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UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

WALTER NISBET, individually, and as successor in interest to and Personal Representative of the Estate of the Decedent Shirley Nisbet, LORI NISBET, individually, MICHAEL NISBET, individually, and THOMAS NISBET, individually,

Plaintiffs

v.

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

Defendants.

Case No.

COMPLAINT FOR DAMAGES

Jury Trial Demanded

(1) Fraudulent Omission and Concealment
(2) Strict Products Liability – Failure to Warn
(3) Strict Products Liability – Manufacturing or Design Defect
(4) Breach of Implied Warranty
(5) Negligence
(6) Negligence Per Se
(7) Wrongful Death

Plaintiffs WALTER NISBET, individually, and as Personal Representative of the Estate of Shirley Nisbet who died on August 30, 2008, LORI NESBIT, individually, MICHAEL NISBET, individually, and THOMAS NISBET, individually, (hereinafter "Plaintiffs"), by and through their counsel, Lieff Cabraser Heimann & Bernstein, LLP, and James A. Dunlap, Jr. & Associates, LLP, allege as follows:

I. INTRODUCTION

1. Plaintiffs, by and through their undersigned counsel, hereby institute this Civil Action Complaint against MEDTRONIC, INC. ("Medtronic"), a Minnesota corporation and MEDTRONIC SOFAMOR DANEK, USA, INC. ("MSD") as a result of injuries, including death suffered by Shirley Nisbet. This case involves spinal stimulating bone graft known as the Infuse® Bone Graft.

2. The medical device in question, the Infuse® Bone Graft, was promoted and sold to be used off-label to treat Shirley Nisbet. Infuse® Bone Graft is approved and indicated for lumbar surgery that is performed through the abdomen. It is not approved for use in cervical surgery. When the medical device is used off-label, it often causes the patient's throat to swell and can cause decreased oxygen to the brain, thereby creating a life-threatening condition, as it did in this case involving the Decedent Shirley Nisbet.

3. Because of Defendants' wrongful conduct, hundred of patients, like Decedent Shirley Nisbet, underwent surgeries without knowing the risks that they faced. These patients' doctors were persuaded by Medtronic and Medtronic's consultant "opinion leaders," who are paid physician promoters, and Medtronic sales representatives, to use the product off-label.

4. As a result, Decedent Shirley Nisbet suffered grievous bodily injuries and death, and her husband, Plaintiff WALTER NISBET, suffered the loss of consortium, society, love and comfort of his beloved wife; and their daughter, Plaintiff LORI NISBET and their sons, Plaintiffs MICHAEL NISBET and

THOMAS NISBET lost the comfort, love and support of their beloved mother.

A. <u>The Infuse® Bone Graft Device</u>

5. MEDTRONIC, INC. and MEDTRONIC SOFAMOR DANEK USA, INC. (collectively "Medtronic" or the "Medtronic Defendants" or "Defendants") designed and marketed the Infuse® Bone Graft device ("Infuse®") for lumbar spine surgery.

6. Infuse® is a bio-engineered bone filling material containing a bone morphogenetic protein ("BMP"), and is used as an alternative to grafting a patient's own bone, typically from the patient's hip. The purpose of Infuse® is to accomplish the same clinical outcomes as grafting a patient's own bone into these locations but without the difficulties of grafting bone from the hip and other sites, since grafting sites typically have side effects such as pain and long recovery

7. It uses a genetically engineered protein – rhBMP – to help fuse vertebrae in the lower (lumbar) spine in order to treat degenerative disc disease.

8. The device consists of three components split among two parts: 1. a metallic spinal fusion cage, and; 2. the bone graft substitute which consists of a genetically-engineered human protein (rhBMP-2) along with a sponge-like carrier or scaffold for the protein (manufactured from bovine collagen) that is placed inside the fusion cage.

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

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

B. Background on bone morphogenetic proteins in the Infuse® Bone Graft

11. The active ingredient in the INFUSE® Bone Graft is rhBMP-2, a manufactured version of a protein already present in the body that promotes new bone growth.

12. Certain BMPs have been studied for decades because of their ability to heal bone and eliminate the need for bone graft harvesting from other parts of the body. Approximately 20 BMPs have been discovered, but only six appear capable of initiating bone growth. Of these, rhBMP-2 has been studied more than any other BMP and is FDA approved for use only in lower spinal, tibia fractures, and dental surgeries.

13. Naturally occurring BMP is found within the bone itself, but only in small amounts. To provide clinically useful and reproducible amounts of isolated, human BMP, it must be manufactured in a special facility.

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

C. The FDA Approval Process

15. Infuse® was approved by the Food and Drug Administration ("FDA") on July 2, 2002, for use only in the lower region of the spine (at levels L4 through S1) to treat degenerative disc disease, and was approved only for anterior surgeries at L4 through S1. That meant that it was initially approved only to be used by surgeons, when the surgeons placed the cage within the vertebrae in the lumbar region of the back, and only by entrance through the abdomen.

16. Infuse® is also used to fill space where bone is needed in order to place dental implants (for example, dental implants with an exposed head used to secure dental devices such as crowns, fixed bridges, or dentures.) In dental

surgeries, Infuse® is used to make enough bone in the sinus area to place dental implants in the upper jaw. Infuse® is also used to increase bone in extraction sites prior to implant placement.

17. Infuse® was approved by the FDA on March 9, 2007, for dental use.

18. In addition to use in lower spine fusion surgeries and dental surgeries, Infuse® has been approved for only one other use, that of repair of tibial fractures that have already been stabilized with IM nail fixation after appropriate wound management.

19. Infuse® has never been approved by the FDA for use in other parts of the body or for use in any other type of procedure, and any such uses are "off-label" uses. And while physicians may use FDA-approved medical devices in any way they see fit, companies are not permitted to promote off-label uses for their medical devices or to pay doctors inducements or kickbacks to promote the off-label uses or to perform procedures using the devices off-label.

20. The use of Infuse® for cervical spine fusion surgery has never been approved by the FDA, and the use of this product in the cervical spine is an off-label use.

D. Infuse® is a very profitable part of Medtronic's business

21. Infuse® has become a best seller for Medtronic.

22. One market analyst has publicly estimated that the product's sales are approximately $815 million for the fiscal year ended in April, 2008. Medtronic has been depending heavily on Infuse® since sales in so many of its other products, such as cardiac defibrillators, have slowed because of the historic recalls of those defibrillators.

E. The off-label use of Infuse® in the cervical spine is not safe or effective

23. Christopher B. Shields, chairman of neurological surgery at the

University of Louisville, says it was apparent by late 2004 that using Infuse® in the neck area could cause serious problems.

24. Susan Levine, a vice president at Hayes, Inc., which evaluates medical technologies for insurers, has reported that she has reviewed the research work on Infuse®, and finds it "really distressing to see something like this used in a potentially harmful way and without adequate evidence." Ms. Levine has reportedly said that, when used properly, Infuse® can be "good for a patient."

25. Questions about off-label use cropped up before the product was approved. For example, in early 2002, one member of an FDA advisory committee reviewing Infuse® asked agency staff for recommendations on "guarding against off-label use of this product."

26. A number of patients say they have been harmed in off-label uses of Infuse®, which is approved by the FDA only for a small section of the spine in the lower, or lumbar, region. At least 280 reports of adverse events involving Infuse® have been made to the FDA. Approximately 75% of those reports involve off-label use.

27. On July 1, 2008, the FDA issued a Public Health Notification 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.

28. 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.

29. 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)

30. 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.

31. 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 under oath 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.

F. Despite lack of safety and effectiveness, Medtronic improperly promoted and marketed to physicians the off-label use of Infuse® in the cervical spine

32. Medical device companies look for surgeons who will use a high volume of their devices and surgeons who are known as "Opinion Leaders." Opinion leaders are physicians whose opinions on medical devices are held in high regard. 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.

33. Many medical device companies, including Medtronic, cultivate relationships with these opinion leaders, paying them handsome consulting fees, travel expenses for seminars, and other perks, to encourage these physicians to promote the use of a particular medical device.

34. 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.

35. 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 and MSD 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.

36. In these lawsuits, the United States Department of Justice contended that between January 1, 1998 and April 30, 2003, MSD 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

37. Based on its investigation, the United States 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.

38. 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.

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

40. Also as a result of this settlement, Medtronic and MSD 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 and MSD agree to a settlement concerning the conduct at issue in the lawsuits.

G. September 30, 2008 letters from United States Senators Herb Kohl and Charles Grassley to Medtronic regarding ongoing concerns over Medtronic's payments to doctors related to the promotion and marketing of Infuse®

41. Despite this July, 2006 Settlement with the United States, concerns regarding Medtronic's off-label marketing activities and related payments to doctors continued.

42. On September 30, 2008, U.S. Senator Herb Kohl sent a letter to

Medtronic noting that earlier in 2008, Medtronic's outside counsel provided to the Special Committee on Aging a written account of Medtronic's efforts to comply with the July, 2006 Settlement Agreement it reached with the United States Department of Justice concerning allegations that Medtronic and its subsidiary improperly compensated surgeons and physicians in connection with the Infuse® device.

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

> That account also addressed the corporate integrity agreement (CIA) that Medtronic and its subsidiary entered into with the Office of the Inspector General of the United States Department of Health and Human Services stemming from those same allegations. In that same letter to the Committee, Medtronic and its subsidiary both denied that "improper payments were made to physicians in the first place (Medtronic's agreement with DOJ does not contain any admission of liability), much less that improper payments 'have continued.'" Consequently, it was with concern that I read recent articles, in the *Wall Street Journal* and elsewhere, which outlined highly disturbing allegations of improper, if not illegal, payments by Medtronic to surgeons and physicians.
>
> These continuing allegations are directly relevant to the Committee's oversight of inappropriate physician compensation practices within the medical device industry. All of the major orthopedic device companies that settled with DOJ over such allegations were

> required to publicly reveal information related to their payments to physicians. Medtronic's response to the Committee's initial inquiry articulated no specific reasons as to why Medtronic has yet to voluntarily make the same disclosures.

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

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

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

> Last week, the *Wall Street Journal (WSJ)* reported on allegations of financial perks provided to doctors that included "entertainment at a Memphis strip club, trips to Alaska and patent royalties on inventions they played no part in."[1] I would appreciate your assistance in better understanding these allegations and would like to take this opportunity to lay out my specific concerns and questions.

47. Senator Grassley went on to express his concern over the *Wall*

[1] David Armstrong, "Lawsuit Says Medtronic Gave Doctors Array of Perks," *Wall Street Journal*, September 25, 2008.

Street Journal's reports "that one of the incentives Medtronic provided physicians was to include them on patents for medical devices and reward them with royalties, even though the physicians may not have contributed to the development of the product."

48. This letter specifically addressed issues related to Medtronic's marketing of Infuse®:

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

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

II. JURISDICTION AND VENUE

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

III. PARTIES

51. The Plaintiffs in this action are as follows:

52. Plaintiff WALTER NISBET, the surviving spouse of Decedent Shirley Nisbet, who was a resident of San Juan Capistrano, California. WALTER NISBET is a resident of San Juan Capistrano, California.

53. Plaintiffs' Decedent, Shirley Nisbet, was the beloved mother of the Plaintiffs LORI NISBET, MICHAEL NISBET, and THOMAS NISBET.

54. LORI NISBET is a resident of Vista, California.

55. MICHAEL NISBET is a resident of Cimarron, Colorado.

56. THOMAS NISBET is a resident of Redondo Beach, California.

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

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

59. Medtronic maintains facilities dedicated to conduct research and development, manufacturing, or distribution in the following Southern California locations: Chatsworth and Northridge (Los Angeles County), Corona (Riverside County), Goleta (Santa Barbara County), and Santa Ana (Orange County). Medtronic also operates two Bakken Education Centers in Los Angeles and Woodland Hills (Los Angeles County), where thousands of medical professionals visit each year to gain hands-on experience with new technologies.

IV. SUMMARY OF ALLEGATIONS

60. Plaintiffs' Decedent, Shirley Nisbet, suffered grievous personal injuries and died on or about August 30, 2008, in Baldwin Park, California as a direct and proximate result of Defendants' misconduct.

61. Decedent would not have chosen to be treated with Defendants'

product had she known of or been informed by Defendants of the true risks of using the product.

62. At all times relevant, the Infuse® bone graft (hereinafter "Infuse®") was researched, developed, manufactured, marketed, promoted, advertised and sold by Medtronic.

63. At all times relevant, Medtronic misrepresented the safety of Infuse®, and negligently manufactured, marketed, advertised, promoted, sold and distributed it as a safe and effective device to be used for spinal fusion surgery. Medtronic negligently, recklessly, and/or intentionally overpromoted Infuse® to physicians and consumers, and downplayed to physicians and consumers its dangerous effects, including but not limited to the overpromotion and downplaying of dangerous effects of Infuse® in off-label cervical spine surgeries.

64. Any warnings Medtronic may have issued concerning the dangers of off-label use of Infuse® in the cervical spine were insufficient in light of Medtronic's promotional efforts and overpromotion of Infuse®.

65. At all times relevant to this action, Medtronic knew, and/or had reason to know, that Infuse® was not safe for the patients for whom it was used "off-label", because it had not been approved for use in the cervical spine; and its safety and efficacy for use in the cervical spine was either unknown, or was known by Medtronic to be unsafe and ineffective.

66. In cervical spine surgeries, Infuse® often leads to serious and sometimes fatal complications including, but not limited to, swelling of the neck and throat tissue resulting in compression of the airway and/or neurological structures in the neck, difficulty swallowing, breathing or speaking, and severe dysphagia – exactly what occurred to Plaintiffs' Decedent Shirley Nisbet.

67. When used in the cervical spine, Infuse® has often failed to work in a safe and effective manner, and was defective, and thereby caused serious medical problems and, in some patients, like Plaintiffs' Decedent, catastrophic

injuries and death.

68. At all times relevant to this action, Medtronic knew, and/or had reason to know, that its representations and suggestions to physicians that Infuse® was safe and effective for use in the cervical spine were materially false and misleading.

69. As a result of defective design and manufacture, the off-label use of Infuse® in the cervical spine can cause serious physical injuries and/or death.

70. Medtronic knew and/or had reason to know of this likelihood and the resulting risk of injuries and deaths, but concealed this information and did not warn Plaintiffs' Decedent or her physicians, preventing Plaintiffs' Decedent and her physicians from making informed choices about the selection of other treatments or therapies.

71. Plaintiffs' Decedent and her physicians relied on Medtronic's misrepresentations regarding the safety and efficacy of Infuse® in connection with their decisions to use Infuse® off-label in Decedent's cervical spine surgery. Plaintiffs' Decedent and her physicians did not know of the specific risks, and/or were misled by Medtronic as to the nature and incidence of the true specific risks, related to the use of Infuse® in cervical spine surgeries.

72. Medtronic promoted and marketed Infuse® to Decedent's physicians for off-label use in the cervical spine, and this promotion and marketing caused Decedent's physicians to decide to implant Infuse® in Decedent's cervical spine.

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

other Defendants, knowing that their collective conduct constituted a breach of duty owed to the Plaintiff.

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

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

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

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

78. The burden of proof should be upon each Defendant to prove

that the Defendant has not caused the harms suffered by the Plaintiffs.

V. PLAINTIFFS' DECEDENT SHIRLEY NISBET

79. Early on August 21, 2008, Shirley Nisbet was admitted by her orthopedic surgeon, Dr. Johannes Bernbeck, to Baldwin Park Medical Center in Baldwin Park, California for cervical spine surgery to address ongoing neck pain.

80. During the surgery, a Medtronic representative was present in the Operating Room. Prior to and during the surgery, the Medtronic sales representative encouraged and recommended to Dr. Bernbeck that he use the Medtronic Infuse® devise in Mrs. Nisbet's cervical spine.

81. During the surgery, Dr. Bernbeck placed the Medtronic Infuse® bone graft into the cervical spine in order to attempt to fuse some of the vertebrae in Mrs. Nisbet's cervical spine.

82. Mrs. Nisbet's post-operative period was marked by increasingly severe pain, swelling of the neck, mental status changes, difficulty swallowing and difficulty breathing. Because of her uncontrolled pain, Mrs. Nisbet required intravenous pain medication, which caused her to become uncharacteristically confused and upset.

83. Although Dr. Bernbeck and his physician's assistant, William Hendry, had prematurely prepared Ms. Nisbet for discharge on August 23, 2008, two days after her surgery, they quickly abandoned that idea early on August 23, 2008.

84. Her symptoms of neck swelling, and difficulty swallowing and breathing became progressively worse, until, in the early morning hours of August 26, 2008, her breathing became so compromised because of neck swelling and compression to her airway that she stopped breathing altogether and went into full respiratory arrest at 4:19 a.m.

85. Unfortunately, it took several minutes to place a breathing tube effectively, depriving Ms. Nisbet's brain of enough oxygen to function during that

crucial time period. She remained in a vegetative state for several days thereafter, being kept alive by artificial means until she succumbed to death on August 30, 2008.

VI. CLAIMS FOR RELIEF

FIRST CLAIM FOR RELIEF
(Fraudulent Omission And Concealment)

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

87. The Medtronic Defendants had a confidential and special relationship with Plaintiffs' Decedent due to (a) Defendants' vastly superior knowledge of the health and safety risks relating to Infuse®, and (b) Defendants' sole and/or superior knowledge of their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® for cervical spine fusion surgery.

88. As a result, Defendants had an affirmative duty to fully and adequately warn Plaintiffs' Decedent and her physicians of the true health and safety risks related to the off-label use of Infuse®, and Defendants had a duty to disclose their dangerous and irresponsible practices of improperly promoting to physicians the off-label use of Infuse® for cervical spine fusion surgery. Independent of any special relationship of confidence or trust, Defendants had a duty not to conceal the dangers of the off-label use of Infuse® to Plaintiffs' Decedent and her physicians.

89. Misrepresentations made by the Medtronic Defendants about the health and safety of Infuse® independently imposed a duty upon Defendants to fully and accurately disclose to Plaintiffs' Decedent and her physicians the true health and safety risks related to Infuse®, and a duty to disclose their dangerous and irresponsible off-label promotion and marketing practices.

90. In connection with their Infuse® products, Defendants

fraudulently and intentionally concealed important and material health and safety product risk information from Plaintiffs' Decedent and her physicians, all as alleged in this Complaint.

91. Any of the following is sufficient to independently establish Defendants' liability for fraudulent omission and/or concealment:

a. Defendants fraudulently concealed the health and safety hazards, symptoms, constellation of symptoms, diseases and/or health problems associated with the off-label use of their Infuse® product in the cervical spine;

b. Defendants fraudulently concealed their practice of promoting and marketing to physicians, including Plaintiffs' decedent's physician, the off-label use of Infuse® in cervical spine surgery;

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

92. Defendants knew that Plaintiffs' Decedent and her physicians would regard the matters Defendants concealed to be important in determining their course of treatment, including their decision whether or not to use Infuse® in cervical spine surgery.

93. As a direct and proximate result of Defendants' fraudulent concealment and suppression of material health and safety risks relating to Infuse® and of Defendants' dangerous and irresponsible off-label promotion and marketing practices, Plaintiffs and the Decedent suffered injuries, harm, and death, and economic loss, and Plaintiffs will continue to suffer injuries, harm, damages and economic loss.

94. As the direct, proximate and legal cause and result of the Defendants' fraudulent concealment and suppression of material health and safety risks relating to Infuse® and of Defendants' dangerous and irresponsible marketing and promotion practices, Plaintiffs have been injured and have incurred damages,

including but not limited to the death of their decedent, medical and hospital expenses, physical and mental pain and suffering, funeral expenses, and Decedent's loss of the enjoyment of life.

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

96. Defendants' conduct, as alleged above, was malicious, intentional and/or reckless, outrageous, and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs' Decedent and was such as warrants an award of punitive damages.

97. The aforesaid cause of action has survived to the Plaintiffs by virtue of the California Survival law, Cal. Code Civ. Proc., §§377.20, 377.30 – 377.35, 377.40 – 377.41.

SECOND CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY – FAILURE TO WARN

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

99. Medtronic had a duty to warn Plaintiffs' Decedent and her physicians about the dangers of Infuse® of which they knew, or in the exercise of ordinary care, should have known, at the time the Infuse® left the Defendants' control. The Medtronic Defendants did know of these dangers of off-label use of Infuse®, and breached this duty by failing to warn Plaintiff's Decedent and her physicians of the dangers of its off-label use in cervical surgery.

100. Medtronic failed to warn Plaintiffs' Decedent and her physicians of the dangers associated with Infuse® when used off-label in cervical spine surgery including, but not limited to, compression of the airway and/or neurological structures in the neck, difficulty swallowing, breathing and speaking, dysphagia, neck and throat swelling, respiratory arrest, and death.

101. As a direct and proximate result of one or more of the above listed dangerous conditions and defects, Plaintiffs' Decedent sustained serious injuries of a personal and pecuniary nature prior to her death on or about August 30, 2008.

102. Plaintiffs' Decedent sustained extreme pain, suffering, and anguish from the date of her cervical spine surgery with Infuse® until she died.

103. The aforesaid cause of action has survived to the Plaintiffs by virtue of the California Survival law, Cal. Code Civ. Proc., §§377.20, 377.30 – 377.35, 377.40 – 377.41.

THIRD CLAIM FOR RELIEF
STRICT PRODUCTS LIABILITY – MANUFACTURING OR DESIGN DEFECT

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

105. The Medtronic Defendants' Infuse® device was defectively designed and manufactured at the time that it left the Defendants' control.

106. Infuse® was unreasonably dangerous in that it was unsafe when used as it was promoted by Medtronic for use in off-label cervical spine surgeries.

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

108. The Infuse® product failed to perform as safely as an ordinary consumer would expect and/or the risk of danger inherent in the design outweighs the benefits of the design.

109. The Medtronic Defendants' unreasonably dangerous and defectively designed and manufactured Infuse® was the direct, legal and proximate cause of Decedent's damages and her death including, but not limited to, medical hospital expenses and funeral expenses in the past.

110. As a direct and proximate result of the Infuse® product's defective design and manufacture, Plaintiffs' Decedent sustained serious injuries of

a personal and pecuniary nature prior to her death on or about August 30, 2008.

111. Plaintiffs' Decedent sustained extreme pain, suffering, and anguish from the date of her cervical spine surgery with Infuse® until she died.

112. The aforesaid cause of action has survived to the Plaintiffs by virtue of the California Survival law, Cal. Code Civ. Proc., §§377.20, 377.30 – 377.35, 377.40 – 377.41.

FOURTH CLAIM FOR RELIEF
BREACH OF IMPLIED WARRANTY

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

114. The Medtronic Defendants' Infuse® product was intentionally designed, manufactured, promoted, distributed and sold to Plaintiffs' Decedent and/or to her physicians to be introduced into the human body for use only in certain types of lumbar spine surgeries, and for dental/facial surgeries.

115. The Medtronic Defendants knew, or had reason to know, the particular purpose for which the Infuse® product would be used and that Plaintiffs' Decedent and/or her physicians were relying on Defendants' skill or judgment to select and/or furnish a product suitable for that purpose.

116. Plaintiffs' Decedent and her physicians relied on the Medtronic Defendants' skill and/or judgment in deciding to purchase and use the Infuse® product.

117. The Medtronic Defendants breached the implied warranties of merchantability and fitness because the Medtronic Defendants' Infuse® product cannot pass without objection in the trade, is unsafe, is not merchantable, is unfit for its ordinary use when sold, is unfit for the purpose for which it was sold, and/or is not adequately packaged and labeled, and did not reasonably conform to the promises or affirmations of fact on the container or label.

118. These Defendants' breach of the warranties of merchantability

and fitness was the direct, legal and proximate cause of Decedent's damages and her death, including but not limited to medical and hospital expenses in the past.

119. As a direct and proximate result of these Defendants' breach of the warranties of merchantability and fitness, Plaintiffs' Decedent sustained serious injuries of a personal and pecuniary nature prior to her death on or about August 30, 2008.

120. Plaintiffs' Decedent sustained extreme pain, suffering, and anguish from the date of her cervical spine surgery with Infuse® until she died.

121. The aforesaid cause of action has survived to the Plaintiffs by virtue of the California Survival law, Cal. Code Civ. Proc., §§377.20, 377.30 – 377.35, 377.40 – 377.41.

FIFTH CLAIM FOR RELIEF
NEGLIGENCE

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

123. The Medtronic Defendants marketed their Infuse® product to and for the benefit of Plaintiffs' Decedent, and additionally marketed it to her physicians, and these Defendants knew or should have known that Plaintiffs' Decedent and her physicians would use their product, including for the off-label use of cervical spine fusion.

124. Defendants owed Plaintiffs' Decedent and her physicians duties to exercise reasonable or ordinary care under the circumstances in light of the generally recognized and prevailing best scientific knowledge.

125. Through the conduct described in the foregoing and subsequent paragraphs of this Complaint, the Defendants breached their duties to Plaintiffs' Decedent and to her physicians.

126. The following sub-paragraphs summarize these Defendants' breaches of duties to Plaintiffs' Decedent and her physicians and describe

categories of acts or omissions constituting breaches of duty by these Defendants. Each and/or any of these acts or omissions establishes an independent basis for these Defendants' liability in negligence:

a. Unreasonable and improper promotion and marketing of Infuse® to physicians, including but not limited to the promotion and marketing for the off-label use of cervical spine fusion surgeries;

b. Failure to warn physicians and Plaintiffs' Decedent of the dangers associated with Infuse® when used off-label in cervical spine surgery including, but not limited to, compression of the airway and/or neurological structures in the neck, difficulty swallowing, breathing and speaking, dysphagia, neck and throat swelling, respiratory arrest, and death.

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

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

128. As the direct, producing, proximate and legal cause and result of the these Defendants' negligence, Plaintiffs' Decedent suffered injuries and death.

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

130. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs' Decedent and was such as warrants an award of punitive damages.

131. The aforesaid cause of action has survived to the Plaintiffs by virtue of the California Survival law, Cal. Code Civ. Proc., §§377.20, 377.30 – 377.35, 377.40 – 377.41.

SIXTH CLAIM FOR RELIEF
NEGLIGENCE PER SE

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

133. The Medtronic Defendants violated applicable federal statutes and regulations relating to medical devices. Plaintiffs' Decedent was a person whom these statutes and regulations were meant to protect.

134. The Medtronic Defendants' violation of these statutes or regulations constitutes negligence *per se*.

135. The Medtronic Defendants' violation of these statutes or regulations was the direct, producing, proximate and legal cause of Plaintiffs' Decedent's injuries and damages. As the direct, producing and legal cause and result of the Defendants' negligence, Plaintiffs' Decedent was injured and died, and Plaintiffs thus incurred damages and losses.

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

137. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs" Decedent and was such as warrants an award of punitive damages.

138. The aforesaid cause of action has survived to the Plaintiffs by virtue of the California Survival law, Cal. Code Civ. Proc., §§377.20, 377.30 – 377.35, 377.40 – 377.41

SEVENTH CLAIM FOR RELIEF
WRONGFUL DEATH

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

140. Defendants marketed their Infuse® product to and for the

benefit of Plaintiffs' Decedent, and marketed it to her physicians, and Defendants knew or had reason to know of the unreasonable dangers and defects in their Infuse® product, and that Plaintiffs' Decedent and her physicians would use the product.

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

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

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

144. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Decedent died on or about August 30, 2008.

145. As the direct, producing, proximate and legal cause and result of the Defendants' breach of their duties, Plaintiffs, individually and as representatives of Decedent, have been injured and have incurred damages, including but not limited to medical and hospital expenses in the past, past mental pain and suffering, and have suffered loss of financial support, services, consortium, and the loss of the familial and emotional love, society and support of the Decedent.

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

147. Defendants' conduct, as alleged above, was malicious, intentional and outrageous and constituted willful and wanton disregard for the rights or safety of others. Such conduct was directed specifically at Plaintiffs' Decedent and was such as warrants an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Defendants, and each of them, as follows:

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

2. For punitive and exemplary damages according to proof against all Defendants;

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.

Dated: December 02, 2008

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DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all issues stated.

Dated: December 02, 2008

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