IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

ANTHONY FOSTER,	)	
	)	
PLAINTIFF,	)	
	)	
	)	
versus	)	**CASE NO.: _____**
	)	
	)	**JURY DEMAND**
MEDTRONIC, INC.,	)	
a Minnesota Corporation, and	)	
MEDTRONIC SOFAMOR DANEK	)	
USA, INC., a Tennessee Corporation,	)	
	)	
DEFENDANTS.	)	

COMPLAINT

Plaintiff Anthony Foster ("Plaintiff), by and through his counsel, alleges as follows:

I.
INTRODUCTION

1. This case involves a bio-engineered bone graft device known as the InFUSE® Bone Graft ("InFUSE®") that was used in Plaintiff's spine surgery which caused him injuries and damages.

2. InFUSE® was and is designed, manufactured, marketed, promoted and sold by Defendants MEDTRONIC, INC., and MEDTRONIC SOFAMOR DANEK, USA, INC. (collectively "Defendants," "Medtronic" or "the Company").

3. For use in spinal surgery, InFUSE® is approved by the Food and Drug Administration ("FDA") for a limited procedure, performed on a limited area of the spine, using

specific components. Specifically, Medtronic received FDA approval for its InFUSE® product only:

a. FDA-Approved Procedure: Anterior Lumbar Interbody Fusion ("ALIF");

b. FDA-Approved Area of Spine: L4 to S1[1];

c. FDA-Approved Components: LT-CAGE® Lumbar Tapered Fusion Device Component ("LT-CAGE") and the InFUSE® Bone Graft Component ("BGC"), which includes recombinant bone morphogenetic protein-2 ("rhBMP-2") – a manufactured version of a protein already present in the body meant to promote new bone growth – applied to an absorbable collagen sponge ("ACS") that is designed to disappear over time.

4. Use of InFUSE® in lumbar surgery through the back (posterior), or side (lateral), on areas of the spine outside of the L4-S1 region (e.g., the cervical spine), or using components other than or in addition to the LT-CAGE and BCG, is not approved by the FDA, and thus such procedures and/or use of non-FDA approved componentry is termed "off-label."

5. When used off-label, InFUSE® frequently causes excessive or uncontrolled (also referred to as "ectopic" or "exuberant") bone growth on or around the spinal cord. When nerves are compressed by such excessive bone growth, a patient can experience, among other adverse events, intractable pain, paralysis, spasms and cramps in limbs.

6. Notwithstanding overwhelming and substantial evidence (including Medtronic-sponsored studies) demonstrating increased risk of adverse reactions from off-label use of InFUSE®, Medtronic recklessly and/or intentionally misrepresented, minimized, downplayed, disregarded, and/or completely omitted these risks from the general public. In fact, Medtronic promoted the use of the product in off-label manners, thereby demonstrating a conscious

[1] On July 29, 2004, the FDA approved a supplement expanding the indicated spinal region from L4-S1 to L2-S1.

disregard for the health and safety of spinal fusion candidates such as the Plaintiff.

7. 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 and its sponsored studies to physicians and the public. With respect to off-label approaches, such as transforaminal lumbar interbody surgeries ("TLIF"), use of off-label components, and/or use in non-approved spinal sections, Medtronic failed to disclose significant risks of which it knew of or should have known. These risks include, but are not limited to, adverse events such as ectopic bone formation, inflammatory reactions, adverse back and leg pain events, radiculitis, retrograde ejaculation, urinary retention, bone resorption, and implant displacement. Medtronic also omitted mention of the risks of sterility and cancer associated with rhBMP-2 use, osteolysis, and worse overall outcomes.

8. As a result of Medtronic's wrongful conduct, tens of thousands of patients, including the Plaintiff, underwent surgeries without knowing the risks associated with off-label use of InFUSE®. These patients and their physicians relied on Medtronic's false and misleading statements of material fact and those of Medtronic's consultant "opinion leaders" (Medtronic-paid physician promoters) to use InFUSE® in off-label manners. Indeed, absent Medtronic's extensive off-label promotion campaign, physicians, such as the Plaintiff's, would be without the requisite knowledge to perform such off-label InFUSE® surgeries.

9. As a result of his off-label InFUSE® surgery using off-label components, Plaintiff suffered extreme bodily injuries and damages, including but not limited to: excessive/uncontrolled bone growth, retrograde ejaculation, severe back/leg pain, loss of sensation in the lower extremities, inability to sit, laydown, or stand, and lost wages (past, present, and future). As a further result, Plaintiff required a second surgery to correct and treat

the adverse events caused by his off-label InFUSE® surgery, and thus was caused further injuries and damages.

II.
PARTIES

10. Plaintiff ANTHONY FOSTER is a resident of the County of Okaloosa, State of Florida.

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

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

III.
VENUE AND JURISDICTION

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

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

15. 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 Northern District of Florida and they are all subject to personal jurisdiction in this District.

IV.
FACTS

A. THE DEVELOPMENT AND APPROVAL OF MEDTRONIC'S InFUSE®

16. This action arises from Defendants' design, manufacture, marketing, promotion, and sale of one of its most important, and lucrative, products: InFUSE®. InFUSE® is a surgically-implanted medical device containing a genetically engineered protein designed to stimulate bone growth. The FDA approved InFUSE® in 2002 for limited surgical applications in the spine.

17. Specifically, InFUSE®is FDA-approved for use only in Anterior Lumbar Interbody Fusion ("ALIF") surgery, from the L4 to S1 area of the spine, using an LT-CAGE® Lumbar Tapered Fusion Device Component and the InFUSE® Bone Graft Component.

18. Medtronic's InFUSE® sales have exceeded $3.6 billion since the launch of InFUSE® Bone Graft in July 2002. As a J.P. Morgan research analyst covering Medtronic noted in a report dated November 12, 2008:

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

19. In spite of limited FDA approval, 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. 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, would push off-label usage in a number of ways, including the authoring of scientific literature and direct solicitation to other spinal surgeons. Medtronic also directed its own sales representatives to promote off-label uses of the product, many of whom went so far as to 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 Department of Justice ("DOJ"), Congress, the United States Army, several major universities, multiple medical journals, numerous major newspapers, independent physicians, and investors.

20. Moreover, Medtronic's unlawful off-label campaign has resulted in, among other adverse events to the Company, two whistleblower lawsuits (resulting in settlement with the DOJ, which included a Corporate Integrity Agreement), a shareholder's derivative lawsuit, several adverse regulatory actions by the FDA, and a congressional investigation (led by the United States Senate Committee on Finance).

21. Indeed, even following Medtronic's settlement with the DOJ for alleged unlawful kickbacks to physicians to use and promote its products, and corresponding entry into a Corporate Integrity Agreement ("CIA"), 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.

22. Off-label use of InFUSE® was and remains particularly concerning due to the known adverse (and in certain cases deadly) side effects discovered at the time of the product's original limited use 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% of all sales.

23. Although undisclosed by Medtronic, the first-hand accounts of its former employees demonstrate that this extraordinarily high off- label use was driven by the Defendant's sales force. Specifically, Medtronic's representatives directed physicians to Medtronic-compensated consultants or "Key Opinion Leaders" – surgeons paid by Medtronic – the sole purpose of which was to promote off-label uses of InFUSE®. Through these practices, Medtronic was able to increase InFUSE® sales, year-after-year, while continuing to misrepresent, through act and omission, the product's dangerous and deadly side effects to the public, including the Plaintiff and his physician.

B. SPINAL FUSION SURGERY, AND THE APPROVAL OF A DRUG AS A DEVICE

24. Surgeons have for decades employed spinal fusion—a surgical technique in which one or more of the vertebrae of the spine are united together ("fused") so that motion no longer occurs between them—to treat a number of spinal conditions and deformities.

25. For years, autologous bone graft has been considered the "gold standard" in spinal fusion surgery. In an autologous bone graft, or "autograft," the surgeon procures bone graft material from another part of the patient's body, typically from the patient's pelvis or iliac crest, and implants the bone graft in the site where fusion is desired. As the harvested bone exhibits all the properties necessary for bone growth—including osteogenic, osteoconductive and osteoinductive properties—successful fusions occur at significantly higher rates in autograft procedures.

26. As an alternative to autograft, patients can undergo an allograft procedure, in which bone is taken from the cadavers of deceased people who have donated their bone to so-called "bone banks." Although healing and fusion is not as predictable as with the patient's own bone, an allograft eliminates the need for, as well as the pain and patient risk associated with, the harvest procedure required in an autograft.

27. Consequently, studies revealing the ability for biologically manufactured protein to generate bone growth in laboratory animals represented a potential to provide a third surgical option to traditional bone graft procedures. The theory was that, if fusion could be accomplished through the use of biologically manufactured proteins, patients could forego the harvest surgery required in an autograft, but could still benefit from the superior fusion rates associated with autograft procedures.

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

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

30. In January 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 certain limited uses.

31. Importantly, the FDA's approval of InFUSE® was limited due to concerns about potential adverse events that had already been reported at the time of the product's approval. As a result, the FDA approved InFUSE® for a small percentage of overall spinal fusion surgeries, with the device label specifying the limited surgical application to be used.

C. FDA MEDICAL DEVICE APPROVAL REQUIREMENTS

32. 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.

33. Manufacturers, such as the Defendants, seeking to market Class III devices, 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").

34. 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 which the device is intended.

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

D. THE FDA's LIMITED USE APPROVAL OF InFUSE® FOR ANTERIOR LUMBAR INTERBODY FUSION

36. In October 1996, Sofamor Danek submitted an IDE to the FDA to study the use of rhBMP-2 as applied to an absorbable collagen sponge ("ACS") inserted into an LT-CAGE interbody fusion device to treat patients with degenerative disc disease. Designed as a pilot study intended to support the initiation of a larger pivotal study, the IDE involved 14 patients—11 of which received spinal fusion procedures using the rhBMP-2/ACS/LT-CAGE device and 3 who received the LT-CAGE with autologous bone—and marked the first time rhBMP-2 was used in patients undergoing spinal fusion. In this initial clinical trial, all 11patients who had been implanted with rhBMP-2 achieved successful fusion within six months from the time of surgery.

37. 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.

38. After acquiring Sofamor Danek in 1999, Medtronic filed the InFUSE® PMA on January 12, 2001, and was granted expedited review status by the Agency.

39. 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. The LT-CAGE® Lumbar Tapered Fusion Device component, a thimble-sized hollow metal cylinder which keeps the two vertebrae in place and provides a frame that contains and directs the development of new bone growth; and

b. The InFUSE® Bone Graft Component, which includes an ACS 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 ACS.

40. Importantly, 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.

41. Furthermore, 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.

42. FDA approval was limited due to instances of adverse events resulting from use of rhBMP-2 in off-label applications. In particular, a Medtronic-sponsored trial examining the application of rhBMP-2 in off-label PLIF procedures was halted in December 1999 when heterotopic bone growth—defined as any bone growth that occurs in areas of the body where such growth is not desired—developed in a number of patients. Indeed, the study reported that one patient required two additional surgeries to remove excessive bone growth from the spinal

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

canal. Such bone overgrowth observed in the PLIF trial was particularly alarming because it could likely result in the very pain that fusion procedure was designed to eliminate.

43. Moreover, the PLIF trial evidenced that bone overgrowth complications from InFUSE® result from the product's very mechanism of action; i.e., rhBMP-2 actually stimulates the growth of new bone. Thus adverse events will 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 associate pain. Such unintended bone growth and swelling can be especially problematic in spinal surgeries because of the sensitive areas in which InFUSE® is used; i.e., the spinal cord.

44. During a FDA Advisory Committee Panel ("FDA Panel") hearing on January 10, 2002 concerning FDA approval of InFUSE®, panel members voiced concerns regarding potential off-label use of the product, and thus prompted Medtronic to describe its efforts to guard against off-label applications of the product.

45. 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 pushing 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 thus, "seems to me to be outside the scope of what we ought to be focusing on today."

46. 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 the voicing of concerns 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 perspective." In other words, the FDA explicitly warned the Defendants against promoting InFUSE® to be used inoff-label PLIF procedures because, according to the findings of the FDA Panel, such use would endanger patients.

47. Clearly, at the time it sought FDA approval in 2002, Defendants were well-aware of the potential off-label uses of InFUSE® and the potential dangers posed by such use.

48. The FDA Panel's fears were confirmed by subsequent medical studies which demonstrate that use of InFUSE® outside of the studied application sought in the PMA could present severe risks to patient safety. For example, a May 15, 2006 medical article in *Spine* noted, "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."

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

50. 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 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.

51. A September 2008 article in *The Spine Journal* similarly observed that the use of InFUSE® in the cervical spine "has been associated with reports of serious adverse events. Postoperative hematoma formation [a collection of blood outside the blood vessels, generally manifesting as bruises], prevertebral soft tissue swelling, [and] swallowing difficulty . . . are a few examples." Of the complications 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 institution of rhBMP2 use. Complications induced by . . . rhBMP-2 were clearly evident in our review."

52. Moreover, a March 2007 *The Spine Journal* article 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 serious swelling of the neck and difficulty swallowing which

required emergency medical treatment such as an exploratory surgery and implantation of a breathing tube.

53. Another patient, Shirley Nisbet, underwent an off-label cervical spine surgery using InFUSE®, experienced neck swelling that resulted in her death.

54. Notwithstanding the FDA Panel's well-founded, indeed proven, concerns regarding off-label use, as well as the medical literature corroborating the same, both of which Medtronic had knowledge, Medtronic intentionally, negligently and recklessly concealed these dangers from the general public, including the Plaintiff and his physicians.

55. Moreover, Medtronic actively promoted off-label use of InFUSE® through its sales representatives and through payments to physicians and "Key Opinion Leaders" in exchange for the publication favorable medical journals, 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 Key Opinion Leaders or their written work to further drive off-label sales of the InFUSE®. Indeed, Defendants engaged in such conduct even *after* its settlement of a whistleblower action with the DOJ in which it agreed to employ stricter compliance controls regarding the sale and marketing of its devices.

56. At no time did Defendants quantify either the amount of InFUSE® sales for off-label applications or the amount Defendants continued to pay surgeons as "consultants" or "Key Opinion Leaders," whose primary roles were to promoted off-label use of InFUSE®. As a result of this undisclosed conduct, the consistent quarter-after-quarter sales of InFUSE® reported by Defendants, and the statements they made regarding those sales, materially misled investors, physicians, and patients alike regarding the true facts and risks known to Defendants:

that InFUSE® sales were inexorably dependent on dangerous off-label applications of the product.

E. MEDTRONIC SETTLES WHISTLEBLOWER LITIGATION WITH THE DOJ AND AGREES TO ENTER INTO A CORPORATE INTEGRITY AGREEMENT

57. On July 18, 2006, Medtronic announced a settlement with the DOJ in which it agreed to pay $40 million to resolve two whistleblower lawsuits alleging Medtronic had engaged in illegal marketing and sales practices, including the payment of improper consulting fees to physicians to promote InFUSE® and other spinal products.

58. According to the DOJ, Medtronic paid unlawful and improper kickbacks to physicians in a number of forms, including consulting agreements, royalty agreements and lavish trips to desirable locations between 1998 and 2003; the purpose of which was to induce surgeons to use Medtronic's spinal products

59. The two whistleblower suits, , *United States ex rel. [UNDER SEAL] v. Medtronic, Inc.*, Civil Action No. 02-2709 (W.D. TN. 2002) (hereinafter "*[Under Seal]*"), and *United States ex rel. Poteet v. Zdeblick*, Civil Action No. 03-2979 (W.D. TN. 2003) (hereinafter "*Poteet I*"), were brought by Medtronic's former employees. These former employees alleged that Defendants' practices to market and sell certain spinal products violated the Federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), *et seq.*, which prohibits individuals from offering, soliciting or making any payment or remuneration to induce business reimbursed under a federal or state health care program, and the False Claims Act, 31 U.S.C. § 3729, *et seq.*, which provides penalties for the submission of false claims to the federal government.

60. *[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 the

Company 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."

61. 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."

62. *Poteet I*, which was brought by a former Medtronic employee who was tasked by the Company to arrange travel (including expense reimbursement) for numerous spinal surgeons to attend Medtronic-sponsored events and other professional meetings. This 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.

63. As part of the DOJ settlement, Medtronic agreed to enter into a five-year Corporate Integrity Agreement ("CIA") with the Office of the Inspector General/Health and Human Services that, as Medtronic described in its July 18, 2006 press release, implemented substantial oversight structures and procedures meant to ensure "top-level attention to corporate compliance measures." Among other things, the CIA required Medtronic to establish an electronic database to capture and manage all non-sales related transactions between Medtronic's Spinal segment and its physicians or customers, with all such transactions subject to an established set of internal controls and review processes, including monitoring by Medtronic senior management and the Company's Chief Compliance Officer.

64. 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.

65. Significantly, the CIA required the Company 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.

66. Clearly, the CIA and the previous whistleblower and wrongful termination litigation, placed Medtronic and its agents on actual notice that is practices to market, promote, and sell its Spinal products, including InFUSE®, were improper and required wholesale change, less the Company risked further adverse regulatory action.

67. Nonetheless, undisclosed to investors, patients, and physicians alike, Medtronic's unlawful practices continued, as did the Company's aggressive efforts to drive InFUSE® sales - primarily for off-label applications, such as those used on the Plaintiff. Indeed, Medtronic's continued unlawful practices lead to both FDA and DOJ action, which, in turn, had an immediate adverse impact on InFUSE® sales and Medtronic's financial performance.

F. DEFENDANTS CONTINUED UNLAWFUL PRACTICES OF PROMOTING OFF-LABEL USE OF InFUSE®

68. Notwithstanding their agreement to settle allegations relating to nearly identical conduct with the DOJ on July 14, 2006, Defendants continued their aggressive and surreptitious off-label promotion of InFUSE® through the very same practices outlined above. Indeed, they were motivated to do so knowing that, absent off-label uses of InFUSE®, sales of InFUSE® would dramatically decline. Fearing such a decline, Defendants continued to covertly employ the same lucrative "consulting" arrangements and other unlawful conduct to push off-label uses of InFUSE®. As a result of Defendants' undisclosed misconduct, the percentage of off-label InFUSE® usage increased over time, including after the DOJ settlement on July 14, 2006.,

69. Medtronic failed to disclose its aggressive off-label promotion of InFUSE® to investors and the general public, including the Plaintiff and his physicians. Indeed, Medtronic's unlawful conduct 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®, Defendants continued to drive sales solely through off-label indications; and were doing so in spite of the CIA, the material risk of further regulatory action, and in conscious disregard for the health and welfare of spinal fusion candidates such as the Plaintiff.

70. The FDCA specifically provides that the FDA has no authority to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed [medical] device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship,"[3] and physicians are free to prescribe or use medical devices in any manner they deem medically appropriate.

71. Importantly, however, device and drug manufacturers, such as the Medtronic Defendants, 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

[3] *See*, 21 U.S.C. § 396.

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.

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

73. 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.

74. Any application of InFUSE® outside of its FDA-approved usage is considered off-label. Examples of off-label uses of the InFUSE® include: application of rhBMP-2 without the LT-CAGE or with a substitute cage; use of InFUSE® in a PLIF, a Posterolateral Fusion, DLIF, TLIF or any other procedure other than an ALIF using the LT-CAGE; use of InFUSE® in an ALIF procedure that involves a multiple-level fusion; or any use of InFUSE® in the cervical spine.

75. Notwithstanding full knowledge of the FDA-approved uses of InFUSE®, Medtronic actively promoted off-label use of InFUSE® through a number of different, wide-ranging, and effective ways. For example, former Medtronic employees report that the Company employed sales representatives to assist and instruct surgeons, during surgery, regarding how to achieve off-label applications of InFUSE®. Moreover, Medtronic employed these surgeons, and

others, who were dubbed "Key Opinion Leaders" and/or "consultants," to instruct and assist other surgeons contemplating or performing off-label InFUSE® surgeries. Importantly, these former employees worked on behalf of Medtronic in regions across the United States, and thus demonstrate Medtronic's unlawful practices were widespread throughout the Company, rather than isolated to particular areas.

G. TESTIMONY OF FORMER MEDTRONIC EMPLOYEES REGARDING OFF-LABEL PROMOTION[4]

76. A shareholders derivative 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), confirms Medtronic's egregious off-label promotion campaign of InFUSE®, even after the CIA. Medtronic's actions, described by confidential witnesses ("CW"), included:

a. Medtronic-sponsored physician meetings, during which Medtronic would employ paid consultants – typically surgeons hand selected by the Company – to present off-label presentations to local physicians. CW1, *Id*. at ¶ 93.

b. Medtronic's instructions to its sales representatives regarding f 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 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.

[4] Because the Medtronic former employees (referred to as "confidential witnesses" or "CW") provided information anonymously, they are identified herein by number (e.g., CW 1, CW 2, etc.) and job description, consistent with legal precedent.

d. Medtronic's creation of sales quotas that were described by of 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 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 them to be used in off-label cervical fusion surgeries. 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 sales representatives were directed to be present in the operating room to show the physician how to assemble the sponge or to explain other products. CW3, *Id*. at ¶ 99.

j. 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.

k. Medtronic directed its sales representatives to instruct physicians to use half the dose of rhBMP-2 during cervical fusion, and the Company, 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.

l. 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.

m. Medtronic issued a small book containing no reference to the Company, 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.

n. Medtronic instructed CW8 and others during sales presentations regarding how to "get around" restrictions on off-label promotion. CW8, ¶ 104.

o. CW13 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 physician referral network; b) Identifyingwhich surgeons would be targeted as part of Medtronic's off-label campaign and what claims the Company 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 CW13, the referral marketing program involved having surgeons meet with other surgeons as a means of prompting discussion of off-label uses of InFUSE® Bone Graft among practitioners. CW13 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.

p. CW13 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.

q. A sales representative was present in the operating room during an off-label cervical procedure which lead to the patient's death. The patient, and subsequent

civil litigation against Medtronic and the sales representative who was directing the off-label procedure at Medtronic's behest.. *Id*. at ¶ 111.

r. Although Medtronic is under an obligation to report all serious adverse events associated withInFUSE®, 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, the Company 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.

s. 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 was promoted. A Medtronic sales representative was in the operating room a lot when 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.

77. The *Minneapolis Firefighters* plaintiffsalso discovered the growing percentage of off-label InFUSE® usage from 2003-2007 by analyzing surgical procedural codes used by hospitals.[5] 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:

Year	Estimated On-Label Procedures	Estimated Off-Label Procedures
2003	25.7%	74.3%
2004	20.6%	79.4%

[5] The methodology employed was consistent with a recent 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. The results of that JAMA-reported study concerning post-operative complications following BMP use is described below

2005	15.8%	84.2%
2006	15.3%	84.7%
2007	14.8%	85.2%

78. 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.

79. Not only did off-label use of InFUSE® continue to increase after the DOJ settlement, but, undisclosed to investors Medtronic's lucrative payments to surgeons who used and promoted InFUSE® "off-label" also continued. In fact, just one of Medtronic's highly compensated "consultants"—Dr. Timothy Kulko, 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* revealed that Dr. Kulko 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. Kulko $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.

80. Dr. Kulko 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® recently uncovered shocking misconduct by this former Army surgeon. For example, Dr. Kulko 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. Kulko responded that the question "was well answered as far as appropriate dosage. I think it's really the bottom line."

81. Although Dr. Kulko'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. Kulko deliberately falsified data by exaggerating the benefits of off-label use of Medtronic's InFUSE® product in a study published in the August 2008 issue of *The Journal of Bone and Joint Surgery*.

82. Dr. Kulko'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, Kulko 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."

83. According to Kulko, 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."

84. Medtronic continued paying Dr. Kulko as a consultant even after his article was discovered by be completely fabricated and thus retracted by *The Journal of Bone and Joint Surgery*. Indeed, Medtronic only placed Dr. Kulko on "inactive status" after reports that he falsified the study's data were published in *The New York Times*.

85. Another highly compensated Medtronic consultant involved in the promotion of off-label InFUSE® use, Dr. David Polly, a professor and Chief of the Spine Service at the University of Minnesota Department of Orthopaedic Surgery, received consulting fees from Medtronic totalling $1.14 million from 2003 to 2007. As with Dr. Kulko, Medtronic's financial relationship with Dr. Polly began while the surgeon was on active military duty at Walter Reed. Although Dr. Polly has claimed that his consulting relationship with Medtronic did not begin until 2004, documents obtained through requests under the Freedom of Information Act ("FOIA") reveal that the Company paid almost $30,000 in travel expenses for Dr. Polly to speak at various medical conferences in the Bahamas, San Diego, and a $10,000 trip to Switzerland, while he was 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.

86. After his discharge from the military, Dr. Polly authored an article with Dr. Kulko 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."

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

88. 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 stated 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 stated. 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.

89. The information recently released by Senator Grassley, which includes billing reports submitted to Medtronic by Dr. Polly and approved by the Company, indicates that throughout this period, Dr. Polly had frequent meetings, telephone calls, and email correspondence with numerous Medtronic senior executives, including Hawkins, 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."

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

91. For example, 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.

92. 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. Gerald Rodts, received payments of $80,000 from Medtronic in 2006 and similar amounts in the previous two years. The SpineUniverse article does not mention that its authors received compensation from Medtronic, nor do the website profiles of Dr. Haid and Dr. Rodts, both of whom serve on the publication's editorial board, disclose their financial ties to the Company.

93. 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 BMP, 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.

94. 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."

95. 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."

96. 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."

97. Another prominent Medtronic consultant, Dr. Scott Boden, who assisted in presenting Medtronic's PMA application before the FDA Advisory Panel in January 2002, received consulting fees of $75,000 in 2006 and similar amounts in prior years. Unsurprisingly, Dr. Boden has also written extensively on the use of InFUSE® in off-label procedures. For example, Dr. Boden wrote that, when used in situations slightly altered from its approved use, rhBMP-2 is likely to be effective. His article, published in Orthopaedic Nursing, also praises the cost benefits of the product, noting that while rhBMP-2 "is quite expensive, [its] potential to

lessen morbidity, accelerate healing, and provide more consistent results undoubtedly justify these costs in appropriately selected patients."

98. Dr. Thomas A. Zdeblick, the Chairman of the Department of Orthopedics and Rehabilitation at the University of Wisconsin, received over $19 million from the Company from 2003 to 2007 for consulting services and royalty payments. Although Dr. Zdeblick only disclosed annual payments exceeding $20,000 in University conflict of interest forms, 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.

99. 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 website, "www.Back.com," Dr. Zdeblick describes the advantages of InFUSE® and appears in an online video discussing the benefits of the product.

100. 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."

101. Another set of highly compensated surgeons, these affiliated with the Norton Hospital Leatherman Spine Center in Louisville, Kentucky, collectively received over 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).

102. 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 of off-label usage of InFUSE®. According to CW 1, "What [Medtronic] would do is bring in one of their 'paid consultants' and set up a dinner in the area and invited a number of physicians to attend." The guest surgeon—the "paid consultant"—would then "basically give a presentation on off-label usage." Importantly, these physician talks were also attended by all Medtronic sales representatives who worked in the area.

103. These same Medtronic-funded surgeons associated with the Leatherman Spine Center have also written extensively on off-label uses of InFUSE®. For example, Dr. Rouben, authored a study published in *The Internet Journal of Minimally Invasive Spinal Technology* in

2007, titled "Mast TLIF Lumbar Spinal Fusion Technique: A Twenty-Four Month Retrospective Analysis For The Treatment of Symptomatic Segmental Lumbar Disc Disease – 'SSLDD'". The focus of Dr. Rouben's study was examination of post-operative results from patients who had undergone minimally invasive TLIF procedures in which InFUSE® was used—an off-label application of the product. According to Dr. Rouben, this procedure featuring off-label use of InFUSE®, "is a viable and appropriate treatment option for symptomatic segmental lumbar disc disease-SSLDD."

104. Additionally, the surgeons associated with the Leatherman Spine Center have collectively authored at least 15 articles addressing the use of BMP, including some of the leading medical articles on the use of InFUSE® in off-label posterolateral and anterior cervical fusion procedures. Specifically, Dr. Campbell has contributed to at least eight articles examining the use of BMP; Dr. Dimar 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.

105. CW 1 also stated that Drs. Lawrence "Larry" G. Lenke and Keith H. Bridwell, two other surgeons from Washington University in St. Louis – where Dr. Kulko worked as an associate professor until recently – similarly acted as KOLs or "guest surgeons" during "corporate visits" in which Medtronic would invite targeted surgeons to attend training sessions in Memphis, Tennessee. While in Memphis, the visiting surgeons 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 CW 1, 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." CW 1 stated that Medtronic chose which surgeons to invite to these corporate visits based, in part, upon the volume of InFUSE® procedures they performed.

106. Moreover, the attending guest surgeons identified also received significant fees from Medtronic. Dr. Bridwell received $10,000 in consulting fees from Medtronic in 2006, Dr. Lenke received payments totaling $175,000 over the same period, and Dr. Daniel Riew, another Washington University faculty member, received $80,000 from Medtronic in consulting fees in 2006.

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

108. Another prominent Medtronic consultant, Dr. Jeffrey Wang, the Chief of Spine Surgery for the Department of Orthopaedic Surgery and Executive Co-Director of the University of California, Los Angeles's ("UCLA") Comprehensive Spine Center, also spoke about off-label uses of InFUSE®. Unsurprisingly, Senator Grassley recently discovered that Dr. Wang received $275,000 in royalty and consulting payments from the Company from 2003 until 2008.

109. Furthermore, Dr. Wang failed to disclose his substantial financial relationship with Medtronic while researching Company products, which violated UCLA 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 such a study of Dr. Wang's. 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 co-executive director of UCLA's Comprehensive Spine Center.

110. 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®.

H. DEFENDANTS KNEW OFF-LABEL InFUSE® USE WAS, IN FACT, INJURING PATIENTS

111. Defendants were well aware of the significantly increased risk of adverse events from off-label uses of InFUSE®. CW 2stated that Medtronic was aware of adverse events

resulting from off-label use of InFUSE® in the cervical spine, including swallowing, and breathing problems.

112. 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 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 the Company 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.)

113. These adverse events were not isolated incidents. Indeed, the FDA's Manufacturer and User Facility Device Experience Database of adverse event reports ("MAUDE Database") indicates that more than 396 adverse event reports regarding rhBMP-2 have been submitted to the FDA from 2003-2008, and most of these reports were submitted from 2005 to 2008.

114. Importantly, the MAUDE Database consists of reports of adverse events and complications ***voluntarily*** submitted by medical professionals, patients, device distributors, and device manufacturers, and the FDA's website specifically states that, because submission is voluntary, it may not include reports of all adverse events that actually occur when a particular product is used. The submitted reports generally provide a short description of the adverse event, with varying degrees of specificity. Because of this varying specificity, it can be difficult to classify some reports as representing an on-label or off-label use.

Notwithstanding this limitation, of the 396 InFUSE®-related adverse events reported from 2003-2008, at least 276 – **an astonishing 69.7%** – occurred during off-label use of the product. The true percentage is likely significantly higher because approximately 26% of the reports examined do not contain sufficient information to classify the use of InFUSE® as on-label or off- label.

115. 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.

116. For example, a July 21, 2008 report indicates that a patient developed massive neck swelling, very thick tracheal and bronchial secretions, and required a tracheostomy—a procedure in which an incision is made in the neck and a tube inserted to allow the patient to breathe—following a cervical fusion procedure with InFUSE®.

117. 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.

118. Similarly, 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.

119. Through Medtronic's monitoring procedures—which include written procedures for complaints, corrective and preventative actions and adverse event reporting—all complaints and adverse events are documented, tracked, and trended in a database. Medtronic is required to "establish and maintain" such an adverse event database by federal regulation. *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."

I. THE FDA WARNS PHYSICIANS AGAINST OFF-LABEL APPLICATIONS OF InFUSE®, RESULTING IN DECLINING SALES OF THE PRODUCT

120. 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. 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."

121. The following day (July 2, 2008), a Medtronic analyst from ThinkPanmure noted that the FDA Notification was both a "rare" comment from the agency on off-label usage of a product and contained "*strong language*" that would hurt enthusiasm for off-label use of InFUSE®, especially in the cervical spine. (Emphasis added) The analyst noted: "[*s*]*eldom does the FDA make such a strong comment on the off-label usage of a product.* We think this will discourage the cervical use of BMP entirely. . . . We also think that this letter will make some physicians think twice about off-label usage in the *lumbar spine*." (Emphasis added)

122. In response to the FDA warning, Defendants' continued false and misleading statements meant to obscure the warning's significance. For example, a July 4, 2008 *Commercial Appeal* article quoted an RBC Capital Markets health care analyst who stated the warning letter was unlikely to affect sales of InFUSE® because it was limited to off-label uses. According to the article:

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

123. On September 4, 2008, *The Wall Street Journal* published a front-page article entitled "Medtronic Product Linked to Surgery Problems." In contrast to the *Commercial Appeal* article, 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.

(Emphasis added). 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, *supra*.

124. 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 the Company's reports of repeated, double-digit, growth in the Spinal segment in previous quarters. Moreover, the Company disclosed, for the first time, that: "*we recently received a subpoena from the Department of Justice looking into off-label use of InFUSE®.*" (Emphasis added.)

125. On November 12, 2008, J.P. Morgan issued the results of a proprietary survey of fifty U.S. spine surgeons that sought to gauge expected use of InFUSE® following the FDA Notification, the adverse reports since the issuance of that FDA warning regarding complications from off-label use of InFUSE®, and the whistleblower suits alleging illegal off-label promotion through payments to physicians. J.P. Morgan concluded that, although InFUSE® had been a

significant driver of growth for Medtronic and was one of the Company's most consistent products, "in the wake of an FDA warning letter on off-label use in the cervical spine, a whistleblower suit targeting leading InFUSE® surgeons, and a resulting increase in reimbursement scrutiny tied to off-label use, sales are starting to slow and likely [will] come in below consensus expectations over the next several quarters." J.P. Morgan further opined that cervical use of InFUSE® "is likely to decline considerably" and that lumbar use would moderate in the wake of the FDA Notification and coverage of the whistleblower suits. J.P. Morgan found that "[o]ne third of surgeons said they expect to reduce InFUSE® use in the wake of these events, forecasting a 57% reduction in cervical applications and 24% decline in lumbar." Surgeons as a whole forecast a 6% decline in InFUSE® use in the coming year, which is a significant reversal for a product that grew 16.9% over the previous year.

126. Thereafter, Medtronic continued to report lower sales of InFUSE®, which it admittedly linked to "a public health notice from the FDA regarding off-label use of recombinant human bone morphogenetic protein in the cervical spine that was issued in July 2008, a previously disclosed government investigation, negative newspaper stories, and a whistleblower lawsuit filed against a number of spine surgeons and distributors of InFUSE® bone graft."

J. DESPITE ACTUAL KNOWLEDGE OF ITS DANGERS, DEFENDANTS CONTINUED TO AGGRESSIVELY AND ILLEGALLY PROMOTE OFF-LABEL APPLICATIONS OF InFUSE®

127. As set forth herein, the Medtronic Defendants knew or should have known and/or recklessly disregarded that the public documents and statements they issued and disseminated regarding the safety and efficacy of off-label applications of InFUSE® were materially incomplete, false, and misleading.

128. By virtue of their receipt and knowledge of information reflecting the true facts regarding InFUSE®, the extent of its off-label use, and their control over, receipt, modification, and falsification of information regarding the true nature of the product, and their reckless promotion of off-label use, Medtronic knowingly and recklessly participated in an egregious off-label promotion campaign to the detriment of the public, including the Plaintiff.

129. 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 regarding InFUSE® and the its undisclosed activities to promote the product for off-label uses that had not 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 the personnel at the highest level of the Company.

130. Medtronic and its agents acted with scienter and intentionally or recklessly misled the public regarding the Company's true state of affairs and concealed that the consistent, double-digit growth in sales of InFUSE® were unsustainable because they were made possible only by aggressive off-label marketing tactics that posed a substantial risk to patients and subjected the Company to a severe regulatory response.

131. Employee Collins, who assumed the role of CEO in May 2001, and employee Ellis, who was then Vice President, Corporate Controller and Treasurer, were both in senior management positions with Medtronic at the time the FDA granted premarket approval of InFUSE®. Therefore, Defendants 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 the

Company guard against off-label use. 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.

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

> Our medical devices are subject to regulation by numerous government agencies, including the FDA and comparable foreign agencies. ***To varying degrees, each of these agencies requires us to comply with laws and regulations governing the development, testing, manufacturing, labeling, marketing, and distribution of our medical devices.***
> ...
>
> Both before and after a product is commercially released, we have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experience and other information to identify potential problems with marketed medical devices. ***We may be subject to periodic inspection by the FDA for compliance with the FDA's good manufacturing practice regulations among other FDA requirements, such as restrictions on advertising and promotion***…. ***The FDA may also impose operating restrictions, enjoin and restrain certain violations of applicable law pertaining to medical devices, and assess civil or criminal penalties against our officers, employees, or us. The FDA may also recommend prosecution to the Department of Justice.*** [Emphasis added.]

133. Medtronic employees Collins, Ellis, and Hawkins, who was then President and COO, also had actual knowledge of the terms of Medtronic's July 2006 settlement with the DOJ and the CIA at the very Medtronic division (Spinal) that markets and sells InFUSE®. Moreover, as a result of the CIA, Collins, Ellis, and Hawkins had actual knowledge of the heightened risks associated with any illegal, improper, and/or unethical promotional off off-label use of InFUSE® by the Company's Spinal division.

134. Collins, Ellis and Hawkins, were assigned specific monitoring and compliance responsibilities pursuant to the CIA entered into with the DOJ as a result of the whistleblower suits, *supra*, including reviewing quarterly reports regarding compliance matters within Medtronic's Spinal division. The obligations imposed by the CIA were meant to ensure that Collins, Ellis, and Hawkins would be regularly informed of the promotional activities at Medtronic's Spinal division, including the consulting arrangements that Medtronic used to promote InFUSE® for off-label purposes.

135. Medtronic and its agents, including Collins, Hawkins, and Ellis, also knew that InFUSE® sales were dependent upon off-label use and/or were personally involved in approving sales quotas that, for continued growth, necessitated an increased number of off-label procedures.

136. 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-label) versus cervical (off-label). Once Medtronic determined its sales

projections, these figures were incorporated into a budget reviewed by Wehrly, former President of Medtronic Spinal and Biologics, who reported directly to Hawkins, and presented the budget and sales projections 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 projections indicated, 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."

137. Numerous confidential witnesses, including CWs 1, 9, 12 and CW 14 (a senior manager for Medtronic Spinal and Biologics from 2005 to 2008), confirm the intense pressure 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, including Ellis, and that they were "very, very, very aggressive." Likewise, CW 12 stated that there was a lot of pressure on Medtronic's Spinal and Biologics division to reach unreasonable sales targets.

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

139. In addition to encouraging its sales representatives to push off-label sales and use of InFUSE®, Defendants also promoted off-label use of the product through outside physicians

who the Company 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 settlement with the DOJ and entry into the CIA as a result of this very activity, the Company continued its practice of providing lucrative consulting fees to surgeons who actively promoted off-label use of InFUSE®, such as Dr. Kulko, Dr. Polly, Dr. Zdeblick, and numerous others (amounting to millions of dollars per year), often with direct involvement from the senior management of Medtronic. For example, Dr. Polly had frequent meetings, telephone calls, and email discussions directly with Hawkins and other senior executives during the time he was engaged in off-label promotion of InFUSE®, as indicated by the billing reports he submitted and which were approved by the Company.

140. Defendants and their agents encouraged the off-label promotion of InFUSE® 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, death. Not only were Defendants aware of these complications, as indicated by the statements of CW 2 discussed, *supra*, the Company itself informed physicians as early as 2004 of complications associated with off-label anterior cervical fusions using InFUSE®.

141. Defendants' actual knowledge of off-label use and increased risk of adverse events resulting from such InFUSE® use is further demonstrated by the Company's adverse event reports submitted to the FDA (required by federal regulations). Indeed, Defendants instituted an internal study (or "Preventative Action") on April 21, 2006 to examine InFUSE®-related complications discovered through internal monitoring of adverse events.

142. According to CW 15, a Senior Vice President who worked at Medtronic for numerous years until 2006, a "Quality Group" at Medtronic's Spine division was responsible for

addressing adverse events. According to CW 15, former COO Michael DeMane, former President of Medtronic Spinal and Biologics Wehrly, and former Worldwide Vice President and General Manager, Biologics, Jon Serbousek, were aware of the adverse events related to InFUSE®. 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, the Company'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®.

143. Defendants 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). More specifically, Defendants pushed off-label cervical spine use of the product by advising and educating surgeons (oftentimes through its representatives who were present with surgeons performing off-label surgeries) to employ only one half (½) rhBMP-2 doses. As a result, sales of the rhBMP-2 component were far less 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 rhBMP-2 does must be used.

144. Defendants' continued and purposeful acts to promote off-label usage of InFUSE®, their knowledge of, but failure to disclose, the growing adverse events associated with the product, the Company's continued payments to physicians and Key Opinion Leaders to promote off-label uses, repeat FDA regulatory action against the Company, two whistleblower lawsuits against the Company, a DOJ settlement and Corporate Integrity Agreement, and a

congressional investigation undeniably evidence a conscious and reckless disregard for the health and safety of spinal surgeon candidates, such as the Plaintiff.

K. ADDITIONAL ADVERSE DISCLOSURES RESULT IN FURTHER DECLINES OF InFUSE® SALES

145. A series of negative news stories and revelations resulting from Congress' investigation into Medtronic's financial arrangements with spinal surgeons and their involvement with and promotion of InFUSE®, as well as the conflicts of interest and risks to patient safety posed by those relationships, continued to adversely affect InFUSE® sales. Such findings demonstrate that the material risks presented by Medtronic's improper marketing of InFUSE® were known and concealed by Defendants and their agents for purposes of continued profits.

146. For example, a December 12, 2008 Minneapolis-St. Paul *Star Tribune* article reported on Medtronic's financial relationship with several surgeons at Twin Cities Spine Center, one of the world's largest spine practices. As noted in the article, documents filed in the Boston whistleblower action earlier that week included a July 2002 letter to Collins from a Twin Cities Spine surgeon, Dr. Ensor Transfeldt, inviting Collins to view an off-label procedure involving InFUSE® scheduled just days after the FDA's approval of the product. The article also discussed two other documents demonstrating the lucrative opportunities for surgeons who "worked" for Medtronic: a 2002 draft consulting agreement providing for payments to several Twin Cities Spine surgeons of $4,000 per day not to exceed a total of $80,000 per year, for a total of $240,000 for the three-year contract term; and a proposed royalty agreement for six Twin

Cities Spine physicians that would provide payments of 5 percent of net sales of "royalty products" sold in the United States to compensate the physicians for their work in helping to develop or contribute to these future "inventions."

147. On January 16, 2009, *The Wall Street Journal* reported on a letter sent by Senator Grassley to Kevin P. Reilly, President at the University of Wisconsin, regarding 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.

148. Similarly, Dr. Jeffrey Wang of UCLA failed to disclose payments received by the Company, resulting in a university probe of his research and his removal as co-executive director of the UCLA Comprehensive Spine Center.

149. On May 13, 2009, *The New York Times* reported that the U.S. Army's investigation into a study authored by Dr. Kulko 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."

150. Per *The New York Times* and *The Wall Street Journal*, the true facts regarding Dr. Kulko'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:

- Dr. Kulko 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;
- 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. Kulko;
- The number of cases cited by Dr. Kulko in the article differed from the number of cases contained in the Wartime casualty database, with no explanation for the discrepancies in the article;
- Contrary to Army policy, Dr. Kulko did not obtain publication review or clearance from Walter Reed prior to submitting the article for publication; and
- The published results of the article suggested a much higher efficacy rate for the InFUSE® than is supported by the experience of the purported co- authors.

151. 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, "It's like a ghost population that were reported in the article as having been treated that we have no record of ever having existed … this really was all falsified information."

152. After receiving correspondence from Walter Reed dated November 6, 2008 stating that Dr. Kulko 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. Kulko from submitting further papers to the Journal. As noted in a May 19, 2009 follow-up article in *The New York Times*, when questioned about its ties

to Dr. Kulko, Medtronic repeatedly declined to disclose when it began its financial relationship with the former Army surgeon or the extent of funding it provided.

153. Upon further investigation, Senator Grassley discovered that Dr. Kulko's name did not appear on a list of paid consultants for InFUSE® provided by the Company that the Senator had requested in a September 30, 2008 letter to the Company. 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 the Company 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. Kulko's name in response to his inquiry that specifically requested information regarding consultants who work on InFUSE®, as it was "clear that Dr. Kulko had some sort of consulting agreement" and was named in *The New York Times* as a consultant on InFUSE®. Indeed, by this time, Dr. Kulko had given countless presentations on behalf of Medtronic about the product.

154. The list provided to Senator Grassley also omitted names of other Medtronic consultants who had spoken about InFUSE®, such as Dr. Polly, another former Walter Reed surgeon. Frustrated with the Company'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®.

155. As a result, on June 18, 2009, Medtronic disclosed to *The Wall Street Journal* that Dr. Kulko had received almost $850,000 in payments from the Company over the past 10 years, the majority of which—nearly $800,000— were made in the preceding three years when

Dr. Kulko was shopping his study to medical journals. Specifically, the Company paid Dr. Kulko $356,242 in 2007, the year Dr. Kulko sought publication of the study in two medical journals, and $249,772 in 2008, the year the study was published. Medtronic made both of these payments after the Company announced the settlement with the DOJ in July 2006.

156. In July 2009, Senator Grassley also publicly disclosed information demonstrating that Dr. Kulko 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, the Company financed two separate, unpublished studies that also examined the use of InFUSE® on Walter Reed patients with combat-related leg injuries while Dr. Kulko was supposedly conducting research for the falsified study. At the time Washington University approved the study protocols, Dr. Kulko indicated on disclosure forms that he did not receive any payments from Medtronic when, in fact, Dr. Kulko signed a contract with the Company shortly after joining the University faculty and had received payments from Medtronic for almost a year into his research.

157. In mid-2007, after Dr. Kulko disclosed to Washington University that he had received funding from Medtronic, the University's internal disclosure review board re-reviewed Dr. Kulko'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. Kulko opted to stop the two studies, which were closed in February 2008.

158. Like Dr. Kulko, Dr. Daniel Riew – another Medtronic consultant who publicly defended Dr. Kulko when reports of his falsified Army study first surfaced – also failed to properly report significant payments from the Company. For example, Dr. Riew reported to the

university that he received less than $10,000 in 2006. However, according to documents obtained by Senator Grassley, "[i]n fact, Medtronic reported [] that there was not a single year from 2003 to 2007 for which Dr. Riew received *less* than $10,000. In fact, he received well over $10,000 in each of those years." (Emphasis added)

159. 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.

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

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

162. 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.

163. The study entitled, "Prevalence, Complications, and Hospital Charges Associated with Use of Bone-Morphogenetic Proteins in Spinal Fusion Procedures," analyzed the

integration of BMP into spinal surgeries since 2002, and the association between its use and postoperative complications, length of hospital stays, and hospital charges. Significantly, the study 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.

164. 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."

165. 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.

166. Significantly, *The Spine Journal* devoted an entire issue to InFUSE® in 2002, in part, to highlight research improprieties and the true state of research using rh-BMP2. The following seminal conclusions were made:

- 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*.
- 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*.
- 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*.
- 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. *It also appears that these data, complete with adverse events, were submitted to the FDA during the approval process, and may have influenced their decision*. *Nonetheless, the events submitted to the FDA were absent in publications using the same patient group in 2003 or 2004*.
- In data submitted to the FDA by Burkus et al., statistical improprieties were employed using flawed methodology (comparing the entire cohort without comparison to the two primary study arms) resulting in a lower alleged rate and incidence of retrograde

ejaculation ("RE"). The difference being an overall rate of RE reported as 4.1%, and later found using proper methodology to be 7.9% (NNH=15, p=0.05). This association was not reported in the publication by Burkus et al. in 2002, 2003, 2004 and more recently in 2009.

- Later, in response to a letter to the editor inquiry, Burkus denied any potential association of this complication with the use of rhBMP-2, instead blaming the excess rate of REs on the approach used. Later research confirms this is not the likely answer. Multiple lines of evidence have since confirmed an incidence of ~7.5%.
- *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 was 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.*
- 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.
- The original estimates of ICBG (Iliac Crest Bone Graft, the pre-rhBMP-2 gold standard procedure for spinal fusion) harvesting morbidity was 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.
- 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.
- In those studies, for which other data sources have been made available on the same patient sets (either FDA documents of 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.*

- *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:
    - Posterior lumbar interbody fusion techniques: 25-50% risk of associated adverse events.
    - Anterior lumbar interbody fusion: 10-15% risk of adverse events.
    - Anterior cervical fusion: 40% greater risk of adverse events in the acute postoperative period including potentially life-threatening complications.
    - 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*. (All emphasis added)

V.
PLAINTIFF'S InFUSE® SURGERY

167. On November 19, 2007, Plaintiff Anthony Foster was admitted to Sacred Heart Hospital for spine surgery to address degenerative disk disease and intractable back pain.

168. Relying on Defendants' misrepresentations regarding the safety and efficacy of InFUSE®, including use in an off-label manner, Plaintiff's surgeon elected to use an off-label TLIF approach to place InFUSE® into the lumbar region of Plaintiff's spine in order to attempt to fuse vertebrae L4-L5. Additionally, Plaintiff's surgeon utilized InFUSE® with an off-label spinal cage system, a "Capstone" cage, rather than the FDA approved LT-CAGE.

169. Approximately 16 months later, in or around March of 2009, Plaintiff began experiencing a recurrence of lumbar back pain, accompanied by additional symptoms of weakness and loss of sensitivity alternating between his left and right extremity and retrograde ejaculation. The delayed onset of his symptoms, approximately 16 months after his InFUSE®

surgery, prompted Plaintiff to follow up with the same physician that performed the off-label surgery.

170. Upon follow up in April of 2009, Plaintiff's physician characterized Plaintiff's recurring and new symptoms as "myofacial," and "ghost pain," attributable to "usual postoperative changes." As a result of such findings, Plaintiff's physician prescribed physical therapy.

171. Plaintiff's recurring and new symptoms continued to worsen for the next year, however, thus prompting him to seek a second opinion. Indeed, it was not until August 2, 2011, that Plaintiff, following a revision surgery performed at the University of Alabama at Birmingham, discovered that InFUSE® had caused, and was continuing to cause, ectopic bone growth in and around the area in which it was implanted, and thus was causing his pain, weakness and loss of sensitivity in his lower extremities, and retrograde ejaculation. During his revision surgery, the excessive bone growth was removed from Plaintiff's spine.

172. As a result of the aforementioned wrongful conduct of the Defendants, Plaintiff was caused to suffer, and continues to suffer, injuries and damages; including but not limited to: a failed spinal fusion surgery using InFUSE® which resulted in overall worsening condition starting approximately 16 months after the surgery; a revision surgery to remove the ectopic bone growth caused by the InFUSE®; associated pain and suffering; and lost wages, past, present, and future.

VI.
SUMMARY OF ALLEGATIONS

173. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

174. 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 extreme danger to patients resulting from off-label uses of InFUSE®.

175. At all times relevant, 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 over-promoted InFUSE® to physicians and consumers, including the Plaintiff and his physicians, and downplayed to physicians and consumers its dangerous effects, including but not limited to the over-promotion and downplaying of the dangerous effects of InFUSE® in off-label spine surgeries such as that performed on the Plaintiff.

176. At all relevant times, the Medtronic Defendants knew, and/or had reason to know that InFUSE® was not safe for off-label 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 the Defendants to be unsafe and ineffective.

177. In off-label lumbar spine surgeries, InFUSE® often leads to serious complications including, but not limited to, radiculitis, ectopic bone formation, osteolysis, and worse overall outcomes, and as in Plaintiff's case, pain and/or weakness in limbs caused by ectopic bone growth.

178. When used off-label, InFUSE® fails to work in a safe and effective manner, and is defective, thereby causing serious medical problems and, in some patients, like the Plaintiff, catastrophic injuries.

179. At all relevant times, the Medtronic Defendants knew, and/or had reason to know, that its 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.

180. The Medtronic Defendants knew and/or had reason to know of the likelihood of injuries and deaths resulting from off-label use of InFUSE®, yet actively concealed this information from Plaintiff and his physicians, and/or failed to warn the Plaintiff, thereby preventing Plaintiff from making informed choices regarding treatment.

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

182. The Medtronic Defendants recklessly and/or fraudulently promoted and marketed InFUSE® to Plaintiff and his physician for off-label use in the spine, and this promotion and marketing causes Plaintiff's physicians to decide to implant InFUSE® in Plaintiff's spine using an off-label approach.

183. Plaintiff would not have chosen to be treated with InFUSE® had been informed by the Medtronic Defendants of the true risks of the off-label use of InFUSE®.

184. Any warnings the Medtronic Defendants may have issued concerning the dangers of off-label use of InFUSE® were insufficient in light of their contradictory prior,

contemporaneous, and continuing promotional efforts and over-promotion of InFUSE® for off-label use.

185. Plaintiff has suffered and continues to suffer from grievous personal injuries as a direct and proximate result of the Medtronic Defendants' misconduct regarding its product InFUSE®.

186. At all times herein mentioned, each Defendant was the agent, servant, partner, aider and abettor, co-conspirator and/or joint venturer of the other 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, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

187. At all times herein mentioned, the Medtronic Defendants were fully informed of the actions of their agents and employees, and thereafter, no officer, director, or managing agent of the Medtronic 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.

188. There exists, and at all times herein mentioned there existed, a uniformity of interest in ownership between the Medtronic Defendants, such that any individuality and separateness between them has ceased and they are alter-egos of each other. Adherence to the fiction of the separate existence of the Medtronic Defendants as distinct entities will permit an abuse of the corporate privilege and would sanction a fraud and/or would promote injustice.

189. At all times herein mentioned, the Medtronic Defendants 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 his physicians. As such, the Medtronic Defendants are individually, as well as jointly and severally, liable to the Plaintiff for his damages. The harm which has been caused to Plaintiff resulted from the conduct of one, or both of the Medtronic Defendants, and through no fault of the Plaintiff. There may be uncertainty as to which one of the Medtronic Defendants caused the harm. Because the Medtronic Defendants have superior knowledge and information regarding which one of them caused Plaintiff's injuries, the burden of proof should be upon each Medtronic Defendant to prove that the other has not caused the harms suffered by Plaintiff.

VII.
PLAINTIFF IS ENTITLED TO PUNITIVE DAMAGES

190. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

191. As a result of the Medtronic Defendants' oppression, fraudulent concealment, wantonness, malice, and reckless disregard for Plaintiff's safety, Plaintiff is entitled to punitive or exemplary damages to the fullest extent necessary and afforded by law.

VIII.
FRAUDULENT CONCEALMENT

192. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

193. The Medtronic Defendants' failure to document or follow up on the known defects in its products, and concealment of known defects, constitutes fraudulent concealment

that equitably tolls any proffered statute of limitation that may bar the recovery sought by Plaintiff herein.

194. The Medtronic Defendants are estopped from relying on any statute of limitations defense because they actively concealed the defects, suppressed reports and adverse information, failed to satisfy FDA notification requirements, and failed to disclose known defects to physicians and the Plaintiff. Instead, Medtronic continued to represent its product was/is safe for use as intended.

195. At all relevant times, the Medtronic Defendants were under a continuing duty to disclose the true character, quality, and nature of risks and dangers associated with their product. Because of the Medtronic Defendants' concealment of the true character, quality and nature of their product, they are estopped from relying on any statute of limitations defense.

196. The Medtronic Defendants furthered their fraudulent concealment through act and omission, including misrepresenting known defects in its product and a continued and systematic failure to disclose such information to the Plaintiff, physicians, and the public.

197. The Medtronic Defendants' acts and omissions, before, during and/or after the act causing Plaintiff's injury, prevented Plaintiff from discovering the injury or cause thereof.

198. The Medtronic Defendants' conduct, because it was purposely committed, was known or should have been known by them to be dangerous, heedless, and reckless, and without regard to the consequences or the rights and safety of the Plaintiff.

IX.
CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION
[Negligence/Gross Negligence]

199. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

200. Defendants designed, tested, manufactured, marketed, sold, and/or distributed InFUSE®.

201. At all relevant times herein, Defendants had a duty to properly manufacture, test, inspect, package, label, distribute, market, examine, maintain, supply, provide proper warnings, and prepare for use and sale these products, as well as comply with the FDA premarket approval order.

202. Defendants breached their duty in one or more ways set forth herein.

203. Defendants' breaches proximately caused Plaintiff's injuries and damages.

SECOND CAUSE OF ACTION
[Negligence Per Se]

204. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

205. At all relevant times, Defendants were obligated not to violate the law.

206. Defendants' sales and distribution of InFUSE® without FDA approval violates the Food Drug and Cosmetic act, 21 U.S.C. § 301, *et seq*, related amendments and codes, federal regulations promulgated thereunder, and other applicable state and federal law.

207. Since FDA approval in 2002, Defendants have manufactured, distributed, and sold the InFUSE® device in the ordinary course of business in the United States.

208. The InFUSE® device consists of two components containing three parts, a tapered metallic spinal fusion cage (the LT-CAGE), a recombinant human bone morphogenetic protein and a carrier/scaffold. FDA premarket approval was conditional on the sale of all

components together for use as a system. Defendants directly violated the premarket approval order through manufacture, sale, and distribution of InFUSE® separate and apart from the LT-CAGE. Defendants' sale, and promotion, of components to be used piecemeal violates FDA premarket approval and applicable law.

209. Moreover, premarket approval of InFUSE® was conditional on its use only in candidates with degenerative disc disease from L_4-S_1 and only using a specified spinal fusion procedure – Anterior Lumbar Interbody Fusion. Defendants violated FDA premarket approved applications by promoting spinal fusion applications beyond the limited FDA-endorsed applications.

210. Marketing, sale, promotion, and distribution of any FDA regulated drug or device beyond the FDA approved uses, as determined by the intent of the manufacturer or its representatives per 21 C.F.R. § 801.4, is a violation of 21 U.S.C. § 352(f) and deemed misbranded for failing to contain adequate instructions for use.

211. Defendants affirmatively promoted InFUSE® for uses in off-label procedures, with unapproved components, and in off-label spinal sections; all violations of federal law.

212. Additionally, sales of InFUSE®, separate and apart from all required (FDA-approved) mechanical components, constitute the sale of a "new drug," and, therefore, require FDA approval of a new drug application. At all relevant times, Defendants failed to apply for such new drug approval in violation of federal law.

213. In the alternative, if InFUSE® sold by Defendants separate and apart from FDA-approved components is considered a device, distribution of products for uses that have not been approved by the agency under a PMA or 510(k) notice is unlawful. At all relevant times,

Defendants violated federal law through their sale of InFUSE® to be used in off-label, or unapproved.

214. Adequate instructions for use of InFUSE® separate and apart from the LT-CAGE, in off-label procedures, or in off-label spinal sections, and corresponding warnings for each such application, were not contained in Defendants' FDA-approved label for InFUSE®.

215. As a direct and proximate result of Defendants' violations of the law, Plaintiff was caused to undergo an off-label spinal procedure using InFUSE®, which directly and proximately caused his injuries and damages.

THIRD CAUSE OF ACTION
[Negligent Misrepresentation]

216. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

217. Defendants represented to Plaintiff and his physicians that InFUSE® was approved, safe, and effective to treat Plaintiff's medical conditions.

218. Defendants knew InFUSE® was not approved for such uses, and, when so used, that it was defective, unreasonably dangerous, not effective, and capable of causing the injuries described herein and, therefore, their representations were false and misleading.

219. Defendants knew or should have known that their false and misleading representations regarding the approved use, safety, and efficacy of InFUSE® off-label to treat Plaintiff's medical conditions would be relied upon by the Plaintiff and his physician.

220. In reasonable and justifiable reliance upon Defendants' false and misleading statements of material fact, Plaintiff and his physicians elected to use InFUSE® off-label, and, as a result, Plaintiff was caused to suffer injuries and damages.

FOURTH CAUSE OF ACTION
[Product Liability – Manufacturing Defect]

221. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

222. Defendants designed, tested, manufactured, marketed, sold, and/or distributed InFUSE® with the intention that it be used in off-label, non-FDA approved, spinal fusion surgical applications, such as the Plaintiff's.

223. InFUSE® was defectively manufactured because it deviated in a material way from the Defendants' specifications and/or from otherwise identical units manufactured to the same specifications; including but not limited to: the manufacture of InFUSE® to be used in conjunction with off-label componentry; the manufacture of InFUSE® to be used in/on off-label sections of the spine; and the manufacture of InFUSE® to be used off-label with reduced amounts of rhBMP-2.

224. The defective condition of Defendants' product rendered it unreasonably dangerous the Plaintiff.

225. The defective and unreasonably dangerous condition of Defendants' product proximately caused the Plaintiff's injuries and damages.

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

227. The Infuse® product was unreasonably dangerous in that it was unsafe when used as it was promoted by Medtronic for use in off-label lumbar spine surgeries.

228. The Infuse® product was not manufactured in conformity with the manufacturer's design

229. The Infuse® product failed to perform as safely as an ordinary consumer would expect.

230. Plaintiff and his physicians used the Infuse® product in the way Defendants intended and promoted it to be used.

231. Plaintiff and his physicians could not have discovered any defect in the Infuse® product through the exercise of due care.

232. Medtronic, as designer, manufacturer, marketer, and distributor of the Infuse® product, is held to a higher level of knowledge in their field.

233. Plaintiff and his physicians did not have substantially the same knowledge as the designer, manufacturer or distributor: Medtronic.

234. Defendants' unreasonably-dangerous and defectively-manufactured Infuse® was the direct, legal and proximate cause of Plaintiff's injuries and damages including, but not limited to, medical hospital expenses and lost wages.

235. As a direct and proximate result of one or more of the above-listed dangerous conditions and defects, Plaintiff has sustained serious injuries of a personal and pecuniary nature.

236. 136. Plaintiff has sustained extreme pain, suffering, and anguish from the date of his off-label lumbar spine surgery with Infuse®.

FIFTH CAUSE OF ACTION
[Product Liability – Design Defect]

237. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

238. Defendants designed, tested, manufactured, marketed, sold, and/or distributed InFUSE® with the intention that it be used in off-label, non-FDA approved, spinal fusion surgical applications, such as the Plaintiff's.

239. InFUSE® was defectively designed because, as promoted by Defendants to be used off-label, it failed to function as expected.

240. At the time of Defendants' design and manufacturer of InFUSE®, there existed a feasible design alternative that, to a reasonable probability, would have prevented Plaintiff's injuries and damages. Such a reasonable alternative design would not have impaired the utility, usefulness, practicality, and/or desirability of the product to the Plaintiff.

241. The defective condition of Defendants' product rendered it unreasonably dangerous the Plaintiff.

242. The defective and unreasonably dangerous condition of Defendants' product proximately caused the Plaintiff's injuries and damages.

SIXTH CAUSE OF ACTION
[Product Liability – Failure to Warn/Inadequate Warning/Inadequate Instructions]

243. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

244. Defendants designed, tested, manufactured, marketed, sold, and/or distributed InFUSE® with the intention that it be used in off-label, non-FDA approved, spinal fusion surgical applications, such as the Plaintiff's.

245. InFUSE® was defective because Defendants failed to adequately warn ordinary consumers regarding its use, and the product failed to contain adequate warnings and/or instructions.

246. Defendants, the manufacturer and seller of InFUSE®, knew, or should have known in light of reasonable available information, that InFUSE® was dangerous and defective when used in off-label applications, such as the Plaintiffs, and that such off-label applications would cause injuries and damages to the user or consumer, such as the injuries and damages suffered by the Plaintiff.

247. Defendants knew, or should have known in light of reasonable available information, that the ordinary consumer, such as the Plaintiff, would not realize the dangerous and defective condition of its product when used off-label.

248. Defendants' failed to communicate sufficient information, including adequate warnings and/or instructions, to Plaintiff and his physician regarding the dangers of InFUSE® of which he knew or should have known, taking into account the characteristics of, and the ordinary knowledge common to, an ordinary consumer, such as the Plaintiff, which rendered the product defective.

249. Any warnings the Defendants may have issued concerning the dangers of off-label use of InFUSE® were insufficient in light of their contradictory prior, contemporaneous, and continuing false statements of material fact regarding the safety and efficacy of off-label InFUSE® use.

250. The defective condition of Defendants' product rendered it unreasonably dangerous the Plaintiff.

251. The defective and unreasonably dangerous condition of Defendants' product proximately caused the Plaintiff's injuries and damages.

SEVENTH CAUSE OF ACTION
[Product Liability – Breach of Express Warranty]

252. Plaintiff hereby incorporates by references, as if fully set forth herein, each and every allegation set forth in this Complaint.

253. Defendants expressly warranted to Plaintiff that InFUSE® was safe, effective, fit, and proper for his intended use.

254. Plaintiff and his physicians reasonably relied upon Defendants' express warranties in using the aforesaid products.

255. Defendants' warranties regarding the product's safety and efficacy, reasonably relied upon by the Plaintiff and his physicians, were untrue and the product failed to conform to them, which rendered to product defective.

256. The defective condition of Defendants' product rendered it unreasonably dangerous the Plaintiff.

257. The defective and unreasonably dangerous condition of Defendants' product proximately caused the Plaintiff's injuries and damages.

EIGHTH CAUSE OF ACTION
[Breach of Implied Warranty]

258. Plaintiff hereby incorporates by reference, as if fully set forth herein, each and every allegation set forth in this Complaint.

259. Defendants impliedly warranted that InFUSE® was merchantable and fit and safe for ordinary use.

260. Defendants further impliedly warranted that InFUSE® was fit for the particular purpose of correcting degenerative disc disease, such as that suffered by the Plaintiff.

261. Defendants breached implied warranties of merchantability and fitness for a particular purpose when its product was sold to the Plaintiff as InFUSE® was defective, unmerchantable, and unfit for ordinary use when sold, and unfit for the particular purpose for which it was sold, subjecting the Plaintiff to severe and permanent injuries.

262. As a result of Medtronic's breach of the implied warranties of merchantability and fitness for a particular purpose, Plaintiff has sustained, and will continue to sustain, injuries and damages.

NINTH CAUSE OF ACTION
[Fraudulent Misrepresentation and Fraud in the Inducement]

263. Plaintiff incorporates by reference all previous paragraphs of this complaint as if fully set forth here and further alleges as follows:

264. Defendants fraudulently misrepresented material and important health and safety product risk information regarding InFUSE® to the Plaintiff and his physicians. But for Defendants' fraudulent misrepresentations, Plaintiff and his physicians would not have chosen to use InFUSE®. Indeed, absent Defendants' fraudulent misrepresentations to the general public, including the Plaintiff and his physicians, Plaintiff's physicians would not have known to use InFUSE® in an off-label application on the Plaintiff.

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

a. Defendants fraudulently concealed and misrepresented the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label lateral-approach use, in non-approved spinal segments, and/or with the use of Medtronic components which had not been approved for use with InFUSE®;

b. Defendants fraudulently concealed and misrepresented their practice of promoting and marketing to physicians, including Plaintiff's physician, the off-label use of InFUSE® in lateral-approach lumbar spine surgery, in non-approved spinal segments, and/or with Medtronic components which had not been approved for use with InFUSE®;

c. Defendants fraudulently concealed and misrepresented information about the known comparative risks and benefits of InFUSE® and the relative benefits and availability of alternative products, treatments and/or therapies.

266. Defendants knew that Plaintiff and his physicians would regard the matters Defendants concealed and misrepresented to be important in determining the course of treatment for the Plaintiff, including Plaintiff and his physician's decision whether or not to use InFUSE® in Plaintiff's spine surgery.

267. Defendants intended that Plaintiff and his physicians rely on their concealment of information and misrepresentations about safety risks related to InFUSE® to induce them to use InFUSE® off-label.

268. Plaintiff and his physicians justifiably relied upon Defendants' concealment of information and misrepresentations about the safety risks related to InFUSE® in deciding to use InFUSE® off-label.

269. As a direct and proximate result of Defendant's fraudulent concealment and misrepresentations and suppressions of material health and safety risks relating to InFUSE®, including but not limited to Defendants' dangerous and irresponsible off-label promotion and marketing practices, Plaintiff suffered, and continues to suffer from, injuries and damages.

TENTH CAUSE OF ACTION
[Constructive Fraud]

270. Plaintiff hereby incorporates by reference all previous paragraphs of this Complaint as if fully set forth here and further alleges as follows:

271. Defendants marketed InFUSE® to and for the benefit of Plaintiff, and marketed it to his physicians, and Defendants knew or had reason to know of the unreasonable dangers and defects of InFUSE®, and that Plaintiff and his physicians would use the product.

272. Defendants owed Plaintiff a duty to exercise reasonable or ordinary care under the circumstances, in light of the generally recognized and prevailing best scientific knowledge, and to design, manufacture, market, and sell InFUSE® in a reasonably safe manner under the circumstances.

273. As set forth herein, specific defects in the InFUSE® product rendered it defective and unreasonably dangerous to users and consumers, such as the Plaintiff.

274. Through the conduct described herein, Defendants consciously and recklessly breached their duties to Plaintiff.

275. Through their breaches, Defendants gained an advantage by profiting from the sale of InFUSE® for off-label use.

276. Plaintiff and his physicians justifiably relied on Defendants' misrepresentations regarding, and concealment of, the actual dangers of off-label use of InFUSE®.

277. As the direct and proximate cause and result of the Defendants' breaches, Plaintiff has suffered, and continues to suffer, injuries and damages.

X.
PRAYER FOR RELIEF

WHEREFORE, PREMISES CONSIDERED, Plaintiff prays for judgment against the Defendants, and each of them, as follows:

1. For compensatory damages and general damages, economic and non-economic, sustained by Plaintiff against all Defendants, jointly and severally, in an amount to be determined at trial;

2. For punitive and exemplary damages according to proof against the Defendants, for all causes of action;

3. For an award of prejudgment interest, costs, disbursements and reasonable attorneys' fees; and,

4. For such other and further relief as the Court deems equitable or appropriate under the circumstances.

XI.
JURY DEMAND

Plaintiff demands a trial by jury on all issues stated.

Respectfully submitted this the 27th day of July, 2012.

/s/ Bryan F. Aylstock
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On behalf of the Plaintiff, Anthony Foster

JS 44 (Rev. 09/11)

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.)*

I. (a) PLAINTIFFS

Anthony Foster

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

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
AYLSTOCK, WITKIN, KREIS & OVERHOLTZ
17 E. Main Street, Suite 200, Pensacola, FL 32502
(850) 202-1010

DEFENDANTS

MEDTRONIC, INC., a Minnesota Corporation, and
MEDTRONIC SOFAMOR DANEK

County of Residence of First Listed Defendant _____
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

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 (Excl. Veterans)
- ❒ 153 Recovery of Overpayment of Veteran's Benefits
- ❒ 160 Stockholders' Suits
- ❒ 190 Other Contract
- ❒ 195 Contract Product Liability
- ❒ 196 Franchise

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 - Med. 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

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

LABOR
- ❒ 710 Fair Labor Standards Act
- ❒ 720 Labor/Mgmt. Relations
- ❒ 740 Railway Labor Act
- ❒ 751 Family and Medical Leave Act
- ❒ 790 Other Labor Litigation
- ❒ 791 Empl. Ret. Inc. Security Act

IMMIGRATION
- ❒ 462 Naturalization Application
- ❒ 463 Habeas Corpus - Alien Detainee (Prisoner Petition)
- ❒ 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

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

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
- ❒ 510 Motions to Vacate Sentence

Habeas Corpus:
- ❒ 530 General
- ❒ 535 Death Penalty
- ❒ 540 Mandamus & Other
- ❒ 550 Civil Rights
- ❒ 555 Prison Condition
- ❒ 560 Civil Detainee - Conditions of Confinement

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 U.S.C. § 1332

Brief description of cause:
personal injury/ product liability

VII. REQUESTED IN COMPLAINT:

❒ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23

DEMAND $

CHECK YES only if demanded in complaint:

JURY DEMAND: ☒ Yes ❒ No

VIII. RELATED CASE(S) IF ANY

(See instructions): JUDGE _____ DOCKET NUMBER _____

DATE
07/27/2012

SIGNATURE OF ATTORNEY OF RECORD
/s/ Bryan F. Aylstock

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____

INSTRUCTIONS FOR ATTORNEYS COMPLETING CIVIL COVER SHEET FORM JS 44

Authority For Civil Cover Sheet

The JS 44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and service of pleading 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. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. The attorney filing a case should complete the form as follows:

I. (a) Plaintiffs-Defendants. Enter names (last, first, middle initial) of plaintiff and defendant. If the plaintiff or defendant is a government agency, use only the full name or standard abbreviations. If the plaintiff or defendant is an official within a government agency, identify first the agency and then the official, giving both name and title.

(b) County of Residence. For each civil case filed, except U.S. plaintiff cases, enter the name of the county where the first listed plaintiff resides at the time of filing. In U.S. plaintiff cases, enter the name of the county in which the first listed defendant resides at the time of filing. (NOTE: In land condemnation cases, the county of residence of the "defendant" is the location of the tract of land involved.)

(c) Attorneys. Enter the firm name, address, telephone number, and attorney of record. If there are several attorneys, list them on an attachment, noting in this section "(see attachment)".

II. Jurisdiction. The basis of jurisdiction is set forth under Rule 8(a), F.R.C.P., which requires that jurisdictions be shown in pleadings. Place an "X" in one of the boxes. If there is more than one basis of jurisdiction, precedence is given in the order shown below.

United States plaintiff. (1) Jurisdiction based on 28 U.S.C. 1345 and 1348. Suits by agencies and officers of the United States are included here.

United States defendant. (2) When the plaintiff is suing the United States, its officers or agencies, place an "X" in this box.

Federal question. (3) This refers to suits under 28 U.S.C. 1331, where jurisdiction arises under the Constitution of the United States, an amendment to the Constitution, an act of Congress or a treaty of the United States. In cases where the U.S. is a party, the U.S. plaintiff or defendant code takes precedence, and box 1 or 2 should be marked.

Diversity of citizenship. (4) This refers to suits under 28 U.S.C. 1332, where parties are citizens of different states. When Box 4 is checked, the citizenship of the different parties must be checked. (See Section III below; federal question actions take precedence over diversity cases.)

III. Residence (citizenship) of Principal Parties. This section of the JS 44 is to be completed if diversity of citizenship was indicated above. Mark this section for each principal party.

IV. Nature of Suit. Place an "X" in the appropriate box. If the nature of suit cannot be determined, be sure the cause of action, in Section VI below, is sufficient to enable the deputy clerk or the statistical clerks in the Administrative Office to determine the nature of suit. If the cause fits more than one nature of suit, select the most definitive.

V. Origin. Place an "X" in one of the seven boxes.

Original Proceedings. (1) Cases which originate in the United States district courts.

Removed from State Court. (2) Proceedings initiated in state courts may be removed to the district courts under Title 28 U.S.C., Section 1441. When the petition for removal is granted, check this box.

Remanded from Appellate Court. (3) Check this box for cases remanded to the district court for further action. Use the date of remand as the filing date.

Reinstated or Reopened. (4) Check this box for cases reinstated or reopened in the district court. Use the reopening date as the filing date.

Transferred from Another District. (5) For cases transferred under Title 28 U.S.C. Section 1404(a). Do not use this for within district transfers or multidistrict litigation transfers.

Multidistrict Litigation. (6) Check this box when a multidistrict case is transferred into the district under authority of Title 28 U.S.C. Section 1407. When this box is checked, do not check (5) above.

Appeal to District Judge from Magistrate Judgment. (7) Check this box for an appeal from a magistrate judge's decision.

VI. Cause of Action. Report the civil statute directly related to the cause of action and give a brief description of the cause. **Do not cite jurisdictional statutes unless diversity**. Example: U.S. Civil Statute: 47 USC 553
Brief Description: Unauthorized reception of cable service

VII. Requested in Complaint. Class Action. Place an "X" in this box if you are filing a class action under Rule 23, F.R.Cv.P.

Demand. In this space enter the dollar amount (in thousands of dollars) being demanded or indicate other demand such as a preliminary injunction.

Jury Demand. Check the appropriate box to indicate whether or not a jury is being demanded.

VIII. Related Cases. This section of the JS 44 is used to reference related pending cases if any. If there are related pending cases, insert the docket numbers and the corresponding judge names for such cases.

Date and Attorney Signature. Date and sign the civil cover sheet.