUTY

II. BASIS OF JURISDICTION *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

III. CITIZENSHIP OF PRINCIPAL PARTIES *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☒ 1	☐ 1	Incorporated *or* Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☒ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT *(Place an "X" in One Box Only)*

CONTRACT
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS—Third Party 26 USC 7609

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

V. ORIGIN *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC Section 1332

Brief description of cause:
product liability regarding medical implant

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:

JUDGE _____ DOCKET NUMBER _____

DATE 4-24-13

SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # 1464300448 AMOUNT $350.00 APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____