UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA [UNDER SEAL], **PLAINTIFF,** *v.* **[UNDER SEAL],** **DEFENDANT.**	**CIVIL ACTION NO.** **0:07-sc-04777** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)**

FIRST AMENDED COMPLAINT

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

UNITED STATES OF AMERICA *EX REL.* **KATHY ONWEZEN, ELAINE BENNETT, and ALAN BRILL** **PLAINTIFFS-RELATORS,** *v.* **MEDTRONIC, INC.,** **DEFENDANT.**	**CIVIL ACTION NO. 0:07-sc-04777** **FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY TRIAL DEMANDED**

FIRST AMENDED COMPLAINT

Plaintiffs and *qui tam* relators Kathy Onwezen, Elaine Bennett and Alan Brill (Plaintiff-Relators), through their attorneys Sanford Wittels & Heisler, LLP and the Law Offices of Grant Morris, for their First Amended Complaint against Medtronic, Inc. (hereinafter "Defendant," "Medtronic," or "Company"), allege 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 Defendant Medtronic and/or its 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 Defendant for conducting a fraudulent inducement campaign that foreseeably caused and continues to cause false or fraudulent claims,

inter alia, in the promotion of Defendant's Cardiac Rhythm Management (CRM) product line. As a direct result of Defendant's improper practices, the federal Treasury has been damaged in a substantial amount yet to be determined.

3. Since at least 1995 and continuing through the present, Medtronic, Inc. has engaged in an illegal kickback scheme within its Cardiac Rhythm Management ("CRM") division designed to induce physicians and hospitals to use Medtronic pacemakers, defibrillators and other related cardiac rhythm devices, thereby increasing the Company's market share of these devices.

4. In furtherance of this scheme, Medtronic, *inter alia*, (1) provides doctors and hospitals with kickbacks in exchange for their use of Medtronic's cardiac rhythm devices; (2) induces doctors and hospitals to conduct and bill for medical services and procedures they do not perform; (3) induces doctors and hospitals to conduct and bill for unnecessary medical services and procedures; (4) requires Medtronic sales personnel to provide medical care and make medical diagnoses in the absence of a licensed physician or staff member; and (5) improperly conducts, through non-licensed, non-medical staff, Medicare billing for physicians and hospitals.

5. Such practices are not new to Medtronic. In 2003, the Department of Justice filed a sealed complaint against Medtronic. The complaint alleged that, between 1998 and 2003, Medtronic paid kickbacks that included sham consulting fees, bogus royalty payments and lavish trips to induce doctors to use the Company's spinal products, in violation of the Anti-Kickback Statute and the False Claims Act.

6. On July 19, 2006, the U.S. Department of Justice issued a press release announcing a settlement. Under the agreement, Medtronic agreed to (1) pay $40 million in fines, (2) enter into a five-year Corporate Integrity Agreement ("CIA") with the Office of the Inspector General of the U.S Department of Health and Human Services, whereby the Company would be required to file regular

reports with the Inspector General and track all non-sales related customer transactions, and (3) set up an outside review organization, improve training and employee screening practices, and designate as a compliance officer a member of senior management who would have access to the Company's board of directors.

7. In direct violation of its agreement with the government, and in contravention of the federal Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b), Medtronic has continued to offer various types of remuneration to hospitals and physicians in exchange for such medical providers' utilization of Medtronic pacemakers and defibrillators. The types of bribes offered by the company run the gamut from invitations to exclusive parties, tickets to sports events, and the use of expensive "loaner" equipment for indefinite periods of time.

8. But by far the most egregious form of remuneration provided by Medtronic is its promise to doctors and physicians that it will provide *substantially all device-related post-implant medical care* to any patient who has received a Medtronic device. In the majority of cases, once a patient receives a Medtronic cardiac rhythm device, Medtronic becomes a "one-stop-shop," through which the Company, and not the doctor, conducts *nearly all follow-up "medical"* care related to the device for that patient. Medtronic uses unlicensed and/or non-medical staff, such as Sales Representatives and Clinicians, to conduct virtually all follow-up consultations with the patient, answer any patient inquiries, make adjustments to the device, and recommend any additional follow-ups.

9. Medtronic also promises doctors that it will assume the responsibilities associated with billing Medicare for the follow-up services that the physician never provided. Accordingly, Medtronic Representatives take it upon themselves to prepare all CPT and ICD-9 coding required for insurance and Medicare billing, although they are not licensed to make diagnoses. The doctor,

who has not seen the implant patient since the date of the initial implant, is then reimbursed by Medicare.

10. Because compliance with the Anti-Kickback Statute is a condition of payment under a federally-funded health care program, claims for reimbursement for procedures performed by a physician who has received a kickback or at a hospital that has received a kickback from Defendant are not eligible for reimbursement by Medicare.

11. Accordingly, kickback-tainted claims for reimbursement are false claims within the meaning of the Federal False Claims Act.

12. As a result of Medtronic's illegal kickback scheme, the taxpayers have been forced to bear the costs of excessive, unnecessary and unqualified medical care. At the same time, Medicare patients have been denied proper medical care, sometimes to the detriment of their health. As a result, the Medicare programs have incurred substantially increased costs.

13. Senator Charles Grassley (R-Iowa) summed up the issue well during a recent Senate floor speech on September 6, 2007. He stated:

> ***There is no question that the drug and device industries have an intricate network of financial ties with practicing physicians. These financial relationships can take many forms. They can include speaking honoraria, consulting fees, free travel to exotic locations for conferences, or funding for research.***
>
> * * *
>
> ***This practice, and the lack of transparency around it, can obscure the most important question that exists between doctor and patient: what is best for the patient? . . . Patients, of course, are in the dark about whether their doctor is receiving this money.***

II. PARTIES

14. Plaintiff-Relator Kathy Onwezen is a resident of Columbia, Missouri. Ms. Onwezen has worked in the medical industry for over 17 years, as a First Aid Nurse and a Nurse Clinician. Beginning in 2003, Ms. Onwezen was employed by Medtronic, Inc. as a Clinical Specialist in the

CRM Sales and Sales Support Division within the Kansas City North District. As a former Clinical Specialist, Ms. Onwezen was required to provide technical, educational and sales support to assist in making bradycardia (pacemaker) and tachycardia (defibrillator) sales and meeting customer needs. As a result of her long history in the field, Ms. Onwezen has specialized knowledge of industry-wide practices regarding the sales and marketing of medical devices, the training of physicians on the proper use of medical devices, and insurance and Medicare billing procedures. Ms. Onwezen also has personal knowledge of Medtronic's illegal billing, coding and diagnosing practices, of the improper practice of medicine undertaken by unlicensed Medtronic Representatives, and of the unnecessary medical procedures urged upon doctors and hospitals by Medtronic. Ms. Onwezen resigned from Medtronic in January 2006 as a result of ethical concerns regarding Medtronic's illegal kickbacks and billing practices.

15. Plaintiff-Relator Elaine Bennett is a resident of Eureka, Missouri. Ms. Bennett was employed by Boston Scientific's Cardiac Surgery Division from June 12, 2006 to September 28, 2006 as a Sales Representative. Ms. Bennett specialized in the sales and marketing of open heart cardiac surgery devices, including open heart bypass surgical devices, endoscopic vessel harvesting devices, and surgical ablation products for the treatment of atrial fibrillation. As a former Sales Representative who was trained to promote and sell cardiac surgical devices and services for the treatment of heart failure, surgical atrial fibrillation and cardiac bypass, Ms. Bennett has specialized knowledge of industry-wide practices regarding the sales and marketing of medical devices, the training of physicians on the proper use of medical devices, and insurance and Medicare billing procedures. Ms. Bennett also has knowledge of Medtronic's illegal billing, coding and diagnosing practices, of the improper practice of medicine undertaken by unlicensed Medtronic Representatives, and of the unnecessary medical procedures urged upon doctors and hospitals by Medtronic. Ms.

Bennett has extensive experience in this field; she has worked in the medical device industry for over 16 years and has been recognized as a distinguished sales representative, including being recognized as a top ten percent sales producer.

16. Plaintiff-Relator Alan Brill is a resident of Overland Park, Kansas. Mr. Brill was employed by Medtronic, Inc. from March 1995 to November 2005. From March 1995 until April 1999, Mr. Brill was employed as a Senior Tachyarrhythmia Field Engineer in Medtronic's Boston, Massachusetts region; from April 1999 until November 2005, he was employed as a Principal Technical Field Engineer for Medtronic's Kansas City North and Kansas City South districts. Mr. Brill holds a Bachelor of Science and a Master of Science in Biomedical Engineering. During his employment at Medtronic, Mr. Brill was responsible for the training and education of Medtronic's field staff (Sales Representatives and Clinical Specialists) and its customers (physicians and nurses) on all of Medtronic's cardiac rhythm management devices. He also oversaw and managed many of Medtronic's post-market clinical trials. Mr. Brill was terminated by Medtronic after using Medtronic's compliance hotline to report that Medtronic was paying doctors to participate in bogus post-market clinical studies and that the company was expending large sums of money on doctors for lunches, dinners and gifts. As such, Mr. Brill has first-hand knowledge of Medtronic's practice of using studies of dubious scientific value, and of offering other types of remuneration to doctors and hospitals, as a kickback for using Medtronic's CRM devices.

17. Defendant Medtronic, Inc. is a Fortune 500 company based in Minneapolis, Minnesota that makes drugs and medical devices for heart conditions, brain disorders and other medical conditions. The Company conducts business in over 120 countries and currently has over 37,000 employees. As of November 28, 2006, the Company's market share for cardiac rhythm devices was approximately 57 percent in the U.S. and 56 percent globally. According to

Medtronic's website, in fiscal year 2007, Medtronic's revenue exceeded $12 billion.

III. JURISDICTION AND VENUE

18. The Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331. It also has subject-matter jurisdiction pursuant to 31 U.S.C. §3732, which specifically provides for jurisdiction over actions brought under the False Claims Act, 31 U.S.C. §§3729 and 3730.

19. There has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

20. This Court has personal jurisdiction over Defendant Medtronic pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because Defendant has at least minimum contacts with the United States. Moreover, Defendant is headquartered in and transacts – or has transacted – business in the District of Minnesota.

21. Venue is proper in this District pursuant to 31 U.S.C. §3732(a) because Defendant can be found in and transacts – or has transacted – business in the District of Minnesota.

IV. BACKGROUND

A. FALSE CLAIMS ACT

22. The FCA was originally enacted in 1863 and was substantially amended in 1986 by the False Claims Amendments Act, Pub. L. 99-562, 100 Stat. 3153. After finding that federal program fraud was pervasive, Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses caused by frauds against the government ("Government Frauds"). The amendments were intended to create incentives for individuals with knowledge of Government Frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's

behalf.

23. 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 up to $11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

24. The Act allows any person having information about false or fraudulent claims ("Plaintiff-Relator") to bring an action for herself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time). Based on these provisions, *qui tam* Plaintiffs-Relators Onwezen and Bennett seek through this action to recover damages and civil penalties arising from the Defendant's knowing fraud on the U.S. Government.

B. ANTI-KICKBACK STATUTE

25. The federal health care Anti-Kickback Statute, 42 U.S.C. §1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult-to-detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to over-utilization or poor quality of care.

26. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending or arranging for the purchase

of any item for which payment may be made under a federally funded health care program. *See* 42 U.S.C. §1320a-7b(b). Under this statute, pharmaceutical companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend products or procedures that may be paid for by a federal health care program. The law prohibits not only bribes and rebate schemes, but also any payment by a company for a purpose of inducing a physician to utilize the company's pharmaceuticals.

27. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider in federal health care programs. Hospitals and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback Statute.

28. Violation of the Anti-Kickback Statute can result in exclusion from participation in federal health care programs, civil monetary penalties, and/or imprisonment of up to five years per violation. *See* 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

29. Any party convicted under the Anti-Kickback Statute must be excluded from federal health care programs (i.e., not allowed to bill for services rendered) for a term of at least five years. *See* 42 U.S.C. §1320a-7(a)(1). In the absence of an actual conviction, the Secretary of the Department of Health and Human Services ("HHS") may nonetheless exclude a provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant State agency(ies) to exclude that provider from the State health program) and/or impose administrative sanctions of $50,000 per kickback violation if it determines that the provider has violated the statute. *See* 42 U.S.C. §1320a-7(b).

C. THE MEDICARE PROGRAM

29. Medicare is a federally funded health insurance program primarily benefiting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare, the nation's largest health insurance program, provides health insurance to people age 65 and over, to those who have end-stage kidney failure, and to certain people with disabilities.

30. Medicare Part A (the Basic Plan of Hospital Insurance) covers the cost of hospital inpatient stays and post-hospital nursing facility care. Medicare Part B (the Voluntary Supplemental Insurance Plan) covers the costs of physician services, certain pharmaceutical products, diagnostic tests, and other medical services not covered by Part A.

31. The Centers for Medicare and Medicaid Services (CMS) administers Medicare, but much of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as Fiscal Intermediaries. Fiscal Intermediaries are responsible for accepting claims for reimbursements under Medicare Part A (and some claims under Part B), and making payments for such claims. "Medicare Carriers" are responsible for accepting and paying claims for reimbursements under Medicare Part B.

1. Medicare Payments to Hospitals

32. Medicare pays hospitals different amounts for various services based, in part, on the setting (*e.g.*, inpatient or outpatient) where the services were performed. Hospitals are generally reimbursed for inpatient services on a "per case" basis. In other words, each inpatient hospitalization is assigned a Diagnosis Related Group ("DRG") based on the nature and severity of the patient's diagnosis and the services performed. Medicare then pays the hospital a pre-determined reimbursement rate based on the DRG. The pre-determined DRG reimbursement rate is

paid to the hospital regardless of how long the patient is admitted or the number of services provided.

33. DRGs are assigned to a case through a process called "grouping." A "grouper" is a type of software that reviews various data related to the hospitalization (especially the patient's diagnosis and the procedures performed) to determine the appropriate DRG for the treatment.

34. In most cases, the procedure performed by the hospital is one of the most significant, if not the determinative, data point affecting the DRG grouper's decision. These procedures are classified and reported using the International Classification of Diseases, Ninth Revision, Clinical Modification ("ICD-9-CM") system, established by CMS and the National Center for Health Statistics. These codes are commonly referred to as "ICD-9 procedure codes."

35. Payments for hospitals in the outpatient setting also bundle items and services so that hospital providers are paid for the procedures performed, including the cost of equipment. Hospitals use APC Codes (Ambulatory Payment Classifications) to bill for costs associated with outpatient services.

2. Medicare Payments to Physicians

36. Physician services provided in conjunction with a procedure performed at a hospital (on either an inpatient or outpatient basis) are billed and reimbursed separately from the hospital's DRG or APC payment.

37. Like hospital reimbursement, Medicare bases physician reimbursement on the assumption that similar types of procedures consume a similar amount of resources, and thus deserve similar reimbursement. Accordingly, Medicare reimburses physicians based on standardized procedure codes – HCPCS and CPT codes, as described below.

38. Each procedure code is assigned a weight or value (called a Resource Based Relative Value Unit or "RBRVU"), as determined by the Resource-Based Relative Value Scale ("RBRVS"). The payment level for any given procedure is then determined by multiplying the RBRVU value for the code times a conversion factor (which takes into account regional and other variable cost factors).

39. The RBRVS system is based on the Healthcare Common Procedure Coding System (HCPCS). HCPCS is a standardized coding system designed to ensure that Medicare, Medicaid and other federal health care programs pay for services rendered to patients by attending physicians and other healthcare professionals 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, both programs tie levels of reimbursement to standardized codes.

40. Current Procedural Terminology ("CPT") codes are Level I HCPCS codes and are published and updated annually by the American Medical Association ("AMA").

41. 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," "Radiology," or general "Medicine") and the specific medical procedures commonly practiced by physicians and other health care professionals working in that field.

42. The instructions that accompany the CPT manual direct providers "not [to] select a CPT code that merely approximates the service provided." Rather, when none of the standard CPT codes provides an accurate description of the services provided or procedure performed, 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 describe the specific procedure or service provided).

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

3. Other Rules Governing Payments to Both Hospitals and Physicians

44. In addition to compliance with other national or local coverage criteria, Medicare requires, as a condition of coverage, that services be reasonable and medically necessary. *See* 42 U.S.C. § 1395y(a)(1)(A). Providers must provide economical medical services, and only where medically necessary. *See* 42 U.S.C. § 1320c-(a)(1). Providers must provide evidence that the service is medically necessary and appropriate. *See* 42 U.S.C. § 1320c-5(a)(3). Providers must ensure that services provided are not substantially in excess of the needs of such patients. *See* 42 U.S.C. § 1320a-7(b)(6)&(8).

45. Federal law also specifically prohibits providers from making "any false statement or representation of a material fact in any application for any ... payment under a Federal health care program." *See* 42 U.S.C. § 1320-a-7b(a)(1). Similarly, Federal law requires providers who discover material omissions or errors in claims submitted to the Medicare to disclose those omissions or errors to the Government. *See* 42 U.S.C. § 1320-a-7b(a)(3). The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program. *See, e.g.*, 42 CFR §§ 1003.105, 1003.102(a)(1)-(2).

46. Physicians may not bill Medicare for services provided by Clinicians or Sales Representatives. Because Clinicians and Sales Representatives employed by device manufacturers

do not meet the definitions of either Provider or Supplier, *see* 42 C.F.R. 400.202, the services they provide are ineligible for payment under Medicare. *See* 42 C.F.R. 424.5(a)(ii)(2) ("The services must have been furnished by a provider, nonparticipating hospital, or supplies that was, at the time it furnished the services, qualified to have payment made for them.").

47. Federal law requires that doctors who are enrolled in medical studies ("Investigators") "prepare and maintain adequate and accurate case histories," including case report forms ("CRF"). See 21 CFR part 312.62b. The Company sponsoring the study is therefore prohibited from filling out the CFR. The reason for this requirement is that if the sponsor has access to the report forms they could "alter" the information contained therein to their own benefit, thereby tainting the study.

D. IMPLANTABLE CARDIAC RHYTHM DEVICES

1. Pacemakers

48. Pacemakers are electronic devices that are implanted in the chest to generate and regulate the heart's rhythm. Generally, pacemakers send electrical impulses to one or more chambers of the heart. These signals make the heart contract in a more regular rhythm than the chamber would otherwise. Although they can be used for a variety of heart conditions, pacemakers are most commonly used to correct an abnormally slow heartbeat.

49. Pacemakers may be either permanent or temporary. A permanent pacemaker is implanted into a patient's chest during a minor surgical procedure. Once the pacemaker is in place, it runs on batteries that last for about 5 to 10 years.

50. Temporary pacemakers are used primarily in emergency settings. The goal with temporary pacing is to reestablish a normal heart rhythm until the condition causing the abnormal heart rhythm resolves or a permanent pacemaker can be implanted.

2. Implantable Defibrillators

51. A defibrillator is an internal "shocking" device that is used to stop a sudden cardiac arrest. An implantable cardioverter defibrillator ("ICD") is used in patients who are at risk for recurrent, sustained arrhythmias known as ventricular tachycardias and or fibrillations.

52. ICDs are small devices that are connected to leads positioned inside the heart or on its surface. The leads are used to monitor the heart and deliver electrical shocks as needed. The various leads are tunneled to a pulse generator, which is implanted in a pouch beneath the skin of the chest or abdomen. Newer devices are smaller and have simpler lead systems that can be installed through blood vessels, eliminating the need for open chest surgery. They also offer a host of other sophisticated functions (such as storage of detected arrhythmic events and the ability to do "noninvasive" electrophysiological testing).

3. Implant Procedure and Follow-Ups

53. Pacemakers and ICDs may be implanted in either (1) a laboratory (usually a Catheterization Laboratory ("Cath Lab")) or (2) a hospital operating room. A cardiologist or electrophysiologist will perform the procedure if it is done at a Cath Lab; a surgeon will conduct the operation if it is in the operating room.

54. It is common practice for a Sales Representative, Clinician or other knowledgeable representative of the manufacturer of the device ("Representative") to be present throughout the procedure to answer any questions that may arise about the device, provide guidance about installation and program the device (or "run the equipment"). Running the equipment requires

conducting an "interrogation" of the device, performing device systems checks and programming the patient's identifying data onto a telemetric (or programming) wand.

55. After the procedure is completed, the Representative prepares an "Implant Data Report," which identifies the specific device and or devices that were implanted, along with all serial numbers, programming data, the name of the physician who performed the procedure, and the name of the device company Representative who was present during the procedure. The Medtronic Representative will also prepare a "Surgical-op Report" that includes a detailed analysis of the entire implant procedure.

56. All Medtronic implant patients are advised to come in for follow-up visits. Medtronic recommends that the first visit occur within one week of the procedure. During follow-up visits, the heart is monitored for irregularities and the mechanisms of the device are checked. The level of the pacemaker or defibrillator may be altered or other adjustments may be made.

57. According to Medtronic's website, medical personnel are critical to the proper monitoring of pacemakers:

> An important element of your follow-up care involves monitoring your pacemaker. ***You, your physician, and other medical professionals, all play important roles in monitoring your pacemaker*** to provide you with the most effective therapy.

58. Medtronic's website also describes the importance of medical personnel to monitoring ICD's:

> Follow-up visits are important to ensure that the implanted defibrillator continues to provide the best treatment for your arrhythmia. The purpose of these visits is to:
>
> - ***Assess your medical condition*** and find out about any lifestyle changes
> - Check the defibrillator's battery status and its programmed instructions for delivering therapy
> - Monitor any medications that are taken

- Provide psychological support
- Answer questions

The frequency of follow-up visits is determined by your doctor. It is common to have a first follow-up visit one month after receiving a defibrillator. Depending upon your doctor's usual practice and your medical condition, later visits are scheduled every three to six months. During the visit, ***the doctor or nurse*** will use the programmer to retrieve stored information from your device. If your medical condition changes, ***the doctor*** may reprogram your defibrillator to better treat a rapid rhythm. . . .

V. ALLEGATIONS

A. DEFENDANT MEDTRONIC PROVIDES ILLEGAL REMUNERATION (KICKBACKS) TO DOCTORS AND HOSPITALS TO INDUCE THEM TO USE MEDTRONIC'S CARDIAC RHYTHM DEVICES.

59. In an effort to corner the market on cardiac rhythm devices, Defendant Medtronic routinely provides illegal kickbacks to physicians and hospitals to induce them to perform procedures using Defendant's cardiac rhythm devices.

1. Defendant Provides Improper Kickbacks in the Form of Payment for Participation in Bogus Studies.

60. As part of its efforts to corner the market, Medtronic creates bogus studies and entices physicians and hospitals to participate in these studies by paying them large sums of money for each patient they enroll in the study. In exchange, the physicians and hospitals agree to use Medtronic products for patients in that study.

61. Medtronic conducts a number of post-market clinical studies (PMCSs), also known as registry trials.

62. There are two types of PMCSs. The first, which requires FDA approval, is typically a continuation of the pre-market clinical study conducted to bolster the device maker's claims of clinical effectiveness. Generally, it is conducted as a condition of FDA approval for the marketing of a new device.

63. The second type of PMCS does not require FDA approval. These are conducted by the device manufacturer to collect data for publication or to learn about possible new devices, techniques or concepts, with the eventual goal of distributing that information to the medical community.

64. As an incentive for doctors and hospitals to choose Medtronic's CRM devices, Medtronic Representatives promises monetary compensation to doctors and hospitals for participating in their PMSCs.

65. Many of these studies, however, have no utility to the medical field whatsoever. Moreover, while these studies are ostensibly conducted to collect data for the production of scientific literature, almost no articles of note have been published as a result.

66. As a result of their participation, doctors are compensated in two ways: (1) they are provided financial payments from Medtronic in amounts ranging from $1,200 for a survey set (in the case of the Attain registry) to as much as $8,200 per patient (in the case of the Improve-HF study), and (2) in cases where the patient is Medicare-eligible, they receive payments from the government. In some cases, doctors receive additional compensation in the form of services. Specifically, Medtronic Representatives will also fill out the Case Report Forms for participating doctors, providing yet another incentive for doctors and hospitals to use their products.

67. Thus, the studies offered by Medtronic serve as an enticing type of kickback.

2. Defendant Provides Improper Kickbacks in the Form of Medical Services Performed By Unlicensed Staff To Physicians and Hospitals to Induce Them to Perform Procedures Using Medtronic's Cardiac Rhythm Devices.

68. As part of its efforts to corner the market, Defendant promises both doctors and hospitals that use Medtronic's cardiac rhythm devices that it will provide all follow-up care for those patients. Physicians often complain that checking the devices during their clinic times is time-

consuming and expensive. As an incentive for doctors and hospitals to choose Medtronic devices, Medtronic Representatives tell doctors and hospitals that if they use a Medtronic device, they will not have to be involved in any of the patient's follow-up care. Instead, Medtronic will send a Representative to the doctor's office or clinic to see the patients, advise the patient on any necessary follow-up care, make adjustments to the implanted device, and even make house calls for the doctor, without a licensed physician or staff member present.

69. When a Medtronic Representative arrives at a doctor's office, s/he collects all of the implant patients' charts, billing sheets and patient visit sheet (or device check form) and then proceeds to take over nearly all follow-up care for those patients. It is not unusual for a Medtronic Representative to see up to forty patients a day.

70. Thus, and unbeknownst to the cardiac patient, the implant of a Medtronic pacemaker or ICD is often the first and last time the implant patient will ever see the doctor. Instead, nearly all follow-up visits, any telephone or other inquiries, and necessary adjustments or programming changes to the device, and medical questions will all be handled by a Medtronic Representative, without a licensed physician or staff member present. The Medtronic Representative will then fill out a "visit sheet" (device check sheet) detailing what s/he did so the physician will know how to document the visit. This is in direct violation of Medicare Regulations. *See* 42 C.F.R. 400.202; 42 C.F.R. 424.5(a)(ii)(2).

71. Medtronic Representatives are instructed to convince the doctors to give them virtually total autonomy over post-surgical patient care.

72. If an implant patient calls in to speak with a doctor, the doctor calls a Medtronic Representative to deal with the patient. If a patient asks to see a doctor, the doctor calls a Medtronic Representative to come to the clinic or doctor's office to deal with the patient.

73. The patient visits occur primarily at the doctors' offices, where Medtronic personnel are provided unfettered discretion to examine patient files, in violation of HIPAA, conduct patient checks and make recommendations.

74. Medtronic Representatives are also sometimes required by the Company to make house calls and visits to nursing homes to follow up on implant patients. In such situations, they are forced to make medical decisions and are denied access to any medical staff. When, on at least one occasion, Plaintiff-Relator Onwezen refused to make a house call, her manager forced her to go.

75. Medtronic Representatives are trained to sit down with the doctor and show him how s/he is under-billing. They are instructed to point out to doctors that, in order to maximize profits, they should turn over all billing responsibilities to a Medtronic Representative.

76. The doctor, who will not have seen the patient since the surgery, will receive ongoing Medicare reimbursement payments for all subsequent follow up medical checkups conducted by Defendant's sales representatives and clinicians, which patients continue to receive well into the future.

77. Medtronic pays Representatives $100.00 for every doctor or clinic that grants Representatives autonomy over their office or clinic for performing device checks and billing.

3. Defendant Provides Improper Kickbacks, in the Form of Free Billing of Medical Services, To Physicians to Induce Them to Perform Procedures Using Medtronic's Cardiac Rhythm Devices.

78. The process of filing insurance claims, particularly where Medicare is involved, is a cumbersome and time-consuming process. Given the amount of paperwork involved and various billing and coding questions that can evolve, a single doctor may need to devote several employees to billing. This can be an expensive process. Doctors therefore have a tremendous interest in delegating their billing responsibilities to others.

79. As an added incentive for doctors to use Medtronic devices, Medtronic Representatives advise doctors that the Representatives will handle all of the paper- work related to billing for implant patients, including filling out the "visit sheets" used by doctors to document the work they have purportedly done, and the "billing sheets" submitted to Medicare. It is improper for a physician to allow non-licensed non-medical personnel to handle their billing.

80. Medtronic advises doctors who perform implants to provide their Medtronic Representative with a billing form. The Medtronic Representative then determines what code to use for the follow-up care s/he provided and fills out the billing sheet for the doctor's signature. Medtronic then submits the billing sheet to the physician's billing department, which submits it to Medicare for reimbursement.

81. Medtronic Representatives are trained to lock the billing sheet in files provided by the hospitals and physician's offices to obscure the fact that Medtronic had direct access to, and input in, doctor's and hospital bills.

82. Later, the doctor, who will not have seen the patient since the initial implant surgery, receives payments for medical services s/he did not provide.

4. Defendant Coaches Doctors To Charge the Government for Unnecessary Follow-Up Care Relating to Cardiac Rhythm Devices.

83. Medtronic's sales and marketing departments train their Representatives to market their cardiac rhythm procedures by advising doctors that the doctor or hospital can obtain extra reimbursements from Medicare if they allow Representatives to perform extra check-ups and follow-up visits on patients with Medtronic devices.

84. Patients with Medtronic pacemakers or ICDs are thus unnecessarily subjected to unnecessary adjustments or changes to the device, which then requires them to return for another check-up. As is the case with all follow-up visits on Medtronic implant patients, these check-ups are

performed by non-medical Medtronic personnel, without a licensed physician or staff member present.

85. As is the case with all follow-up care, Medtronic causes doctors to bill Medicare for these unnecessary visits. Later, the doctor, who will not have seen the patient since the initial implant surgery, receives Medicare payments for medical services s/he did not provide.

5. Defendant Coaches Doctors and Hospitals To Perform and Bill for Unnecessary Procedures and Unnecessary Upgrades to Newer Devices.

86. Defendant's sales and marketing departments also train their Representatives to advise hospitals and doctors to perform extra and often unnecessary procedures to increase their Medicare billing.

87. To this end, Medtronic Representatives go into the doctor's office and ask to see all Medicare bills for a specific procedure over a certain period of time. The Representative then sits in the doctor's office with the billing records and reviews the files.

88. Per instructions from management, the Representative goes through the files, one at a time, and circles any and all codes that could possibly apply to a given procedure. The Representative then instructs the doctor that, in order to increase billing, s/he should perform these other procedures.

89. Plaintiff-Relator Onwezen has knowledge that Representatives advised doctors to perform unnecessary and sometimes invasive procedures such as EP Studies (special catheterization tests used to study the cardiac electrical system) and/or right heart catheterization prior to implanting defibrillator/pacemaker combinations. After the implants were performed, the Representatives would advise the doctor to perform other unnecessary procedures such as Echo studies (ultrasounds of the heart). Doctors would perform these procedures, at the behest of Medtronic, despite their

being medically unnecessary. The Medtronic Representative then prepares the bill on behalf of the doctor or hospital.

90. Later, the doctors and hospitals are reimbursed for the unnecessary procedures.

91. Medtronic also encourages Representatives to go through client files (in violation of HIPAA), find patients who are candidates for upgraded cardiac rhythm devices, and convince doctors and hospitals to purchase Medtronic upgrades.

92. Medtronic pays its Representatives $100.00 for every Medtronic upgrade that a doctor purchases.

93. As is the case with nearly all follow-up care, Medtronic Representatives prepare the billing sheets for the unnecessary upgrades.

94. Later, the doctor who performs the unnecessary upgrade at the advice of untrained Medtronic personnel receives Medicare payments for the upgrade.

6. Defendant Uses CareLink® To Maximize its Profits as Well as the Profits of Doctors Who Use its Cardiac Rhythm Devices.

95. In 2002, Medtronic completed the first phase of the rollout of its CareLink Network® ("CareLink"). CareLink® is an internet-based monitoring system that allows patients to receive post-implant care from their homes without having to meet face-to-face with a physician. The system works by transmitting information obtained from the implanted device through the internet to the doctor's office. The doctor can then use the information to determine whether the device is working properly, and whether any adjustments are needed.

96. According to Medtronic, over 80,000 patients currently use CareLink®.

97. According to Medtronic, CareLink® "takes remote monitoring to the next level, ***paving the way to true cardiac disease management***" by health care professionals.

98. Medtronic's website describes the important role physicians play in the proper use of

CareLink®:

> The Medtronic CareLink Network ensures timely identification of clinically important issues, such as asymptomatic atrial fibrillation or device integrity issues. Patients express reassurance ***knowing their clinicians have critical information*** for managing their cardiac disease and appreciate the ability to send device information from home and away. ***Clinicians can review*** device data when and where they choose on the Medtronic CareLink Clinician Website.
>
> * * *
>
> This advanced technology includes a patient monitor that enables you to "connect" your implanted device ***to your clinic*** via a standard phone line, ***allowing your doctor to conduct a routine checkup or review a special*** situation no matter where you are.** And to make it easy for you to get answers to your questions, we offer a patient services helpline, as well as multiple websites that feature information about a wide range of health issues, heart conditions, and devices.
>
> * * *
>
> Patient confidentiality is a priority of the Network. The website is secure, protected by username and password ***for use by authorized clinic personnel.***

99. Steve Mahle, President of Medtronic Cardiac Rhythm Management, has specifically touted CareLink® as a means of "***expanding how physicians and patients interact.***"

100. Yet, in contravention of Medtronic's own stated policy, Medtronic convinces doctors not to use medical personnel to perform any of the CareLink® treatment of patients with Medtronic devices. Rather, the Company uses non-licensed, non-medical personnel, such as Sales Representatives and Clinicians, to handle almost all aspects of the patient's medical follow-up care, without a licensed physician or staff member present.

101. During the CareLink® phone checks, patients therefore receive no attention from certified medical personnel of any kind.

102. Because CareLink® phone checks cost less than office visits, Medtronic Representatives also agree to conduct more consultations in order to increase billing for the doctor.

103. As is the case with nearly all follow-up care, Medtronic Representatives then coach

the physician offices on how to bill Medicare for maximum reimbursement regarding bills Medicare for the CareLink® services.

104. Later, the doctor who performed the initial implant receives Medicare payments for the CareLink® phone checks as if the doctor had performed them.

7. Defendant Provides Bonuses, Free Equipment and other "Gifts" to Doctors and Hospitals to Induce Them to Purchase Defendant's Products, and to Discourage the Use of Competitors' Products.

105. Defendant routinely provides kickbacks to doctors and hospitals in the form of free tickets or the free use of "loaner" equipment, disguised in the form of discounts or equipment loans. Often these improper inducements are given on the explicit condition that the doctor or hospital will predominantly (or exclusively) use Defendant's products. Medtronic encourages hospitals to bill Medicare as if they owned this equipment.

106. Defendant routinely provides hospitals with free products, including programmers and printers. These gifts are given in exchange for the hospital's agreement to buy Medtronic's cardiac rhythm devices.

107. By receiving free products, hospitals reduce costs and increase reimbursement on each procedure performed. Because the DRG-based reimbursement to the hospital is fixed, the hospital pockets 100% of these "discounts."

108. Medtronic includes in its contracts with hospitals a provision that binds the hospital to purchase at least 90% of their cardiac rhythm device purchases from Medtronic. Medtronic performs audits on a quarterly basis to ensure that hospitals comply with this condition and rewards compliant hospitals with large bonus checks.

109. These bonuses vary in amount but can be as high as $30,000 to $50,000 per quarter.

COUNT I

Violation of the False Claims Act
31 U.S.C. §3729(a)(1)-(2), (7)

110. Plaintiff-Relators reallege and incorporate by reference the allegations in the preceding paragraphs of this Complaint.

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

112. As described above, Defendant has, through the use of illegal kickbacks, fraudulently induced physicians and hospitals to use Medtronic's Cardiac rhythm devices and, in some instances, to conduct unnecessary procedures on cardiac patients.

113. Defendant has also illegally permitted Medtronic Representatives, who are not members of doctors' staff, to illegally complete Medicare billing and diagnosis forms, to upcode Medicare billing forms, and to bill for unnecessary procedures.

114. Through the acts described above, Defendant knowingly made, used, and caused to be made and used false records and statements in order to obtain reimbursement from the United States for Medtronic devices.

115. The United States, unaware of the falsity or fraudulence of the statements, records or claims made or submitted by Defendant, its agents, and employees, approved, paid and continues to approve and pay claims that otherwise would not have been approved or paid, and has not recovered funds that would otherwise have been recovered.

116. Through the acts described above, Defendant 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.

117. 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
Violation of the False Claims Act (Retaliatory Discharge)
31 U.S.C. §3730(h)

118. Plaintiff-Relator Onwezen realleges and incorporates by reference the allegations in paragraphs 1-109.

119. Pursuant to 31 U.S.C. §3730(h), the False Claims Act prohibits an employer from discharging, demoting, suspending, threatening, harassing, or in any other manner discriminating against an employee in the terms and conditions of employment because of lawful acts done by the employee in furtherance of an action under the Act.

120. On several occasions beginning in approximately February 2004 and continuing until her resignation in January 2006, Plaintiff-Relator Onwezen told her manager that she would not complete the doctors' billing or diagnosing forms because, under law, she is not permitted to do so. Ms. Onwezen's manager responded by threatening that Ms. Onwezen would lose her job if she did not complete the billing or diagnosing form do the billing, stating words to the effect of, "if you don't like it, there are hundreds of other people who want your job."

121. Plaintiff-Relator Onwezen's act of confronting Defendant and challenging the billing practices engaged in by Defendant was lawful conduct "in furtherance of" a False Claims Act action.

122. Plaintiff-Relator Onwezen's protected conduct put Defendant on notice of the distinct possibility of a *qui tam* action.

123. Defendant discriminated against Plaintiff-Relator Onwezen in the terms and conditions of her employment by threatening to terminate her employment because she confronted Defendant regarding their illegal and improper billing practices.

COUNT III
Violation of the False Claims Act (Retaliatory Discharge)
31 U.S.C. §3730(h)

124. Plaintiff-Relator Brill realleges and incorporates by reference the allegations in paragraphs 1-109.

125. Pursuant to 31 U.S.C. §3730(h), the False Claims Act prohibits an employer from discharging, demoting, suspending, threatening, harassing, or in any other manner discriminating against an employee in the terms and conditions of employment because of lawful acts done by the employee in furtherance of an action under the Act.

126. In April of 2005, Plaintiff-Relator Brill used Medtronic's compliance hotline to report that Medtronic was paying doctors to participate in bogus post-market clinical studies that provided nothing of any scientific value to either Medtronic or the industry. Plaintiff-Relator. Brill also reported that Medtronic was spending large sums of money on doctors for lunches, dinners and gifts.

128. The Hotline had been presented to Medtronic employees as a third party company. Employees were given a 1-800 number to call "anonymously" and report violations of the AdvaMed's Code of Ethics.

129. Yet, just 60 days after reporting the bogus studies, Plaintiff-Relator was terminated from his employment with Medtronic. Mr. Brill was given no explanation for his termination.

127. Plaintiff-Relator Brill's act of confronting Defendant and challenging its practice of paying doctors to participate in bogus studies was lawful conduct "in furtherance of" a False Claims Act action.

128. Plaintiff-Relator Brill's protected conduct put Defendant on notice of the distinct possibility of a *qui tam* action.

129. Defendant discriminated against Plaintiff-Relator Brill in the terms and conditions of her employment by threatening to terminate his employment because he confronted Defendant regarding its illegal practices.

VI. PRAYER FOR RELIEF

WHEREFORE, Plaintiff-Realtors pray for judgment against the Defendant as follows:

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

2. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's 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 Plaintiff-Relators be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

4. that Plaintiff-Relators be awarded all costs of this action, including attorneys' fees and expenses; and

5. that the United States and Plaintiffs recover such other and further relief as the Court deems just and proper.

6. that Plaintiff-Relator Onwezen be awarded the maximum amount she is entitled to, pursuant to 31 U.S.C. §3730(h) of the False Claims Act, to make her whole, including two times the amount of back pay, interest on the back pay, and compensation for any special damages sustained as a result of the retaliatory discharge, including litigation costs and reasonable attorneys' fees.

VII DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiffs-Relators hereby demand a trial by jury.

Dated: April 18, 2008

Respectfully submitted,

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