UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

THE UNITED STATES OF AMERICA *ex rel.* [UNDER SEAL] Plaintiffs, v. [UNDER SEAL] Defendants.	Civil Action No. 14-1387 (KSW) Filed Under Seal Pursuant to 31 U.S.C. § 3720(b)(2)

AMENDED COMPLAINT AND JURY DEMAND

SEALED CASE – DO NOT PUT ON PACER

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

THE UNITED STATES OF AMERICA *ex rel.* JOHN DOE, Plaintiffs, v. SPECTOCOR ENTERPRISE SERVICES, LLC, D/B/A SPECTOCOR; AMI MONITORING INC., D/B/A AMI MONITORING; MEDICAL ALGORITHMICS, SA; MEDI-LYNX CARDIAC MONITORING, LLC; JOSEPH BOGDAN; AND ANDREW BOGDAN, Defendants.	Civil Action No.14-1387 (KSW) Filed Under Seal Pursuant to 31 U.S.C. § 3720(b)(2)

AMENDED COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

I. INTRODUCTION

1. This is an action brought on behalf of the United States of America by Plaintiff John Doe (hereafter referred to as "Relator") to recover damages and penalties under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*("FCA"), from Defendants Spectocor Enterprise Services, LLC ("Spectocor"), AMI Monitoring, Inc. ("AMI"), Medical Algorithmics, SA, Medi-Lynx Cardiac Monitoring, LLC, Joseph Bogdan, and Andrew Bogdan (hereinafter collectively "Defendants").

2. The violations of the FCA arise out of claims for payment submitted to the federal health programs for an expensive multi-purpose ambulatory telemetry cardiac monitoring device, called PocketECG, and related services, for which Defendants induced enrollment and

reimbursement for patients covered by government health care programs regardless of medical necessity and reasonableness and eligibility for coverage under such programs.

3. The FCA provides that any person who violates the FCA is liable for a civil penalty of between $5,500 and $11,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990, for each such claim, and three times the amount of the damages sustained by the government. The FCA permits a person (known as a "relator") having information regarding such conduct against the government to bring an action on behalf of the government and to share in any recovery. The complaint must be filed under seal, without service on the defendant. The complaint remains under seal for a period of time while the government conducts an investigation of the allegations in the complaint and determines whether to join the action.

4. Pursuant to the FCA and the Medicare-Medicaid Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), Relator seeks to recover, on behalf of the United States, damages and civil penalties arising from Defendants' defrauding of Medicare, Medicaid, CHAMPUS/TRICARE, the Federal Employees Health Benefit Plan, and other government funded health insurance programs, as detailed below.

5. The facts and circumstances which give rise to Defendants' violations of the False Claims Act have not been publicly disclosed within the meaning of 31 U.S.C. § 3730(e)(4)(A).

6. In any event, Relator is an "original source" as that term is used in the False Claims Act, 31 U.S.C. § 3730(e)(4)(B). Relator has provided the United States with disclosures of his identity, relevant information and his allegations prior to filing this Complaint.

II. PARTIES

A. Plaintiffs/Relator

7. The United States of America is the real party in interest to all claims arising under the False Claims Act as set forth herein.

8. Relator John Doe is a citizen of the United States. He is familiar with the Defendants' business operations. Further details regarding Relator and Relator's knowledge have been and will be provided to the United States.

B. Defendants

9. Defendant AMI Monitoring, Inc., d/b/a AMI Monitoring ("AMI"), is headquartered in McKinney, Texas. AMI Monitoring operates as an Independent Diagnostic Testing Facility (IDTF) providing remote attended cardiac monitoring services.

10. AMI Monitoring is currently owned by Joseph Bogdan and at all times relevant to this Complaint served as Chief Executive of AMI. Upon information and belief, he shared a co-ownership interest with Defendant Andrew Bogdan (his brother) in AMI Monitoring (and Defendant Spectocor) until at least August 7, 2013.

11. Medical Algorithmics, SA (also known as Medicalgorithmics) is a limited liability biotechnology company based in Poland with a local place of business at 245 West 107th Street, Suite 11A, New York, NY 10025.

12. Medical Algorithmics is a publicly-traded company on the Warsaw Stock Exchange. The company's stock symbol is listed as MEDICALG (MDG).

13. The founder of Medical Algorithmics, Dr. Marek Dziubinski, designed the PocketECG device and founded Medical Algorithmics for the purpose of marketing PocketECG.

Dr. Dziubinski acts as President and Chief Technology Officer and individually owns 14.73 percent of the company's voting and equity shares.

14. Defendants AMI (now Spectocor) and Medical Algorithmics entered into an exclusive nationwide distribution agreement for marketing the PocketECG device across the United States. The agreement ensured no other competitor could market the PocketECG device within any U.S. jurisdiction.

15. In or around March 2012, Joseph Bogdan rebranded AMI Technologies as Spectocor Enterprise Services, LLC, d/b/a Spectocor, but maintained AMI Technologies as a shipping supplier to providers nationwide, including within this District.

16. Defendant Spectocor Enterprise Services, LLC, d/b/a Spectocor ("Spectocor"), is headquartered in McKinney, Texas, with additional corporate offices in San Francisco and Los Angeles, California. Like AMI Monitoring, Spectocor operates an IDTF for remote cardiac monitoring. Spectocor's IDTF is located in McKinney, Texas, and is staffed by technicians who collect, monitor, analyze and report data for PocketECG patients across the country. Technicians provide cardiac monitoring services for a national provider base, including clients in this District.

17. Defendant Joseph Bogdan is an individual residing in Fairview or McKinney, Texas. He currently owns Defendant Spectocor and at all times relevant to this Complaint served as Chief Executive of Spectocor. Upon information and belief, he shared a co-ownership interest with Defendant Andrew Bodgan (his brother) in AMI Monitoring and Spectocor until at least August 7, 2013.

18. Defendant Andrew Bodgan is an individual residing in McKinney, Texas. Upon information and belief, Andrew Bodgan shared a co-ownership interest in AMI Monitoring and Spectocor with his brother Defendant Joseph Bodgan until at least August 07, 2013, at which

time Spectocor was effectively split into two companies, with Defendant Andrew Bogdan forming Medi-Lynx Cardiac Monitoring, LLC ("Medi-Lynx"). As part of the split, the Defendants Joseph and Andrew Bogdan divided up their account list nationally as well as employees, sales force, cardiac monitoring technicians, and monitoring centers. Defendant Medi-Lynx has its principal place of business in Plano, Texas, and operates an IDTF for a national provider base. Medi-Lynx offers the same nationwide product line as Spectocor, including the PocketECG device. Medi-Lynx operated as a private company wholly owned by Defendant Andrew Bogdan from at least January 1, 2014-March 30, 2016, at which time Defendant Medical Algorithmics acquired a 75% ownership interest in Medi-Lynx (with Defendant Andrew Bogdan retaining a 25% ownership interest); since then Medi-Lynx operates as a subsidiary of Defendant Medical Algorithmics.

III. JURISDICTION AND VENUE

19. This action arises under the False Claims Act, 31 U.S.C. §§ 3729 *et seq*.

20. The court has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331 and has personal jurisdiction over Defendants because they committed the alleged acts and continue to transact business within this judicial district.

21. Venue is proper in this district, pursuant to 28 U.S.C. § 1391(b) and (c) and 31 U.S.C. §3732(a) because Defendants operate and transact business within this district and facts forming the basis of this Complaint occurred within this district.

IV. APPLICABLE FEDERAL LAW

A. Federally Funded Health Care Programs

22. The Medicare Program ("Medicare") is a Health Insurance Program administered by the Government of the United States that is funded by taxpayer revenue. Medicare is directed

by the United States Health and Human Services Department ("HHS"). Medicare was designed to assist in providing medical services and durable medical equipment to persons over sixty-five (65) years of age and certain others who qualify for Medicare because of disability or end stage renal disease. Generally speaking, if you are eligible for Medicare, Part A covers hospital, inpatient, nursing home, and other institutional care; Part B covers doctor visits and outpatient services; and Part D provides prescription drug coverage.

23. The Medicaid Program, Title XIX of the Social Security Act, 42 U.S.C. §§ 1396-1396v (hereafter "Medicaid"), is a Health Insurance Program administered by the Government of the United States and the various individual States and is funded by State and Federal taxpayer revenue. The Medicaid Program is overseen by the United States Department of Health and Human Services through its Centers for Medicare and Medicaid Services ("CMS").

24. Medicaid was designed to assist participating states in providing medical services, durable medical equipment and prescription drugs to, among others, financially needy individuals that qualify for Medicaid. The States directly pay providers, with the States obtaining the federal share of the payment from accounts which draw on the United States Treasury. 42 C.F.R. §§ 430.0-430.30 (1994).

25. Federal funding for the Medicaid Program includes support for Medicare Savings Programs which help qualifying Medicare beneficiaries pay Part A and B premiums, co-payments, co-insurance, and deductibles. The Medicare Savings Programs consist of the Qualified Medicare Beneficiary (QMB) Program, 42 U.S.C. §1396d(p)(1), the Specified Low-Income Medicare Beneficiary (SLMB) Program, 42 U.S.C. § 1396a(a)(10)(E)(iii), the Qualifying Individual (QI) Program, 42 U.S.C. § 1396a(a)(10)(E)(iv), and the Qualified Disabled and Working Individuals (QDWI) Program, 42 U.S.C. § 1396d(s).

26. There are a number of other government health insurance programs funded by the federal government. Among these are the following.

(a) the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS") (now known as "TRICARE"), 10 U.S.C. §§ 1071-1106, provides benefits for health care services furnished by civilian providers, physicians, and suppliers to members of the Uniformed Services and to spouses and children of active duty, retired and deceased members. The program is administered by the Department of Defense and funded by the Federal Government. TRICARE/CHAMPUS pays for, among other items and services, medical devices, and surgeries for its beneficiaries.

(b) the Federal Employees Health Benefits Program ("FEHBP") provides health care benefits for qualified federal employees and their dependents. It pays for, among other items and services, medical devices and surgeries for its beneficiaries.

In addition, the federal government operates hospitals, including through its Department of Defense and its Department of Veterans Affairs. Together the programs described above, and any other government funded health care programs, shall be referred to as "Federal Health Care Programs" or "Government Health Care Programs."

B. Obtaining Reimbursement Under the Federal Healthcare Programs

27. Reimbursement practices under all Government Health Care Programs closely align with the rules and regulations governing Medicare reimbursement. The most basic requirement for reimbursement eligibility under Medicare, Medicaid, and other Government Health Care Programs is that the service provided must be reasonable and medically necessary. *See, e.g.*, 42 U.S.C. § 1395y(a)(1)(A); 42 U.S.C. § 1396, *et seq.*; 42 C.F.R. §§ 410.50, 411.15, 411.406; *United States v. Rutgard*, 116 F.3d 1270, 1275 (9th Cir. 1997) (TRICARE and Railroad

Retirement Health Insurance Program plan follow the same rules and regulations as Medicare, citing, *e.g.,* as to TRICARE, 10 U.S.C. § 1079(a)(13); 32 C.F.R. § 199.4). Medical providers are not permitted to bill the government for medically unnecessary services or procedures performed solely for the profit of the provider. *See generally*, *supra*. For example, the requisite level of medical necessity may not be met where a particular procedure was deleterious or performed solely for profit. *United States ex rel. Kneepkins v. Gambro Healthcare*, Inc., 115 F. Supp.2d 35, 41-42 (D. Mass.2000) (procedures chosen solely for defendants' economic gain are not "medically necessary" as required by claim submission form). Health care providers are obligated to assure that services or items ordered or provided to patients will be provided "economically and only when, and the extent, medically necessary" and "will be of a quality which meets professionally recognized standards of health care," and will be supported by evidence of medical necessity and quality …" 42 U.S.C. § 1320c-5(a)(1)-(3).

28. Moreover, coverage for Medicare reimbursement for a particular service may be defined at the national level through a National Coverage Determination (NCD) or pursuant to a Local Coverage Determination (LCD) issued by the Medicare contractor within a particular jurisdiction.

29. Claims for payment of outpatient services from the federal health care programs must be submitted on Form CMS-1500. The form provides fields prompting the provider submitting the claim to provide appropriate Current Procedural Terminology codes ("CPT codes") and ICD-9 codes for identifying the particular service for which reimbursement is sought and the basis for its medical necessity.

30. CPT codes are numbers assigned to every task and service a medical practitioner may provide to a patient, including medical, surgical and diagnostic services. CPT codes are then

used by insurers, including the federal health care programs, to determine the amount of reimbursement received. For purposes of this Complaint, the relevant CPT codes for telemetry are 93228 and 93229.

31. The ICD-9-CM is the official system for assigning codes to describe diagnoses or clinical signs or symptoms associated with the conditions for which health care goods and services are rendered in the United States.

32. Reimbursement rules issued by the federal health programs identify acceptable ICD-9 code(s) required to demonstrate medical necessity for particular covered goods and services. Eligibility for reimbursement from the federal health programs requires consistency between the diagnosis code(s) submitted by the provider and the patient's symptoms and conditions. The ICD-9 codes reported in support of the medical necessity of the associated CPT-code must reflect conditions and diagnoses fully supported by medical documentation in the patient's record.

33. Each of the Government Health Care Programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Statute (discussed *infra*) and with other federal laws governing the provision of health care services in the United States.

34. For example, physicians, hospitals, and IDTFs enter into Provider Agreements with CMS in order to establish their eligibility to seek reimbursement from the Medicare Program. As part of that agreement, without which the hospitals and physicians may not seek reimbursement from Federal Health Care Programs, the provider must sign the following certification:

> I agree to abide by the Medicare laws, regulations and program instructions that apply to [me]. The Medicare laws, regulations, and program instructions are

> available through the [Medicare] contractor. I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider's] compliance with all applicable conditions of participation in Medicare.

Form CMS-855A; Form CMS-8551 (effective 2001). In addition, the claims themselves as submitted contain a similar certification. *See, e.g.*, Form CMS-1500.

35. When a provider submits a claim for payment, he or she does so subject to and under the terms of its certification to the United States that the services for which payment is sought were delivered in accordance with federal law, to include without limitation the Medicare Medicaid Anti-Kickback Statute.

36. In addition to the general provider enrollment requirements for reimbursement under the federal health care programs, IDTFs such as Defendants Spectocor, AMI, and Medi-Lynx must comply with a number of specific conditions to maintain federal health care program billing privileges, including the requirement to "[o]perate[] its business in compliance with all applicable Federal and State licensure and regulatory requirements for the health and safety of patients." 42 C.F.R. 410.33(g).

C. Federal False Claims Act

37. The federal False Claims Act, as amended by the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 provides, in relevant part:

> **Liability for Certain Acts**.
> (1) **In General** – Subject to paragraph (2), any person who – (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; (C) conspires to commit a violation of subparagraph (A), (B)…or (G). . . or (G) knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government, is liable to the United States for a civil

> penalty of not less than [$5,500] and not more than [$11,000] . . . plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1). Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, the civil monetary penalty was increased to between $5,500 and $11,000 per claim for claims made on or after September 29, 1999, and to $10,781 to $21,563 per claim for claims made on or after August 1, 2016.

> **Actions by Private Persons**.
> (1) A person may bring a civil action for a violation of section 3729 for the person and for the United States Government. The action shall be brought in the name of the Government.

31 U.S.C. § 3730(b)(1).

38. The Federal FCA defines a "claim" to include any request or demand, whether under contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested. 31 U.S.C. § 3729(b)(2).

39. The FCA, 31 U.S.C. § 3729(b)(1) provides that "(1) the terms 'knowing' and 'knowingly' – (A) mean that a person, with respect to information – (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information; and (B) require no proof of specific intent to defraud."

40. The FCA, 31 U.S.C. § 3729(b)(4) provides that "(4) the term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property."

41. The Federal FCA defines an "obligation" to pay as "an established duty, whether or not fixed, arising from an express or implied contractual, grantor-guarantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, *or from the retention of any overpayment*." (emphasis added). Moreover, in the health care context, such as Medicare and Medicaid, the term "obligation" is further defined as "Any overpayment retained by a person after the deadline for reporting and returning the overpayment…is an obligation (as defined [in the FCA])", and an overpayment must be reported "By the later of …60 days after the date on which the overpayment was identified…or the date any corresponding cost report is due, if applicable." Patient Protection and Affordable Care Act, March 23, 2010 ("PPACA"), Pub. L. 111-148 (Mar. 23, 2010), Section 6404(a), codified at 42 U.S.C. § 1128J9(d). *See also* 42 U.S.C. § 1320a-7k(d).

D. The Anti-Kickback Laws of the United States

42. Enacted in 1972, and amended many times since, the Medicare and Medicaid Patient Protection Act, also known as the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) ("AKS"), arose out of congressional concern that the remuneration and gifts given to those who can influence health care decisions corrupts medical decision-making and could result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of the federal health care programs, Congress enacted a prohibition against the payment of kickbacks in any form "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

43. In 1977, Congress amended the AKS to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the anti-kickback statute was to combat fraud and abuse in medical settings which "cheats taxpayers who must ultimately bear the financial burden of misuse of funds . . . diverts from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and] erodes the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill the obligations of their medical assistance programs." H.R. Rep. No. 95-393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.1. 1

44. In 1987, Congress again strengthened the AKS to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

45. The AKS prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good or item for which payment may be made in whole or in part by a federal health care program, which includes any State health program or health program funded in part by the federal government. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

[1]Through the amendments Congress sought to "give a clear, loud signal to the thieves and the crooks and the abusers that we [Congress] mean to call a halt to their exploitation of the public and the public purse." 123 Cong. Rec. S31767 (daily ed. Sept 30, 1997)(statement of Sen. Talmadge).

46. The statute provides, in pertinent part:

> (b) Illegal remunerations**
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
>
> > (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Federal health care program, or
> >
> > (B) To purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

47. In addition to criminal penalties, a violation of the AKS can also subject the perpetrator to exclusion from participation in federal health care programs (42 U.S.C. § 1320a-7(b)(7)), civil monetary penalties of $50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose. 42 U.S.C. § 1320a-7a(a).

48. The AKS not only prohibits outright bribes and rebate schemes, but also prohibits any payment to a physician or other person which has as one of its purposes inducement of the physician to write prescriptions for the company's products or to influence or recommend the prescribing of the product.

49. Compliance with the AKS is a precondition to participation as a health care provider under a Government Health Care Program, including the Medicare program. Moreover, compliance with the AKS is a condition of payment for claims for which Medicare or Medicaid reimbursement is sought. *See United States ex rel. Hutcheson v. Blackstone Medical, Inc.*, 647

F.3d 377 (1st Cir. 2011) (Medicare and Anti-Kickback Act); *State of New York, et al. v. Amgen Inc.*, 652 F.3d 103 (1st Cir. 2011) (Medicaid and the Anti-Kickback Act), in which the United States Court of Appeals for the First Circuit has recognized that preconditions for payment in statutes, regulations, and provider agreements of participation may form the basis for a FCA case where there is an underlying course of fraudulent conduct.

V. FACTS AND ALLEGATIONS

50. As described more fully herein, Defendants acted and conspired to establish a marketing, enrollment, and billing scheme through which use of the PocketECG device would render the greatest possible rate of reimbursement from federal health care programs (and certain private payors whose members may be enrolled in the FEHBP) regardless of medical necessity or reasonableness, and did so solely for their own profit.

51. Defendants marketed the PocketECG device as an Event or Telemetry device based upon a patient's insurance coverage rather than their symptoms and conditions. In particular, Defendants configured an enrollment process designed to restrict physicians or billing technicians to selecting PocketECG for the more expensive telemetry for Medicare and TRICARE patients, and some private payors who participate in the FEHBP, while offering PocketECG for Event monitoring exclusively to private payors which do not cover telemetry for any indication. Where Medicaid was a secondary payor to Medicare or another federal or private health care program that was defrauded, Medicaid was also defrauded and damaged.

52. Defendants secured enrollments of Medicare and TRICARE beneficiaries by offering inducements and kickbacks to providers with large federal health program patient populations. In particular, these providers were provided the opportunity to use PocketECG

monitoring for privately insured patients whom otherwise would be limited to traditional cardiac monitoring methods.

53. To further entice lucrative provider arrangements, Defendants waived the co-payments and deductibles of privately-insured patients—a marketing advantage made possible by rapidly increasing Medicare and TRICARE telemetry enrollments.

A. Federal Reimbursement Limitations for Cardiac Monitoring Devices

54. Medicare covers costs associated with the diagnosis of cardiac arrhythmias. Reimbursable services are defined by CPT codes.

55. Cardiac arrhythmias refers to the occurrence of abnormal heart rhythms. Arrhytmias may be accompanied by symptoms (e.g., palpitations, fainting, dizziness, weakness blood clots) or present asymptomatically. Arrhythmias can also occur infrequently and unpredictably.

56. Some cardiac conditions can be diagnosed upon physical examination or in-office testing. However, if a physician cannot diagnose a patient's condition this way, a variety of ambulatory electrocardiographic monitoring devices may be used to assist with diagnosing the patient. The degree and frequency of arrhythmias symptoms dictates the appropriate type and duration of cardiac monitoring.

57. There are three main types of cardiac monitors—Holter monitors, Cardiac Event monitors, and Mobile Cardiac Telemetry monitors or devices, as described below. These monitors and the interpretation of the results are reimbursed at differing rates by Medicare. The highest reimbursement is for Mobile Telemetry.

B. Types of Cardiac Monitoring Devices

58. Holter monitors record heart rhythms continuously for up to 48 hours. The entire uninterrupted recording is captured on magnetic tape or digital media. After patient recording concludes, the patient must return the device and recorded media to the physician or technician who then interprets a computer-generated report providing analysis of the data. Holter monitors are appropriate for patients with demonstrated symptoms occurring at a daily frequency.

59. Cardiac Event monitors (sometimes referred to as "event monitors") record heart rhythms intermittently for up to 30 days. These devices begin recording heart rhythms upon activation. Some event monitors are designed to be activated by the patient upon experiencing symptoms, while others are designed to be automatically triggered by a pre-set computer algorithm intended to detect arrhythmias. Standard "loop" recorders are capable of storing only a few minutes of data, however, newer event monitors can store several hours of data. Similar to a Holter monitor, the recorded data is captured on an internal media and interpreted by the physician after the patient returns the device or recording. Cardiac Event monitors are generally used for patients with infrequent or irregular presentation of symptoms.

60. Mobile Cardiac Telemetry devices record heart rhythms continuously for up to several weeks. Segments of recorded data are transmitted wirelessly through a cellular signal to a designated remote technician who immediately reviews the data in real-time for occurrences or trends warranting physician notification. Telemetry services have a much more narrow use than Holter and event monitors, and are only medically necessary when symptoms of arrhythmias are suspected but they are rare and difficult to capture by other means.

61. Medicare generally covers Holter and event monitoring for diagnostic purposes and such monitors are approved for Medicare reimbursement when a physician requires the

additional information to evaluate a patient's condition because a diagnosis could not be made on physical examination of the patient.

62. Mobile Cardiac Telemetry monitoring is covered and payable by Medicare only in limited circumstances, as described below. Generally speaking, reimbursement of telemetry services is not addressed by a Medicare National Coverage Determination. Whether telemetry services are covered and payable under Medicare thus turns on the statute and regulations and a determination by the local contractor as to the criteria by which such services are deemed reasonable and necessary.

C. Defendants' Cardiac Monitoring Product Line

63. Spectocor markets ambulatory electrocardiographic devices capable of remotely monitoring cardiac rhythms. Spectocor distributes devices pursuant to agreements with independent device manufacturers.

64. Spectocor operates an Independent Diagnostic Technical Facility (IDTF) where Spectocor technicians monitor data reported by the device and provide physicians with reported results and analysis.

65. From approximately 2005 until March 2010, Mednet Healthcare Technologies, Inc. ("Mednet") supplied Spectocor and AMI with a variety of Holter and Cardiac Event monitors and eventually (in about March 2009) a stand-alone mobile telemetry device marketed as the HEARTRAK External Cardiac Ambulatory Telemetry ("Heartrak ECAT").

66. In approximately March 2010, Spectocor entered into an exclusive agreement with Defendant Medical Algorithmics to market the PocketECG device. The PocketECG device features technology "unif[ying] traditional Holter, event and mobile telemetry monitoring."

Spectocor, Pocket ECG (available at http://spectocor.com/physician-solutions/products/pocket-ecg) (last accessed Feb. 04, 2014).

67. Under the agreement, Spectocor discontinued its affiliation with Mednet for distribution of the Heartrak ECAT and began replacing all of their existing accounts that were using Mednet's Heartrak ECAT device with Medical Algorithmics' Pocket ECG Device.

68. Spectocor's listed inventory still includes two Mednet Event monitors—the Heartrak 2 and Heartrak Smart AF. However, only 10% of Spectocor's Medicare beneficiaries use either Mednet device.

69. Upon information and belief, Spectocor only stocks Mednet monitors for the purpose of maintaining select, existing provider accounts and diverts other provider business towards the company's PocketECG offering.

70. Dr. Dziubinski invented the PocketECG device and established Defendant Medical Algorithmics to manufacture and market the device worldwide, and in the United States through agreement with Defendants AMI and now Spectocor and Medi-Lynx. Dr. Dziubinski currently acts as President and Chief Technology Officer of Medical Algorithmics.

71. By combining all three technologies, Defendants boast that the PocketECG device "offers all the functionality typical of outpatient cardiac telemetry solutions, with comprehensive reporting and statistical analysis comparable to that of the most effective Holter system." Id.

72. The 510(K) Premarket Notification for the device explains the significance of telemetry technology to the PocketECG's function:

> [A]n ambulatory ECG monitor which analyzes electrographic signal, classifies all detected heart beats and recognizes rhythm abnormalities. All detection results, including annotations for every detected heart beat and the entire ECG signal are transmitted via cellular telephony network to a remote server accessible by a Monitoring Center for reviewing by trained medical staff.

73. The PocketECG device was first approved for use in the United States on May 22, 2009 pursuant to the FDA 510(K) premarket approval process. See PocketECG, 510(K) No. K090037 (May 22, 2009). An updated PocketECG version 2 and version 3 were similarly approved as 501(K) substantially equivalent devices on May 16, 2012 and February21, 2013, respectively. See PocketECG v2; 510(K) No. K112921 (May 16, 2012); PocketECG v3,510(K) No.K124060 (Feb. 21, 2013).

74. The PocketECG device is featured as Spectocor's flagship product and is used in approximately 90 percent of the company's accounts. A "Pocket ECG Instruction Video' may be found at http://www.youtube.com/watch?v=8T0qEVK8EII. A "Spectocor Heart Monitor Cardiac Monitoring Advanced Reports" video may be found at http://www.youtube.com/watch?v=PHGx3zAIvz8 . Similarly, the PocketECG device is central to Medi-Lynx's business.

D. Reimbursement for Cardiac Monitoring Devices

75. Separate CPT codes are assigned for billing a particular monitor type and the technical monitoring and analytical services provided by an IDTF.

76. Billing for Mobile Cardiac Telemetry is divided into a professional and technical component. Beginning in January 2009, CMS assigned CPT code 93228 to professional telemetry services and CPT code 93229 to technical telemetry services.

77. Providers such as doctors or hospitals seek reimbursement under CPT code 93228 for the professional component of cardiac monitoring telemetry services—including the rental cost of the device, concurrent computerized real-time data analysis, and the physician's review and interpretation component.

78. IDTFs such as Spectocor seek reimbursement under CPT code 93229 for the technical component of telemetry services—including attended surveillance of reported data, transmission of data reports based upon physician-specified criteria and/or frequency.

79. Prior to January 2009, CMS required billing of telemetry services under CPT code 93271, which corresponds to the technical component of loop-memory event monitoring devices. Reimbursement for CPT code 93271 was approximately $200 prior to January 2009, and has subsequently increased to $235.

80. Beginning in January 2009, reimbursement for the technical component of mobile telemetry was initially set at approximately $1,120, and subsequently reduced by CMS to $766.36, which is the current rate for mobile telemetry technical services.

81. Billing and coverage of mobile telemetry is not addressed by any Medicare National Coverage Determination (NCD). Therefore, payment and coverage of telemetry services are subject to the Local Contractor Determination (LCD) issued by the Medicare contractor in the jurisdiction where services are rendered.

82. LCDs approving telemetry under limited circumstances have been issued by Medicare contractors for each of the fifty states, the District of Columbia, and territories.

83. For example, Novitas Solutions, Inc. serves as the Medicare Part A and Part B contractor in several jurisdictions nationwide, including New Jersey, where the conduct alleged herein occurred, and Texas, where the Spectocor IDTF is located.

84. For each jurisdiction in which it operates, Novitas issued an LCD establishing the narrow criteria under which mobile telemetry services may be covered and the effective date of coverage for such claims. See, e.g., Local Coverage Determination (LCD), Real-Time,

Outpatient Cardiac Telemetry (L33075) (Texas) (stating criteria for telemetry coverage in Texas, effective July 11, 2008).

85. Under the Novitas LCD, telemetry is not reasonable and necessary "for all patients with symptoms such as palpitations, dizziness, or weakness" or if "other testing (e.g., ECG, 24 hour Holter, event recorder, etc.) could be expected to provide the data/information needed for the diagnosis and/or treatment of the patient's condition/symptoms." Likewise, telemetry "is not covered when used for screening."

86. Rather, coverage for telemetry services is limited to "patients who have demonstrated a specific need for this type of cardiac telemetry service." This need is met only where: (1) the ordering physician determined and documented that the patient is at a low-risk for a life threatening cardiac event; and (2) the medical record demonstrates that testing will provide diagnostic and/or treatment information useful to the patient's ongoing care; and (3) other cardiac monitoring cannot be expected to provide data and information needed to treat the patient.

87. Even when telemetry services are approved, "[t]he use of multiple forms of cardiac surveillance services (e.g., Holter monitor, other event recorder) provided to the same patient on the same day is NOT medically necessary[,]" and thus not covered.

88. The LCD sets forth the ICD-9 codes deemed to support a claim that a patient's condition or diagnosis meets the covered indications identified by LCD as medically necessary:

426.0	ATRIOVENTRICULAR BLOCK COMPLETE
426.–0 - 426.13	ATRIOVENTRICULAR BLOCK UNSPECIFI–D - OTHER SECOND DEGREE ATRIOVENTRICULAR BLOCK
426.81	LOWN-GANONG-LEVINE SYNDROME
426.89	OTHER SPECIFIED CONDUCTION DISORDERS
427.0	PAROXYSMAL SUPRAVENTRICULAR TACHYCARDIA

427.1	PAROXYSMAL VENTRICULAR TACHYCARDIA
427.2	PAROXYSMAL TACHYCARDIA UNSPECIFIED
427.31	ATRIAL FIBRILLATION
427.32	ATRIAL FLUTTER
427.81	SINOATRIAL NODE DYSFUNCTION
435.9	UNSPECIFIED TRANSIENT CEREBRAL ISCHEMIA
780.2	SYNCOPE AND COLLAPSE
780.4	DIZZINESS AND GIDDINESS
785.0	TACHYCARDIA UNSPECIFIED
785.1	PALPITATIONS
V58.61[2]	LONG-TERM (CURRENT) USE OF ANTICOAGULANTS

89. The submission of an ICD-9 code alone is not determinative of medical necessity. Rather, the submission of a specific ICD-9 CM code is an attestation that the patient (beneficiary) not only has the condition but the context or circumstances of that condition meet the indication criteria outlined in the LCD, and that documentation is supported in the records.

E. Defendants Acted And Conspired To Manipulate Providers, Billing Technicians, And Other Health Professionals Into Completing Telemetry Enrollments Regardless Of Medical Necessity

1. Defendants confined physicians and billing technicians to enrollment options dependent upon the patient's insurance coverage

90. Defendants made a conscious business decision to ensure patients were enrolled in the cardiac monitoring services that would provide the highest rate of reimbursement from private and government payors regardless of the reasonableness or medical necessity of such services.

91. Defendants intended to maximize enrollments in telemetry by characterizing the nature of the device based on the method of reimbursement available. Further, on information

[2] "Group 1 Medical Necessity ICD-9 Codes Asterisk Explanation: []Report V58.61 in conjunction with 427.31 to indicate monitoring to determine appropriateness of anticoagulation therapy discontinuation."

and belief, Defendants designed the web portal to increase the likelihood of getting Telemetry enrollments approved regardless of what was in the patient's medical record.

92. For example, Spectocor provides an online web portal for providers to enroll patients in one of Spectocor's cardiac monitoring devices. A "Spectocor Enrollment Video" that will demonstrate the steps described below may be viewed here: http://www.youtube.com/watch?v=hAZpXTmZmLU.

93. Once logged into the system, the provider begins an enrollment process comprised of six main sections: Patient Demographic Information, Patient Insurance Information, ICD-9 Diagnosis, ICD-9 Symptoms, Physician Information, and Monitor Selection.

94. The section for "Diagnosis" and "Symptoms" collectively contain thirty-eight ICD-9 codes relating to coverage eligibility for various different cardiac monitoring services. Only one ICD-9 code is required by Medicare, but Spectocor's Enrollment page encourages or requires providers to select more than one ICD-9 code, by including separate sections for "Diagnosis" and "Symptoms."

95. The section for "Monitor Selection" contains separate fields for specifying the monitor type (e.g., holter, cardiac event loop recorder, PocketECG telemetry), duration of use, and device delivery method. The monitor type may be selected from a drop-down list of available options.

96. To achieve consistent telemetry billings for Medicare patients, Spectocor aligned its online enrollment process to present "PocketECG telemetry" as the only available option for the PocketECG device whenever Medicare or TRICARE was entered as the patient's primary payor.

97. Conversely, the technician completing enrollment would be presented "PocketECG Event" if the patient had private insurance coverage which did not cover telemetry—such as Blue Cross Blue Shield and for the most part United Healthcare.

98. Along with Medicare and TRICARE—which both cover telemetry in narrow circumstances—the enrollment process would present "PocketECG telemetry" as the only available option for the PocketECG device if the patient had private insurance which did cover telemetry—such as with Aetna.

99. Likewise, enrollment options for a patient covered by Medicaid—which does not cover telemetry—would only include "PocketECG Event." However, false claims were made to the Medicaid program where Medicaid was billed for telemetry services as a Medicare beneficiary's secondary payor—for example, where a Medicare beneficiary received payment of Part B deductibles and coinsurance through eligibility for enrollment in a Qualified Medicare Beneficiary Medicaid Program (QMB).

100. In effect, the distinction foreclosed a Medicare or TRICARE patient from enrolling in "PocketECG Event" and automatically converted the enrollment attempt into enrollment in the higher-cost telemetry service regardless of the patient's medical condition and true diagnosis.

101. Defendants processed enrollments for telemetry monitoring regardless of whether the patient's medical record contained documentation supporting medical necessity. Indeed, Defendants were aware that telemetry enrollments contained ICD-9 codes unrelated to the covered indication for telemetry, including by selecting the field for "OTHER."

102. Defendants also approved telemetry enrollments based upon use of other ICD-9 codes, including "426.9 – Conduction Disorder, Unspecified" and "427.9 - Arrhythmia

Unspecified," for processing telemetry claims, even though the then-applicable LCD criteria did not consider the code relevant to supporting medical necessity.

2. Defendants induced enrollment in telemetry services by marketing PocketECG as a multi-purpose monitor device capable of outperforming competitors in the event-monitoring market

103. Spectocor formulated a nationwide sales strategy, later followed by Medi-Lynx, presenting PocketECG as a flexible single-device option for telemetry, event monitoring, *or* Holter services while maintaining inflexible enrollment and internal billing practices designed to ensure Spectocor (and later also Medi-Lynx) received the highest reimbursement rate for cardiac monitoring services offered by the insurer regardless of the particular cardiac monitoring method being used.

104. In a publicly-disseminated press release, Dr. Dziubinski--the inventor of Pocket ECG and President of the company which manufactures the device--explicitly recognized that the PocketECG device "is now used in cardiac telemetry."

105. However, rather than marketing PocketECG as primarily a telemetry device applicable to a narrow set of covered indications, Spectocor sales representatives marketed the PocketECG device to hospitals and cardiologist practices as a multifunctional device "combining traditional ambulatory arrhythmia diagnostic methods, including Holter, Event and Mobile Telemetry into a single device." Spectocor, Pocket ECG (available at http://spectocor.com/physician-solutions/products/pocket-ecg) (last accessed Feb. 04, 2014).

106. Defendants' marketing and inconsistent approval criteria resulted in misconceptions among some providers who believed the device could be appropriately used for patients with covered indications limited to event monitoring. Such providers ordered Spectocor's PocketECG Device over competitors' event monitors.

107. At the same time, Spectocor processed enrollments for telemetry even where the patient's conditions and symptoms only satisfied the lesser criteria applicable to Cardiac Event monitoring. Further, Spectocor billed Medicare and other health care programs for the technical component of Mobile Telemetry and caused providers to bill such programs for the professional component of Mobile Telemetry when the appropriate billing and reimbursement was for Cardiac Event monitoring.

108. The configuration of the enrollment process ensured that PocketECG telemetry services were ordered for any Medicare patient even when a provider believed to be enrolling a patient in PocketECG for its other monitoring capabilities. This scheme begun at Spectocor continued at Medi-Lynx after Andrew and Joseph Bogdan divided up Spectocor's national account list as well as employees, sales force, cardiac monitoring technicians, and monitoring centers.

3. Defendants arranged to reimburse private insurers for PocketECG as an event monitor and offered to waive deductibles in order to induce business with a provider's Medicare and TRICARE beneficiary population

109. Defendants sought to secure market share among providers with large Medicare and TRICARE beneficiary populations by offering PocketECG as an *event monitor* exclusively to the provider's privately insured patient populations.

110. Sales representatives marketed the PocketECG device using the concept that it is "the only event monitor that can provide physicians with AF Burden and AF Analytics for all your private payers."

111. The PocketECG device reports the same analysis and patient information whether used as a telemetry or event-monitoring device. The telemetry report contains additional documentation showing all daily measurements, but provides no additional analysis,

documentation of abnormalities, or other data of substantive purpose. Examples of each comparable report have been provided to the government.

112. In addition to promoting the device as an event monitor with enhanced features, sales representatives offered to waive co-payments and deductibles on PocketECG devices for patients covered by private payors in order to access the provider's Medicare and TRICARE beneficiaries. In relation to these private payor benefits, providers were told that their patients "would never receive a bill."

113. Sales representatives were authorized to offer these inducements in order to establish business relationships with providers connected to substantial Medicare and TRICARE populations in the hope of securing high-reimbursement telemetry billings.

114. Providers eagerly accepted the arrangement as access to PocketECG as an event monitor attracted privately insured patients to their practice and enabled the physician to treat his entire patient population with the benefit of comprehensive data reporting typically only reserved for the narrow patient group eligible for telemetry. It further reduced the provider's overhead and paperwork for billing, insurance, etc.

115. Defendants provided PocketECG as an event monitor and waived co-payments and/or deductibles to increase patient access in order to induce additional business with the provider' Medicare and TRICARE patient population.

4. Defendants Knew Their Conduct Resulted in False Claims

116. Defendants were aware that they were submitting false and fraudulent claims for technical services to government health care programs and that they were causing providers to submit false claims for PocketECG telemetry professional component. In addition, providers and Defendants' claims were tainted by the illegal inducements offered and accepted.

117. Defendants identified regions and provider groups with large Medicare and TRICARE populations and offered to waive co-payments and deductibles for patients with private insurance in the hope of accessing the provider's lucrative Medicare and TRICARE beneficiary population.

118. Likewise, Defendants presented the PocketECG device to private payors as a market-leading event monitor in order to undermine competitors such as LifeWatch and access Medicare and TRICARE beneficiaries which Spectocor billed for the more expensive telemetry.

119. Defendants also intended to deceive providers into submitting a false claim by marketing PocketECG as an event monitor despite the absence of any option to enroll a patient in PocketECG event monitoring through Spectocor's enrollment process.

120. The inventor of the device and President of Defendant Medical Algorithmics understood that the device was intended to be used for telemetry, stating in a February 27, 2013 press release "I see a lot more applications for the new device [i.e. the newest version of PocketECG] . . . . *It is now used in cardiac telemetry*, but we also have plans to extend the range of the industry." (emphasis added).

121. Spectocor's CEO Joseph Bogdan was aware that PocketECG was intended to function as a telemetry device, stating that "[t]he PocketECG system was developed in response to physicians who demand a monitoring device that analyzes every heartbeat, provides remote access to full-disclosure ECG data and generates quantitative statistical reports for all ventricular and supraventricular arrhythmias." See Press Release, PRWeb, "Spectocor Announces Comprehensive Mobile Cardiac Monitoring System that Wirelessly Transmits and Analyzes Important Arrhythmic Events," (May 02, 2012) (available at http://www.prweb.com/pdfdownload/9447499.pdf) (last accessed Feb. 04, 2014).

122. Defendant Joseph Bogdan was also aware of the intense scrutiny over the medical necessity of mobile telemetry devices following a $18.5 million settlement between LifeWatch Services, Inc. and the federal government in March 2012 resolving claims that LifeWatch submitted false claims to Medicare for mobile telemetry services lacking medically necessity. Since then another competitor, CardioNet, Inc, settled similar claims with the government for $6.4 million in March 2015.

123. Nonetheless, Defendant Joseph Bogdan and the other Defendants continued to construct and accelerate an enrollment, marketing, and billing scheme designed to generate claims for costly mobile telemetry services to Medicare and certain other payors.

124. Defendant Andrew Bogdan formed Medi-Lynx Cardiac Monitoring, LLC in August 2013, and left Spectocor. He as sole owner, and now also Defendant Medical Algorithmics as majority owner, have operated Medi-Lynx using the same enrollment, marketing, and billing scheme developed by Defendants Andrew and Joseph Bogdan at Spectocor and designed to generate claims for costly mobile telemetry services to Medicare and certain other payors.

5. Damages Caused by Defendants to Government Health Care Programs

125. Defendants have engaged in fraudulent billings for PocketECG since the device entered the U.S. market in 2010. Prior to Spectocor's partnership with Medical Algorithmics, Joseph Bogdan operated AMI Monitoring which Relator has reason to believe engaged in false claims for reimbursement of telemetry services with the MedNet ECAT device.

126. As a result of Defendants' fraudulent marketing, enrollment, and billing practices, the federal health care programs paid for millions of dollars in medically unnecessary "telemetry" services.

127. Medicare reimburses PocketECG telemetry monitoring at a rate of approximately $760 per episode of monitoring for an enrolled beneficiary, much higher than for event monitoring.

128. Prior to January 2009, Medicare reimbursed MedNet ECAT telemetry monitoring at up to $1200 per episode.

129. Spectocor initiated an aggressive sales push beginning in May 2012 to market an updated version of the PocketECG device. Spectocor's monthly Medicare enrollments dramatically increased each month thereafter.

130. Within one sales region alone, monthly Medicare enrollments more than doubled in just four months.

131. In a press release dated December 20, 2012, Medical Algorithmics announced that its partnership with Spectocor "significantly increased the number of American patients" using the PocketECG device.

132. On information and belief, close to 1,000 Medicare patients nationwide have been and are being actively enrolled in PocketECG monitoring each month, accounting for a significant percentage of Spectocor's overall revenues.

133. PocketECG enrollments continue to trend towards upward growth as evidenced by significant increases in the valuation of Medical Algorithmics—the device's manufacturer.

134. Spectocor's rapid growth of PocketECG telemetry billings between FDA approval of the second version of the device on May 21, 2012 and 2014 coincided with a 412.28 percent increase in the market value of Medical Algorithmic's publicly traded stock over the same period of time.

135. Defendants enroll approximately 1,050 Medicare patients per month, and of these, 90% (or about 945) are enrolled in telemetry. Spectocor's annual national revenue for all payors for all cardiac monitoring services was approximately $27-30 million in 2013. Thus, when Spectocor was broken into 2 separate companies, Spectocor and Medi-Lynx, each had roughly $15 million in annual revenue. However, according to Medical Algorithmics, in the twelve months to the end of June 2015, Medi-Lynx reached $32.7 million in revenue and $ 12.5 million in EBITDA.

136. Fraudulent marketing and billing practices by cardiac monitoring companies cost the federal government millions of dollars in medically unnecessary services. Indeed, spending for telemetry services have sharply risen in recent years with annual Medicare expenditures for telemetry (CPT code 93229) totaling $73 million in 2011—making telemetry the 177th most costly billing code among the over-9500 CPT codes presently in use.

137. Defendants' two main competitors have already faced federal scrutiny: LifeWatch settled with the government in March 2012 over allegations of improper billing; and CardioNet settled similar claims in March 2015.

CLAIMS FOR RELIEF

Count I: Violations of the False Claims Act,

31 U.S.C. §§ 3729(a)(1)(A), (a)(1)(B), (a)(1)(G), and (a)(1)(C)

138. The allegations of the foregoing paragraphs are incorporated herein as if fully realleged.

139. Defendants, by and through their agents, officers, and employees, knowingly presented or caused to be presented to officers or employees of the United States false claims for

payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A) for professional and technical services related to the use of the PocketECG device.

140. Defendants, by and through their agents, officers, and employees knowingly made, used, or caused to be made or used, a false record or statement material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B).

141. Defendants fraudulently concealed and intentionally failed to report funds improperly received from the United States for devices and procedures that were not reasonable and medically necessary in violation of 31 U.S.C. § 3729(a)(1)(G).

142. Defendants also knowingly presented or caused to be presented, false or fraudulent claims for payment or approval to the United States for devices provided pursuant to illegal kickback arrangements as described herein, in violation of the Anti-Kickback statute.

143. Defendants acted in violation of the False Claims Act for conspiring to commit a violation of the False Claims Act at 31 U.S.C. § 3729(a)(1)(A), (B), and/or (G) in violation of 31 U.S.C. § 3729(a)(1)(C).

144. In engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in 31 U.S.C. § 3729.

145. As a result of Defendant's violations of 31 U.S.C. § 3729, the United States has suffered damages in an amount to be determined at trial.

PRAYERS FOR RELIEF

WHEREFORE, Relator John Doe, acting on behalf of the United States, requests that this Court enter an order:

a. That Defendants violated the False Claims Act;

b. That Defendants pay an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty against each Defendant for each FCA violation in the maximum statutory amount;

c. That Defendants cease and desist from violating the False Claims Act;

d. That Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to the False Claims Act;

e. That the Relator be awarded the maximum amount allowed as a relator share pursuant to 31 U.S.C. § 3730(d);

f. That the United States Government and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

DEMAND FOR JURY TRIAL

Plaintiff requests, pursuant to Federal Rule of Civil Procedure 38(b), that all of the issues in this matter be tried to a jury.

Respectfully Submitted on this 18th day of August, 2016 by:

CARTUSCIELLO & KOZACHEK LLC

By: */s/ Neil S. Cartusciello*

Neil S. Cartusciello (NSC-2460)
101 Farnsworth Avenue
Bordentown, NJ 08505
(609) 324-8200
Fax: (609) 324-8201
Email: n.cartusciello@verizon.net

Suzanne E. Durrell (Mass. BBO #139280)
DURRELL LAW OFFICE
180 Williams Avenue
Milton, Massachusetts 02186
(617) 333-9681
Fax: (617) 333-0014
Email: suzanne.durrell@verizon.net

Robert M. Thomas, Jr. (Mass. BBO #645600)
THOMAS & ASSOCIATES
20 Park Plaza, Suite 438
Boston, MA 02116-4322
(617) 371-1072
Fax: (888) 676-7420
Email: rmt@thomasandassoc.net