IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS,
COUNTY DEPARTMENT, LAW DIVISION

KARL L. SANDA,

Plaintiff,

vs.

MEDTRONIC, INC, MEDTRONIC SOFAMOR DANEK USA, INC., NORTHWESTERN MEMORIAL HOSPITAL, NORTHWESTERN ORTHOPAEDIC INSTITUTE LLC and MARK T. NOLDEN, M.D.,

Defendants.

2013L000305
CALENDAR/ROOM Z
TIME 00:00
Product Liability

Case No.:

COMPLAINT AT LAW

The plaintiff states the following in support of this complaint:

PARTIES AND VENUE

1. Defendant Northwestern Memorial Hospital is an Illinois corporation with a registered office at 211 East Ontario in Chicago that operates a hospital campus in Chicago generally bounded by Inner Lake Shore Drive on the East, Michigan Avenue on the West, Chicago Avenue on the North and Ontario Street on the South.

2. Defendant Northwestern Orthopaedic Institute LLC is an Illinois corporation with a registered office and principal office located on Northwestern Memorial Hospital's campus at 680 N. Lake Shore Drive, that in 2010 and 2011 provided, *inter alia*, spine surgery services at Northwestern Memorial Hospital.

3. Defendant Mark T. Nolden, M.D, is an orthopaedic surgeon who resides in Chicago, Illinois and practices in the field of spine surgery in Chicago.

4. In 2010 and 2011 Dr. Nolden was the agent, servant, employee or apparent agent of defendants Northwestern Memorial Hospital and Northwestern Orthopaedic Institute LLC, acting within the course and scope of his agency relationship with both of these entities.

5. Defendant Medtronic, Inc. is a Minnesota corporation registered to do business in Illinois with a registered office located at 208 South LaSalle Street in Chicago.

6. Defendant Medtronic Sofamor Danek USA, Inc. is a Tennessee corporation registered to do business in Illinois with a registered office located at 208 South LaSalle Street in Chicago.

7. Defendants Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. (hereafter referred to collectively as "Medtronic") have, at all relevant times, been in the business of manufacturing, marketing, promoting and selling medical products and devices for use on Illinois citizens and others including but not limited to a biologic product branded as *INFUSE Bone Graft*, a surgically implanted medical device containing a genetically engineered protein designed to stimulate bone growth.

8. The causes of action set forth in this lawsuit relate to severe and disabling injuries the plaintiff suffered as a result of a cervical spine surgery performed on him at Northwestern Memorial Hospital on January 10, 2011 by defendant Mark T. Nolden, M.D., who chose to utilize *INFUSE Bone Graft* as part of the procedure.

9. Venue is proper in the Circuit Court of Cook County pursuant to ILCS 735 § 5/2-101(1) and (2) because the defendants reside in Cook County and the surgery out of which the causes of action set forth in this complaint arise occurred in Cook County.

BACKGROUND

10. This is a product liability and medical malpractice lawsuit alleging negligence, strict liability, breach of warranty and willful-wanton conduct causes of action against Medtronic and negligence causes of action against Northwestern Memorial Hospital, Northwestern Orthopaedic Institute LLC and Mark T. Nolden, M.D. All of these causes of action are brought under Illinois law.

11. Defendant Dr. Mark T. Nolden diagnosed the plaintiff with, among other things, advanced subaxial cervical spondylosis and degenerative cervical stenosis from C-2 through C-7 of the cervical spine.

12. On January 10, 2011 Dr. Nolden performed a posterior cervical fusion, C2 through C6, which is a procedure utilized to fuse the cervical vertebral body with the sacrum (sacralisation). During this procedure, the center of the diseased disc is removed, and bone growth material is inserted in its place with the intention that it would stimulate bone growth over time in order to "fuse."

13. To achieve fusion, Dr. Nolden performed an off-label procedure by using *INFUSE* in the cervical spine instead of limiting the cervical surgery to an approved autograft or allograft procedure. The FDA had not approved the Medtronic *INFUSE Bone Graft* to be used in a cervical procedure.

14. Plaintiff is informed and believes and based thereon alleges that Medtronic, through its sales representatives and paid Key Opinion Leaders directly and indirectly promoted, trained and encouraged Dr. Nolden to use the *INFUSE Bone Graft* in an off-label manner, including utilizing it in posterior cervical spine surgery.

15. Among other things, Dr. Nolden never informed the plaintiff that he would be using the Medtronic *INFUSE Bone Graft*; he never informed the plaintiff that this product had only received limited FDA approval for certain specific procedures; he never informed the plaintiff that he would be using the *INFUSE Bone Graft* in a procedure that had never been tested or approved by the FDA; never informed the plaintiff that use of the *INFUSE Bone Graft* could result in unwanted bone growth, seroma, bone migration, bone resorption, swelling of the neck and throat tissue which results in compression of the airway and/or neurological structures in the neck, paralysis, and difficulty swallowing, breathing and speaking, oftentimes requiring emergency treatment, including tracheotomies and the insertion of feeding tubes and emergency corrective surgeries; he never informed the plaintiff that use of the *INFUSE Bone Graft* could cause severe, debilitating, permanent pain; he never informed the plaintiff of available alternative methods of surgery, and having failed to inform the plaintiff of these facts and risks, Dr. Nolden never actually obtained the plaintiff's informed consent to perform the procedures that he performed.

16. Following the January 10, 2011 cervical spine surgery the plaintiff developed a massive seroma caused by the off label use of INFUSE. When diagnosed on January 16, 2011, the massive seroma was life-threatening and required an emergency corrective surgery. Although the seroma was evacuated, it left the plaintiff partially paralyzed with permanent disability and pain.

17. The plaintiff has never recovered from his two surgeries and continues to have daily severe disabling pain and paralysis.

18. In July of 2011, looking retrospectively, the prominent medical journal, *The Spine Journal*, dedicated an entire issue publishing numerous articles laying bare facts revealing years of evidence of promotion by Medtronic of off-label uses of *INFUSE Bone Graft* with unproven efficacy and great risks, in an area of medicine that simply did not need this product innovation due to the proven efficacy and reliability of autografting and other techniques and procedures. The journal articles discuss Medtronic's failure to accurately report the side effects from its clinical trials; Medtronic's failure to report that many of the authors who studied and promoted *INFUSE Bone Graft* had significant financial ties to Medtronic; that *INFUSE Bone Graft* can cause severe problems with nerves and spinal cords; and that off-label use of *INFUSE Bone Graft* can lead to severe side effects.

19. Medtronic's unlawful off-label campaign which was taking place for years before January 10, 2011, has resulted in, among other adverse events to Medtronic, two whistleblower lawsuits (resulting in settlement with the United States Department of Justice which included a Corporate Integrity Agreement), a

shareholder's derivative lawsuit, several adverse regulatory actions by the United States Food & Drug Administration ("FDA") and a Congressional investigation (led by the United States Senate Committee on Finance).

PREMARKET APPROVAL ("PMA")

20. At all relevant times the United States Food and Drug Administration ("FDA") was the federal agency responsible for protecting the health and safety of the public and enforcing The Food Drug and Cosmetic Act, 21 U.S.C. §§321 *et seq.* as amended by the Medical Device Amendments of 1976 (collectively, "the FDCA").

21. The FDCA prohibits the introduction of adulterated medical devices into interstate commerce.

22. A device is adulterated under the FDCA if, among other things it: (1) does not comply with applicable performance standards; (2) it is a Class III device that does not comply with PMA requirements; or (3) if the methods, facilities, or controls used for its manufacture, packing, storage, or installation are not in conformity with current Good Manufacturing Practices ("cGMPs"). 21 U.S.C. §§351(e), (f), and (h). This Act ensures, among other things, that medical devices intended for use in humans are safe and effective for each of their intended uses and that the labeling of such medical devices bears true and accurate information.

23. At all times herein relevant, the FDCA required every manufacturer of a new device to obtain approval from the FDA prior to marketing and selling its device in interstate commerce.

24. To obtain such approval, the FDCA assigns all devices into one of three classes, depending on the degree of regulatory control necessary to provide reasonable assurance of the safety and effectiveness of the device for its intended use. Class I devices pose the lowest risk to consumers' health and do not require FDA approval for marketing. This includes devices such as tongue depressors. Class II devices pose intermediate risk and often include special controls, including post-market surveillance and guidance documents. Class III devices pose the greatest risk and encompass most implantable surgical devices, including several types of implantable orthopedic devices for spine and hip surgery. INFUSE has been classified as a Class III device.

25. At all times herein relevant, the FDCA provided four different ways for a manufacturer to obtain approval to introduce a device intended for human use into interstate commerce. One way is to seek Premarket Approval ("PMA") of the particular device. Before a company can market a Class III device, it is required to submit a PMA application to the FDA that provides the FDA with a reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. §§ 360e(a)(2), (d)(2). In order to show safety and effectiveness, the applicant must submit proof to the FDA, typically in the form of clinical trial results. *INFUSE* received PMA on July 2, 2002 for certain limited uses as will be set forth herein.

26. The FDCA requires that a submission for a device approval include proposed labeling for the purported intended uses of the device that includes, among other things, the conditions for therapeutic use. A device manufacturer is

not permitted to promote and market a new device until it has an approval, including approval for the proposed labeling. Moreover, if approved, the device manufacturer is permitted to promote the device only for the medical conditions specified in the approved labeling. Uses not approved by the FDA are known as "unapproved" or "off-label" uses. Devices that are promoted for off-label uses that have not been approved by the FDA are deemed misbranded under the FDCA.

27. *INFUSE*'s label specified the limited surgical application for which it was approved. Notwithstanding this limited approval Medtronic actively promoted, marketed, sold, and distributed *INFUSE* for use in surgeries that was not approved for such promotion under the PMA requirements violating the FDCA by introducing adulterated medical devices into interstate commerce.

28. Additionally, Defendants violated the FDCA by introducing adulterated medical devices into interstate commerce when they failed to comply with cGMP.

INFUSE PMA LIMITATIONS

A. Spinal Fusion Surgery

29. Spine surgeons have, for decades, employed spinal fusion to treat a number of conditions, including treatment of a fractured vertebra, spinal deformities (spinal curves or slippages), back pain from instability, or abnormal or excessive movement between vertebrae. Spinal fusion is similar to the concept of welding, and is 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.

Spinal fusion eliminates or reduces movement between vertebrae through the use of bone grafts.

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

31. For many years, autologous bone graft has been considered the "gold standard" in spinal fusion surgery.

32. 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.

33. As an alternative to autograft, some 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 the harvest procedure required in an autograft.

34. Studies revealing the ability for biologically manufactured protein to generate bone growth in laboratory animals represented a potential to provide a

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

35. Attempting to seize on this potentially lucrative opportunity to develop an alternative spinal fusion procedure, Medtronic acquired the exclusive rights rhBMP-2 for spinal applications. rhBMP-2 is a genetically engineered version of a naturally occurring protein that stimulates bone growth, and is developed as a commercially viable bone morphogenetic protein ("BMP") technology.

36. On January 12, 2001, Medtronic filed for *INFUSE* PMA and was granted expedited review status by the FDA.

B. *INFUSE* was *Only* Approved for *ALIF* Procedures

37. On July 2, 2002, the FDA approved *INFUSE* as a medical device containing an absorbable collagen sponge that is treated with rhBMP-2, but only for certain limited uses.

38. The FDA's limited use approval of *INFUSE* was based on concerns about potential adverse events that already had been reported with the product by the time of approval. As a result, the FDA approved *INFUSE* only for a small percentage of the spinal fusion surgery marketplace, with the device label specifying the limited surgical application for the device.

39. In July 2002, the FDA initially-approved *INFUSE* as two components:(1) the *LT-CAGE® Lumbar Tapered Fusion Device Component*, a

thimble-sized hollow metal cylinder which keeps the two vertebrae in place and provides a frame that contains and directs the development of new bone growth; and (2) the *Infuse Bone Graft Component*, which includes (a) an absorbable collagen sponge ("ACS") that acts as a carrier and scaffold for the active ingredient in Infuse Bone Graft, and (b) rhBMP-2, the actual active ingredient that is reconstituted in sterile water and applied to the ACS. Although these two components are sold separately, the initial approved labeling for the product indicates that *Infuse Bone Graft* must be used with the *LT-CAGE* component.

40. The labeling also directs the specific manner in which both components are to be used in a fusion procedure, requiring the use of both components in any approved surgery.

41. According to the label sought by Medtronic in the PMA phase, and subsequently approved by the FDA, *INFUSE* can only be used in an Anterior Lumbar Interbody Fusion ("*ALIF*") procedure, involving a single-level fusion in the L4-S1 region of the lumbar spine. *ALIF* is performed by approaching the spine from the front through an incision in the abdomen. It is primarily used to treat pain resulting from disc collapse.[1]

42. There are numerous other lumbar spine surgical procedures for which *INFUSE* has not been approved but for which it was promoted and/or utilized. These other lumbar procedures include: (a) Posterior Lumbar Interbody Fusion

[1] 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 and later granted approval for uses in certain oral maxillofacial surgeries.

("*PLIF*"), a procedure that is used to treat nerve compression and back pain resulting from a number of causes, and involves approaching the spine from the back. *PLIF*, however, is a more sensitive surgical approach and procedure because the spinal canal and nerves are posterior to the vertebral body, and because a surgeon must manipulate the dural sac (the membranous sac that encases the spinal cord within the vertebral column) to perform the *PLIF* procedure; (b) Posterolateral Fusion which is similar to the *PLIF* procedure, but instead of removing the disc space and replacing it with a bone graft, the disc space remains intact and the bone graft is placed between the transverse processes in the back of the spine. This allows the bone to heal and stabilize the spine by fusing the transverse process of one vertebra to the transverse process of the next vertebra; and (c) Transforaminal Lumbar Interbody Fusion ("*TLIF*"), which is also similar to the *PLIF* procedure, and is a technique utilized when an inter-body fusion is performed via a posterior approach. *TLIF* allows the surgeon to perform a fusion from a posterior approach without disturbing the dural sac by approaching the spine via a more lateral, or sideways, approach.

43. There are numerous other surgical spine procedures for which *INFUSE* was not approved but for which it was promoted and/or utilized. These other procedures include: (a) all cervical spine placements of *INFUSE*; (b) all thoracic spine placements of *INFUSE* and (c) all surgeries where the *LT-CAGE* and/or the collagen sponge, are not used.

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

45. Complications from clinical trials resulted from *INFUSE*'s very mechanism of action. In such cases, *INFUSE* can stimulate bone growth where new bone is not desired and can lead to excessive bone growth in the target area, causing severe swelling.

46. There is insufficient scientific evidence concerning the proper dosages of rhBMP-2 for use in different procedures or the expected responses to the protein in different biological environments.

47. Many adverse events associated with the use of *INFUSE* resulted from off-label use of the product by surgeons who did not fully understand the powerful nature of this rhBMP-2 protein, nor did Medtronic provide any clinical or other scientific evidence to support the usages recommended by Medtronic. In fact, Medtronic provided the medical community with misleading and false studies showing unfounded support for off-label *INFUSE* usage.

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

49. At the conclusion of the hearing, the FDA Advisory Panel again reiterated concerns regarding the potential for off-label use, specifically admonishing Medtronic to guard against use of the device for surgical procedures other than the specific *ALIF* procedure it was approved for. Panel member Dr. John Kirkpatrick noted his concern that procedures other than *ALIF* could result in harm to patients.

50. Plaintiff is informed and believes and based thereon alleges that Medtronic assured the Panel that there would be full compliance with the approval of *INFUSE* as indicated in the label, despite knowing that such compliance would reduce the potential market for *INFUSE* by 85%, and having no intention of complying with, and meeting, the concerns of the Panel.

51. Plaintiff is informed and believes and based thereon alleges that, even at the time of *INFUSE*'s FDA approval, Medtronic and its senior management were well aware of the concern regarding off-label uses of *INFUSE* and the potential dangers posed by them.

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

product were concealed by Medtronic from surgeons, including plaintiff's surgeon, hospitals, and operating room staffs.

53. Numerous medical studies published since the introduction of *INFUSE* have shown that its use in procedures not approved by the FDA can lead to serious, and even deadly, adverse events.

54. The authors of a May 15, 2006 medical article in *Spine* entitled *Controlling Bone Morphogenetic Protein Diffusion and Bone Morphogenetic Protein-Stimulated Bone Growth Using Fibrin Glue* observed that these complications often result from the product's mechanism of action: "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."

55. Although *INFUSE*'s two main and separate components, the rhBMP-2 and the LT-Cage, were approved by the FDA to only be used together; these two components were packaged and sold separately. Further, the sales of the rhBMP-2 component greatly outpaced those of the *LT-Cage*, which is an obvious indicator of the rampant off-label use of *INFUSE* that Medtronic promoted, knew about and fostered from the start

56. In 2008, the FDA published a public health notification linking the off-label use of *INFUSE* in the cervical spine with life-threatening swelling in patient's throats and necks.

57. Plaintiff is informed and believes and based thereon alleges that in 2011, the FDA declined to approve a higher strength version of *INFUSE* called *AMPLIFY* due to concerns that the product may cause cancer.

58. In July of 2011, the prominent medical journal, *The Spine Journal*, dedicated its entire journal to publishing numerous articles regarding the risks associated with *INFUSE*. The Journal's articles discussed Medtronic's failure to accurately report the side effects from its clinical trials, Medtronic's failure to report that many of the authors who studied and promoted *INFUSE* had significant financial ties to Medtronic, and that *INFUSE* can lead to severe side effects.

59. Plaintiff is informed and believes and based thereon alleges that in furtherance of the unlawful over-promotion of *INFUSE*, Medtronic engaged numerous non-employee physicians to publically challenge the findings of the authors contributing to articles in *The Spine Journal*, offering unsubstantiated and false declarations of the safety of *INFUSE*, as well as maliciously and falsely attacking the credibility of those authors.

MEDTRONICS PROMOTED INFUSE FOR UNAPPROVED AND OFF LABEL USES, INCLUDING USE IN THE CERVICAL SPINE

60. Plaintiff is informed and believes and based thereon alleges that, at all times herein relevant, notwithstanding these reports and the FDA Advisory Panel's earlier concerns, as set forth below, Medtronic's senior management concealed Medtronic's surreptitious effort to promote the widespread off-label use of *INFUSE*.

61. Plaintiff is informed and believes and based thereon alleges that Medtronic did also enter into an agreement that despite the FDA's narrow

indication for *ALIF*, that they would promote the product for other off-label uses, including but not limited to cervical and thoracic placement, thus expanding the market to include surgeons and medical institutions treating patients such as the plaintiff, who, without the patient even knowing, would receive *INFUSE* in an experimental and dangerous surgery.

62. Plaintiff is informed and believes and based thereon alleges that Medtronic did create a marketing plan that explicitly included the improper over-promotion of off-label uses, by artificially lowering the price of the surgery and instructing their sales forces to visit physicians and other health care providers and mislead them into the false belief that *INFUSE* was proven safe and effective for many forms of spinal surgeries, if not all of them.

63. Plaintiff is informed and believes and based thereon alleges that as a result of its extensive, proactive efforts at off-label promotion, use of Medtronic's *INFUSE* is estimated to be off-label 85% of the time.

64. Plaintiff is informed and believes and based thereon alleges that Medtronic provided millions of dollars in undisclosed payments to doctors (including so-called "Key Opinion Leaders") who published articles in medical journals, delivered presentations at continuing medical education courses, and appeared at consulting engagements addressing off-label applications of *INFUSE*. In turn, Medtronic's sales force would direct other doctors to these consultants and Key Opinion Leaders or their written work to further drive off-label sales of *INFUSE*.

65. Plaintiff is informed and believes and based thereon alleges that Dr. Thomas A. Zbeblick, the Chairman of the Department of Orthopedics and Rehabilitation at the University of Wisconsin, who co-authored preliminary studies that led to the FDA's approval of *INFUSE*, received over $34 million from Medtronic from 1996 to 2010 for consulting services and royalty payments, without any indication of this obvious conflict of interest, required by authors similarly situated.

66. Plaintiff is informed and believes and based thereon alleges that several of Medtronic's physician payments from 1996 to 2010 reached upwards of $22 million for Dr. Scott Boden, Dr. Regis Haid, Jr., and Dr. Volker Sonntag. Numerous other physician payments amounted to several millions of dollars.

67. Under applicable FDCA and FDA regulations, device and drug manufacturers such as Medtronic are prohibited from actively promoting 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 were designed to ensure that the FDA's careful, deliberate consideration of a product's suitability for public consumption is not undermined by manufacturers seeking to circumvent that process.

68. Plaintiff is informed and believes and based thereon alleges that on July 18, 2006, Medtronic announced that it had entered into a settlement agreement with the Department of Justice ("DOJ") and agreed to pay $40 million to

resolve two whistleblower lawsuits that alleged that Medtronic's Spinal division had engaged in illegal marketing and sales practices, including the payment of improper consulting fees to doctors to promote spinal products. However, Medtronic determined to continue their aggressive and surreptitious off-label promotion of *INFUSE* through the very practices that led to the initiation of the whistleblower litigation and the DOJ Settlement.

69. Plaintiff is informed and believes and based thereon alleges that as part of the DOJ settlement, Medtronic agreed to enter into a five-year Corporate Integrity Agreement 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 Corporate Integrity Agreement 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 transactions subject to an established set of internal controls and review processes, including monitoring by Medtronic senior management and Chief Compliance Officer.

THE OFF-LABEL USE OF *INFUSE* IN THE CERVICAL SPINE IS NOT SAFE OR EFFECTIVE

70. Plaintiff is informed and believes and based thereon alleges, that as a result of Medtronic's undisclosed misconduct, the percentage of off-label INFUSE usage increased over time, including after the Department of Justice Settlement. Medtronic's continuous over-promotion of *INFUSE* in off-label uses led the FDA to

issue a Public Health Notification warning letter on July 1, 2008. This warning, issued approximately two years after the DOJ Settlement, warned Medtronic against the off-label use of *INFUSE* in the cervical spine.

71. Plaintiff is informed and believes and based thereon alleges, that the July 1, 2008, Public Health Notification letter warned about complications from the off-label use of *INFUSE* in the neck, or cervical, area of the spine. The FDA reported that it had received 38 reports over a four year period through July 1, 2008, of complications from cervical uses of *INFUSE*; and, that some reports were of life-threatening and fatal events. Some of the complications were associated with swelling of the neck and throat tissue, which resulted in compression of the airway and/or neurological structures in the neck, and patients reported difficulty swallowing, breathing and speaking. Several patients required emergency treatment, including tracheotomies and the insertion of feeding tubes.

72. Plaintiff is informed and believes and based thereon alleges, that the FDA noted that the anatomical proximity of the cervical spine to airway structures in the body has contributed to the seriousness of the events reported and the need for emergency medical intervention with the off-label use of *INFUSE* in the cervical spine.

73. The July 1, 2008 FDA safety alert regarding Medtronic's *INFUSE* product was intended to alert physicians to:

> ... reports of life-threatening complications associated with recombinant human Bone Morphogenetic Protein

(rhBMP) when used in the cervical spine. **Note that the safety and effectiveness of rhBMP in the cervical spine have not been demonstrated and these products are not approved by FDA for this use.**

FDA Public Health Notification: Life-threatening Complications Associated with Recombinant Human Bone Morphogenetic Protein in Cervical Spine Fusion, issued July 1, 2008 (http://www.fda.gov/cdrh/safety/070108-rhbmp.html) (emphasis in original).

74. These concerns are not limited to the FDA. At a recent spine conference in 2008, a group of North Carolina surgeons reported on a study that found a complication rate of 59% in cervical spine surgeries with *INFUSE*, as compared to a 21% complication rate using conventional fusion surgery, which involves bone grafts or collagen. The study, conducted between July 2005 and December 2007, examined 76 patients.

75. In one lawsuit related to the off-label use of *INFUSE* in the cervical spine, surgeon Bryan Wellman, M.D., a defendant in the suit, testified at deposition that a Medtronic sales representative encouraged him to use *INFUSE* off-label in cervical spine operations, and that he has done more than 100 such procedures with the product. Dr. Wellman testified that he discussed with the Medtronic employee the right dosage of the *INFUSE* material to use in the cervical spine surgeries, but determined the dosage on his own.

MEDTRONIC IMPROPERLY PROMOTED AND MARKETED THE OFF-LABEL USE OF INFUSE IN THE CERVICAL SPINE TO PHYSICIANS

76. Medical device companies look for surgeons who will use a high volume of their devices in addition to surgeons who are known as "Key Opinion Leaders." Key Opinion Leaders are physicians whose opinions on medical devices are held in high regard by their colleagues. If these influential physicians are willing to promote the use of a certain device, then other surgeons are likely to follow suit and use that device.

77. Many medical device companies, including Medtronic, cultivate relationships with these Key Opinion Leaders, paying them large consulting fees, travel expenses for seminars, and other perks, to encourage these physicians to promote the use of a particular medical device.

78. Not only did Medtronic engage in such activities with respect to *INFUSE*, it improperly paid doctors to promote the off-label use of *INFUSE* in cervical spine fusions.

79. Medtronic, Inc. and Medtronic Sofamor Danek USA, Inc. have been named as defendants in two qui tam actions, *United States ex rel. (UNDER SEAL) v. Medtronic. Inc., et al.,* Civil Action No. 02-2709 (W. D. Tenn.), and *United States ex rel. Poteet v. Medtronic, Inc., et al.,* Civil Action No. 03-2979 (W. D. Tenn.) (the "Qui Tam Lawsuits"), both of which allege that Medtronic violated the False Claims Act, 31 U.S.C. 3729, *et seq.,* by paying illegal kickbacks to certain physicians in connection with promoting the off-label use of *INFUSE* in the cervical spine, which resulted in the submission of false or fraudulent claims to federal health care programs.

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

81. Based on its investigation, the federal government contended that certain of the payments, services, and remuneration discussed above were improper, resulted in the submission of false or fraudulent claims, and gave rise to certain legal claims.

82. In July, 2006, Medtronic agreed to pay $40 million to the United States to settle these lawsuits under the False Claims Act, 31 U.S.C. §§ 3729-3733; the Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a, and the Program Fraud Civil Remedies Act, 31 U.S.C. §§ 3801-3812.

83. As a result of this settlement, Medtronic agreed to enter into a Corporate Integrity Agreement with the Department of Health and Human Services Office of Inspector General.

84. Also as a result of this settlement, Medtronic agreed to negotiate with

representatives of the National Association of Medicaid Fraud Control Units to reach an agreement that provides for distribution of certain sums to the several states with which Medtronic defendants agree to a settlement concerning the conduct at issue in the lawsuits.

85. Plaintiff is informed and believes and based thereon alleges that Medtronic presently markets smaller and unapproved sizes of *INFUSE* despite the fact that *INFUSE* was only approved for placement within the lumbar region of the spine, thus increasing their sales. Plaintiff is informed and believes and based thereon alleges, that as a result of its illegal off-label promotion, sales of Medtronic *INFUSE* have soared and have totaled billions of dollars.

86. Plaintiff is informed and believes, and based thereon alleges that Medtronic sales representatives/consultants received a small booklet the size of an address book that was about five pages long and contained information regarding the volume and dosage of rhBMP-2 that should be used in off-label applications of *INFUSE*.

87. Plaintiff is informed and believes and based thereon alleges that Medtronic developed a CD series that included information on off-label procedures, and even sponsored a physician training program that involved cadaver labs as a way of instructing surgeons on off-label applications.

88. Absent Medtronic's extensive off-label promotion campaign, physicians, such as the plaintiff's would be without the requisite specific information to even attempt to perform off-label *INFUSE* surgeries.

89. Plaintiff is informed and believes and based thereon alleges that Medtronic over-promoted to plaintiff's physician, and plaintiff's physician relied on Medtronic's over-promotion to his detriment and the detriment of the plaintiff. Furthermore, plaintiff's orthopaedic surgeon would not have performed the off-label surgeries had he not been encouraged and instructed on how to do so by other defendants in this lawsuit.

90. In October of 2012, the United States Senate Committee on Finance printed a document entitled, *Staff Report on Medtronic's Influence on Infuse Clinical Studies* and concluded as its findings:

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

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

3) An e-mail exchange shows that a Medtronic employee recommended against publishing a complete list of adverse events possibly associated with *INFUSE* in a 2005 *Journal of Bone and Joint Surgery* article.

4) Medtronic officials inserted language into studies that promoted *INFUSE* as a better technique than taking a bone graft from the pelvic bone (autograft technique) by emphasizing the pain of the autograft technique.

5) Documents indicate that Medtronic prepared Dr. Hal Mathew's remarks to the FDA Advisory Panel meeting prior to *INFUSE* being approved. At the time, Dr. Mathews was a private physician but was hired as a vice president at Medtronic in 2007.

6) Medtronic documents show the company unsuccessfully attempted to adopt weaker safety rules for a clinical trial studying *INFUSE* in the cervical spine that would have allowed the company to continue the trial in the event that patients experienced severe swelling in the neck.

91. Plaintiff is informed and believes and based thereon alleges that to bolster the

> findings herein described, the United States Senate Committee Finance Report described and attached numerous key emails between high level Medtronic employees and consultants, including but not limited to:In 2002, Dr. John Kenneth Burkus, an orthopedic surgeon and a self-described "consultant" for Medtronic, wrote a frustrated email pertaining to a Medtronic study, wherein he writes, "ALL I NEED IS FOR THE OTHER ASSHOLES ON THE PAPER TO SIGN THE COPYRIGHT RELEASE FORM. Maybe they feel bad because they did not write one word."
>
> Julie Bearcroft, Director of Technology Management within Biologics for Medtronic, wrote to Dr. Burkus, "I personally think it is appropriate to simply report the adverse events were equivalent in the two groups without the detail." Dr. Burkus followed Julie Bearcroft's advice

> and omitted reports of adverse events associated with INFUSE.
>
> Rick Treharne, who worked in various VP positions for Medtronic, but is not a doctor of any sort, wrote in an email to Dr. Burkus, with a revised copy of a spinal surgery study attached, "[thanks] for letting me help out with this. This was fun." Bill Martin, VP of spinal marketing for Medtronic, commented on surgeons using the off-label posterior approach to spinal fusion surgery with INFUSE, "We may want to steer clear of calling it a flawed technique. There are still quite a few surgeons utilizing [it]."

92. Plaintiff is informed and believes and based thereon alleges that 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, Congress, the United States Army, several major universities, multiple medical journals, numerous major newspapers, independent physicians, and investors.

COUNT I

(NEGLIGENCE AGAINST MEDTRONIC DEFENDANTS)

93. The plaintiff repeats and alleges each prior and subsequent allegation as if fully set forth herein.

94. On January 10, 2011, the plaintiff underwent a cervical spine surgery. His surgeon, Dr. Nolden, performed a cervical fusion using the Medtronic *INFUSE Bone Graft*. *INFUSE Bone Graft* had only received limited approval by the FDA to be used in an Anterior Lumbar Interbody Fusion ("*ALIF*") and had not been approved for a cervical procedure. In fact, the FDA had warned that *INFUSE* was unsafe and not effective in cervical procedures. However, as a means of enhancing

sales, Medtronic illegally promoted *INFUSE* beyond the legal and limited uses for which it had been approved.

95. A proximate cause of the plaintiff's injuries and damages is the negligence of Medtronic through its agents, sales representatives, paid Key Opinion Leaders, servants and/or employees acting within the course and scope of their employment, negligently, carelessly and recklessly researching, manufacturing, selling, merchandising, advertising, promoting, labeling, analyzing, testing, distributing, and marketing *INFUSE Bone Graft*, and including among other things:

(a) Negligently and carelessly engaging in the illegal off-label promotion of *INFUSE Bone Graft* by recommending its use to physicians, including Dr. Nolden, and instructing them to use *INFUSE Bone Graft* in procedures for which it had not been approved;

(b) Negligently, carelessly and recklessly promoting the off-label use of *INFUSE Bone Graft* by instructing, promoting and directing the use of the product without the mandatory *LT-CAGE* component;

(c) Negligently, carelessly and recklessly failing to disclose that usage of *INFUSE Bone Graft* in cervical procedures had not been approved by the FDA;

(d) Negligently, carelessly and recklessly failing to disclose to physicians that the promoted off-label use of *INFUSE Bone Graft* can result in serious side effects;

(e) Negligently, carelessly and recklessly failing to fully disclose the results of the testing and other information in its possession regarding the possible adverse reactions associated with the off-label use of *INFUSE Bone Graft*;

(f) Negligently, carelessly and recklessly representing that the off-label use of *INFUSE Bone Graft* was safe when, in fact, it was unsafe;

(g) Negligently, carelessly and recklessly promoting *INFUSE Bone Graft* beyond the narrow and limited uses for which it was approved;

(h) Negligently, carelessly and recklessly failing to adequately warn the medical community, the general public, plaintiff's surgeon and plaintiff of the dangers, contra-indications, and side effects from the off-label use of *INFUSE Bone Graft*; and/or

(i) Negligently, carelessly and recklessly failing to act as a reasonably prudent drug manufacturer.

96. Before the plaintiff was given the *INFUSE Bone Graft* through a cervical procedure, Medtronic, based upon the state of knowledge as it existed at the time, knew or should have known that such a use could be dangerous and unsafe, and knew or should have known that such a use could result in, among other things, unwanted bone growth, seroma, bone migration, bone resorption, swelling of the neck and throat tissue which results in compression of the airway and/or neurological structures in the neck, paralysis, and difficulty swallowing, breathing and speaking, oftentimes requiring emergency treatment, including tracheotomies and the insertion of feeding tubes and emergency corrective surgeries.

97. As a direct and proximate result of the acts and conduct of Medtronic, the plaintiff has been injured in his health, strength and activity, and has suffered, continues to suffer and, on information and belief, will suffer indefinitely into the future, severe, lasting and debilitating physical and mental pain and suffering, some of which injuries may be permanent, all to his damage in an amount in excess of the jurisdictional minimum of the Court.

98. As a further direct and proximate result of the acts and conduct of the Medtronic defendants, plaintiff has lost earnings and earning capacity, and will continue to incur such losses for an indefinite period of time in the future, and some of which losses may be permanent, all in an amount excess of the jurisdictional minimum of the Court.

99. As a further direct and proximate result of the acts and conduct of the Medtronic defendants, and each of them, plaintiff has incurred medical, hospital and related expenses and, on information and belief, will continue to incur such expenses in the future, all in an amount in excess of the jurisdictional minimum of the Court.

WHEREFORE, the plaintiff requests that judgment be entered in his favor against each of the Medtronic defendants for the full amount of his compensatory damages as determined in a trial by jury, which amount greatly exceeds the minimum jurisdictional amount in the Circuit Court of Cook County, Law Division, along with costs and all other relief the Court determines just and appropriate.

COUNT II

(STRICT LIABILITY AGAINST MEDTRONIC DEFENDANTS)

100. The plaintiff repeats and alleges each prior and subsequent allegation as if fully set forth herein.

101. At the time the *INFUSE Bone Graft* utilized in the plaintiff's surgery on January 10, 2011 left the control of the Medtronic defendants it was defective and unreasonably dangerous in one or more of the following respects:

(a) Due to illegal off-label promotion to physicians, including Dr. Nolden;

(b) The off-label use of *INFUSE Bone Graft*, as given to the plaintiff, was ineffective, defective and

dangerous when manufactured, designed, promoted, and instructed by Medtronic, who is strictly liable for the injuries arising from its use;

(c) The risks attendant to the off-label use of *INFUSE Bone Graft* promoted by Medtronic greatly outweighed any possible benefits to be expected;

(d) The off-label use of *INFUSE Bone Graft* failed to perform in a manner that a reasonable consumer would expect it to perform;

(e) Medtronic knew that the *INFUSE Bone Graft* manufactured, designed, and sold by it, when used off-label in the manner described above and as promoted and instructed by Medtronic, was defective and dangerous in the manner hereinbefore described;

(f) That Medtronic knew that, because said use was dangerous and defective when so used off-label, the product could not be safely used for the purpose intended;

(g) That Medtronic, knowing that said product when used off-label was defective and dangerous, acted in a despicable manner and in conscious disregard of the safety of the public, including the plaintiff, when it placed the product on the market without warning of the defect, and knew when so placed that it would be used without inspection for defect when so used;

(h) By placing said product on the market and promoting said off-label use, Medtronic impliedly represented it was safe for the purpose intended, and intended that doctors should rely on their misrepresentations;

(i) Due to promoting the off-label use of *INFUSE Bone Graft* without the mandatory *LT-CAGE* component;

(j) Not disclosing that usage of *INFUSE Bone Graft* in cervical procedures had not been approved by the FDA;

(k) Not revealing to physicians that the promoted off-label use of *INFUSE Bone Graft* can result in serious side effects;

(l) Not fully disclosing the results of the testing and other information regarding the possible adverse reactions associated with the off-label use of *INFUSE Bone Graft*;

(m) Due to representations that the off-label use of *INFUSE Bone Graft* was safe when, in fact, it was unsafe;

(n) Due to promotion of *INFUSE Bone Graft* beyond the narrow and limited uses for which it was approved; and/or

(o) Due to inadequate warnings to the medical community, including plaintiff's surgeon of the dangers, contra-indications, and side effects from the off-label use of *INFUSE Bone Graft*.

102. As a direct and proximate result of one or more or all of the aforementioned unreasonably dangerous conditions, the plaintiff sustained personal injuries and damages of a personal and pecuniary nature including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability, disfigurement and loss of a normal life. These losses are permanent.

WHEREFORE, the plaintiff requests that judgment be entered in his favor against each of the Medtronic defendants for the full amount of his compensatory damages as determined in a trial by jury, which amount greatly exceeds the minimum jurisdictional amount in the Circuit Court of Cook County, Law Division, along with costs and all other relief the Court deems just and appropriate.

COUNT III

(BREACH OF WARRANTY AGAINST MEDTRONIC DEFENDANTS)

103. The plaintiff repeats and alleges each prior and subsequent allegation as if fully set forth herein.

104. At the time the *INFUSE Bone Graft* utilized in the plaintiff's surgery on January 10, 2011 left the control of the Medtronic defendants it was defective and in breach of express and implied warranties in one or more of the following respects:

(a) Due to illegal off-label promotion to physicians, including Dr. Nolden;

(b) The off-label use of *INFUSE Bone Graft*, as given to the plaintiff, was ineffective, defective and dangerous when manufactured, designed, promoted, and instructed by Medtronic, who is strictly liable for the injuries arising from its use.

(c) The risks attendant to the off-label use of *INFUSE Bone Graft* greatly outweighed the benefit to be expected from said use as promoted by Medtronic;

(d) The off-label use of *INFUSE Bone Graft* failed to perform in a manner that a reasonable consumer would expect it to perform;

(e) Medtronic knew that the *INFUSE Bone Graft* manufactured, designed, and sold by it, when used off-label in the manner described above and as promoted and instructed by Medtronic, was defective and dangerous in the manner hereinbefore described;

(f) That Medtronic knew that, because said use was dangerous and defective when so used off-label, the product could not be safely used for the purpose intended;

(g) That Medtronic, knowing that said product when used off-label was defective and dangerous, acted in a despicable manner and in conscious disregard of the safety of the public, including the plaintiff, when it placed the product on the market without warning of the defect, and knew when so placed that it would be used without inspection for defect when so used;

(h) By placing said product on the market and promoting said off-label use, Medtronic impliedly represented it was safe for the purpose intended, and intended that doctors should rely on their misrepresentations;

(i) Due to promoting the off-label use of *INFUSE Bone Graft* without the mandatory *LT-CAGE* component;

(j) Not disclosing that usage of *INFUSE Bone Graft* in cervical procedures had not been approved by the FDA;

(k) Not revealing to physicians that the promoted off-label use of *INFUSE Bone Graft* can result in serious side effects;

(l) Not fully disclosing the results of the testing and other information regarding the possible adverse reactions associated with the off-label use of *INFUSE Bone Graft*;

(m) Due to representation that the off-label use of *INFUSE Bone Graft* was safe when, in fact, it was unsafe;

(n) Due to promotion of *INFUSE Bone Graft* beyond the narrow and limited uses for which it was approved; and/or

(o) Due to inadequate warnings to the medical community, including plaintiff's surgeon of the dangers, contra-indications, and side effects from the off-label use of *INFUSE Bone Graft.*

105. As a direct and proximate result of one or more or all of the aforementioned breaches of warranty, the plaintiff sustained personal injuries and damages of a personal and pecuniary nature including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability, disfigurement and loss of a normal life. These losses are permanent.

WHEREFORE, the plaintiff requests that judgment be entered in his favor against each of the Medtronic defendants for the full amount of his compensatory damages as determined in a trial by jury, which amount greatly exceeds the minimum jurisdictional amount in the Circuit Court of Cook County, Law Division, along with costs and all other relief the Court deems just and appropriate.

COUNT IV

(WILLFUL AND WANTON CONDUCT AGAINST THE MEDTRONIC DEFENDANTS)

106. The plaintiff repeats and alleges each prior and subsequent allegation as if fully set forth herein.

107. The Medtronic defendants are guilty of willful and wanton conduct which shows an utter indifference to or conscious disregard for the safety of the plaintiff and others.

108. As a pharmaceutical company, Medtronic had an affirmative continuing duty to warn the medical community regarding risks it knew, learned, or should have known about associated with its medical devices and pharmaceutical products.

109. Medtronic concealed adverse information and provided inaccurate or misleading information which was material to treating surgeons' treatment decisions, which misled surgeons and patients who were relying on those surgeons' professional judgment, including the plaintiff and his treating surgeon.

110. This misleading information, along with omissions of material facts related to *INFUSE Bone Graft*'s safety and efficacy, caused health care providers, patients and the general public, including the plaintiff and his surgeon, to be misled about *INFUSE Bone Graft*'s risks and benefits and interfered with surgeons making proper risk/benefit assessments about the use and off-label use of *INFUSE Bone Graft*.

111. Through internal adverse event reports, Medtronic knew that the off-label use of *INFUSE Bone Graft* could lead to serious side effects, including but not limited to, unwanted bone growth, seroma, bone migration, bone resorption, swelling of the neck and throat tissue which results in compression of the airway and/or neurological structures in the neck, paralysis, and difficulty swallowing, breathing and speaking, oftentimes requiring emergency treatment, including tracheotomies and the insertion of feeding tubes and emergency corrective surgeries. Medtronic failed to take any measures whatsoever to alert surgeons or the public regarding these risks and instead continued to promote the off-label use of *INFUSE Bone Graft* as safe and effective.

112. Plaintiff is informed and believes and based thereon alleges that, despite knowing that the off-label promotion of *INFUSE Bone Graft* was illegal, Medtronic, through its sales representatives and Key Opinion Leaders, promoted the off-label use of *INFUSE Bone Graft* to Dr. Nolden and the staff and physicians at Dr. Nolden's hospitals, including Northwestern Memorial Hospital, and concealed that the off-label use of *INFUSE Bone Graft* could result in unwanted bone growth, seroma, bone migration, bone resorption, swelling of the neck and throat tissue which results in compression of the airway and/or neurological structures in the neck, paralysis, and difficulty swallowing, breathing and speaking, oftentimes requiring emergency treatment, including tracheotomies and the insertion of feeding tubes and emergency corrective surgeries.

113. Plaintiff is informed and believes and based thereon alleges that, when the above representations and/or omissions were made by Medtronic, it knew those representations and/or omissions to be false, or willfully and wantonly and recklessly disregarded whether the representations and/or omissions were true. These representations and/or omissions were made by Medtronic with the intent of defrauding and deceiving the public and the medical community and with the intent of inducing surgeons, hospitals and medical practices (including Dr. Nolden, Northwestern Memorial Hospital and Northwestern Orthopaedic Institute LLC) to use *INFUSE Bone Graft* off-label.

114. Plaintiff is informed and believes and based thereon alleges that, at the time the aforesaid representations and/or omissions were made by Medtronic, the plaintiff and his medical providers were unaware of the falsity of said representations and/or omissions and reasonably relied upon Medtronic's assertions, promulgated through aggressive sales tactics as set forth herein, that the off-label use of *INFUSE Bone Graft* was safe and effective when, in fact, it was neither.

115. Plaintiff is informed and believes and based thereon alleges that, in direct and indirect reliance upon said representations and/or omissions, Dr. Nolden used *INFUSE Bone Graft* in an off-label cervical procedure. Had Dr. Nolden been made aware of the serious risks associated with such use, he would not have used it.

116. Plaintiff is informed and believes and based thereon alleges that Medtronic's motive in failing to advise surgeons and the medical community of these risks and inefficacies was for financial gain and fear that, if it provided proper and adequate information, the *INFUSE Bone Graft* would lose sales and market share.

117. Plaintiff is informed and believes and based thereon alleges that, at all times herein mentioned, the actions of Medtronic, its agents, servants, and/or

employees was wanton, grossly negligent, and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of the plaintiff in particular and to the public generally in that Medtronic did willfully and knowingly promote the off-label use of *INFUSE Bone Graft* with the specific knowledge that it would be used by surgeons without adequate instructions and without adequate knowledge regarding its efficacy, risks and side effects.

118. Plaintiff is informed and believes and based thereon alleges that, at all times relevant herein, Medtronic's conduct was malicious, fraudulent, and oppressive toward the plaintiff in particular and the public generally, and Medtronic conducted itself in a willful, wanton, and reckless manner. Despite its specific knowledge regarding risks as set forth above, Medtronic deliberately recommended the off-label use of INFUSE Bone Graft and promoted it as being safe and effective.

WHEREFORE, the plaintiff requests that judgment be entered in his favor against each of the Medtronic defendants for the full amount of his compensatory damages as determined in a trial by jury, which amount greatly exceeds the minimum jurisdictional amount in the Circuit Court of Cook County, Law Division, along with costs and all other relief the Court deems just and appropriate. In addition, at the appropriate time under Illinois law, the plaintiff expects to file a motion for leave to add a claim for punitive damages based on evidence already in plaintiff's possession and which will be obtained during discovery in this case.

COUNT V

(MEDICAL MALPRACTICE—NEGLIGENCE)

119. The plaintiff repeats and alleges each prior and subsequent allegation as if fully set forth herein.

120. At all relevant times Mark T. Nolden, M.D. was an employee, agent and/or apparent agent of Northwestern Memorial Hospital and Northwestern Orthopaedic Institute LLC acting within the scope of his employment, agency and/or apparent agency rendering these entities vicariously liable for Dr. Nolden's negligent care and treatment of the plaintiff.

121. It was the duty of the defendant Mark T. Nolden, M.D. to provide treatment to the plaintiff that complied with the applicable standard of care, yet in violation of this duty, Dr. Nolden did:

(a) Negligently and carelessly use INFUSE Bone Graft during surgery on the plaintiff on January 10, 2011; and/or

(b) Negligently and carelessly fail to possess the knowledge he should have had about the absence of benefits and the unnecessary risks involved in using INFUSE Bone Grafting on the type of surgery he performed on the plaintiff on January 10, 2011.

122. As a direct and proximate result of this negligence, the plaintiff suffered and will continue to suffer past and future damages of a personal and pecuniary nature including, but not limited to, medical expenses, pain and suffering, disfigurement, disability, emotional distress, caretaking expenses, loss of earnings and earning capacity, and loss of a normal life.

123. Counsel for the plaintiff has attached an affidavit as required by § 2-622(a)(2) of the Illinois Code of Civil Procedure, which is incorporated by reference.

Wherefore, the plaintiff respectfully requests judgment be entered in his favor and against Northwestern Memorial Hospital, Northwestern Orthopaedic

Institute LLC and Mark T. Nolden, M.D. in an amount which will fully and fairly compensate him for all of his losses, which substantially exceed the minimum jurisdictional amount in the Circuit Court of Cook County.

COUNT VI

(MEDICAL MALPRACTICE—LACK OF INFORMED CONSENT)

124. The plaintiff repeats and alleges each prior and subsequent allegation as if fully set forth herein.

125. At all relevant times Mark T. Nolden, M.D. was an employee, agent and/or apparent agent of Northwestern Memorial Hospital and Northwestern Orthopaedic Institute LLC acting within the scope of his employment, agency and/or apparent agency rendering these entities vicariously liable for Dr. Nolden's negligent care and treatment of the plaintiff.

126. Dr. Nolden failed to inform the plaintiff he was going to use *INFUSE Bone* Graft, off-label or otherwise, and of those risks of and or alternatives to the use of *INFUSE Bone Graft* which a reasonably well-qualified spine surgeon would have disclosed under the same or similar circumstances.

127. If Dr. Nolden had disclosed he was going to use *INFUSE* and those risks of and or alternatives to the use of *INFUSE Bone Grafting* a reasonable person in the plaintiff's position would not have submitted to use of *INFUSE Bone Grafting.*

128. As a result of the use of *INFUSE Bone Grafting* the plaintiff was injured.

129. Dr. Nolden's failure to disclose those risks of and or alternatives to the use of *INFUSE Bone Grafting* was a proximate cause of the plaintiff's injury and the plaintiff suffered and will continue to suffer past and future damages of a

personal and pecuniary nature including, but not limited to, medical expenses, pain and suffering, disfigurement, disability, emotional distress, caretaking expenses, loss of earnings and earning capacity, and loss of a normal life.

130. Counsel for the plaintiff has attached an affidavit as required by § 2-622(a)(2) of the Illinois Code of Civil Procedure as Exhibit A to this conplaint, which is incorporated by reference.

Wherefore, the plaintiff respectfully requests judgment be entered in his favor and against Northwestern Memorial Hospital, Northwestern Orthopaedic Institute LLC and Mark T. Nolden, M.D. in an amount which will fully and fairly compensate him for all of his losses, which substantially exceed the minimum jurisdictional amount in the Circuit Court of Cook County.

COUNT VII

(NORTHWESTERN MEMORIAL HOSPITAL – INSTITUTIONAL NEGLIGENCE)

131. The plaintiff repeats and alleges each prior and subsequent allegation as if fully set forth herein.

132. In this case, on information and belief, Northwestern Memorial Hospital was negligent in that its professional standards, bylaws, regulations, policies, procedures and practices apparently permitted cervical spine surgery to occur at the hospital using *INFUSE Bone Grafts* that were not approved by the FDA for use in cervical spine surgery, were not proven effective for this application and which were fraught with needless and senseless unnecessary risks that the plaintiff was not even told about.

133. As a direct and proximate result of the aforementioned negligent acts or omissions, the plaintiff suffered and will continue to suffer past and future damages of a personal and pecuniary nature including, but not limited to, medical expenses, pain and suffering, disfigurement, disability, emotional distress, caretaking expenses, loss of earnings and earning capacity, and loss of a normal life.

134. Counsel for the plaintiff has attached an affidavit as required by § 2-622(a)(2) of the Illinois Code of Civil Procedure, which is incorporated by reference.

Wherefore, the plaintiff respectfully requests judgment be entered in his favor and against Northwestern Memorial Hospital in an amount which will fully and fairly compensate him for all of his losses, which substantially exceed the minimum jurisdictional amount in the Circuit Court of Cook County.

COUNT VIII

(NORTHWESTERN ORTHOPAEDIC INSTITUTE LLC – INSTITUTIONAL NEGLIGENCE)

135. The plaintiff repeats and alleges each prior and subsequent allegation as if fully set forth herein.

136. In this case, on information and belief, Northwestern Orthopaedic Institute LLC was negligent in that its professional standards, bylaws, regulations, policies, procedures and practices apparently permitted cervical spine surgery to be performed by its spine surgeons using *INFUSE Bone Grafts* that were not approved by the FDA for use in cervical spine surgery, were not proven effective for this application and which were fraught with needless and senseless unnecessary risks that the plaintiff was not even told about.

137. As a direct and proximate result of the aforementioned negligent acts or omissions, the plaintiff suffered and will continue to suffer past and future damages of a personal and pecuniary nature including, but not limited to, medical expenses, pain and suffering, disfigurement, disability, emotional distress, caretaking expenses, loss of earnings and earning capacity, and loss of a normal life.

138. Counsel for the plaintiff has attached an affidavit as required by § 2-622(a)(2) of the Illinois Code of Civil Procedure, which is incorporated by reference.

Wherefore, the plaintiff respectfully requests judgment be entered in his favor and against Northwestern Orthopaedic Institute LLC in an amount which will fully and fairly compensate him for all of his losses, which substantially exceed the minimum jurisdictional amount in the Circuit Court of Cook County.

PLAINTIFF DEMANDS TRIAL BY JURY

Karl L. Sanda,

By: _____
One of his attorneys

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IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS,
COUNTY DEPARTMENT, LAW DIVISION

KARL L. SANDA, Plaintiff, v. MEDTRONIC, INC., MEDTRONIC SOFAMOR DANEK USA, INC., NORTHWESTERN MEMORIAL HOSPITAL, NORTHWESTERN ORTHOPAEDIC INSTITUTE, LLC and MARK T. NOLDEN, M.D., Defendants.	)	Case No.

AFFIDAVIT OF PLAINTIFF'S COUNSEL

I, David E. Rapoport, under oath do swear the following facts are true and correct to the best of my knowledge:

1. My name is David E. Rapoport and I am an attorney licensed to practice law in Illinois.

2. On January 2, 2013, my firm and I were retained to represent Karl Sanda in personal injury claims he has arising out of a surgery that was performed at Northwestern Memorial Hospital on January 10, 2011.

3. Mr. Sanda and I believe he has valid medical malpractice, product liability and other claims arising out of this surgery.

4. I am familiar with the requirements of § 2–622 of the Illinois Code of Civil Procedure and since we were retained so recently, I am unable to obtain the consultation required by § 2–622(a)(1) before the expiration of the statute of

limitations. Therefore, I am filing this affidavit pursuant to § 2–622(a)(2) of the Illinois Code of Civil Procedure which states: "If an affidavit is executed pursuant to this paragraph, the certificate and written report required by paragraph 1 shall be filed within 90 days after the filing of the complaint. The defendant shall be excused from answering or otherwise pleading until 30 days after being served with a certificate required by paragraph 1."

David E. Rapoport

SUBSCRIBED & SWORN
to before me, this 10th day of
January, 2013

Notary Public

OFFICIAL SEAL
MARY REID
NOTARY PUBLIC - STATE OF ILLINOIS
MY COMMISSION EXPIRES:01/10/15