UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

SEALED

UNITED STATES OF AMERICA, ET AL. EX REL. [UNDER SEAL], Plaintiff, v. [UNDER SEAL], Defendant.	No. COMPLAINT JURY TRIAL DEMANDED

[FILED IN CAMERA AND UNDER SEAL]

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, ET AL. EX REL. TRICIA NOWAK, Plaintiff, v. MEDTRONIC, INC., Defendant.	No. COMPLAINT FOR VIOLATIONS OF THE FEDERAL FALSE CLAIMS ACT [31 U.S.C. § 3729, *et seq.*]; CALIFORNIA FALSE CLAIMS ACT [Cal. Govt. Code § 12650, *et seq.*]; DELAWARE FALSE CLAIMS AND FALSE REPORTING ACT [6 Del. C. § 1201]; FLORIDA FALSE CLAIMS ACT [Fla. Stat. Ann. § 68.081, *et seq.*]; HAWAII FALSE CLAIMS ACT [Haw. Rev. Stat. § 661-21, *et seq.*]; ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT [740 Ill. Comp. Stat. § 175, *et seq.*]; INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT [Ind. Code Ann. § 5-11-5.5-1, *et seq.*]; LOUISIANA MEDICAL ASSISTANCE PROGRAM INTEGRITY LAW [La. Rev. Stat. § 46:437.1, *et seq.*]; MASSACHUSETTS FALSE CLAIMS LAW [Mass Gen Laws ch.12 § 5, *et seq.*]; MICHIGAN MEDICAID FALSE CLAIMS ACT [Mich. Comp. Laws. § 400.601, *et seq.*]; MONTANA FALSE CLAIMS ACT [Mont. Code Ann. § 17-8-401, *et seq.*]; NEVADA FALSE CLAIMS ACT [Nev. Rev. Stat. Ann. § 357.010, *et seq.*]; NEW HAMPSHIRE FALSE CLAIMS ACT [N.H. Rev. Stat. Ann. § 167:61, *et seq.*]; NEW MEXICO MEDICAID FALSE CLAIMS ACT [N.M. Stat Ann. § 27-2F-1, *et seq.*]; TENNESSEE FALSE CLAIMS ACT AND TENNESSEE MEDICAID FALSE CLAIMS ACT [Tenn. Code Ann. § 4-18-101, *et seq.* and § 71-5-181, *et seq.*]; TEXAS MEDICAID FRAUD PREVENTION LAW [Tex. Hum. Res. Code Ann. § 36.001, *et seq.*]; VIRGINIA FRAUD AGAINST TAXPAYERS ACT [Va. Code Ann § 8.01-216.1, *et seq.*]; DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT [D.C. Code Ann. § 1-1188.13, *et seq.*].

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Plaintiff and Relator Tricia Nowak, through her attorneys Hagens Berman Sobol Shapiro LLP, on behalf of the United States of America, the State of California, the State of Delaware, the State of Florida, the State of Hawaii, the State of Illinois, the State of Indiana, the State of Louisiana, the State of Massachusetts, the State of Michigan, the State of Montana, the State of Nevada, the State of New Hampshire, the State of New Mexico, the State of Tennessee, the State of Texas, the State of Virginia and the District of Columbia (collectively "the States"), for her Complaint against Defendant Medtronic, Inc., alleges based upon personal knowledge and relevant documents, as follows.

I. INTRODUCTION

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

2. As set forth below, Medtronic's acts also constitute violations of the California False Claims Act, CAL. GOVT. CODE § 12650, *et seq.*; the Delaware False Claims and False Reporting Act, 6 DEL. C. § 1201, *et seq.*; the Florida False Claims Act, FLA. STAT. ANN. § 68.081, *et seq.*; the Hawaii False Claims Act, HAW. REV. STAT. § 661-21, *et seq.*; the Illinois Whistleblower Reward and Protection Act, 740 ILL. COMP. STAT. § 175/1, *et seq.*; the Indiana False Claims and Whistleblower Protection Act, IND. CODE ANN. § 5-11-5.5-1, *et seq.*; the Louisiana Medical Assistance Program Integrity Law, LA. REV. STAT. § 46:437.1, *et seq.*; the Massachusetts False Claims Law, MASS. GEN. LAWS CH. 12 § 5, *et seq.*; the Michigan Medicaid False Claims Act, MICH. COMP. LAWS. § 400.601, *et seq.*; the Montana False Claims Act, MONT. CODE ANN. § 17-8-401, *et seq.*; the Nevada False Claims Act, NEV. REV. STAT. ANN. § 357.010,

et seq.; the New Hampshire False Claims Act, N.H. REV. STAT. ANN. § 167:61, *et seq.*; the New Mexico Medicaid False Claims Act, N.M. STAT. ANN. § 27-2F-1, *et seq.*; the Tennessee False Claims Act and Tennessee Medicaid False Claims Act, TENN. CODE ANN. § 4-18-101, *et seq.* and § 71-5-181, *et seq.*; the Texas Medicaid Fraud Prevention Law, TEX. HUM. RES. CODE ANN. § 36.001, *et seq.*; the Virginia Fraud Against Taxpayers Act, VA. CODE ANN. § 8.01-216.1, *et seq.*; and the District of Columbia Procurement Reform Amendment Act, D.C. CODE ANN. § 1-1188.13, *et seq.*

3. For more than five years, Medtronic, the world's largest medical technology company with nearly 38,000 employees, has unlawfully and unabashedly marketed and promoted its biliary stent medical devices for uses unapproved by the Food and Drug Administration ("FDA"). Medtronic, a Fortune 500 company listed on the New York Stock Exchange ("NYSE"), has knowingly promoted the "off-label" (*i.e.*, unapproved) application of these medical devices in contravention of federal law and explicit warning from the FDA.

4. As explained *infra*, Medtronic, with net sales of over $12 billion in fiscal year 2007 (a $5 billion increase since 2003), has pressured and incentivized its sales force to promote biliary stent devices for vascular, or "peripheral," uses for which they are unapproved, and ineligible for reimbursement under various government health care programs, such as Medicare.

5. While unlawfully creating demand in the medical community for off-label application of its biliary stents, Medtronic is circumventing the FDA's regulatory safeguards for the use of approved medical devices. Such circumvention relieves Medtronic of the expense and time needed to satisfy the requirements for FDA approval of such devices for additional uses. By some estimates, the off-label promotional efforts of Medtronic have resulted in nearly 90% of the uses for its biliary stents now being off-label. This off-label market has increased

Medtronic's profits at the expense of public safety, and patient health. This unlawful practice also gives Medtronic an unfair competitive advantage over those companies who have spent, and continue to spend, time and money to secure FDA approval for their comparable *on-label* medical devices.

6. As a direct result of Medtronic's unlawful marketing campaign, federal and state health care programs including, but not limited to, Medicare, Medicaid, Medi-Cal, CHAMPUS/TRICARE, CHAMPVA, the Veterans Administration and the Federal Employee Health Benefits Program have been caused to pay false or fraudulent claims for reimbursement of costs associated with the off-label use of biliary stents among patients for whom biliary stents are unapproved for use in the medical procedures they undergo.

7. *Qui tam* plaintiff seeks through this action to recover damages and civil penalties arising from Medtronic's making or causing to be made false or fraudulent records, statements and/or claims in connection with the marketing of its biliary stents for off-label purposes. Medtronic has knowingly encouraged the submission of innumerable claims to federal and state health insurance programs for non-FDA approved and potentially harmful uses of biliary stents.

II. PARTIES

8. Plaintiff/relator, Tricia Nowak, is a resident of the State of California. Since 2005, Ms. Nowak has been employed by Medtronic as a Sales Representative in the Endovascular Group.

9. Defendant Medtronic, Inc., is a publicly traded company listed on the NYSE, with corporate headquarters and its principal place of business in Minneapolis, Minnesota. Medtronic is a medical device manufacturer that markets, promotes, and sells its devices across the United States and around the world.

III. JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions, such as this, brought pursuant to 31 U.S.C. §§ 3729 and 3730(b). In addition, 31 U.S.C. § 3732(b) specifically confers jurisdiction on this Court over the state-law claims asserted in this Complaint. Under 31 U.S.C. § 3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

11. This Court has personal jurisdiction over the Defendant and is a proper venue pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a) because those sections authorize nationwide service of process and because the Defendant has minimum contacts with the United States. Moreover, the Defendant can be found in, resides, transacts, or has transacted business in the District of Massachusetts.

12. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) because the Defendant can be found in and transacts or has transacted business in the District of Massachusetts. At all times relevant to this Complaint, Defendant regularly conducted substantial business within the District of Massachusetts, and made significant sales within the District of Massachusetts.

IV. BACKGROUND

A. The FDA Regulatory System

13. In 1976, Congress enacted the Medical Device Amendments ("MDA"), 21 U.S.C. § 360*c, et seq.*, to the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, in order to synchronize FDA regulation of medical devices with that of pharmaceuticals products, and "to provide for the safety and effectiveness of medical devices intended for human use." Pub. L. No. 94-295, 90 Stat. 539, 539 (1976) (preamble). The MDA expanded the authority of

the FDA to regulate medical devices, a business that has since grown exponentially into a multi-billion dollar industry, consisting of over 100,000 products in nearly 2,000 medical categories.

14. A "medical device" is broadly defined as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is – (1) recognized by the official National Formulary, or the United States Pharmacopeia (USP), or any supplement to them, (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in a man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve any of its principal intended purposes through chemical action within or on the body of the man or other animals, and which is not dependent upon being metabolized for the achievement of its principal intended uses." 21 U.S.C. § 321(h).

15. Under the MDA, medical devices are divided into three categories, or "classes." Class I devices (such as bandages and sterile gloves) are subject to minimal regulation; Class II devices (such as powered wheelchairs and surgical drapes) are subject to moderate regulation; and Class III devices, those devices that either "present a potential unreasonable risk of illness or injury," or which are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," are subject to the strictest controls. 21 U.S.C. § 360*c*(a)(1)(C).

16. Class III devices may not be introduced into the market until and unless the FDA has approved the device for its "intended use," that is, the use intended by the manufacturer, or, "the objective intent of the persons legally responsible for the labeling of the devices." 21 C.F.R. § 801.4. Three routes exist for manufacturers of Class III devices to obtain FDA approval. Most

commonly, manufacturers seek "premarket approval" ("PMA") from the FDA, establishing, through extensive and lengthy review of data from clinical trials, bench and animal tests, "reasonable assurance" that the device is safe and effective for its intended use. 21 U.S.C. § 360*e*(d)(2). To obtain PMA, the FDA demands a complete report of all clinical and laboratory testing, a full statement of the components and design of the product, a description of the manufacturing process and quality controls, sample labeling instructions, and other detailed information. 21 U.S.C. § 360*e*(c)(1). This rigorous process requires the FDA to spend an average of 1200 hours reviewing and evaluating each such application, often in lengthy discussions with the manufacturer regarding safety and other concerns.

17. Two limited and exclusive exceptions to the PMA process exist for manufacturers seeking to introduce their medical devices to consumers. First, a device can be sold if cleared by the FDA under the so-called 510(k) process, whereby the manufacturer can market and sell a device which is a "substantial equivalent" to a device already approved. Second, devices judged to reflect innovative technology may be marketed under a restricted "investigational device exemption," or "IDE," for purposes of conducting investigations of that device. 21 U.S.C. § 360*j*(g); 21 C.F.R. § 812.1.

18. A medical device may not lawfully be marketed or promoted for a use not previously approved by the FDA under at least one of the three routes described above – the PMA process, the 510(k) process, or the IDE process.

19. A medical device is only approved on the basis of its intended use, or approved "indication," which must then be included in the device's labeling. 21 U.S.C. § 352(f); 21 C.F.R. § 801.5. A medical device is not approved *in general*. If the manufacturer wishes to market a new, unapproved use for a device, it must obtain FDA approval (through one of the

routes explained above) so that its labeling is changed to reflect the government approval of such additional or substitute uses. 21 C.F.R. § 807.81(a)(3).

20. A medical device is deemed "misbranded," and its promotion therefore unlawful, where, *inter alia*, it is promoted or otherwise marketed in a manner inconsistent with its approved FDA label. 21 U.S.C. § 331, 352. "Off-label" refers to the promotion or use of an approved medical device for any purpose, or in any manner, other than what is stated in the drug's labeling (i.e., what has been approved by the FDA as an "indication"). Off-label promotion, that is, promotion by the manufacturer of a medical device for an unapproved use, is unlawful, and renders a medical device "misbranded." This is because, in that instance, the manufacturer's actual "intended use," *i.e.*, the use for which they are promoting the medical device, is inconsistent with the "intended use" approved by the FDA, and therefore the promotion is off-label.

21. What the manufacturer "intends" can be determined by the "expressions" of the manufacturer (or its agents) in promoting the device, or "by the circumstances surrounding [its] distribution." 21 C.F.R. § 801.4. "This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by [the manufacturer] or their representatives. It may be shown by the circumstances that the [device] is, with the knowledge of [*inter alia*, manufacturers] or their representatives, offered and used for a purpose for which it is neither labeled nor advertised." *Id.* Importantly, "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 that accords with such other uses to which the article is put to be." *Id.*

22. It is important to note that once a device is approved for a particular use, the FDA does not prohibit doctors from *using* that device for purposes different than those approved by the FDA – the manufacturer, however, is prohibited from *promoting* any unapproved use.

23. The statutory prohibition on off-label promotion by medical device manufacturers protects patients and consumers by seeking to ensure that manufacturers do not promote their devices for uses other than those found to be safe and effective by an independent, scientific governmental body – the FDA.

B. Reimbursement of Medical Devices Under Federal Health Care Programs

1. The Medicare program

24. Medicare is a federal health care program serving approximately 43 million elderly and disabled Americans.

25. The Medicare program is administered by the Centers for Medicare and Medicaid ("CMS") on behalf of the Secretary of Health and Human Services (the "Secretary"). CMS contracts with so-called "fiscal intermediaries," typically private insurance companies, to act as agents of the Secretary in administering the Medicare program.

26. In conformity with federal law, these intermediaries review claims to determine whether they are appropriate for reimbursement. Medicare "Part A," 42 U.S.C. §§ 1395*c*-1395*i*, provides insurance for covered inpatient hospital and related services. Medicare "Part B," 42 U.S.C. §§ 1395*j*-1395*w*, is a supplemental program insuring other items and services, such as out-patient hospital and physician services, supplies, and laboratory tests.

27. Broad wording excludes from Medicare coverage, "under part A or part B…any expenses incurred for items or services [which] …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. § 1395*y*(a)(1)(A); *see also* 42 C.F.R. § 411.15(k)(1).

28. The Secretary is charged with the task of clarifying those services that are covered under the "reasonable and necessary" standard. 42 U.S.C. § 1395*ff*(a). Historically, the Secretary clarified this standard through less formal instructional manuals and letters, and held simply, as per the 1986 Manual Instruction, that medical devices not approved for marketing by the FDA are considered investigational and non-reimbursable. More recently, in 1995, the FDA, in conjunction with CMS, modified this general prohibition on reimbursement to allow payment by Medicare for IDEs classified by the FDA as "Category B" (non-experimental/non-investigational), where all other approval and coverage requirements were met.

29. Experimental or investigational devices, however, have remained uncovered. The Code of Federal Regulations sets forth "Particular services excluded from coverage" excluding, *inter alia*, "experimental or investigational devices" which are not considered Category B, nor "furnished in accordance with FDA-approved protocols governing clinical trials." 42 C.F.R. § 411.15 (o); 42 C.F.R. § 405.201.

30. The CMS Intermediaries' Manual reflects this same coverage restriction. The Intermediary Manual provides, under "General Exclusions from Coverage," that "[m]edical devices which have not been approved for marketing by the FDA are considered investigational by Medicare and are not reasonable and necessary… Program payment, therefore, may not be made for medical procedures or services performed using devices which have not been approved for marketing by FDA." Inter. Manual § 3151.1

31. Some reimbursement for unapproved devices is allowed where both the beneficiary and provider "did not know, and could not reasonably have been expected to know" the services provided were not covered by Medicare. 42 U.S.C. § 1395pp(a).

32. Additionally, when an otherwise approved medical device is used in an unapproved, off-label manner, the use is considered investigational and experimental, and therefore non-reimbursable. 42 C.F.R. § 411.15(o). Also, "Medicare payment is not made for medical and hospital services that are related to the use of a device that is not covered because CMS determines the device is not 'reasonable' and 'necessary'...or because it is excluded from coverage for other reasons." 42 C.F.R. § 405.207.

2. The Medicaid program

33. Medicaid, 42 U.S.C. § 1396, *et seq.* (the "Medicaid Act"), is a public assistance program providing for payment of medical expenses for approximately 50 million low-income patients. Funding for Medicaid is shared between the federal government and state governments.

34. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines, and some services, such as inpatient hospital services, vaccines for children, and prenatal care, must be provided under the state program in order to receive federal funding. 42 U.S.C. § 1396*a*(a)(10). States may offer additional, non-mandatory services if they elect to do so.

35. Both federal and state law regulate the extent of coverage for medical devices, and their approved applications. Unapproved uses are typically excluded from reimbursement under Medicaid, as they are under Medicare.

3. Reimbursement under other federal health care programs

36. In addition to Medicaid and Medicare, the federal government provides reimbursement, in whole or part, for approved medical devices under several other federal health care programs, including, but not limited to, CHAMPUS/TRICARE/CHAMPVA and the Federal Employees Health Benefit Program.

37. CHAMPUS/TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disabilities. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

38. The off-label use of biliary stent medical devices promoted by Medtronic is not eligible for reimbursement under any of these federal health care programs.

4. Direct purchases by federal agencies

39. In addition to reimbursement through Medicare, Medicaid, and other federal health care programs, the United States is a significant *direct* purchaser of medical devices through various federal prograMs. Defendant's unlawful, off-label promotion of its biliary stents has resulted in purchases for off-label use by the following two government prograMs.

a. Programs administered by the Department of Veteran Affairs

40. The Department of Veteran Affairs ("VA") maintains a system of medical facilities serving approximately four million veterans. The VA directly purchases medical devices that are utilized through its facilities and programs.

b. Programs administered by the Department of Defense

41. The Department of Defense ("DOD") provides medical benefits to approximately eight million active duty personnel, retirees, and their families, including the utilization of medical devices.

V. ALLEGATIONS

A. Medtronic's CardioVascular Division

42. Medtronic has developed hundreds of medical devices intended to address a variety of medical conditions and procedures. Various divisions within Medtronic are responsible for promotion and marketing of the company's devices. In 2007, Medtronic created the Medtronic CardioVascular (or "Vascular") division when it combined its Vascular and Cardiac Surgery divisions. This division is now responsible for development and promotion of products that treat conditions related to the heart and circulatory systems. Such products include various stents (typically metal or plastic tubes inserted into a passage, such as a blood vessel, to keep it open) and catheters (hollow tubes typically inserted into a body cavity duct or vessel) used for treating coronary and peripheral (*i.e.*, outside the heart) vascular conditions, as applied in various medical procedures.

43. Within the CardioVascular division are both the Endovascular Group and the Coronary Group. The Endovascular Group primarily promotes the use of non-coronary medical devices "within a blood vessel," and its primary medical device is the AneuRx AAAdvantage Stent Graft System ("AneuRx") used for the treatment of Abdominal Aortic Aneurysms. An aneurysm is a bulge that forms within the wall of a blood vessel, typically from an accumulation of fatty deposits on the vessel wall. With time, the force of normal blood pressure in the aneurysm can lead to a rupture. When the aneurysm forms in the aorta, one of the body's main blood vessels extending through the abdomen, it is called an abdominal aortic aneurysm. For many patients, a substantial risk exists that such an aneurysm will burst, potentially causing death.

44. The AneuRx medical device is offered by Medtronic as an alternative to conventional surgery to address these aneurysms. A procedure known as "endovascular stent

grafting" involves placement of the AneuRx stent graft, a woven polyester tube covered by a metal web, inside of the diseased vessel without opening the surrounding tissue. When done properly, the stent graft excludes the aneurysm from normal blood flow, thus preventing rupture.

45. Medtronic's Coronary Group develops and promotes, according to its website, "a full line of products for use in the diagnosis and treatment of coronary arteries that are restricted or blocked by atherosclerotic plague. Primary products include coronary stents (for both smaller and larger vessels), guide catheters, balloon catheters, diagnostic catheters and guidewires." Coronary arteries, termed such because they encircle the heart in the shape of a crown, are the vessels that supply the heart muscle with blood rich in oxygen.

46. Among the Medtronic products promoted for approved use by the Coronary Group are the Driver Coronary Stent System and the Micro-Driver, both "bare-metal" (as opposed to "drug-eluting") stents for use by interventional cardiologists in treating patients with symptomatic ischemic heart disease. The Coronary Group also sells approved catheters and guidewires for use by cardiologists treating heart patients.

47. In addition to promoting the sale of Medtronic's cardiovascular-related medical devices for approved, indicated uses, Medtronic requires its sales representatives ("sales reps") in both the Endovascular and Coronary Groups to sell so-called "peripheral products." Peripheral products are those intended for application in the vascular system, outside the heart. Medtronic does this with full knowledge that the vast majority of its peripheral product sales are for unapproved, off-label uses, and that its promotion of such uses is unlawful. Sales representatives in both the Endovascular Group, such as plaintiff/relator Tricia Nowak, and the Coronary Group are relentlessly instructed to sell peripheral products, and financially punished or rewarded based upon such sales, in contravention of federal law, and explicit FDA warning not to do so.

B. Medtronic's Off-Label Promotion of Biliary Stents

48. Until early 2007, Medtronic maintained a Peripheral Products Group. That group was conspicuously dissolved last year, and its workforce absorbed into the Vascular Group. Prior to its dissolution, the Peripheral Group was responsible for the promotion of peripheral products, again, those products that address conditions within the circulatory blood system outside of the heart. The vast majority of peripheral product sales unlawfully consist of biliary stents – of which Medtronic manufactures three brands: Aurora, Racer, and Assurant.[1]

49. Each of Medtronic's three biliary stent products (each with multiple model variations for sizing) are indicated, i.e., approved, by the FDA, for one use only - the "palliation of malignant neoplasm in the biliary tree." In lay terms, they are approved to treat, though not to help prevent or cure, cancer in the bile ducts and gallbladder by relieving the narrowing of the duct. These devices relieve obstruction and allow the bile duct to properly drain, thereby typically relieving some discomfort for patients. Biliary stents are commonly used in patients with advanced pancreatic cancer.

50. Medtronic has received approval from the FDA to market each of its biliary stent medical devices for their approved, and singular, indication, *to wit*, the "palliation of malignant neoplasm in the biliary tree." Each of the devices in Medtronic's biliary stent inventory, including biliary stent models that have received 510(k) approval based upon their similarity to previously approved Medtronic biliary stents, are Class II devices, subject to moderate regulation by the FDA. Approval of new biliary stent devices for their accepted use is far less rigorous than would be approval of a new indication for vascular application.

[1] Recently, the FDA approved a fourth Medtronic biliary stent for the same limited indication as its other three biliary stents. A forthcoming Amended Complaint will set forth in detail the extent to which Medtronic is unlawfully promoting this newest stent, the "Complete SE," for unapproved, off-label uses. Medtronic has already instructed its Vascular sales force to promote the Complete SE as a peripheral product.

51. As explained further below, the FDA has expressed serious concern about the off-label promotion of biliary stents by medical device manufacturers for vascular use. Despite this, Medtronic has explicitly promoted its biliary stents for off-label, unapproved vascular use in the treatment, *inter alia*, of three common vascular conditions: renal stenosis (the narrowing of the major artery that supplies blood to the kidney, often elevating blood pressure), peripheral vascular disease ("PVD") in the superficial femoral artery ("SFA") (a disease of the blood vessels in the region of the femoral artery), and conditions requiring iliac artery stenting (iliac arteries being those that branch off the aorta). These conditions are commonly referred to, respectively, as "renal," "SFA," and "iliac."

52. FDA approved, Class III medical devices are available in the marketplace to address the procedures and conditions listed above. Medtronic's competitors have spent, and continue to spend, time and money seeking FDA approval for their devices indicated for each of these three medical uses. For example, Cordis, owned by Johnson and Johnson, manufactures the Smart Control stent for iliac stenting and superficial femoral disease. Other companies, such as Boston Scientific, manufacture similar devices. Because they involve significant risk, and seek to preserve life, these are Class III devices. Medtronic has achieved an unfair competitive advantage, and increased risk to the public, by forgoing the Class III PMA process with the FDA, and, instead, aggressively promoting its Class II biliary stents for unapproved, off-label Class III use. Further, the widespread use of biliary stents for unapproved vascular use limits the ability of manufacturers seeking approval from the FDA for such uses to enroll patients in clinical studies, since many patients and providers are already receiving biliary stents off-label due to off-label marketing by Medtronic.

53. Most tellingly, Medtronic does not promote, and has not promoted, biliary stents for their *approved* uses. Medtronic does not maintain a sales force instructed to sell biliary stents for their *approved* use. In an e-mail from Chris Mueller, subsequent to Medtronic's meeting with the FDA (discussed *infra*), Medtronic instructed its sales representatives to "destroy" all promotional materials for its biliary stents because the materials explicitly promoted biliary stents *as* "peripheral devices." For example, in its brochure for the Racer Biliary Stent System, Medtronic advertises its product in prominent text as "the first cobalt chromium stent launched for peripheral applications...." Medtronic's promotion of biliary stents for peripheral use is widespread, unabashed, and unabated.

54. Medtronic engages in this off-label promotion of biliary stents because it is profitable to do so, and because it avoids the costly, uncertain, time-consuming process of Class III review, and FDA approval. However, because biliary stents have not been evaluated and approved by the FDA for off-label use, their unlawful promotion by Medtronic also presents a grave risk to public safety.

C. Medtronic Instructs Sales Reps to Promote Unapproved Use

55. Though each of its biliary stents is considered by the company to be a "peripheral device," Medtronic does not list these devices under the Peripheral Products section of its website. Despite this, Medtronic keeps constant track of the "peripheral sales" each of its Vascular sales representatives makes, as often as each week, and chief among those "peripheral devices" are the three biliary stent products Medtronic offers. These biliary stents constitute the vast majority of peripheral sales within Medtronic.

56. Prior to warnings from the FDA in early 2007, as discussed further *infra*, Medtronic was less subtle in promoting off-label use of its biliary stents, having created a Peripheral Products group to accomplish that mission. Following FDA reprimand, Medtronic

dissolved that group, and shifted the responsibilities for unlawful promotion of biliary stents into the CardioVascular division – both the Endovascular and Coronary Groups.

57. Medtronic's "Endovascular Sales Representative FY08 Compensation Plan Communication," dated May 2007, lists as a "Key Priority for Endovascular" that the Group "[c]ontribute to the success of Peripheral Product sales." "Peripheral Commissions" are included in the sales rep compensation plan, as are "peripheral bonus[es]." Peripheral sales by sales reps are tracked throughout the year, including which biliary stents are sold by which sales reps and to whom, and sales rep rankings (upon which compensation is based) are calculated, in part, based upon figures derived from peripheral sales.

58. As recently as October of 2007, Medtronic maintained a "Summit Quest Contest" for its Endovascular sales representatives, including Ms. Nowak. Such contests have continued in 2008. The "objective" of the contest is to "recognize and reward the 3 Sales Representatives who achieve peak performance each quarter." Awards worth several thousand dollars are given to the sales representatives with the highest revenue. Primarily, sales reps within the Endovascular Group are responsible for promotion of the AneuRx device (discussed *supra*), and related endovascular medical devices. Medtronic, however, requires that each sales representative "must meet or exceed your Peripheral number to participate" in the contest. The minimal peripheral quota is $10,000 in sales. In other words, no matter how many approved devices a sales rep sells in a given quarter, they are not eligible for this financial incentive unless they meet a target for mostly off-label, unapproved sale of peripheral devices.

59. An updated report on peripheral sales, e-mailed to Vascular sales reps and managers on October 4, 2007, illustrates with clarity that the Endovascular group (again, responsible for selling products *outside* the "biliary tree," the single approved location for use of

biliary stents) is engaged in significant promotion and sale of Assurant, Aurora, and Racer biliary stents for off-label use. The report shows that although a small number of peripheral sales are for approved Pioneer catheter systems, most sales are for biliary stents. It is important to note that the Pioneer system was *not available for sale* during most of fiscal year 2007 (though Ms. Nowak, with others, was misleadingly informed by Medtronic management that requiring peripheral sales was legally compliant because *some* devices within the peripheral unit, *i.e.*, Pioneer, are approved). Most importantly, the sales report details dozens of Assurant, Aurora, and Racer biliary stents sold across the United States by the Endovascular group, promoted for unapproved vascular use.

60. The unlawful promotion and sale of biliary stents for off-label use is recognized and appreciated by Medtronic management. An e-mail from a Endovascular Group sales representative, Danny Lewis, to management and colleagues, dated September 21, 2007, expressed satisfaction in the successful sale and application of biliary stents, "two Aurora's and an Assurant," for off-label use by a cardiologist in addressing an iliac occlusion. The e-mail continues, "I know that working with Cardiologists has been somewhat taboo in our business for some time, but by using a combination of data, relationships, and some of the other tools in our bag, these practitioners can, and should, become our allies over time."

61. Rather than responding with words of caution about off-label promotion of biliary stents, Brad Baxter, Area Director for U.S. Sales – SW, in the CardioVascular division at Medtronic, responded with thanks for the "excellent use of resources," "[a]wesome to see you supplying MDT [Medtronic] stents for Pioneer procedures – you would be surprised how often it is overlooked. It is as important to provide stents for Pioneer as it is Reliants for AAAdvantage

cases." Mr. Baxter closes, "Danny, excellent job." This constitutes explicit encouragement to promote the sale and use of biliary stents for unapproved vascular use.

62. The Coronary Group is also given a peripheral quota to reach, despite their explicit responsibilities to promote and sell approved, coronary medical devices. In September of 2007, sales representatives in the Coronary Group, were provided "FY'08 2nd Quarter Targets" which included significant peripheral numbers in the thousands of dollars. These targets determine the compensation given to a sales representative within the Coronary Group, just as they do the Endovascular Group. On June 11, 2007, the sales reps in the Coronary Group were provided a "peripheral quota," reminding them of their obligation, like that of the Endovascular sales reps, to sell and promote biliary stents off-label.

63. In addition to requiring the CardioVascular division sales reps to unlawfully promote biliary stents as a condition of their compensation, Medtronic also encourages these sales reps to attend peripheral training with practicing physicians in fields of medicine for which biliary stents are unapproved so the reps can sell biliary stents with greater knowledge of vascular applications. Medtronic also asks its sales reps to encourage their client physicians to attend these trainings. A recent example is found in an e-mail from Debbie Shaver, Director of Key Accounts in the CardioVascular division, to Medtronic's Endovascular Group, dated September 11, 2007, informing them of peripheral training "led by a surgeon and cardiologist" that "cover[s] common peripheral interventions, i.e. renal, iliac, SFA." Sales reps are promised to be instructed on "what size devices to use along with ancillary equipment selection." Similar e-mails are frequently sent. Medtronic trains its vascular sales reps on unapproved vascular applications for biliary stents approved only for use in the biliary tree.

64. Ms. Nowak, following a Medtronic legal training, held early in 2007, e-mailed her supervisor, Mr. Smeltzer, on March 4, 2007, concerning the unlawful promotion of medical devices within her group. After hearing at the training that off-label promotion was unlawful, and that sales reps could be held individually responsible for such (the DVD presentation of the training includes PowerPoint documents explaining the absence of a "Nuremberg defense"). Ms. Nowak asked "how we as a company…could be promoting and pushing representatives to sell biliary stents for peripheral vascular and pushing so much, that the 'off-label' sales target is required for winning a trip." "It seems," she continued, "that by requiring the AAA sales force [*i.e.*, the Endovascular Group] to sell peripheral stents that management is putting a tremendous number of people at risk, mostly themselves….We signed up to sell an FDA approved device for its on-label usage." Mr. Smeltzer elected not to respond in e-mail, and instead spoke with Ms. Nowak in person, reminding her that sale of peripheral devices was part of the job.

D. FDA Warnings and the Dangers of Unapproved Use of Biliary Stents

65. The conduct detailed above is all the more troubling in light of the fact that the FDA, in March of 2007, in an unprecedented (described by a Medtronic executive as "extraordinarily unique") widely publicized meeting, gave explicit warning to Medtronic and other biliary stent manufacturers to cease and desist in the promotion of off-label use of their biliary stents. On March 12, 2007, Daniel Schultz, MD, Director of the FDA's Center for Devices and Radiological Health ("CDRH"), and other FDA CDRH staff, met with executives from the various biliary stent manufacturers, including the Defendant. The FDA warned the companies, including the Defendant, of its concern about the knowing, willful promotion of biliary stents for unapproved vascular uses.

66. At the meeting, the FDA also expressed its great concern about the substantial number of biliary stent malfunctions reported to the FDA "adverse events" database. According

to the WALL STREET JOURNAL and others. Mr. Schultz added that the "adverse events" were almost all reported by doctors who were using biliary stents for unapproved uses in the arteries, *i.e.*, for vascular use. Mr. Schultz further noted that the use of biliary stents for off-label application is a public health issue, and demanded that the respective companies, including Medtronic, submit detailed plans, within three weeks, outlining the efforts the companies would take to better monitor and control their sales reps, and to inform customers about unapproved use.

67. Although the FDA meeting was held in early March 2007, Medtronic waited over five months, until August 31, 2007, to send a letter, from Medtronic's Chief Medical Officer, Coronary and Peripheral (V.P. Medical Affairs within CardioVascular) LeRoy LeNarz, MD, advising potential biliary stent customers that the "FDA recently met with all of the manufacturers of biliary stents expressing concern about reports of serious adverse events associated with off-label use of biliary stents in conjunction with vascular therapy, including *death, seizure, stroke, thrombosis, and vessel perforation*." (Emphasis added.) The letter concedes that Medtronic's biliary stents "Medtronic Racer, Bridge Assurant, and Aurora" are only "cleared by the FDA for palliation of malignant neoplasm in the biliary tree."

68. Sales representatives within the CardioVascular division were not informed of the March FDA meeting, nor the letter in response, until late September of 2007. In a widely disseminated e-mail dated September 24, 2007, David Moeller, Group Marketing Manager for Peripheral, stated "we apologize for the lack of communication to the sales representatives..." Rather than disrupting the off-label promotion of its biliary stents following the FDA meeting, Medtronic elected to remain silent and only belatedly inform its sales force about the increased FDA scrutiny.

69. A follow-up teleconference was held within Medtronic on September 25, 2007, to discuss the March 2007 FDA meeting, and Medtronic's response. This teleconference was recorded and available for sales reps, and others, to inquire of Medtronic executives about the FDA issues. Medtronic executives, during the call, explained that the FDA "more or less…summoned" them to the table, and directed them to take action, alerting the companies that both they and Congress "would be watching." A Medtronic executive, when asked by an employee during the call whether it was fair considering the "layoff of our peripheral sales force and all that" to "justify the coronary sales force taking on that bag," the executive answered that dissolving of the peripheral group "really didn't have anything to do with what the FDA has requested of us," but rather, "is more of a strategic decision" designed to align the "vascular teams and the coronary teams" with the doctors who utilize their biliary stents for off-label use. This practice has continued, unabated.

70. Ms. Nowak's former Sales Manager, John Smeltzer, in addressing Ms. Nowak's concern regarding Medtronic's continued promotion of biliary devices in light of the recent FDA warning not to do so, instructs her, via e-mail on September 13, 2007, to inform her customers that the "FDA is asking us to remind physicians that these [biliary] stents are approved for biliary use and do not have FDA approval for vascular use… [and that] Medtronic has never completely tested these stents in the vasculature and that we can not guarantee their safety if used in an off label application." In attempting to explain the practice, Mr. Smeltzer continues, "you know this has been going on for a long time…[s]o this is a sticky point for all involved, FDA, doctors, and companies. Getting a vascular indication will mean long approval times for new stents…I have always wondered why the FDA let this go on for so long."

71. Medtronic responded to this FDA warning by dissolving and reintegrating the peripheral sales force, attempting to destroy all evidence of its unlawful biliary stent promotional materials, waiting many months to issue a warning letter to customers, and many months to inform its sales reps of the FDA involvement. Medtronic has not, however, curbed its willful promotion of biliary stents for off-label use – if anything, it has only intensified those efforts.

72. The continued promotion of biliary stents for off-label use is particularly worrisome in light of the concerns expressed by the FDA regarding the significant reporting of adverse effects. The Class III approval process, circumvented by Medtronic, is designed to prevent this sort of public health danger. Medtronic, in its belated August 31, 2007, letter to biliary stent customers, admitted that "review of serious adverse events for Medtronic's three biliary stents when used in the vascular system revealed reports of vessel perforation and stent dislodgement issues."

73. In addition to endangering public health, Medtronic's conduct in promoting biliary stents for off-label, vascular uses, has resulted in the submission of countless improper claims for reimbursement from federal and state health care programs. These false claims to the government have been improperly reimbursed as a direct result of Medtronic's unlawful promotional activity.

VI. COUNTS

COUNT I

FEDERAL FALSE CLAIMS ACT

31 U.S.C. §§ 3729(A)(1) AND (A)(2)

74. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

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

76. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval. Each claim for reimbursement for off-label use represents a false or fraudulent claim for payment.

77. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

78. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by the Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion of off-label use.

79. By reason of the Defendant's acts, the United States has been damaged, and continues to be damaged, in substantial amounts to be determined at trial. Federal health care programs have paid significant amounts for the off-label use of biliary stents that continue to be unapproved for such uses by the FDA.

COUNT II

CALIFORNIA FALSE CLAIMS ACT

CAL. GOVT. CODE § 12651(A)(1) AND (2)

80. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

81. This is a claim for treble damages and penalties under the California False Claims Act.

82. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the California State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

83. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

84. The California State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

85. By reason of the Defendant's acts, the State of California has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

86. The State of California is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT III

DELAWARE FALSE CLAIMS AND REPORTING ACT

6 DEL. C. § 1201(A)(1) AND (2)

87. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

88. This is a claim for treble damages and penalties under the Delaware False Claims And Reporting Act.

89. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Delaware State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

90. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

91. The Delaware State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

92. By reason of the Defendant's acts, the State of Delaware has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

93. The State of Delaware is entitled to the maximum penalty of $11,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT IV

FLORIDA FALSE CLAIMS ACT

FLA. STAT. ANN. § 68.082(2)

94. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

95. This is a claim for treble damages and penalties under the Florida False Claims Act.

96. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Florida State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

97. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

98. The Florida State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

99. By reason of the Defendant's acts, the State of Florida has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

100. The State of Florida is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT V

HAWAII FALSE CLAIMS ACT

HAW. REV. STAT. § 661-21(A)

101. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

102. This is a claim for treble damages and penalties under the Hawaii False Claims Act.

103. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Hawaii State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

104. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

105. The Hawaii State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

106. By reason of the Defendant's acts, the State of Hawaii has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

107. The State of Hawaii is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT VI

ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

740 ILL. COMP. STAT. § 175/3(A)(1), (2)

108. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

109. This is a claim for treble damages and penalties under the Illinois Whistleblower Reward And Protection Act.

110. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Illinois State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

111. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

112. The Illinois State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

113. By reason of the Defendant's acts, the State of Illinois has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

114. The State of Illinois is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT VII

INDIANA FALSE CLAIMS AND WHISTLEBLOWER PROTECTION ACT

IND. CODE ANN. § 5-11-5.5-2(B)(1)-(2)

115. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

116. This is a claim for treble damages and penalties under the Indiana False Claims and Whistleblower Protection Act.

117. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Indiana State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

118. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

119. The Indiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful conduct.

120. By reason of the Defendant's acts, the State of Indiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

121. The State of Indiana is entitled a penalty of at least $5,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT VIII

LOUISIANA MEDICAL ASSISTANCE PROGRAM INTEGRITY LAW

LA. REV. STAT. § 46:437, *ET SEQ.*

122. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

123. This is a claim for treble damages and penalties under the Louisiana Medical Assistance Program Integrity Law.

124. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Louisiana State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

125. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

126. The Louisiana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

127. By reason of the Defendant's acts, the State of Louisiana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

128. The State of Louisiana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT IX

MASSACHUSETTS FALSE CLAIMS LAW

MASS. GEN. LAWS CH. 12 § 5B(1), (2)

129. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

130. This is a claim for treble damages and penalties under the Massachusetts False Claims Law.

131. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Massachusetts State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

132. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

133. The Massachusetts State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

134. By reason of the Defendant's acts, the State of Massachusetts has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

135. The State of Massachusetts is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT X

MICHIGAN MEDICAID FALSE CLAIMS ACT

MICH. COMP. LAWS. § 400.601, *ET SEQ.*

136. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

137. This is a claim for treble damages and penalties under the Michigan Medicaid False Claims Act.

138. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Michigan State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

139. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

140. The Michigan State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

141. By reason of the Defendant's acts, the State of Michigan has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

142. The State of Michigan is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XI

MONTANA FALSE CLAIMS ACT

MONT. CODE ANN. § 17-8-403(1)(A)-(B)

143. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

144. This is a claim for treble damages and penalties under the Montana False Claims Act.

145. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Montana State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

146. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

147. The Montana State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

148. By reason of the Defendant's acts, the State of Montana has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

149. The State of Montana is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XII

NEVADA FALSE CLAIMS ACT

NEV. REV. STAT. ANN. § 357.040(1)(A), (B)

150. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

151. This is a claim for treble damages and penalties under the Nevada False Claims Act.

152. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Nevada State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

153. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

154. The Nevada State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

155. By reason of the Defendant's acts, the State of Nevada has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

156. The State of Nevada is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XIII

NEW HAMPSHIRE FALSE CLAIMS ACT

N.H. REV. STAT. ANN. § 167:61-B(I)(A)-(B)

157. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

158. This is a claim for treble damages and penalties under the New Hampshire False Claims Act.

159. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Hampshire State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

160. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

161. The New Hampshire State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

162. By reason of the Defendant's acts, the State of New Hampshire has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

163. The State of New Hampshire is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XIV

NEW MEXICO MEDICAID FALSE CLAIMS ACT

N.M. STAT. ANN. § 27-2F-4(A)-(C)

164. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

165. This is a claim for treble damages and penalties under the New Mexico Medicaid False Claims Act.

166. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the New Mexico State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

167. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

168. The New Mexico State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

169. By reason of the Defendant's acts, the State of New Mexico has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

170. The State of New Mexico is entitled to the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XV

TENNESSEE FALSE CLAIMS ACT AND TENNESSEE MEDICAID FALSE CLAIMS ACT

TENN. CODE ANN. §§ 4-18-103(A), *ET SEQ.* AND 71-5-182(A)(1), *ET SEQ.*

171. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

172. This is a claim for treble damages and penalties under the Tennessee False Claims Act and Tennessee Medicaid False Claims Act.

173. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Tennessee State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

174. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

175. The Tennessee State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

176. By reason of the Defendant's acts, the State of Tennessee has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

177. The State of Tennessee is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XVI

TEXAS MEDICAID FRAUD PREVENTION LAW

TEX. HUM. RES. CODE ANN. § 36.002

178. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

179. This is a claim for treble damages and penalties under the Texas Medicaid Fraud Prevention Law.

180. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Texas State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

181. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

182. The Texas State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

183. By reason of the Defendant's acts, the State of Texas has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

184. The State of Texas is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XVII

VIRGINIA FRAUD AGAINST TAXPAYERS ACT

VA. CODE ANN. § 8.01-216.3(A)(1), (2)

185. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

186. This is a claim for treble damages and penalties under the Virginia Fraud Against Taxpayers Act.

187. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the Virginia State Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

188. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

189. The Virginia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

190. By reason of the Defendant's acts, the State of Virginia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

191. The State of Virginia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

COUNT XVIII

DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

D.C. CODE ANN. § 1-1188.14(A)(1), (2)

192. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1 through 73 of this Complaint.

193. This is a claim for treble damages and penalties under the District of Columbia Procurement Reform Amendment Act.

194. By virtue of the acts described above, Defendant knowingly presented or caused to be presented, false or fraudulent claims to the District of Columbia Government for payment or approval. Each claim for reimbursement for such off-label use submitted to a State-funded health insurance program represents a false or fraudulent claim for payment.

195. Plaintiff cannot at this time identify all of the false claims for payment that were caused by Medtronic's conduct. The false claims were presented by thousands of separate entities, across the United States, over many years. Plaintiff has no control over or dealings with such entities and has no access to the records in their possession.

196. The District of Columbia Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendant, paid and continues to pay the claims that would not be paid but for Medtronic's unlawful promotion.

197. By reason of the Defendant's acts, the District of Columbia has been damaged, and continues to be damaged, in substantial amounts to be determined at trial.

198. The District of Columbia is entitled to the maximum penalty of $10,000 for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Medtronic.

PRAYER

WHEREFORE, Plaintiff prays for judgment against the Defendant as follows:

A. That Defendant cease and desist from violating 31 U.S.C. § 3729, *et seq*. and the equivalent provisions of the State statutes set forth above:

B. 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;

C. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of California has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of CAL. GOVT. CODE § 12651(a);

D. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Delaware has sustained because of Defendant's actions, plus a civil penalty of $11,000 for each violation of 6 DEL. C. § 1201(a);

E. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Florida has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of FLA. STAT. ANN. § 68.082(2);

F. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Hawaii has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of HAW. REV. STAT. § 661-21(a);

G. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Illinois has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of 740 ILL. COMP. STAT. § 175/3(a);

H. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Indiana has sustained because of Defendant's actions, plus a civil penalty of at least $5,000 for each violation of IND. CODE ANN. § 5-11-5.5-1.2(b);

I. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Louisiana has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of LA. REV. STAT. § 46:438.6(C)(1)(a);

J. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Massachusetts has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of MASS. GEN. L. CH. 12 § 5B;

K. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Michigan has sustained because of Defendant's actions, plus civil penalties for each violation of MICH. COMP. LAWS. § 400.601, *et seq.*;

L. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Montana has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of MONT. CODE ANN. § 17-8-401;

M. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Nevada has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of NEV. REV. STAT. ANN. § 357.040(1)(a), (b);

N. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New Hampshire has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of N.H. REV. STAT. ANN. § 167:61-b(1);

O. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of New Mexico has sustained because of Defendant's actions, plus civil penalties for each violation of N.M. STAT. ANN. § 27-2F-4;

P. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Tennessee has sustained because of Defendant's

actions, plus a civil penalty of $10,000 for each violation of TENN. CODE ANN. § 4-18-103(a) and § 71-5-182(a)(1);

Q. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Texas has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of TEX. HUM. RES. CODE ANN. § 36.002;

R. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the State of Virginia has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of VA. CODE ANN. § 8.01-216.3(a)(1), (2);

S. That this Court enter judgment against Defendant in an amount equal to three times the amount of damages the District of Columbia has sustained because of Defendant's actions, plus a civil penalty of $10,000 for each violation of D.C. CODE ANN. § 1-1188.14(a)(1), (2);

T. That Plaintiff be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act and the equivalent provisions of the State statutes set forth above;

U. That Plaintiff be awarded all costs of this action, including attorneys' fees, costs, and expenses pursuant to 31 U.S.C. § 3730(d) and the equivalent provisions of the State statutes set forth above; and

V. That the United States, the States, and Plaintiff/Relator be granted all such other 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.

Dated: March 5, 2008

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