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. _____

Filed Under Seal Pursuant to
31 U.S.C. § 3720(b)(2)

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. BIOTELEMETRY, INC., CARDIONET, INC., AND MEDNET HEALTHCARE TECHNOLOGIES, INC., Defendants.	Civil Action No. _____ Filed Under Seal Pursuant to 31 U.S.C. § 3720(b)(2)

COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

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 BioTelemetry, Inc., CardioNet, Inc., and Mednet Healthcare Technologies, Inc. (collectively "Defendants").

2. The violations of the FCA arise out of a fraudulent scheme to use various forms of illegal remuneration (prohibited by the Medicare-Medicaid Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)), to induce health care providers to use Defendants' cardiac monitoring devices and services instead of competitors' devices and services, thus gaining market share and profit for Defendants. This scheme caused claims to and payments therefor by federal health care programs such as Medicare for services that were tainted by such kickbacks, and in some instances for services that were not medically necessary or reasonable and/or were not provided to the patient.

3. The FCA provides that any person who violates the FCA is liable for a civil penalty of between $5,500 and $11,000 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 voluntarily provided the United States with disclosures of his identity, relevant information, and his allegations prior to filing this Complaint.

PARTIES

A. Plaintiffs/Relator.

7. Plaintiff 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. Plaintiff John Doe is the Relator and 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 Mednet Healthcare Technologies, Inc. ("Mednet") is a Delaware corporation headquartered in Ewing, New Jersey. Mednet operates as an Independent Diagnostic Testing Facility ("IDTF") providing remote cardiac monitoring services under exclusive supplier agreements with health care providers such as physicians and hospitals. Over the years, Mednet has manufactured and supplied various types of cardiac monitoring devices.

10. Frank Movizzo formed Mednet in 1989 and served as Chief Executive of Mednet until February 2014 at which time he sold his interest in the company to Defendant CardioNet, Inc.

11. Defendant CardioNet, Inc. ("CardioNet" NASDAQ: BEAT), a Delaware corporation, represents itself as "the world's leading supplier of Mobile Cardiac Outpatient Telemetry (MCOT) and other wireless medical technologies for delivering health information. … ." CardioNet recently changed its name to BioTelemetry, Inc.and adopted a holding company structure under which CardioNet would become a wholly owned subsidiary of BioTelemetry.

12. Defendant BioTelemetry, Inc. ("BioTelemetry" NASDAQ: BEAT), is a Delaware corporation which, as described above, now owns CardioNet.

13. Mednet's IDTF operation is based in Ewing, New Jersey and is staffed "24/7" by certified cardiac monitoring technicians providing cardiac monitoring services nationwide. During the period relevant to this Complaint, Mednet employed over 150 employees nationwide

and provided cardiac monitoring services for 8,000 physicians from hundreds of hospitals across the nation, including clients in this district.

JURISDICTION AND VENUE

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

15. 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.

16. 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.

APPLICABLE FEDERAL LAW

A. Federally Funded Health Care Programs.

17. 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.

18. 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").

19. 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).

20. 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).

21. 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 Health Care Programs.

22. 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 must be provided and 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 a provider's 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 to 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).

23. 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.

24. Claims for payment of outpatient services from the Government 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.

25. 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 Government Health Care Programs, to determine the amount of reimbursement received. For purposes of this Complaint, the relevant CPT codes for cardiac Event monitoring are 93270-93272 and for cardiac mobile Telemetry monitoring are 93228 and 93229.

26. 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.

27. Reimbursement rules issued by the Government Health Care Programs identify acceptable ICD-9 code(s) required to demonstrate medical necessity for particular covered goods and services. Eligibility for reimbursement from the Government Health Care 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.

28. 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.

29. 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 Government 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.

30. 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.

31. In addition to the general provider enrollment requirements for reimbursement under Government Health Care Programs , IDTFs such as the one operated by Defendants 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).

32. Contractual arrangements reassigning Medicare billing privileges are impermissible if essentially a means of camouflaging inappropriate fee splitting for referrals. *See* 69 Fed. Reg. 47,525 (Aug. 5, 2004).

C. Federal False Claims Act.

33. The federal False Claims Act, 31 U.S.C. §§ 3729, *et seq.*, as amended by the Fraud Enforcement and Recovery Act of 2009, Pub. L. No. 111-21 ("FERA"), 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). (For conduct pre-dating FERA, certain provisions of the 1986 version of the FCA may apply).

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).

34. The Federal FCA, 31 U.S.C. § 3729(b)(2), 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.

35. 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."

36. 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."

37. The Federal FCA, 31 U.S.C. § 3729(b)(3), 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.

38. 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 corrupt 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 Government 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.

39. 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 AKS 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.

40. 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.

41. 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).

42. 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).

43. 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).

44. 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.

45. 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).

FACTS AND ALLEGATIONS

46. As described more fully herein, Defendant Mednet acted and conspired to establish a billing scheme through which it provided kickbacks to physicians and health care providers as an inducement to gain referrals for cardiac monitoring services reimbursed by Government Health Care Programs (and certain private payors whose members may be enrolled in the FEHBP) in violation of the AKS and regardless of the medical necessity or reasonableness

of such services and/or whether such services were provided. Since Defendant Mednet was acquired by Defendants CardioNet/BioTelemetry, such misconduct has, on information and belief, continued and the United States has not been informed of such misconduct by Defendants nor have overpayments been returned to Government Health Care Programs. This misconduct has been ongoing since at least 2005 and encompasses Mednet's cardiac Event monitoring service and its mobile Telemetry monitoring service, as well as other services such as Holter monitoring services and Pacemaker monitoring service.

A. Cardiac Monitoring Devices and Reimbursement.

47. Cardiac arrhythmias refers to the occurrence of abnormal heart rhythms. Arrhythmias may be accompanied by symptoms (e.g., palpitations, fainting, dizziness, weakness blood clots) or present asymptomatically. Arrhythmias can also occur infrequently and unpredictably. Medicare covers costs associated with the diagnosis of cardiac arrhythmias.

48. 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 arrhythmia symptoms dictates the appropriate type and duration of cardiac monitoring.

1. Types of Cardiac Monitoring Devices.

49. Prior to 2009 or so, cardiac monitoring generally involved the use of two main types of cardiac monitoring devices—Holter monitors and cardiac Event monitors. Starting around 2009, mobile cardiac Telemetry monitors entered the market and quickly gained market share.

50. When a patient is using a cardiac device, IDTFs such as the one operated by Defendant Mednet monitor the patient's electrical heart activity, analyze results, and provide interpretations and reports to the patient's treating physician.

51. Cardiac monitoring services are reimbursed at various rates by Medicare and other insurers depending upon the type of device or service. Furthermore, CPT codes dictate reimbursement levels for the respective services separately performed by physicians versus those monitoring services performed by the IDTF provider.

52. 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 with daily frequency.

53. 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.

54. 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.

55. Medicare generally covers Holter and Event monitoring for diagnostic purposes, specifically where the treating physician requires the additional information to evaluate a patient's condition because a diagnosis could not be made on physical examination of the patient.

56. Mobile cardiac Telemetry monitoring is covered and payable by Medicare only in limited circumstances. 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.

2. Defendants' Cardiac Monitoring Product Line.

57. At all times relevant to this Complaint, Defendant Mednet has manufactured and marketed various cardiac monitoring devices and provided and marketed technical services related to ambulatory cardiac monitoring devices capable of detecting abnormal cardiac rhythms.

58. At all relevant times, Defendant Mednet has also operated an IDTF staffed by technicians who monitor data reported by the device and provide physicians with reported results and analysis.

59. Over the years, Defendant Mednet manufactured, marketed, and supplied two primary cardiac Event monitoring devices—Heartrak Smart (looping and non-looping) and Heartrak Smart AF (atrial fib device)—in addition to Holter monitors/services.

60. The Heartrak Smart device originally operated as a "non-loop memory" cardiac Event monitor capable of detecting cardiac conditions and recording a patient's heart activity on

magnetic tape or other digital medium. This device was Mednet's first generation trans-telephonic Event monitor.

61. Monitored patients wear the Heartrak Smart device throughout the performance of normal daily activities while diagnostic algorithms stored on the device enable detection of cardiac conditions such as atrial fibrillation, cardiac pause, tachycardia and Bradycardia.

62. Patients may also record up to 30 minutes of electrical heart activity (i.e. electrocardiogram, or "ECG"). The device may be programmed to automatically begin recording upon occurrence of particular events, symptoms, or pre-programmed time intervals.

63. The Heartrak Smart device was first approved for use in the United States on May 3, 1995 pursuant to the FDA 510(K) premarket approval process. The original Heartrak device was limited to post-event recording. See Heartrak Smart, 510(K) No. K943124 (May 03, 1995).

64. Later generations of the Heartrak Smart device operated as a "loop memory" Event monitor and improved upon the original Heartrak Smart design by increasing total recording time. The device featured programming enabling patients to select from multiple settings for pre- and post-event monitoring. See Heartrak Smart, 510(K) No. K033451 (Feb. 04, 2004).

65. In 2008, Mednet obtained approval for the Heartrak Smart AF which added proprietary algorithms programmed to capture a variety of cardiac conditions and asymptomatic events. The device further featured additional memory and programming capabilities over the prior iteration. See Heartrak Smart AF, 510(K) No. K071130 (May 14, 2008).

66. Beginning around March 2009, Defendant Mednet introduced a stand-alone mobile device marketed as the HEARTRAK External Cardiac Ambulatory Telemetry ("Heartrak ECAT"); this device purported to be and was marketed as a telemetry device.

67. The Heartrak ECAT uploads recorded ECG data to an RF compatible receiver. Once uploaded, data may be analyzed at an IDTF and reported to the patient's treating physician.

68. The Heartrak ECAT was approved for use in the United States on December 15, 2008 pursuant to the FDA 510(k) premarket approval process. See Heartrak ECAT, 510(K) No. K083535 (Dec. 15, 2008).

3. Reimbursement for Cardiac Monitoring Devices.

69. Cardiac monitoring services are reimbursed in accordance with separate CPT codes assigned to the respective services performed by physicians and IDTFs in connection with patient use of the device.

70. Billing for Event monitors is divided into professional versus technical components. Accordingly, CMS and private payers assigned CPT codes 93270 and 93272 to reimburse treating physicians for their professional services and CPT code 93271 to reimburse the IDTF for its technical services.

71. Treating physicians seek reimbursement under CPT code 93270 for hooking up the Event monitor and under CPT code 93272 for physician review and interpretation. At all times relevant to this Complaint, billing requests under CPT code 93270 and 93272 were reimbursed at approximately $15 and $32, respectively.

72. IDTFs such as Defendant Mednet seek reimbursement under CPT code 93271 for the technical component of Event monitoring services which involves 24/7 monitoring by technicians, emergent notification, and reporting of patient data and technician observations. At the time relevant to this Complaint, billing requests under CPT code 93271 were reimbursed at approximately $300 per test.

73. In addition to separate billing codes for the professional versus the technical services (i.e. CPT codes 93270-72), there is a "global" reimbursement rate for bundled professional and technical services under CPT code 93268. At all times relevant to this Complaint, global reimbursement levels for bundled Event monitoring services averaged $360 per test. In general, in order to bill globally for cardiac Event monitoring, the health care provider (i.e. hospital) must own or buy the equipment, and do their own monitoring.

74. CMS covers cardiac Event monitoring when there are documented signs and symptoms or other clinical indications for performing a stand-alone electrocardiogram (EKG), but where an EKG could not "provide the physician with documented episodes of arrhythmia," or "evaluate symptoms that may correlate with intermittent cardiac arrhythmias and/or myocardial ischemia," or "to evaluate patient response to initiation, revision, or discontinuation of arrhythmic drug therapy." (Medicare National Coverage Determinations Manual, Ch. 1, Section 20.15).

75. Defendant Mednet's customer agreement identified ICD-9 codes deemed to support a claim of medical necessity sufficient to support reimbursement:

426.7	Anomalous atrioventricular excitation
426.89	Other specified conduction disorders
427	Paroxysmal supraventricular tachycardia
427.1	Paroxysmal ventricular tachycardia
427.2	Paroxysmal tachycardia, unspecified
427.31	Atrial fibrillation
427.32	Atrial flutter
427.41	Ventricular fibrillation

427.42	Ventricular flutter
427.89	Other specified cardiac dysrhythmias
435.9	Unspecified transient cerebral ischemia
780.2	Syncope and collapse
780.4	Dizziness and giddiness
785.1	Palpitations
786.09	Other Dyspnea and respiratory abnormalities

76. By 2009, companies such as Mednet began offering cardiac mobile Telemetry products and services in addition to the Event monitoring discussed above. In January 2009, reimbursement for the technical component of mobile telemetry was initially set at approximately $1,120 by CMS, and subsequently reduced by CMS to $766.36, which is the current rate for mobile telemetry technical services. Because there is no hook up fee for Telemetry the way there is for Event monitors, the only CPT code for the professional service of the physician is for professional interpretation which was reimbursed at approximately $30 at all times relevant to this Complaint. Unlike Event monitoring, there is no "global" reimbursement or CPT code for mobile Telemetry monitoring.

77. Unlike Event monitoring, cardiac Telemetry is not covered by the Government Health Care Programs under an NCD. Rather, the determination whether to cover mobile telemetry is left to the local coverage determination (LCD) of individual Medicare contractors operating across the country.

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

79. For example, Novitas Solutions, Inc. serves as the Medicare Part A and Part B contractor in several jurisdictions nationwide.

80. 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).

81. 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."

82. 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 has 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.

83. 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.

84. 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 for telemetry services:

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[1]	LONG-TERM (CURRENT) USE OF ANTICOAGULANTS

85. 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.

[1] "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."

B. Defendants' Fraudulent Kickback Schemes Caused False Claims to be Submitted to Government Health Care Programs and the United States was Damaged by This Misconduct.

1. Defendants' Fraudulent Kickback Schemes.

86. Defendant Mednet aggressively marketed to providers the financial advantage of what it called "Split Bill Medicare and Fee for Service for Private Payors" (hereafter "Split Bill/Fee for Service") arrangements to induce providers to enter agreements with Defendant to provide cardiac monitoring services. This Split Bill/Fee for Service arrangement was the most common agreement Mednet had with larger health care providers around the country including, for example, Brigham and Women's Hospital and Massachusetts General Hospital in Boston, Massachusetts. In practice, this arrangement as described below violated the AKS.

87. Defendant's willingness to offer these lucrative kickbacks resulted in significant competitive imbalances in the market and enabled Defendant to exclude its primary competitors, including LifeWatch and CardioNet, from large health care providers with large Government Health Care Program patient populations. This is because its competitor IDTFs rarely, if ever, offered Split Bill/Fee for Service billing arrangements during the period of time relevant to the Complaint. Rather, they offered agreements that were "Split Bill All" (government and private payors).

88. Defendant Mednet's marketing strategy operated upon the notion that any loss from allowing providers such as hospitals to bill globally for Event monitoring services for private insurance patients while paying Mednet a below market and commercially unreasonable "fee for service" for its technical service on private patients, would be greatly outweighed by the anticipated profit attainable by Mednet accessing the provider's Government Health Care Program patients which Mednet and the provider would Split Bill (i.e. provider would bill for the

professional services while Mednet would bill for its technical services and be reimbursed at a rate far higher than it received from the provider under Fee for Service for private patients).

89. Remuneration to providers from private payors under this Split Bill/Fee for Service arrangement for Mednet Event monitoring services resulted in referrals and arrangements reimbursed by Government Health Care Programs, in violation of the federal AKS.

90. Under this Split Bill/Fee for Service arrangement, Mednet entered into Customer Enrollment Agreements engaging providers "in a business relationship" to serve as the exclusive source of all cardiac monitoring services (Event, Holter, and Pacemaker) sought by the provider for a designated period of time. Under the Fee for Service part of this arrangement, Defendant Mednet essentially allowed providers to bill *private insurance companies* the *global* reimbursement fee encompassing both the professional component services performed by the individual provider (i.e. device hook-up and physician interpretation) and the technical component services actually being performed by Defendant (i.e. monitoring and reporting). The provider would then remit to Defendant Mednet a fraction of the global reimbursement fee and retain a reimbursement share significantly higher than the provider would have received had it billed separately for services actually performed (as it did under the Split Bill arrangement for *Government Health Care Program* patients).

91. Since the average global reimbursement for an Event monitor from private insurers during the relevant time was approximately $360 per test, the hospital or private cardiology group would then make about $240-$250 per test rather than making just the physician interpretation (CPT Code 93272 at about $32) and hook up fee (CPT Code 93270 at about $15) totaling about $47/test. As a result, providers earned approximately $240-$250 per patient test as their lopsided share of the global reimbursement fee as opposed to approximately

$47 per patient test if billed only for services performed. In other words, the net difference to the provider was about $193-$203/per patient/test. Moreover, Mednet clients were not doing any of the monitoring/technical services, but Mednet was nevertheless allowing them to bill *globally*.

92. By purposefully allowing its clients to bill private insurance companies/payers for the entire global amount for Event monitoring (roughly $360 per test at the time), and pay Mednet a "fee for service" amount, generally $110-$120 per test (with Mednet performing only the technical component), Defendant Mednet easily "beat" the rest of its competitors. For example, competitors Lifewatch and CardioNet generally only offered "Split Bill All" agreements encompassing both Medicare and private insurers, (very rarely did either ever offer a "fee for service" rate for private insurers). The net result to the providers was that they could earn far more money per test for each private insurance patient by using Mednet's SplitBill Medicare/Fee for Service Privates rather than a competitor's Split Bill All. Specifically, if they used Mednet, they netted between approximately $240-$250/test/private insurance patient versus if they used Lifewatch or CardioNet they netted approximately $47 for the same patient (the total of the professionalcomponents for the hook up fee and the interprestation of results). By using Mednet, the providers earned over *five times* more per test per private patient.

93. The Split Bill/Fee for Service arrangement offered by Mednet was so lucrative for hospitals and doctors, that many eagerly accepted it and signed up with Mednet. Its sales representatives were authorized and encouraged to offer these agreements; essentially what they would say to the customer was "for all your private payers, we can steer more of the reimbursement your way." In return, Mednet would also get all the Government Health Care Program patients. By offering this Split Bill/Fee for Service arrangement, Mednet reduced or

eliminated competition for its Event monitoring services and got access to the Government Health Care Program business.

94. Defendant Mednet offered similar kickbacks under Split Bill/Fee for Service arrangements for Holter and Pacemakers monitoring services.

95. By 2009, Mednet introduced its Heartrak eCat (cardiac Telemetry) device to the market, and it began to develop and employ variations of the Split Bill/Fee for Service scheme used with its other cardiac monitoring services described above. The telemetry market promised to be a lucrative market and various kickbacks paved the way for Mednet gaining and keeping market share.

96. Defendant leased its telemetry device, the Mednet Heartrak eCat, to providers for a low, fixed monthly payment and established a billing scheme designed to encourage utilization of Mednet's telemetry services over those of competitors.

97. Similar to the Split Bill/Fee for Service scheme for Event monitoring services, Defendant allowed providers to bill using both the professional and technical CPT codes for Telemetry services (having leased the device) and retain substantial portions of the resulting reimbursement from insurers as a kickback for referring or arranging to furnish services reimbursable under the Government Health Care Programs.

98. In addition to lucrative billing arrangements, Defendant Mednet offered providers remuneration in the form of consulting agreements to induce referrals and the furnishing of services reimbursable under the Government Health Care Programs.

99. For example, Defendant compensated Dr. Leon Feldman as a consultant and entered into an agreement with his practice, Desert Cardiology in California, to lease the eCat

device for approximately $30 per month and bill both the professional and technical CPT codes for telemetry even though Mednet provided all the technical services.

100. Moreover, Defendant was not committed to collecting or pursuing lease payments theoretically owed to it under the Agreement with Desert Cardiology pay invoices.

101. Under this arrangement, Desert Cardiology received approximately $728 under the technical services CPT 93229, and approximately $27 per test under the professional services CPT 93228, for a total of $755 per telemetry test under its agreement with Defendant. In return, it remitted $300 from that amount to Defendant as a "fee for service." As a result, Desert Cardiology netted $455 per telemetry test.

102. The $455 net to Desert Cardiology per telemetry test dwarfed the $27 reimbursement fee for professional interpretation it would otherwise receive had the parties billed separately for professional and technical services, respectively.

103. Defendant's financial billing arrangement ensured Desert Cardiology would receive the bulk of the reimbursement despite the fact that Desert Cardiology did not perform any cardiac monitoring services. Moreover, this arrangement was made even more profitable by Mednet's lack of commitment to collecting the $30 monthly lease amount for the device.

104. As a result of the substantial financial incentive to enroll patients in telemetry tests, some providers intentionally shortened the typical study period of 14 days (though study periods may extend up to 30 days) to as few as 5-7 days in order to maximize the number of enrollments derived from a single Heartrak eCat device. For example, if the provider used 1 device in a given month on 3 patients that were enrolled for 7 days each, practices such as Desert Cardiology would *net* from the reimbursement approximately $455 per study x 3 studies or $1,365/device/month on a device ostensibly leased for $30/month.

105. Defendant has offered variations of these mobile Telemetry agreements to providers in California, Washington and Florida, and on information and belief, these agreements are part of a nationwide practice of offering illegal remuneration in return for referring, arranging, or furnishing telemetry services reimbursable by Government Health Care Programs .

2. Defendants Knew This Misconduct Resulted in False Claims.

106. Defendant Mednet offered illegal kickbacks in connection with the actual or potential provision of items and services reimbursable under Government Health Care Programs. Defendant knew or should have known that its fraudulent actions caused and would cause false and fraudulent claims to be submitted to Government Health Care Programs.

107. Defendant Mednet purposely targeted providers serving large Government Health Care Program patient populations and offered and paid such providers kickbacks in exchange for the referral or arrangement of items and services reimbursed by these Government Health Care Programs.

108. Defendant aggressively promoted the "financially advantageous" terms of its "Split Bill Medicare, Fee for Service Private Payors" scheme in order to undermine competitors such as LifeWatch and CardioNet and access Medicare and other Government Health Care Program beneficiaries for whom Defendant received a large volume of high-rate reimbursements for the provision of technical cardiac monitoring services.

109. Defendant Mednet intended to attract provider market share by encouraging providers to maximize high-reimbursement telemetry billings on each device leased from Defendant.

110. Defendant's own sales and marketing materials acknowledge the "financially advantageous" nature of provider enrollment with Defendant. The President of Mednet and other managers authorized and encouraged these arrangements to be offered and made by the sales force.

111. Defendant CardioNet (now known as Defendant BioTelemetry), as a competitor of Mednet, was aware of the Split Bill/Fee for Service and other arrangements offered by Mednet and the effect these had on CardioNet's ability to compete for clients. Moreover, Defendant CardioNet recently acquired Mednet and as a result of that process knows or should know about Mednet's marketing tactics.

3. Damages Caused to Government Health Care Programs.

112. Defendant Mednet secured substantial annual revenue as a result of its fraudulent kickback scheme, reaching $25 million in annual revenue in 2014.

113. Defendant's fraudulent actions solidified Mednet's market share and built a foundation of financial success culminating in Defendant CardioNet's acquisition of Mednet in 2014 for approximately $16 million.

114. As a result of Defendant's fraudulent marketing, enrollment, and billing practices, Government Health Care Programs paid for millions of dollars in claims resulting from fraudulent inducement in violation of the Anti-Kickback Statute.

115. Defendant Mednet aggressively marketed its lucrative reimbursement agreements to providers with large Government Health Care Program patient populations. Defendant's monthly Medicare (and other Government Health Care Program) enrollments dramatically increased as a result of these fraudulent inducements.

116. On information and belief, none of the Defendants has taken action to notify the United States of these fraudulent practices or to identify or return overpayments received from Government Health Care Programs.

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)

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

118. 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, technical, and global services related to the use of Mednet's cardiac monitoring devices.

119. 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).

120. Defendants fraudulently concealed and intentionally failed to report funds improperly received from the United States for devices and procedures that were tainted by violations of the AKS and in some instances were not reasonable and medically necessary and/or were not provided, all in violation of 31 U.S.C. § 3729(a)(1)(G).

121. Defendants knowingly presented or caused to be presented, false or fraudulent claims for payment or approval to the United States for devices and services provided pursuant to illegal kickback arrangements as described herein, in violation of the AKS.

122. Defendants acted in violation of the False Claims Act by conspiring among themselves and with health care providers 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).

123. While engaging in the conduct alleged above, Defendants acted "knowingly" as that term is defined in 31 U.S.C. § 3729 and in the AKS as amended by PPACA, 42 U.S.C. § 1320a-7b(g)-(h).

124. As a result of Defendants' 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 AKS and 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 of not less than $5,500 and not more than $11,000 for each violation of the False Claims Act;

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 this 24 day of September, 2014 by:

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