UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF GEORGIA DUBLIN DIVISION

UNITED STATES OF AMERICA, and the STATE OF GEORGIA, ex rel. DR. MICHAEL FENSTER,

Plaintiffs.

Case No.

COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT AND GEORGIA FALSE MEDICAID CLAIMS ACTS

vs.

HOSPITAL CORPORATION OF AMERICA, FAIRVIEW PARK HOSPITAL, DUBLIN-MACON CARDIOLOGY, P.C., DR. JOSEPH DEJUNCO, AND DR. MANUEL VEGA, FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)

JURY TRIAL DEMANDED

Defendants.

COMPLAINT

Plaintiff-Relator Michael Fenster brings this Complaint, through his attorneys, on behalf of the United States of America (the "Government," or the "Federal Government") and the State of Georgia against defendants Hospital Corporation of America, Fairview Park Hospital, Dublin-Macon Cardiology, P.C., Dr. Joseph DeJunco, and Dr. Manuel Vega (collectively "Defendants"), alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action to recover damages and civil penalties on behalf of the United States of America and the State of Georgia arising from false and/or fraudulent records, statements and claims made and caused to be made by Defendants and/or their agents, employees, and co-conspirators in violation of the federal False Claims Act, 31 U.S.C. §§ 3729

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et seq. ("the FCA") and the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 et seq.

- 2. Since at least November 2008, Dr. Vega, a physician at Fairview Park Hospital, has performed unsafe and medically unnecessary invasive coronary procedures and defendants have submitted false claims for reimbursement for these procedures to Medicare, Medicaid and other federal health care programs.
- 3. Dr. Vega has performed procedures for which he does not have the proper training, causing very serious harm to patients. Defendants have also endangered patients by unnecessarily delaying procedures and performing elective procedures at Fairview Park Hospital, which should only have been performed at a facility equipped for immediate cardiac surgery.
- 4. Dr. Vega and Dr. DeJunco have also performed medically unnecessary procedures. They have misled patients, overstating the severity of their condition and the importance of procedures, in order to obtain patients' consent to perform invasive coronary procedures, including angioplasty and stent placement.
- 5. Relator informed officials at Fairview Park Hospital and Hospital Corporation of America of the unsafe and unnecessary procedures, but rather than intervening, Defendants concealed the records of these procedures.
- 6. Defendants have submitted numerous claims to federal health care programs for medically unnecessary procedures and services of a quality that do not meet professional standards of care. Each submission is a false or fraudulent claim in violation of the False Claims Act.
- 7. The FCA was enacted during the Civil War, and was substantially amended in 1986 and 2009. Congress amended the Act in 1986 to enhance the Government's ability to recover losses sustained as a result of fraud against the United States after finding that fraud in federal programs was pervasive and that the Act, which Congress characterized as the primary

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tool for combating government fraud, was in need of modernization. The amendments created incentives for individuals to come forward with information about fraud against the government without fear of reprisals or Government inaction, and enable the use of private legal resources to prosecute fraud claims on the Government's behalf.

- 8. The FCA provides that any person who knowingly submits, or causes the submission of, a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the Government. 31 U.S.C. § 3729(a)(1)(G) (as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 [28 U.S.C. § 2461 note; Public Law 104-410]).
- 9. The FCA allows any person having information about a false or fraudulent claim against the Government to bring an action for himself and the Government, and to share in any recovery. The Act requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendants during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.
- 10. Georgia has enacted a law similar to the FCA to enable them to recover for fraud affecting Georgia state treasuries. Dr. Fenster alleges that the Defendants' conduct violated the FCA and the Georgia False Medicaid Claims Act, Ga. Code Ann. § 49-4-168 et seq.
- 11. Based on the foregoing laws, qui tam plaintiff Dr. Michael Fenster seeks, through this action, to recover damages and civil penalties arising from the false or fraudulent records, statements and/or claims that the Defendants made or caused to be made in connection with provision of medical services that were medically unnecessary and that were not of a quality meeting professionally recognized standards of care. Even where Defendants did not directly submit claims to the Government or the State of Georgia, they knew that claims would be submitted to federal heath care programs for procedures Defendants performed that were

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medically unnecessary and of a substandard quality, and that therefore were not eligible for program reimbursement.

II. PARTIES

- 12. Plaintiff-Relator Dr. Michael Fenster is a cardiologist residing in Brooksville, Florida. From July 2008 until December 2009, Dr. Fenster served as the Executive Medical Director of Cardiovascular Services for the Hospital Corporation of America's Fairview Park Hospital. Dr. Fenster completed his internship and residency in Internal Medicine at the North Carolina Baptist Medical Center, Bowman Gray/Wake Forest University in Winston-Salem North Carolina. He also completed fellowships in cardiology and interventional cardiology at the University of Virginia Health Sciences Center in Charlottesville, Virginia. He is board certified by the American Board of Internal Medicine in Internal Medicine, Cardiovascular Disease, and Interventional Cardiology.
- 13. Defendant Hospital Corporation of America ("HCA") is a Delaware corporation and the largest private operator of health care facilities in the United States. HCA owns and operates over 275 hospitals and freestanding surgery centers in twenty states and England.
- 14. Defendant Fairview Park Hospital ("FPH") is a 175-bed tertiary hospital in Dublin, Georgia wholly owned and operated by HCA. During Relator Fenster's employment at FPH, the hospital's Cardiovascular Center employed three physicians, only two of whom (Relator and Dr. Manuel Vega) were board certified in cardiology.
- 15. Defendant Dublin-Macon Cardiology, P.C., ("DMC") is a medical practice incorporated in Georgia. The practice is made up of two partners, Dr. Joseph DeJunco and Dr. Manuel Vega, and has offices in Dublin and Vidalia, Georgia.
- 16. Defendant Dr. Joseph DeJunco is a cardiologist, employed and granted cardiology privileges by FPH. He attended Ross University School of Medicine in the Caribbean. He is not certified by the American Board of Internal Medicine.

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17. Defendant Dr. Manuel Vega is an interventional cardiologist, employed and granted cardiology privileges by FPH since 2004. Dr. Vega completed his internship, residency, and a cardiology fellowship at Catholic Medical Center of Brooklyn & Queens in Jamaica, New York. He also completed a cardiology fellowship at St. Francis Hospital/Metropolitan Hospital in Roslyn, New York. Dr. Vega is certified by the American Board of Internal Medicine in Internal Medicine, Cardiology, and Interventional Cardiology.

III. JURISDICTION AND VENUE

- U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. In addition, 31 U.S.C. § 3732(b) vests this Court with jurisdiction over the state law claims asserted in this Complaint. Under 31 U.S.C. § 3730(e) and Ga. Code Ann. § 49-4-168.2(j), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint. Even if there had been any such public disclosure, Dr. Fenster is the original source of the allegations herein because he has both direct and independent knowledge of the information that forms the basis of this complaint and voluntarily disclosed the complaint to the United States before filling.
- 19. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C.
 § 3732(a) because that section authorizes nationwide service of process and because Defendants have minimum contacts with the United States. Moreover, Defendants can be found to have transacted business in the Southern District of Georgia.
- 20. Venue is proper in the Southern District of Georgia pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because Defendants can be found in and/or transact or have transacted business in this district. At all times relevant to this Complaint,

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Defendants regularly conducted substantial business within this district and/or maintained employees and offices in this district.

IV. APPLICABLE LAW

A. Medicare

- 21. Medicare is a federally-funded health insurance program which provides for certain medical expenses for persons who are over 65, who are disabled, or who suffer from End Stage Renal Disease.
- 22. The Medicare Program has four parts: Part A, Part B, Part C and Part D. Medicare Part A, the Basic Plan of Hospital Insurance, covers the cost of inpatient hospital services and post-hospital nursing facility care. Medicare Part B, the Voluntary Supplemental Insurance Plan, covers the cost of services performed by physicians and certain other health care providers, both inpatient and outpatient, if the services are medically necessary and directly and personally provided by the provider. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.
- The Medicare program is administered through the Department of Health and Human Services, Centers for Medicare and Medicaid Services ("CMS").
- 24. Medicare coverage is limited to those items and services which are reasonable and medically necessary. 42 U.S.C. §1395y(a)(1). Health care practitioners and providers are required to ensure that all services are "provided economically and only when, and to the extent, medically necessary." 42 U.S.C. §1320c-5(a)(1),(3). Providers who furnish services or items substantially in excess of the needs of their patients may be excluded from participation in federal health care programs altogether. 42 U.S.C. §1320a-7(b)(6).
- 25. Participating providers are also required to ensure that all services are "of a quality that meets professionally recognized standards of care." 42 U.S.C. §1320c-5(a)(2).

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- As a prerequisite to payment for Medicare, CMS requires hospitals to submit annually a Form CMS-2552 (previously Form HCFA-2552), more commonly known as the Hospital Cost Report. Cost Reports are the final claim that a provider submits to the fiscal intermediary for items and services rendered to Medicare beneficiaries.
- 27. Every Hospital Cost Report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator.
 - 28. In or about 1996, the Hospital Cost Report form was revised to state:

Misrepresentation or falsification of any information contained in this cost report may be punishable by criminal, civil and administrative action, fine, and/or imprisonment under federal law. Furthermore, if services identified in this report were provided or procured through the payment directly or indirectly of a kickback or where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

29. A hospital is required to disclose all known errors and omissions in its claim for Medicare reimbursement (including its cost reports) to its fiscal intermediary. 42 U.S.C. § 1320a-7b(a)(3) specifically creates a duty to disclose known errors in cost reports.

Whosoever... having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment... conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such payment or benefit is authorized... shall in the case of such a ... concealment or failure... be guilty of a felony.

- 30. Under Medicare Part B, "Medicare carriers" are responsible for accepting and paying claims for certain reimbursements under Medicare Part B.
- 31. Under Part B, the physician typically submits a bill using Form CMS-1500. On the claim form, the physician certifies that the services were "medically indicated and necessary to the health of the patient."
- 32. In addition, each provider must sign a provider agreement as a condition of participation that agrees to comply with all Medicare requirements including the fraud and abuse provisions. A provider who fails to comply with these statutes and regulations is not entitled to payment for services rendered to Medicare patients. By submitting a claim for Medicare

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reimbursement, the provider certifies that the submitted claim is eligible for Medicare reimbursement and that the provider is in compliance with all Medicare requirements

B. Medicaid and TRICARE/CHAMPUS

- 33. Medicaid is a public assistance program providing for payment of medical expenses for low-income and disabled patients. Funding for Medicaid is shared between the Federal Government and those states participating in the program.
- 34. Although Medicaid is administered on a state-by-state basis, the state programs adhere to federal guidelines. Federal statutes and regulations restrict the drugs and drug uses for which the federal government will pay through its funding of state Medicaid programs.
- 35. Each physician that participates in the Medicaid program must sign a Medical provider agreement with his or her state. The Georgia Department of Health Provider Enrollment Application requires any prospective Medicaid provider to certify that he or she will comply with all of the Department's Medicaid requirements, which incorporate the Federal fraud and abuse provisions.
- 36. TRICARE/CHAMPUS, administered by the United States Department of Defense is a health care program for individuals and dependents affiliated with the armed forces. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors. 10 U.S.C. §§ 1971-1104; 32 C.F.R. § 199.4(a).
- 37. Like Medicare, Medicaid and other federal health care programs require, as a condition of coverage, that services be medically necessary and of a quality that meets professionally recognized standards of care. 42 U.S.C. §1320c-5(a).
- 38. The Georgia Medicaid State Plan also limits coverage to medically necessary procedures. The Georgia Medicaid Manual dictates that providers must "[b]ill the Division for only those covered services that are medically necessary and within accepted standards of

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practice," and defines the requirement as a "condition of payment." § 106(K). Additionally, on the Provider Enrollment Application for participation in Georgia's Medicaid program, the prospective provider must certify that he or she will only submit claims for medically necessary covered services. For a procedure to qualify as medically necessary, there must be "no other effective and more conservative or substantially less costly treatment, service and setting available." Georgia Medicaid Manual Definitions § 24.

V. BACKGROUND

- 39. Angioplasty is a technique used to widen a stenotic (narrowed) or occluded (blocked) blood vessel. An empty balloon on a guide wire, known as a balloon catheter, is passed into the narrowed areas and then inflated, crushing the plaque buildup and opening the blood vessel. The balloon is then collapsed and withdrawn.
- 40. Percutaneous coronary intervention ("PCI") is angioplasty used to treat coronary arteries of the heart. Often, PCI will also involve the implantation of a small mesh wire tube, or "stent", to hold the artery open and maintain the free flow of blood. Although PCI is less invasive than coronary bypass surgery, it is still an invasive, risky procedure.

VI. ALLEGATIONS OF FACT

- 41. Dr. Fenster was hired as the Executive Director of the Cardiovascular Center at Fairview Park Hospital in July 2008. The hospital had previously received complaints that both of its cardiologists, Dr. DeJunco and Dr. Vega, had performed unnecessary procedures, so Dr. Fenster was brought on to manage the Cardiology Center and review all cardiology procedures to ensure the hospital's compliance with relevant standards of medical necessity and quality.
- 42. Dr. Fenster was also made the Principal Investigator for FPH's re-launching of the CPORT trial in November 2008. CPORT is a nationwide study started by Johns Hopkins to determine whether PCI can safely be performed in small, community hospitals. FPH had previously participated in CPORT in 2006 with Dr. Vega in charge, but HCA voluntarily shut

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the trial down after three months as a result of an internal investigation indicating that Dr. Vega was performing unnecessary interventional procedures.

- 43. For participation in the CPORT trial, an angioplasty procedure cannot be considered emergent unless the patient experiences an ST segment myocardial infarction ("STEMI"), which occurs when the coronary artery is completely blocked. All angioplasty procedures performed on non-STEMI patients require a consent and potential randomization procedure unless extenuating circumstances arise.
- 44. On November 20, 2008, FPH began to provide emergent cardiac stents and angioplasty procedures as part of the CPORT study and began offering elective PCI procedures on November 25th.

A. FPH Provided Services That Did Not Meet Professionally Recognized Standards of Care

- 45. The American College of Cardiology ("ACC")/American Heart Association ("AHA") Guidelines for PCI procedures advise that PCI should not be performed by low-volume operators, individuals performing fewer than 75 PCI procedures per year, at low volume centers, hospitals performing 200 to 400 PCI procedures per year. Neither Dr. Vega, nor FPH performed any PCI procedures in the two years preceding the re-launch of the CPORT trial, thus they were classified as a low-volume operator and center. For this reason, when CPORT was re-launched in 2008, Dr. Fenster, in his role as Executive Director, recommended to the Medical Executive Committee of FPH that Dr. Vega not be given full PCI privileges. Instead, Dr. Fenster sought to have Dr. Vega proctored by an independent cardiologist to ensure the quality and medical appropriateness of all interventional cardiology procedures.
- 46. Initially, HCA and FPH officials assured Dr. Fenster that they would follow his proctoring recommendation. However, after Dr. Vega completed only a handful of cases under a

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proctor, a cardiologist from Macon, Georgia, HCA gave Vega unrestricted interventional privileges and he began to perform PCI procedures with no oversight.

- 47. Dr. Fenster spoke with FPH and HCA officials and expressed his concerns regarding the risks involved in permitting Dr. Vega to perform invasive cardiology procedures without a proctor. His objections were acknowledged, but no steps were taken to intervene. Dr. Vega continued to perform unsupervised procedures, many of which were reimbursed by Medicare, Medicaid, or other federal health care programs.
- 48. In April 2009, one patient, a 46 year-old woman on Medicaid who had been found to have a large pericardial effusion over a month prior, was diagnosed with "impending cardiac tamponade" based on an Echocardiogram performed at Dr. Vega's office. Impending cardiac tamponade is an emergent condition requiring immediate hospitalization, as death can occur quickly with progression and little warning. However, rather than transferring her to a facility which could treat her immediately, Dr. Vega allowed her to go home and scheduled her to return to FPH for an "elective" emergent pericardiocentesis.
- 49. ACC guidelines on catheterization laboratory standards instruct that, while urgent or emergent pericardiocentesis may appropriately be performed in a small community hospital, elective procedures where the patient is stable and "pre-tamponade" should only be performed at hospitals equipped for immediate cardiac surgery in case ventricular perforation or coronary laceration were to occur. Despite these guidelines, Dr. Vega performed the procedure at FPH with no surgical backup.
- 50. During the pericardiocentesis procedure, in which a pig tail catheter was placed in the right ventricle, the patient suffered a known risk which rendered her unable to care for herself and committed to living in a nursing home. A physician with experience in pericardiocentesis should be able to perform the procedure with low risk, particularly when echocardiographically guided. Dr. Vega's failure to avoid known risks calls into question his ability to perform

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pericardiocentesis. Despite the substandard quality of Dr. Vega's services, FPH fraudulently submitted the claim for the pericardiocentesis to Medicaid and was reimbursed.

- 51. In addition, when patients presented to FPH with acute coronary syndrome ("ACS"), the hospital would regularly schedule them for deferred PCI procedures at FPH, rather than transferring them to other facilities which could immediately address the patients' needs.

 Dr. Fenster discovered this disturbing trend and voiced his concerns to both HCA and FPH officials, but no action was taken to rectify the conduct.
- 52. FPH and HCA knew of Dr. Vega's insufficient training in PCI and other invasive coronary procedures, resulting in numerous procedures performed with a substandard quality of care. Additionally, they knew that patients were regularly endangered when FPH delayed PCI procedures at their hospital, despite professional standards of care dictating that those patients should be sent elsewhere for immediate treatment. Nevertheless, each time Dr. Fenster addressed these issues with FPH and HCA management, his concerns were dismissed and no action was taken.
- 53. The poor quality of services rendered by Dr. Vega at FPH, the lack of proctoring of Dr. Vega and the lack of sufficient training or oversight, if known to Medicare or other federal programs would have disqualified claims submitted by Dr. Vega, and FPH for Dr. Vega's procedures, from reimbursement by federal healthcare programs.
- 54. Defendants have submitted numerous false claims to federal healthcare programs that are ineligible for reimbursement because of the poor quality of the services rendered in violation of the FCA and the Georgia False Medicaid Claims Act.

B. Dr. Vega and Dr. DeJunco Performed Medically Unnecessary Procedures

55. From the beginning of his employment at FPH, Dr. Fenster observed a disturbing pattern of medically unnecessary procedures performed by the hospital's cardiovascular center.

In his review of patient records from November 2008, Dr. Fenster identified numerous

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procedures of questionable necessity. After raising his concerns with hospital officials, Dr. Fenster was restricted from performing further investigation, and was thus unable to conduct a thorough evaluation. However, even with his limited access, Dr. Fenster gathered information evidencing FPH's continued practice of regularly performing medically unnecessary procedures.

- 56. Since the re-launch of the CPORT trial in November 2008, Dr. Vega has performed hundreds of medically unnecessary interventional cardiology procedures at FPH, including PCI procedures. Medical records demonstrate Dr. Vega's pattern of misleading patients, exaggerating the severity of their conditions and overstating the importance of procedures, in order to fraudulently obtain their consent to perform elective, invasive cardiology procedures.
- 57. One patient, a 67 year-old woman on Medicare with a history of serious health problems including hypertension, went to FPH in January 2009 complaining of shortness of breath. Upon a medical examination including an angiogram by Dr. Vega's partner, Dr. DeJunco, the patient was diagnosed with full blown pulmonary edema, or fluid accumulation in her lungs, as well as congestive heart failure. After providing diuretic treatment for her edema, Dr. Vega performed two elective PCI stenting procedures in the proximal right coronary artery and proximal left anterior descending artery ("LAD") of her heart and wrote in her medical records that she had occlusion in these vessels of 75% and 80%. FPH submitted a claim to Medicare for this procedure and was reimbursed.
- 58. Under the American College of Cardiology ("ACC")/American Heart Association ("AHA") Guidelines, stenting of this type of stenosis should only be performed when additional adjunctive testing clearly demonstrates coronary ischemia in that arterial territory as a result of the stenosis. Dr. Vega had access to the equipment used to make these evaluations (intravascular cardiogram, pressure wire and nuclear cardiology evaluation), but declined to use it.

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- 59. Only four days after the procedure's completion, the patient presented in cardiopulmonary arrest and died. Given that Dr. Vega placed stents in her major coronary artery and across a particularly large branch of that artery, it is extremely likely that the occlusion of one or both of these stents caused her cardiopulmonary arrest and death.
- 60. As Principal Investigator for the CPORT trial, Dr. Fenster was responsible for reviewing the records of any patient who died in the catheter lab and the hospital was required to provide him access to those charts. In his review of this patient's medical records, Dr. Fenster found that none of the patient's presenting symptoms or test results justified the LAD stent placement and the occlusion in the arteries was not 75% and 80% as Dr. Vega had reported, but only 35% and 45%, significantly less than the 70% occlusion required to justify elective PCI stenting procedures.
- 61. Dr. Fenster has since had three independent cardiologists review the angiogram and all three confirmed that there is no evidence of an occlusion between 70-80% and that one of the stented vessels, the proximal LAD, had only a 45% stenosis. Although there is some occlusion in another distal vessel which was not stented, the proper course of treatment for this patient would have been to treat the patient medically (without stents) unless the patient was refractory to medication.
- 62. This medically unnecessary procedure was not eligible for Medicare coverage, but FPH nevertheless submitted a claim and received payment. Furthermore, even after Dr. Fenster explained to HCA and FPH officials that the procedure was unnecessary and any representations of an 80% occlusion were false, no efforts were made to return the fraudulently-obtained payment.
- 63. In addition to PCI procedures, Dr. Fenster has observed both Dr. Vega and Dr. DeJunco implant pacemakers and automated implantable cardioverter-defibrillators ("AICDs") in asymptomatic patients.

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- 64. One patient, an elderly man who was taking beta blockers (which slow the heart) came into FPH with a slow heart rate, but no underlying abnormal rhythm. The staff stopped his medication, the heart rate improved and the patient showed no evidence of distress or any symptoms, hemodynamic or otherwise. Once the patient recovered, no interventional medical action should have been taken, nevertheless, Dr. DeJunco placed a pacemaker in the man for "symptomatic sinus brachycardia."
- 65. Medical records reveal that Dr. Vega has inserted at least one pacemaker under similar circumstances. A patient on beta blockers presented with a slow heart rate, however once the medication was stopped, the heart rate recovered to a normal rhythm. No interventional action was necessary, but Dr. Vega persuaded the patient that implantation of a pacemaker was necessary.
- 66. In May 2009, Dr. Martha Smith, a cardiologist with Emory Healthcare, sent a patient to Dr. Fenster for a cardiologic evaluation. However, when the patient arrived at FPH and asked for Dr. Fenster, she was instead sent for an evaluation with Dr. Vega who scheduled her for a pacemaker implantation the following morning. The patient and her family were concerned about the seriousness of the procedure and contacted Dr. Smith who got in touch with Dr. Fenster. Dr. Fenster intervened and reviewed the patient's records and found nothing that would have justified the implantation of a pacemaker.
- 67. Dr. Vega's pattern of persuading patients to undergo medically unnecessary procedures is further evidenced by the sheer number of interventional procedures he has performed. Between November 2008 and February 2009, Dr. Vega performed at least 287 invasive cardiology procedures. That is a strikingly large number of PCI and AICD procedures for a small hospital in such a short time frame, particularly for a physician without prior background experience or proctoring.

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- 68. The vast majority of the patients receiving medically unnecessary procedures were covered by Medicare or Medicaid.
- 69. Dr. Vega and FPH submitted claims for reimbursement for services rendered to patients to the Medicare and Medicaid programs.
- 70. Claims for services rendered that were not medically necessary or performed in such a way as to deliberately increase costs and reimbursement were not eligible for reimbursement. Submission of such claims constitutes a false or fraudulent claim under the federal False Claims Act, 31 U.S.C. § 3729 and the Georgia False Medicaid Claims Act.
- 71. FPH fraudulently submitted millions of dollars worth of claims to federal health care programs for procedures that were medically unnecessary, and thus not eligible for reimbursement. Each of those claims was a violation of the FCA.

C. HCA and FPH Knew of and Concealed Records of Unnecessary and Dangerous Procedures

- 72. As FPH's Principal Investigator for the CPORT trial, Dr. Fenster was to review the medical records of all cardiology procedures. In initial conversations FPH's CEO Don Avery told Dr. Fenster that he would have access to all patient records to ensure the medical necessity and safety of all procedures. However, the hospital began to deny his access to these records almost immediately after he began his work with the hospital.
- 73. In September, Mr. Avery, while still assuring Dr. Fenster that he would have access to patient records going forward, told Dr. Fenster that he would be given no involvement in or knowledge of the outcome of an investigation stemming from an earlier complaint from a patient who alleged that Dr. DeJunco had performed an unnecessary procedure on her.
- 74. In the first months of his employment, November 2008, Dr. Fenster was permitted some access to patient records and identified a concerning pattern of medically unnecessary procedures performed at FPH, particularly among those performed by Dr. DeJunco and Dr.

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Vega. Dr. Fenster compiled a list of these questionable procedures and presented it to Mr. Avery at the beginning of December, requesting an opportunity for further review of those cases. However, after receiving his report, Mr. Avery told Dr. Fenster that the "necessity" of a procedure should be determined by the acting physician and the hospital should not get in the way. Avery also said that review of medical records would not be part of Dr. Fenster's job.

- 75. Dr. Fenster also met with FPH's Chief of Staff and expressed his concerns regarding medically unnecessary procedures, but was again told that he would not be permitted access to patient records. The Chief of Staff told Dr. Fenster that "someone else" at the hospital would handle the record review although no other hospital employee had sufficient cardiology experience to perform adequate evaluations. Following these conversations, Dr. Fenster's attempts to review medical charts were consistently met with resistance.
- 76. On or about February 2009, Dr. Fenster again went to Mr. Avery following the death of the patient in the CPORT trial and presented his findings that the patient did not have 80% occlusion as reported and expressed his concerns that the hospital was continuing to perform medically unnecessary procedures. Mr. Avery acknowledged that perhaps something should be done, but still did not give Dr. Fenster access to review patient records. Later that day, Dr. Fenster presented the same information to Donna Trickey, the Chief Nursing Officer at FPH, who also merely acknowledged that there may be an issue.
- 77. Dr. Fenster also shared his concerns and his findings regarding unsafe and medically unnecessary procedures with several other individuals within the HCA system, including Mickey Pickler, the Division Vice President of Operations for HCA Physician Services, Brian Lancaster, the Division Office Manager for HCA Physician Services, and Patrice Vance, the Division Vice President in charge of Quality and Risk. However, even those who recognized that there was a problem were either unable or unwilling to do anything about it.

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- 78. When Dr. Fenster persisted in his efforts to correct the dangerous practices at FPH, the hospital barred him from performing any review of Dr. Vega's control cases, claiming that an independent, external party would review the cases to ensure "unbiased reviewing." Dr. Fenster then requested that this independent party conduct a retrospective evaluation of the cases from November 2008 through April 2009, but was again denied because such a review could be "perceived as punitive."
- 79. Accordingly, defendant FPH had the requisite scienter that Dr. Vega performed procedures without medical necessity and rendered services of poor quality and submitted claims for reimbursement for these services to the Medicare and Medicaid programs.

Count I False Claims Act 31 U.S.C. §§3729(a)(1)(A)-(B) and (G)

- 80. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 79 above as though fully set forth herein.
- 81. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq., as amended.
- 82. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.
- 83. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims.
- 84. By virtue of the acts described above, Defendants knowingly concealed overpayments from the United States Government and failed to remit such overpayments.
- 85. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' illegal conduct.

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- 86. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 87. Additionally, the United States is entitled to the maximum penalty of up to \$11,000 for each and every violation alleged herein.

Count II Georgia False Medicaid Claims Act Ga. Code Ann. § 49-4-168.1(1), (2) and (7)

- 88. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 79 above as though fully set forth herein.
- 89. This is a claim for treble damages and penalties under the Georgia False Medicaid Claims Act.
- 90. By virtue of the acts described above, Defendants knowingly presented or caused to be presented, false or fraudulent claims to the Georgia State Government for payment or approval.
- 91. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used false records and statements, and omitted material facts, material to false and fraudulent claims submitted to the Georgia State Government.
- 92. By virtue of the acts described above, Defendants knowingly concealed overpayments from the Georgia State Government and failed to remit such overpayments.
- 93. The Georgia State Government, unaware of the falsity of the records, statements and claims made, used, presented or caused to be made, used or presented by Defendants, paid and continues to pay the claims that would not be paid but for Defendants' unlawful conduct.
- 94. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.
- 95. Additionally, the Georgia State Government is entitled to the maximum penalty of \$11,000 for each and every violation alleged herein.

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III. PRAYER

WHEREFORE, Dr. Fenster prays for judgment against the Defendants as follows:

- That Defendants cease and desist from violating 31 U.S.C. § 3729 et seq., and Ga.
 Code Ann. § 49-4-168 et seq.;
- 2. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. § 3729;
- 3. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the State of Georgia has sustained because of Defendants' actions, plus a civil penalty of \$11,000 for each violation of Ga. Code Ann. § 49-4-168.1;
- 4. That Dr. Fenster be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act, and Ga. Code Ann. § 49-4-168.2(i);
- That Dr. Fenster be awarded all costs of this action, including attorneys' fees and expenses; and
 - 6. That Dr. Fenster recover such other relief as the Court deems just and proper.

IV. <u>DEMAND FOR JURY TRIAL</u>

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

| Dated: April 1 | 3 . ₂₀₁₀ | |
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| {00011690; 1} | COMPLAINT | |

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By:

3414 Peachtree Road, N.E.

mbw@wilbanks-bridgeslaw.com

#7 George C. Wilson Court Augusta, Georgia 30909

Atlanta, Georgia 30326

Suite 1975

404-842-1075

(706)863-2255

WILBANKS & BRIDGES LLP

(ProHac Vice, pending application) Georgia Bar Number 758223

KLOSINSKI OVERSTREET LLP

Georgia Bar No. 425230

Attorneys for Plaintiff Relator Dr. Michael Fenster

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| {00011690; 1} | COMPLAINT | |