UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK
BUFFALO DIVISION

UNITED STATES OF AMERICA *EX REL.* JASON W. NICKELL,	)	CIVIL ACTION NO.
PLAINTIFF,	)	
v.	)	**FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730 (b)(2)**
MEDTRONIC, INC., ST. JUDE MEDICAL, INC. & BOSTON SCIENTIFIC CORPORATION	)	
DEFENDANTS	)	JURY TRIAL DEMANDED

COMPLAINT

Plaintiff and *qui tam* relator, Jason W. Nickell, through undersigned counsel, files this his False Claims Act Complaint against Defendants, Medtronic, Inc., St. Jude Medical, Inc. and Boston Scientific Corporation and respectfully shows the Court as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent statements, records, and claims made and caused to be made by Defendants and/or their agents and employees in violation of the Federal False Claims Act, 31 U.S.C. § 3729, *et seq*. (the "FCA" or "the Act").

2. This *qui tam* case is brought against Defendants for schemes by which they have provided unlawful remuneration to physicians as an inducement to refer neuromodulation implantation procedures to health care providers billing government health care programs and have knowingly caused health care providers to present false or fraudulent claims to Medicare

and other federal healthcare programs (collectively the "federal programs") for unapproved uses of misbranded neuromodulation devices in connection with novel, rapidly-evolving neurological procedures that have not yet been scientifically established as safe and effective. The intended uses for which Defendants have promoted their devices in connection with these procedures have not been approved by the Food and Drug Administration ("FDA") and the experimental procedures themselves are not reimbursable under the federal programs because they are medically unnecessary, investigational procedures that unnecessarily drive up the Government's costs. See *Svidler v. United States*, 2004 U.S. Dist. LEXIS 18325 (N.D. Calif. 2004).

3. By encouraging physicians to bill such investigational procedures under codes established many years ago for approved uses of the Defendants' devices and by providing unlawful remuneration of tens of thousands of dollars to physicians as an inducement to refer permanent implantation procedures to other health care providers, the Defendants have created a new, rapidly-expanding market for their devices and a potentially huge source of profit for themselves at the expense of the federal treasury.

II. PARTIES

4. Relator Jason W. Nickell is a resident of Austin, Texas.

5. Defendant, Medtronic, Inc., is a Minnesota corporation with its registered office at 710 Medtronic Parkway, Minneapolis, Minnesota. It is headquartered in Minneapolis and maintains regional offices, manufacturing facilities, service facilities, research and development facilities, and education centers worldwide. Medtronic is the industry leader in the neuromodulation market.

6. Defendant St. Jude Medical, Inc. is a Minnesota corporation with its registered office at 1 Lillehei Plaza, St. Paul, Minnesota 55117. It is headquartered in St. Paul and maintains more than 20 principal operational and manufacturing facilities worldwide. In 2005 it acquired Advanced Neuromodulation Systems of Plano, Texas, which holds the second place in the neuromodulation market.

7. Defendant Boston Scientific Corporation is a Delaware corporation with its headquarters at One Boston Scientific Place, Natick, Massachusetts 01760. It is the world's largest medical device company with 26 manufacturing, distribution and technology centers worldwide. It holds third place in the neuromodulation market.

III. JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. § 1331 and 31 U.S.C. § 3732. Section 1331 confers jurisdiction upon this Court for actions involving a federal question, and Section 3732 specifically confers jurisdiction upon this Court for actions such as this one brought pursuant to the False Claims Act. Further, Relator asserts that there has been no statutorily relevant public disclosures of the "allegations or transactions" upon which this Complaint is based, that he is the "original source" for these "allegations or transactions" due to his direct and independent knowledge of the information upon which the allegations are based, and that he has voluntarily provided the information upon which this Complaint is based to the Government before filing this action. *See* 31 U.S.C. § 3730 (e) (4).

9. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732 (a). Defendants can be found in, reside in, and/or transact business in the Western District

of New York. *See* 31 U.S.C. § 3732 (a). Further, Defendants have engaged in acts proscribed by the False Claims Act in the Western District of New York. *Id.*; 31 U.S.C. § 3729.

10. Venue is also proper in this District pursuant to 31 U.S.C. § 3732 (a). Defendants can be found in, transact, or have transacted business in the Western District of New York. *See* 31 U.S.C. § 3732 (a).

11. Upon information and belief, divisional venue is appropriate in the Buffalo division of the Western District of New York because Defendants have sold medical devices for off-label uses in one or more of the eight western counties of New York comprising this division. Local Rule 5.1 (b).

IV. BACKGROUND

Neuromodulation Technology

12. Neuromodulation is a rapidly evolving area of medical science. It involves the bionic use of implanted electrical devices similar to cardiac pacemakers to deliver low-voltage electrical stimulation to different parts of the nervous system. Neuromodulation is being touted as a potential treatment for a wide range of neurological and emotional conditions, including chronic pain, Parkinson's disease, Alzheimer's disease, migraine headaches, epilepsy, depression, obsessive-compulsive disorder, obesity and sexual dysfunction, among others.

13. Defendants and other medical device manufactures are viewing neuromodulation as one of their brightest prospects for rapid growth. For example, in recent press releases, Defendant Medtronic, the industry leader, has projected annual revenue growth in its neuromodulation segment of 13 to 15% annually. Defendant St. Jude Medical of St. Paul, Minnesota, acquired Advanced Neuromodulation Systems of Plano, Texas, in 2005 and recently

rechristened the business as the St. Jude Medical Neuromodulation Division, touting its "ongoing collaboration with physicians to develop new therapies for patients who have exhausted most other therapeutic options."

14. While development of new therapies and devices for treatment of pain and neurological disorders is a laudable objective, there is considerable marketing hype surrounding neuromodulation in no small part because it holds considerable profit potential not only for manufacturers, but also for physicians and other health care providers. In many if not most of its current and potential applications, neuromodulation has not yet withstood rigorous scientific study in controlled clinical trials.

15. In a 2006 article published in the Journal of Neurosurgery, Robert Coffey, M.D., a Medtronic employee, concluded that "[t]o date, there has been no successful clinical study focused on establishing the efficacy of neurostimulation for pain and incorporating sufficient numbers of participants, matched control groups, sham stimulation, randomization, prospectively defined end points, and methods for controlling experimental bias." Coffey et al, "Neurostimulation for Chronic Noncancer Pain: An Evaluation of the Clinical Evidence and Recommendations for Future Trial Design," J. NEUROSURGERY, Vol. 105, p. 175 (August, 2006). Dr. Coffey further stated that "[w]ell-designed studies are especially important to measure the efficacy of new and emerging neurostimulation treatments for chronic pain." Id, p. 186.

16. Many of the medical procedures for use of neuromodulation are peculiarly subject to the placebo effect because pain and the other neurological conditions they treat are subjective in nature. Unless the FDA and government healthcare providers exercise a gate-keeping function to restrain the pell-mell proliferation of these procedures by patients who will try almost

anything, physicians who stand to profit greatly and device manufacturers who stand to increase sales, the cost to the federal treasury could be considerable.

17. Relator is a 29-year-old medical device salesman who formerly made as much as $600,000 per year selling Medtronic neuromodulation devices to physicians and hospitals. He quit his job over concerns about the way that Medtronic devices were being promoted for an investigational procedure known as subcutaneous stimulation, Sub-Q or subcutaneous peripheral nerve field stimulation ("PNFS"). Because the three major medical device manufacturers have competing products, deal with the same physicians and utilize parallel sales techniques, Relator believes that Medtronic's competitors St. Jude and Boston Scientific promoted their products in the same way.

18. Although the schemes detailed in this complaint involve a discreet set of devices and procedures, the profit motives and methods of promotion disclosed may be only the tip of the iceberg in a burgeoning field that is ripe for abuse by both device manufacturers and health care providers.

The False Claims Act

19. President Abraham Lincoln originally proposed the False Claims Act, and the United States Congress enacted it in 1863 to combat fraud by defense contractors during the Civil War (hence, the Act was often called the "Lincoln Law"). Act of March 2, 1863, ch. 67, 12 Stat. 696. In 1986, after finding that federal program fraud was pervasive, Congress substantially amended the Act to enhance and modernize the Government's ability to recover the losses sustained. *See* Pub. L. 99-562, 100 Stat. 3153. The amendments were intended to create incentives for individuals with knowledge of federal program fraud to disclose the information

without fear of reprisals or Government inaction and to encourage the private bar to commit resources to prosecute fraud on the Government's behalf. *Id.*

20. The Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from $5,500 to $11,000 for each such claim, plus three times the amount of the damages sustained by the Federal Government. 31 U.S.C. § 3729 (a); Federal Civil Monetary Penalties Inflation Adjustment Act of 1990, Pub. L. 101–410; 64 FR 47099, 47104 (Aug. 30, 1999).

21. The Act allows any person having information about false or fraudulent claims to bring an action for himself and the Government and to share any recovery. 31 U.S.C. § 3730 (b). The Act requires that the complaint be filed under seal for a minimum of sixty days without service on the defendant during that time. *Id.* Based on these provisions, *qui tam* Relator Nickell seeks through this action to recover damages and civil penalties arising from Defendants' knowing fraud on the U.S. Government.

22. The violations of the False Claims Act set forth in this complaint are based upon the theory that the Defendants have knowingly caused physicians, hospitals and other health care providers to bill Medicare and other federal healthcare programs for (1) "misbranded" neuromodulation devices that are being promoted for an "intended use" for which they have not received FDA approval and are not properly labeled; (2) investigational, experimental procedures that are not medically necessary and are not subject reimbursement under federal healthcare plans; and (3) permanent implantation procedures that are referred to health care

providers as the result of illegal remuneration paid to pain physicians as an inducement for such referrals. See *United States v. Caronia*, 576 F. Supp. 2d 385 (E. D. N.Y. 2008) and *Svidler v. United States*, 2004 U.S. Dist. LEXIS 18325 (N. D. Calif. 2004).

V. ALLEGATIONS

Relator's Direct and Independent Knowledge of the Schemes

23. Relator Nickell began working for Defendant Medtronic in February 2005 as an Associate Therapy Consultant assigned to Medtronic's central and south Georgia territory. In May 2006, Medtronic promoted Mr. Nickell to Therapy Consultant, and he was given sole responsibility of the central and south Georgia territory. Mr. Nickell was then transferred to Austin, Texas, in June 2007, where he would eventually become the senior representative for the territory's Neuromodulation Unit in August 2007. He continued in this capacity until he resigned from Medtronic in August 2008.

24. When Relator Nickell was transferred to Texas, he was told he would be replacing Todd Zenisek, who had agreed to take a position with Medtronic's education department. Zenisek had finished the 2007 fiscal year as a "President's Club Award" winner, which meant Zenisek was in the top 5% of the national sales force with annual sales of $3.5 million in pain products. The other members of the Austin team included Evan Pritchard, also an associate therapy consultant, and Shelly Scamardo, a nurse/clinical specialist.

25. Upon meeting Zenisek, he informed Nickell of a unique way to market and sell Medtronic's neurostimulation products. Zenisek referred to this as "Sub-Q stim," short for subcutaneous stimulation. As a Medtronic sales rep, Relator Nickell was familiar with all approved uses for Medtronic's product; these approved uses were epidural leads placed in the

spine or peripheral leads placed directly on nerves. Zenisek described the Sub-Q stimulation as placing two leads just beneath the skin to produce a "TENS" unit-like paresthesia.

26. During Nickell's first week in Austin, he witnessed one of Zenisek's best customers, Dr. Andy McDavid of Temple, Texas perform four or five Sub-Q stimulation procedures. This new procedure took less than five minutes to complete. Zenisek instructed Nickell how the hospitals and doctors should bill or code the procedure for Medicare reimbursement. While Nickell was present, Zenisek instructed Dr. McDavid to bill the Sub-Q leads as peripheral nerve lead placements using CPT Code 64555.

27. Zenisek and Nickell worked together in Austin for approximately one month. During that time, Nickell accompanied Zenisek on various sales calls, many of them promoting Sub-Q stimulation. On each one of these sales calls, Zenisek instructed physicians to bill 64555 (peripheral nerve stimulation) for the placement of the Sub-Q leads. Zenisek explained to the physicians that they could combine the Sub-Q implants with their epidural implants and make upwards of $10,000 profit on each patient, while adding only minutes to the procedure time. Nickell witnessed Zenisek promoting Sub-Q stimulation to Dr. Mark Malone of Austin, Texas, Dr. Robert Wills, Dr. Matt McCarty, and Dr. Brannon Frank of Austin Pain Associates, and Dr. Rasheed Singleton and Dr. Biral Patel of Scott and White in Round Rock, Texas. Nickell witnessed each of these physicians implant and subsequently bill Sub-Q leads under the 64555 code as they had been instructed by Zenisek.

28. Zenisek left in August of 2008 to pursue his position with Medtronic's education department, and Mr. Nickell took over sole leadership of the Austin territory. Nickell's manger at that time was Marcus Reid out of Houston, Texas. During Mr. Nickell's time, Sub-Q implants in

Mr. Nickell's territory grew exponentially. Pain physicians performing trial procedures made thousands of dollars per patient, and the ambulatory surgical centers and hospital outpatient centers to which the pain physicians referred their patients for the permanent implantation procedures followed Medtronic's guidelines on how to bill using the 64555 billing code.

29. When billing and/or coding questions or issues arose, Medtronic's reimbursement specialist, Bill Douglas from Houston, Texas, would meet with the physician and/or hospital personnel, and explain to them Medtronic's recommended billing procedures.

30. It was quite common for physicians to question this off-label use and/or the billing and coding recommendations by Medtronic. In fact, Dr. Matt Schocket of Austin, Texas said that Sub-Q stimulation was “fraud, and bullshit, and unproven long-term." Other neurosurgeons refused to implant Sub-Q leads (Dr. Daniel Peterson, Austin, and Dr. Stokes, Austin). However, there were always more doctors willing to implant Sub-Q leads and make upwards of $10,000 for a five to fifteen minute procedure.

31. In the spring of 2008, Marcus Reid transitioned Manager responsibility to Mike Elkins of Dripping Springs, Texas. Elkins noticed how well the territory was performing, but raised and questioned the legitimacy of the Sub-Q stimulation procedure, and questioned whether Medicare would stop reimbursement for the procedure. Elkins mentioned this concern was also shared by Mike Carroll, the Regional Vice President for Medtronic located at the regional office in Kansas City. Even though Medtronic agents had concerns, Medtronic increased sales quotas nearly 20% more in business for the 2009 fiscal year.

32. From time to time Nickell was asked to train other representatives on the Sub-Q stimulation procedure, coding, and billing. Nickell trained Chad German and Gary Williams from Houston on Sub-Q implant techniques and on the billing techniques from Medtronic. Mike Elkins, Marcus Reid, and Mike Carroll were aware of this training. Additionally, Nickell was ordered to go to Georgia to train the South Georgia sales team on the Sub-Q stimulation procedure, coding, and billing.

33. Medtronic also paid Dr. McDavid fees of $750 per half day and $1,500 per full day to permit pain physicians from other parts of the country to observe him perform Sub-Q procedures.

FDA Approval & Clearance of Medical Devices

34. The Food, Drug and Cosmetics Act ("FDCA") was amended in 1976 to give the FDA a gatekeeper role in approving the safety and effectiveness of medical devices similar to its role in regulating prescription drugs. Section 513 of the FDCA (21 USC 360c) requires the FDA Secretary to classify all medical devices into one of three classes designated as Class I (General Controls), Class II (Special Controls) and Class III (Premarket Approval) depending upon the level of regulation required to assure their safety and effectiveness.

35. Class I involves the lowest level of regulation and Class III the highest level of regulation. Class I devices, which include items such as forceps and reading glasses, can be commercially marketed subject to general controls such as those applicable to labeling. Class II devices, which include items such as mercury thermometers, can be commercially marketed if a Section 510(k) pre-market notification is provided to the FDA and the FDA issues a clearance letter finding that the device is "substantially equivalent" to a predicate device that was being

marketed in interstate commerce prior to the 1976 amendments. Class III devices, which include items such as replacement heart valves and pacemakers, require a pre-market application ("PMA") demonstrating the safety and effectiveness of the device.

36. Any post-1976 device (that was not introduced into interstate commerce for commercial distribution before enactment of the 1976 amendments) is classified under Class III by default and requires a PMA demonstrating safety and effectiveness unless it is "substantially equivalent" to a pre-1976 device or the FDA has acted to classified it as a Class I or Class II device. 21 U.S.C. 360c (f) (1).

37. After adoption of the 1976 amendments to the FDCA, the FDA Classification Panels of experts studied all devices introduced into interstate commerce for commercial distribution before the date of enactment of the amendments and recommended to the FDA Secretary descriptions for each such category of device and its recommended classification into one of the three classes. Based upon these recommendations, the FDA Secretary adopted regulations describing and classifying each such category of device. Through a similar process, the FDA describes and classifies each category of new device upon application of the device manufacturer or distributor.

FDA Classification, Approval and Clearance of Neurostimulation Devices

38. Certain neuromodulation procedures, and devices to perform them, were developed as early as 1965 and were used in interstate commerce prior to enactment of the 1976 amendments to the FDCA. These were limited to (1) TENS or transcutaneous (outside the skin) electric nerve stimulation of nerves by means of electrodes attached to the external surface of the skin; (2) SCS or spinal cord stimulation for the direct stimulation of the spinal cord by means of

the percutaneous (through the skin) insertion of electrode-bearing leads or wires through the skin into the epidural region between the spinal cord and the bones of the spine; and (3) PNS or peripheral nerve stimulation of major nerves outside the spine by means of (a) a surgical incision to locate a major nerve and wrap it with an electrode bearing cuff or (b) the percutaneous insertion of electrode-bearing leads or wires through the skin to make direct contact with one of the major peripheral nerves.

39. The medical theory behind all neurostimulation procedures and devices in use prior to 1976 was the "gate-control" theory of Melzack and Wall that the direct electrical stimulation of the spinal cord and major peripheral nerves might scramble or modulate the electrically transmitted signals of pain emanating from damaged or diseased organs and being transmitted to the brain. It was postulated that by interrupting the flow of these signals at a midpoint between the organ and the brain, the perception of pain could be relieved.

40. The particular procedure and intended use of neurostimulation devices at issue in this case, sometimes referred to as Sub-Q, subcutaneous targeted neurostimulation ("STN") or peripheral nerve field stimulation ("PNFS"), is a novel new procedure and application of neurostimulation devices first developed about 2005 and still in an experimental or investigational stage. This new procedure, which does not yet have an agreed-upon name, involves the insertion of electrode-bearing leads or wires immediately below the skin in the specific area where the patient is experiencing pain, often in the lower back. Rather than directly stimulating the spinal cord or a major peripheral nerve to interrupt the flow of pain signals, the new procedure purports to stimulate the broad "field" of tiny nerve fibers that terminate in the

skin. Its mechanism of action has not yet been explained and its ultimate safety and effectiveness have not yet been scientifically demonstrated.

41. Within two or three years of the adoption of the 1976 amendments to the FDCA, the FDA adopted regulations classifying the pre-1976 devices in use for neuromodulation as Class II devices requiring 510(k) notification and proof of "substantial equivalence" before marketing of modifications to such devices or changes in their intended use.

42. 21 CFR 882.5879 (Implanted peripheral nerve stimulator for pain relief) describes PNS devices as follows:

> An implanted peripheral nerve stimulator for pain relief is a device that is used to stimulate electrically a peripheral nerve in a patient to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed around a peripheral nerve and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

21 CFR 882.5880 (Implanted spinal cord stimulator for pain relief) describes SCS devices as follows:

> An implanted spinal cord stimulator for pain relief is a device that is used to stimulate electrically a patient's spinal cord to relieve severe intractable pain. The stimulator consists of an implanted receiver with electrodes that are placed on the patient's spinal cord and an external transmitter for transmitting the stimulating pulses across the patient's skin to the implanted receiver.

21 CFR 882.5890 (transcutaneous electrical nerve stimulator for pain relief) describes TENS devices as follows:

> A transcutaneous electrical nerve stimulator for pain relief is a device used to apply an electric current to electrodes on a patient's skin to treat pain.

43. The foregoing PNS, SCS and TENS devices are the only pre-1976 neuromodulation devices described and classified in the FDA regulations. Product codes

assigned to such devices were GZF (for PNS), GZB (for SCS) and GZJ (for TENS). In approximately 1984, a new product code LGW (Stimulator, Spinal-Cord, Totally Implanted for Pain Relief) was established by the FDA to classify SCS devices under Class III. No regulation was adopted to define such devices but it appears that they differ from the old product code GZB for SCS devices described in 21 CFR 882.5880 by the fact that the pulse generators in newer neuromodulation systems are implanted along with the electrodes. Thus, newer model fully-implanted SCS systems are Class III devices requiring proof of safety and effectiveness.

Violations of the FDCA and FDA Regulations by Defendants

44. Over the years since 1976, Defendants have introduced new lines of neuromodulation systems for which they have filed both PMAs seeking approval of the safety and effectiveness of their systems for SCS and PNS and 510(k) pre-market notifications based upon "substantial equivalence" of their newer systems to those in use prior to 1976 for SCS and PNS. However, Defendants have failed to obtain approval or clearance for the intended use of their products in Sub-Q procedures.

45. Defendant Medtronic filed a PMA in 1984 for its Itrel System (PMA No. P840001), relying upon medical literature and product labeling describing traditional SCS and PNS therapies and substantial equivalence to its earlier line of products. Medtronic has subsequently filed several supplemental PMAs and 510(k) premarket notifications seeking approval of its Restore, Synergy and Prime systems based upon substantial equivalence.

46. Advanced Neuromodulation Systems, now owned by Defendant St. Jude Medical, Inc., filed a PMA for its Genesis system in 2001 (PMA No. P010032), relying upon medical

literature and product labeling describing traditional SCS therapy and substantial equivalence to the Medtronic products.

47. Defendant Boston Scientific filed a PMA for its Precision Spinal Cord Stimulation System in 2003 (PMA No. P030017) relying upon the same SCS literature and product labeling and substantial equivalence to the Medtronic systems.

48. As stated previously, any post-1976 device (that was not introduced into interstate commerce for commercial distribution before enactment of the 1976 amendments) is classified under Class III by default and requires a PMA demonstrating safety and effectiveness unless it is "substantially equivalent" to a pre-1976 device or the FDA has acted to classified it as a Class I or Class II device. 21 U.S.C. 360c (f) (1).

49. Section 513 of the FDCA, 21 U.S.C. 360c (i), defines "substantial equivalence," with respect to a device being compared to a predicate device, as meaning "that the device has the same intended use as the predicate device and that the Secretary by order has found that the device (i) has the same technological characteristics as the predicate device, or (ii)(l) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (ll) does not raise different questions of safety and effectiveness than the predicate device." (emphasis added). Regulations adopting the same definition appear at 21 CFR 807.100 (b).

50. The Sub-Q procedure is a different "intended use" that raises different questions of safety and effectiveness from the traditional SCS and PNS procedures because there is no medical theory that would explain why subcutaneous stimulation should be effective under the traditional "gate-control" theory of Melzack and Wall that is the foundation for traditional SCS and PNS procedures.

51. Reports of the procedure in the medical literature all recognize that it is a novel procedure the effectiveness of which has not yet been established. See e.g. Stuart & Winfree, "Neurostimulation Techniques for Painful Peripheral Nerve Disorders," 20 NEUROSURG. CLIN. N. AM 111, 118 (2009) ("The primary limitation of [Sub-Q] is the lack of randomized-control studies or large case series demonstrating its efficacy and potential advantages to existing neuromodulation techniques"). Moreover, Relator Nickell has direct and independent knowledge of several Sub-Q patients who experienced safety problems including burning sensations and lead displacement or movement due to inability to anchor leads in the fat deposits beneath the skin, requiring the eventual explantation of the implanted devices.

52. The FDA regulations make it clear that a manufacturer must submit a PMA establishing the safety and effectiveness of any device that "was not on the market . . . before May 28, 1976, and is not substantially equivalent to a device on the market before May 28, 1976, or to a device first marketed on, or after that date, which has been classified into class I or Class II . . . ." 21 CFR 814.1 (c)(1) (emphasis added).

53. The FDA regulations also make it clear that a 510(k) premarket notification is required at least 90 days before marketing any device "that is about to be significantly changed or modified in . . . intended use." 21 CFR 807.81 (When a premarket notification submission is

required) (emphasis added). A significant change or modification requiring a premarket notification includes "[a] major change or modification in the intended use of the device." 21 CFR 807.81 (a)(3)(ii) (emphasis added).

54. Intended use is defined in the FDA regulations as "the objective intent of the persons legally responsible for the labeling of devices." 21 CFR 801.4. This regulation further states that:

> The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer.

55. Relator Nickell has direct and independent knowledge that the intended use of Medtronic's neuromodulation systems changed no later than 2007 as he was encouraged to market that system off-label for the new Sub-Q procedure and was assigned sales quotas that could only be achieved through sales of the Medtronic system for the off-label Sub-Q use.

56. The change in intended use is also demonstrated by a series of patent applications that have been filed by two of the Defendants. With the advent of subcutaneous nerve field stimulation in 2005 as a promising and potentially very profitable new medical procedure, the President and CEO of Advanced Neuromodulation Systems, now a division of Defendant St. Jude Medical, Inc., filed U.S. patent application No. 11/066,669 (System and Method for Neurological Stimulation of Peripheral Nerves to Treat Low Back Pain) on February 25, 2005. That application was followed in 2006 by three patent applications by employees and assignors of Defendant Medtronic: No. 11/378,094 (Peripheral Nerve Stimulation) dated March 17, 2006;

No. 11/450,144 (Peripheral Nerve Field Stimulation and Spinal Cord Stimulation) dated June 9, 2006; and No. 11/450,133 (Combination Therapy Including Peripheral Nerve Field Stimulation) dated June 9, 2006. On January 28, 2008, U. S. Patent No. 7,324,852 B2 was issued in connection with the St. Jude application. The Medtronic applications are still pending.

57. All of the above patent applications describe in one form or another the novel new subcutaneous field stimulation procedure that is the subject of this complaint and distinguish it from the "prior art" by which neuromodulation devices have been utilized for the old procedures of SCS, PNS and TENS for many years.

58. Although it is obvious from the patent applications and off-label marketing quotas that Sub-Q is a novel intended use of existing neuromodulation devices, no manufacturer has submitted a PMA or 510(k) notice of intent to market such devices for the new "intended use."

59. Defendants also have not changed the labeling on their devices to reflect the new "intended use." FDA Regulations require that "if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put." 21 CFR 801.4.

60. The labeling on Defendants' neuromodulation systems describe only the traditional SCS and PNS procedures. They do not describe the new Sub-Q nerve field stimulation procedure and would require FDA approval of a PMA or clearance of a 510(k) premarket notification if they did. Defendants' devices are therefore misbranded devices in violation of Section 502 of the FDCA, 21 U.S.C. 352.

61. Pursuant to 21 U.S.C. § 331, the introduction into interstate commerce of any device that is misbranded is a prohibited act. Acts prohibited under Section 331 constitute a crime for which a guilty party may be imprisoned for not more than one year and fined not more than $1,000 or both on the first offense. See 31 U.S.C. 333(a)(1); *United States v. Caronia*, 576 F. Supp. 2d 385 (E. D. N.Y. 2008). An organization found guilty of this offense may also be sentenced to pay a criminal fine not more than "twice the gross gain" realized from the offense. 18 U.S.C. 3571(d). The Government may also pursue criminal forfeiture of the misbranded devices pursuant to 21 U.S.C. 334, 28 U.S.C. 2461(c) or forfeiture of substitute assets pursuant to 18 U.S.C. 2461(c) and 21 U.S.C. 853 (p). Section 333 also imposes civil penalties upon device makers of $15,000 for each offense not to exceed $1,000,000 in each proceeding for prohibited acts. 21 U.S.C. 331 (f)(1)(A).

62. Claims made against federal health care programs for misbranded devices are false or fraudulent claims within the meaning of the False Claims Act because they misrepresent that the billed use of the device is an approved, medically necessary and non-experimental use of the device and/or fail to disclose that the device has been utilized for an unapproved, medically unnecessary and investigational use. By knowingly marketing such devices for off-label uses to health care providers who make claims against the federal programs, Defendants have caused false or fraudulent claims to be submitted to the federal programs.

The Medicare & Federal Health Care Programs

63. Medicare is a federally funded health insurance program primarily benefiting the elderly that is administered by the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS"). It was created in 1965 upon Congress's enactment

of Title XVIII of the Social Security Act and is the largest health insurance program in the nation. There are four parts to the Medicare Program: (1) Medicare Part A is hospital insurance that covers the cost of inpatient hospital services and post-hospital nursing facility care; (2) Medicare Part B is medical insurance that covers the cost of physician services and outpatient care; (3) Medicare Part D is prescription drug coverage; and (4) Medicare Part C provides the benefits of Parts A, B, and D through a private health insurance plan, such as an HMO or PPO.

64. Through these programs, and similar ones such as Medicaid, VA, CHAMPUS, TRICARE and FEHBP that benefit the poor, veterans, military personnel, federal employees and their families (collectively "the federal programs"), providers submit claims to and are paid by the United States Government. The rules for reimbursement under most of the programs are substantially identical to those of Medicare.

65. The Healthcare Common Procedure Coding System ("HCPCS") is a standardized coding system designed to ensure that Medicare and other federal health care programs pay for services and devices in accordance with payment schedules tied to the level of professional effort required to render specific categories of medical care. To ensure normalization of descriptions of medical care rendered and consistent compensation for similar work, all programs tie levels of reimbursement to standardized codes.

66. The Current Procedural Terminology ("CPT") codes are Level I HCPCS codes and are published and updated annually by the American Medical Association ("AMA"). Level II Codes are alpha-numerical codes promulgated by CMS and cover products, supplies and services not included in the CPT codes, including medical devices.

67. Base CPT codes are five-digit numbers organized in numeric sequences that identify both the general area of medicine to which a procedure relates (such as "Evaluation and Management," "Anesthesiology," "Surgery," "Neurology," or general "Medicine") and the specific medical procedures commonly practiced by physicians and other health care professionals working in that field.

68. The instructions that accompany the CPT manual direct providers "not select a CPT code that merely approximates the service provided." Rather, if no accurate service procedure or service exists among the standard CPT codes, providers are instructed to "report the service using the appropriate unlisted procedure or service code" (i.e. the special CPT codes provided for use when none of the standard CPT codes reasonably and adequately describes the specific procedure or service provided). Codes listed after each subsection of the CPT Manual and ending in -99 are "unlisted" codes.

69. As new medical procedures become accepted by the medical profession, the AMA adds new codes to the CPT Manual to replace the "unlisted" procedure codes. A 17-member CPT Editorial Panel meets three times a year to consider proposals for addition of codes to the CPT Manual and is assisted by a CPT Advisory Committee made up of representatives of over 100 medical specialty societies and other health care professional organizations.

70. The AMA provides a Coding Change Request Form and instructions for its use by individuals, physicians and specialty groups in submitting requests for new CPT codes. The acceptance of new codes is "generally based upon the procedure being consistent with contemporary medical practice and being performed by many physicians in clinical practice in

multiple locations." See Background and Categories of CPT, www.ama-assn.org (last visited January 30, 2008). The AMA further states that:

> In developing new and revised Category I CPT codes the Advisory Committee and the Editorial Panel requires:
>
> - That the service/procedure receive approval from the Food and Drug Administration (FDA) for the specific use of devices or drugs;
>
> - That the service/procedure is performed across the country in multiple locations;
>
> - That many physicians or other health care professionals perform the service/procedure; and
>
> - That the clinical efficacy of the service/procedure has been well established and documented.
>
> Id.

71. Thus, the AMA acts as a gatekeeper to the Medicare reimbursement system by declining to establish CPT codes for experimental or investigational medical procedures that involve a "specific use" of a device that is off-label in the sense that it has not yet been approved by the FDA. When a physician submits a billing to Medicare for an "unlisted" code, he thereby alerts Medicare that it must make an individualized determination whether the service is properly reimbursable.

72. Physicians typically submit claims for professional services on Form CMS-1500. The claim form sets forth the diagnostic code describing the patient's presenting condition and the procedural codes. On the claim form, the physician certifies that the services were "medically indicated and necessary to the health of the patient . . . ."

The Medicare Exclusions from Coverage for Unnecessary, Uneconomical Procedures & Experimental or Investigational Devices

73. The Medicare statute and regulations exclude from coverage services that are not "reasonable and necessary" for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. 42 U.S.C. 1395y(a)(1)(A); 42 CFR 411.15 (k). Health care providers also have an obligation to assure that services or items ordered or provided "will be provided economically and only when, and to the extent, medically necessary." 42 USC 1320-5(a)(1).

74. Medicare regulations specifically exclude from coverage "experimental or investigational devices," unless they are furnished in connection with certain FDA-approved clinical trials. 42 CFR 411.15 (o). Medicare will pay for services and devices in connection with formal clinical trials, but only under tightly-controlled circumstances involving pre-approval by Medicare or sponsorship by recognized research organizations. See generally "Medicare National Coverage Decision for Routine Costs in Clinical Trials," Medicare Manual Section 310.1 (effective July 9, 2007).

75. Thus a physician who chooses to provide experimental or investigational treatments not yet generally accepted in medical practice is not entitled to reimbursement. Medicare does not guarantee payment for all medical services that a physician deems necessary. See *Goodman v. Sullivan*, 891 F.2d 449 (2nd Cir. 1989) (denying coverage for MRI procedures before their general acceptance).

76. Moreover, health-care providers are deemed to have actual or constructive knowledge of the exclusion from coverage for investigational or experimental devices. See

Svidler v. United States, 2004 U.S. Dist. LEXIS 18325 (N.D. Calif. 2004) (denying coverage for use of a neuromodulation device for an experimental use different than its FDA-approved use).

Defendants Cause Healthcare Providers to Bill Sub-Q under a False Code for PNS

77. Neuromodulation devices have been used in traditional TENS, SCS and PNS procedures since 1965 and the AMA long ago established CPT codes for these procedures.

78. CPT Code 64550, described by the AMA as "application of surface (transcutaneous) neurostimulator," is the traditional TENS procedure described in FDA Product Code GZJ and the FDA regulation at 21 CFR 882.5890. Medicare pays $8.62 to $14.29 for each procedure billed under this code.

79. CPT Code 63650, described by the AMA as ""percutaneous implantation of neurostimulator electrode array, epidural," is the traditional SCS procedure described in FDA Product Codes GZB & LGW and the FDA regulation at 21 CFR 882.5880. Medicare pays $376.83 for each procedure billed under this code.

80. CPT Code 64555, described by the AMA as "percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral)," is the traditional PNS procedure[1] described in FDA Product Code GZF and the FDA regulation at 21 CFR 882.5870. Medicare pays $143.53 to $196.06 for each procedure billed under this code.

81. The AMA has also promulgated additional codes for PNS procedures targeting specific peripheral nerves that involve different levels of risk and effort for the physician. For

[1] That this code refers to the traditional PNS procedure rather than Sub-Q is also demonstrated by Medicare's National Coverage Decision for Electrical Nerve Stimulators. That NCD describes PNS as the "implantation of electrodes around a selected peripheral nerve," rather than as the stimulation of a field of tiny peripheral nerves in or just below the skin. See MEDICARE MANUAL, Publication 100-3, Section 160.7.

example, CPT Code 64561, "percutaneous implantation of neurostimulator electrodes, sacral nerve (transforaminal placement)," is a more difficult procedure that Medicare reimburses at a rate of $402.00 to $1,055.00 per procedure.

82. The AMA has not yet promulgated a CPT code for the new Sub-Q or PNFS procedure, apparently because it does not meet the AMA's criteria for the establishment of a new code. Among other reasons it does not qualify, the FDA has not yet approved neuromodulation devices for this "specific use" and "the clinical efficacy of the service/procedure has [not] been well established and documented" as required by the AMA's coding guidelines.

83. All of the reports of the procedure in the medical literature recognize that it is a novel new procedure the effectiveness of which has not yet been established. See Stuart, Neurostimulation Techniques for Painful Peripheral Nerve Disorders," 20 NEUROSURG. CLIN. N. AM. 111 (January, 2009); Kouroukli, "Peripheral Subcutaneous Stimulation for the Treatment of Intractable Postherpetic Neuralgia: Two Case Reports and Literature Review, PAIN PRACTICE (January, 2009); Henderson, "Peripheral Nerve Stimulation for Chronic Pain, 12 CURRENT PAIN & HEADACHE REP. 28 (December , 2008); Tamimi, "Subcutaneous Peripheral Nerve Stimulation Treatment for Chronic Pelvic Pain," 11 NEUROMODULATION 277 (October , 2008); Krutsch, "A Case Report of Subcutaneous Peripheral Nerve Stimulation for the Treatment of Axial Back Pain Associated with Postlaminectomy Syndrome," 11 NEUROMODULATION 112 (February, 2008); Slavin, "Peripheral Nerve Stimulation for Neuropathic Pain, 5 NEUROTHERAPEUTICS 100 (January, 2008); Bernstein, "Spinal Cord Stimulation in Conjunction with Peripheral Nerve Field Stimulation for Treatment of Low Back and Leg Pain: A Case Series," 11 NEUROMODULATION 116 (February, 2008); Paicius, "Peripheral Nerve Field Stimulation in Chronic Abdominal Pain,"

9 PAIN PHYSICIAN 261 (September, 2006); Goroszeniuk, "Subcutaneous Neuromodulating Implant Targeted at the Site of Pain," 31 REG. ANES. & PAIN MED., 168 (March-April, 2006).

84. At least two writers have noted that the procedure involves off-label use of neuromodulation devices and have questioned the ability to obtain insurance reimbursement for it. See Slavin and Paicius articles, supra. As Paicius noted:

> The nomenclature needs to be more carefully defined and specific Common Procedural Terminology (CPT) codes need to be assigned so that this therapy can be offered to appropriate candidates. PNFS is a unique form of neuromodulation, neither synonymous with direct peripheral nerve stimulation nor SCS. There is considerable controversy surrounding the naming and coding of this procedure . . . . It will remain a challenge to obtain insurance approval until there is general agreement on terminology and CPT coding for PNFS.
>
> 9 PAIN PHYSICIAN 261, 266 (September, 2006).

85. Since there is no specific CPT code for use of neuromodulation devices for this specific Sub-Q or PNFS procedure, physicians should be billing their services, if they bill Medicare at all (considering the experimental and investigational nature of the procedure), under CPT Code 64999 which is described by the AMA as "unlisted procedure, nervous system." By so doing, they would flag for Medicare and other federal programs that this procedure is not the old PNS procedure for which Medicare has made a coverage decision.[2]

86. Instead, with the encouragement of Defendants, they are billing Code 64555 as though Sub-Q were the traditional PNS procedure, thereby denying Medicare and other federal programs the opportunity to make a coverage determination not only concerning payment for physician services, but also concerning reimbursement for the devices themselves.

[2] See Medicare National Coverage Decision, footnote 1, supra.

87. Defendants know that Sub-Q or PNFS is a novel, investigational procedure, as demonstrated by the medical literature and their own patent applications claiming that the procedure is a new invention that is not part of the "prior art." Therefore, they are knowingly causing health care providers to submit false claims to the federal programs in violation of the False Claims Act.

Defendants Also Cause Healthcare Providers to Falsely Bill Combination Procedures

88. Not only is Sub-Q an experimental and investigational procedure, but also the use of Sub-Q in combination with SCS is an experimental and investigational procedure that appears to be scientifically unsound and may drive up the government's costs unnecessarily.

89. Based upon the Relator's experience, approximately 70% to 80% of Sub-Q procedures billed under CPT Code 64555 are performed in conjunction with traditional SCS procedures billed under CPT Code 63650. The patient has two sets of lead arrays inserted percutaneously into the epidural area of the spine (the SCS procedure) and a second set of two lead arrays inserted subcutaneously under the skin in the area where he is experiencing the most pain, usually the lower back (the Sub-Q procedure). This doubling up occurs both during the initial "trial" phase and during the permanent implantation procedure. At the permanent implantation, two separate pulse generators are implanted.

90. Thus, the government is billed for as many as 64 separate electrodes (eight on each of four lead arrays, twice), two pulse generators, related supplies and professional services. The total cost to the government can be $75,000 or more.

91. Scientifically, it makes no sense to conduct a "trial" of both SCS and Sub-Q at the same time. The physician should test one procedure or the other in isolation in order to conduct

a scientifically-valid trial. If SCS works by itself, there would be no medical necessity to charge the government for an additional Sub-Q procedure. If Sub-Q works by itself, there would be no medical necessity to charge the government for an additional SCS procedure.

92. By doubling up the procedures, physicians accomplish nothing except to drive up the government's cost, their own profits and the profits of the Defendants. Based upon Relator's experience, Defendants market to pain physicians the profitability of the combination procedure and most of them permit the allure of profit to overcome their scientific scruples.

93. The combination procedure is rationalized on the premise that the patient is allowed to compare SCS and PNFS "to indicate a preference for one over the other or for the combination." See Bernstein, supra, 11 NEUROMODULATION 116 & 122. However, in almost all cases the patient assumes that more is better and opts for permanent implantation of both systems. The systems described by Bernstein were ANS (St. Jude) systems. Medtronic promotes the same dual stimulation system and has applied for patents on the combination procedure.

94. By encouraging physicians to implant dual systems at both the trial and permanent implantation stages, Defendants have caused physicians to submit false claims to the federal programs not only for medically unnecessary procedures, but also for the "combination" procedure that is itself wholly experimental and investigational, even though a traditional SCS procedure by itself might have been reimbursable.

The Anti-Kickback Statute

95. The federal Anti-Kickback statute ("AKS") makes it a felony punishable by imprisonment of up to five years and a fine of up to $25,000 to "offer or pay remuneration

(including any kickback, bribe, or rebate)" to any person to "induce such person . . . to purchase, lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal health care program . . . ." 42 U.S.C. 1320a-7b(b)(2).

96. Discounts, rebates and other reductions in the price of goods or services sold to a health care provider can be a form of "remuneration" that, if offered with the requisite *mens rea*, can be illegal remuneration under the AKS if not properly disclosed to the Government. *United States v. Shaw*, 106 F. Supp. 2d 103 (D. Mass. 2000). The AKS is violated if one purpose of the remuneration is to induce future referrals of business reimbursable under federal health care programs. Id at 121, citing *United States v. Greber*, 760 F.2d 68 (3rd Cir. 1985) and *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989). "The gravamen of Medicare Fraud [under the AKS] is inducement . . . ." Id at 121, citing *United States v. Bay State Ambulance and Hospital Rental Service*, 874 F.2d 20 (1st Cir. 1989).

97. The courts have consistently held that actions that violate the AKS may serve as a basis for liability under the False Claims Act. See *U.S. ex rel Thompson v. Columbia/HCA*, 125 F.3d 899, 903 (5th Cir. 1997); *U.S. ex rel. Barrett v. Columbia/HCA*, 217 F. Supp. 2d 28, 29 (D. D.C. 2003); *U.S. ex rel. Bidani v. Lewis*, 264 F. Supp. 2d 612, 613 (N.D. Ill. 2003); *U.S. ex rel Pogue v. Diabetes Treatment Centers of America*, 238 F. Supp. 2d 258 (D. D.C. 2002).

Violations of the AKS by Defendants

98. Defendant Medtronic has consistently offered and paid remuneration in the form of low list prices, discounts and rebates on its trial lead arrays to induce pain physicians to refer patients to surgeons, ambulatory surgery centers and hospital outpatient surgery centers for

permanent implantation of Sub-Q and SCS neuromodulation systems at the expense of the federal health care programs.

99. Medtronic's scheme provides powerful inducements to pain physicians, who serve as gate keepers for permanent implantation procedures that can cost the government in excess of $40,000 to $63,000 each by marketing the spread between the reimbursement price the physician receives for trial leads from Medicare and the artificially low price at which Medtronic sells the same leads to the physician. If the pain physician can be induced to perform neuromodulation trials by the lure of substantial profit on the sale of trial leads to the Government, the patient almost always elects to follow through with the permanent implantation procedure at considerable profit to Medtronic and huge expense to the Government.

100. Medtronic's scheme creates a serious conflict of interest for pain physicians. It converts them from dispassionate medical professionals weighing considerations of medical necessity, cost and the best interests of their patients into retail salesmen pushing "snake oil" because of the large profits they can realize.

101. The key to the scheme is a questionable interpretation of the Medicare rules for reimbursement to physicians of the cost of trial lead arrays, the small wires bearing electrode contacts that are inserted into the epidural space between the spinal cord and the spine in a traditional SCS procedure and under the skin (subcutaneously) in the new Sub-Q procedure. The HCPCS Level II code for these leads is L8680, described as "implantable neurostimulator electrode, each." Medicare reimburses physicians $399 for this code billed on CMS Form 1500 when temporary trial leads are implanted in the physicians' offices.

102. Medtronic advises pain doctors that they can bill this code for each electrode contact on an eight-contact lead array, producing a selling price to Medicare of $3,192 per trial lead array. Medtronic's list price charged to the doctor for each trial lead array is $1,390, but the list price is subject to rebates and discounts that frequently reduce the doctor's cost to $700 or less per array. Thus, the pain doctor has a built-in profit of approximately $2,492 (on each array at the discounted price) or $1,802 (on each array at the list price) over and above the fee paid to him by Medicare for his services as a physician for implanting the trial lead array. Since the doctor is paid a fee of only $196.06 for implantation of a PNS lead array and $376.83 for implantation of an SCS lead array, his profit on selling the trial lead array is 1,271% of the fee for his service in a Sub-Q trial procedure billed as a PNS trial procedure.[3]

103. In the typical combined Sub-Q/SCS trial, the pain physician implants two SCS lead arrays on either side of the spine and two Sub-Q lead arrays in the area of the lower back where the patient is experiencing the most pain. The doctor's profit from selling the trial leads to the Government is therefore anywhere from $7,208 to $9,968 per patient. Relator has witnessed at least one pain specialist, Andrew McDavid, M.D., in Temple, Texas, perform trial procedures on eight patients in a single morning, yielding a profit to the physician of anywhere from $57,664 to $79,744 for selling trial lead arrays in addition to the fee for his services, which would be about $9,166.24 for half a day of work.

104. The comparable lead arrays for permanent implantation, which are substantially identical to the trial lead arrays, have a list price of $2,390 and are sold not to the pain physician who makes the referral for permanent implantation, but to the Ambulatory Surgical Center

[3] As explained above, the Sub-Q procedure is not properly billed as a PNS procedure, but this is how Medtronic has

("ASC") or hospital Outpatient Surgical Center ("OSC") where the permanent implantation is performed by an orthopedic surgeon or neurosurgeon on referral from the pain doctor. The ASC or OSC does not bill the same device code L8680 to the Government because the cost of the permanent lead arrays are bundled with other equipment and services provided by the surgery center under Medicare's Prospective Payment System.

105. Thus, by pricing its trial lead arrays at a list price that is $1,000 less than its substantially equivalent permanent lead arrays ($1,390 versus $2,390) and offering rebates and discounts to pain physicians that drop their cost to $700 or less, Medtronic provides a powerful inducement to pain doctors to conduct Sub-Q trials and combination Sub-Q/SCS trials that inevitably lead to the referral of permanent implantation business to surgeons, ASCs and OSCs who bill government health care plans for an additional $40,000 to $63,000 for the permanent implantation procedures and devices.

106. The huge profits made by pain physicians in their role as gatekeepers in this process is a form of remuneration offered and paid by Medtronic through its artificially low pricing of trial leads and transfer to the doctors of profits that Medtronic would otherwise make on sales of its trial leads. Medtronic, in effect, subsidizes the pain physicians' practice by transferring a portion of the manufacturer's profits to the pain physician during the trial stage.

107. In addition, Relator alleges on information and belief that Medtronic pays speaker or educator fees to pain physicians. Relator knows that Medtronic paid Dr. McDavid of Temple, Texas fees of $750 per half day and $1,500 per full day to permit pain physicians from other parts of the country to observe him perform Sub-Q procedures.

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instructed pain physicians to bill it.

108. The remuneration, subsidization and transfer of profits to pain doctors is intended to be an inducement to the doctors to initiate the process that will result in referrals of permanent implantation procedures to other health care providers who will purchase products from Medtronic and bill government health care plans. The inducement is so effective that pain physicians, after trying one or two stimulations trials, exponentially increase the number of trials they perform and the number of permanent implantation cases they refer to other health care providers.

109. If Medicare and other federal health care programs knew that pain physicians were performing these trial procedures and making referrals not because of medical necessity and honest medical judgment, but instead because they are reaping windfall profits from illegal pricing, rebates and discounts, the federal programs would not be willing to pay for either the trial or permanent implantation procedures.

110. Medtronic's scheme is therefore a violation of the AKS that has caused the submission of false or fraudulent claims to federal health care programs and is actionable under the False Claims Act. Upon information and belief, St. Jude Medical and Boston Scientific compete with Medtronic for the business of pain doctors and offer them the same inducement for the same purpose. Therefore, Defendants St. Jude Medical and Boston Scientific are also in violation of the AKS and are liable under the False Claims Act for causing false claims to be submitted to federal health care programs.

Harm to Patients

111. Defendants' schemes not only harm the federal treasury, they also pose a significant risk of harm to patients. Implantation procedures are invasive procedures whether they are traditional SCS procedures or the new Sub-Q procedures.

112. Because of the profits to be made on combined SCS/Sub-Q procedures, many more SCS procedures are being performed than in the past. SCS procedures pierce the epidural sack protecting the spinal cord and impose a significant risk of injury to, or infection of, the spinal cord.

113. The new Sub-Q procedures are less invasive than SCS procedures, but their effectiveness over traditional TENS procedures has not been demonstrated. TENS procedures involve no penetration of the skin, yet stimulate the same field of tiny nerves in the skin from its exterior surface.

114. No mechanism of action has been suggested that would cause subcutaneous electrical stimulation to have a superior effectiveness to transcutaneous electrical stimulation of the same painful areas of the lower back. Long-term studies have demonstrated that TENS procedures are not highly effective. There is no reason to believe that Sub-Q procedures will be any more effective in the long term, yet they are vastly more costly and invasive.

115. Relator has personal knowledge that Sub-Q procedures present issues of safety and effectiveness for patients because he was routinely in touch with patients during their trial periods of one week to 10 days before permanent implantation, gave patients his cell phone number to assist them with programming and operating their devices and, in some cases, has had continuing contact with patients after their permanent implantations.

116. Many patients develop problems with their Sub-Q implants that cause them to turn off the pulse generator or have the entire system explanted. In some cases, the lead arrays are implanted too close to the surface of the skin and produce burning sensations in the skin. In other cases, the lead arrays are implanted too close to the underlying muscle tissue and produce burning sensations there. In yet other cases, the long, linear lead arrays slice their way through the subcutaneous fat tissue like a knife slicing through butter or, worse still, coil up beneath the skin.

117. In traditional SCS and PNS procedures, leads are securely fastened to the bone of the spine (in SCS), to a peripheral nerve (by means of cuff electrodes that wrap around the nerve in traditional PNS done by means of an incision) or to surrounding tissues (in traditional PNS where a lead array is percutaneously inserted alongside a major peripheral nerve). In the new Sub-Q procedure, there is nothing to which to anchor the lead arrays, other than fluid fatty tissue, and the manufacturers do not even manufacture fastening devices designed for these procedures. In some Sub-Q cases, physicians attempt to attach the lead arrays to bunched-up pieces of fat tissue, but this solution does not appear to be effective in preventing lead migration.

118. On balance, Relator believes that the new Sub-Q procedure is the latest medical fad that has caught on with manufacturers and pain control doctors because of its profit potential rather than its safety, effectiveness or economic efficiency. The inexpensive and non-invasive TENS procedure is probably just as effective and is vastly safer for the patient. By steering patients to the new procedure combined with SCS, the Defendants and pain physicians are exposing patients to significant risks and are failing to utilize alternate procedures that are less dangerous, just as effective and much less costly to the Government.

COUNT I – False Claims Act, 31 U.S.C. § 3729 (a)(1)

119. Plaintiff re-alleges and incorporates by reference the allegations in paragraphs 1 to 118 above.

120. This claim is for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq*.

121. Through the acts described above, Defendants knowingly presented, or caused to be presented, false or fraudulent claims to the United States Government in order to obtain government reimbursement for health care services provided under Medicare and other federal programs.

122. As a result of these false claims, the United States has been damaged and continues to be damaged in an amount yet to be determined.

COUNT II – False Claims Act, 31 U.S.C. § 3729 (a)(2)

123. Plaintiff re-alleges and incorporates by reference the allegations in paragraphs 1 to 118 above.

124. This claim is for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq*.

125. Through the acts described above, Defendants knowingly made, used, and caused to be made and used, false records and statements to get false or fraudulent claims paid in order to obtain government reimbursement for health care services provided under Medicare, and other federal programs.

126. As a result of these false claims, the United States has been damaged and continues to be damaged in an amount yet to be determined.

COUNT III – False Claims Act, 31 U.S.C. § 3729 (a)(7)

127. Plaintiff re-alleges and incorporates by reference the allegations in paragraphs 1 to 118 above.

128. This claim is for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq*.

129. Through the acts described above, Defendants knowingly failed to disclose to the United States material facts in order to obtain government reimbursement for health care services provided under Medicare and other federal programs.

130. As a result of these false claims, the United States has been damaged and continues to be damaged in an amount yet to be determined.

VI. PRAYER

WHEREFORE, Relator prays for a judgment against the Defendant as follows:

1. That Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq*.;

2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

3. That Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730 (d) of the False Claims Act;

4. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

5. That the United States and Relator recover such other and further relief as the

Court deems just and proper.

Demand for Jury Trial

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, plaintiff hereby demands a trial by jury.

Respectfully submitted,

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