UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
HAMMOND DIVISION

THE UNITED STATES OF AMERICA

ex rel.

DAVID JAYAKAR, M.D. and
BRIAN DECKER, R.N.

Relators,

-vs-

MUNSTER MEDICAL RESEARCH FOUNDATION, INC. d/b/a THE COMMUNITY HOSPITAL, CARDIOLOGY ASSOCIATES OF NORTHWEST INDIANA, P.C., and ARVIND GANDHI, M.D.,

Defendants.

Case No.: 2 08 CV 350

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

SECOND AMENDED FALSE CLAIMS ACT COMPLAINT

Introduction

1. This is a *qui tam* action to recover damages and civil penalties, brought by David Jayakar, M.D. ("Dr. Jayakar") and Brian Decker ("Mr. Decker") (hereinafter collectively, the "Relators") on behalf of the United States of America (the "Government") arising from false claims made by Munster Medical Research Foundation, Inc. d/b/a the Community Hospital ("Community Hospital"), Cardiology Associates of Northwest Indiana, P.C. (the "Group") and Arvind Gandhi, M.D ("Dr. Gandhi") (hereinafter collectively, the "Defendants"), in violation of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, as amended (the "Act").

2. The Act generally provides that any person who knowingly presents a false or fraudulent claim to the Government for payment or approval is liable for a civil penalty of up to

$10,000 for each such claim, plus three times the amount of damages sustained by the Government, including attorneys' fees. 31 U.S.C. § 3729(a). The Act allows any person, including a corporation, having information regarding a false or fraudulent claim against the Government to bring a private cause of action for himself and/or itself and on behalf of the Government and share in any recovery. 31 U.S.C. § 3729(b)(1). The complaint is to be filed under seal for 60 days (without service on Defendant during such 60-day period) to enable the Government to: (i) conduct its own investigation without the Defendant's knowledge; and (ii) determine whether to join the action. 31 U.S.C. § 3730(b)(2).

3. Based on § 3730(d) of the Act, Relators seek to recover damages, civil penalties, attorneys' fees and costs, and other relief arising from Defendants' presentation of false claims to the Government in connection with the furnishing of health care services and medical devices.

Parties

4. Dr. Jayakar is a cardiothoracic surgeon who currently resides in, and does business in, Erie, Pennsylvania. At all relevant times until August 2008, Dr. Jayakar practiced medicine in Lake County, Indiana, maintaining offices or having staff privileges at defendant Community Hospital.

5. Mr. Decker ("Mr. Decker") currently resides in Lake County, Indiana. Until February 2007, Mr. Decker was employed by defendant Community Hospital as the Administrative Director of its Cardiac Catheterization Laboratory ("Cath Lab").

6. Munster Medical Research Foundation, Inc. is an Indiana not-for-profit corporation that does business under the name and style of the Community Hospital. Its principal place of business is in Munster, Lake County, Indiana.

7. Cardiology Associates of Northwest Indiana, P.C. (the "Group") is an Indiana professional corporation that operates a cardiology physician practice. Its principal place of business is in Munster, Lake County, Indiana.

8. Arvind Gandhi, M.D. ("Dr. Gandhi") is a cardiologist and a principal in the Group. He practices medicine from the Group's offices in Munster, Lake County, Indiana. Dr. Prakash Makam, Dr. Ravi Bhagvat, Dr. Wail Assfour, and Dr. Miguel Gambetta are the other physicians and members of the Group.

Jurisdiction and Venue

9. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, which specifically confers jurisdiction upon this court for actions brought pursuant to Sections 3729 and 3730 of Title 31 of the United States Code.

10. This Court has personal jurisdiction over Defendants because they reside and/or have their principal places of business in the State of Indiana.

11. Venue is proper in this District because all of the Defendants reside and/or have their principal places of business in the Northern District of Indiana.

Factual Allegations

A. Introduction

12. This action seeks redress for damages suffered by the Government as a result of a scheme among the defendants to implant defibrillators and pacemakers and bill the Government for those services and devices in cases where: (i) such devices were not medically indicated or were improper; (ii) the implanting physicians were not properly credentialed to implant the

devices; and (iii) these already improperly services were billed excessively, resulting in charges that were even greater than they would have been had the implantations been properly performed by properly credentialed physicians. These improper medical services were facilitated by Medtronic, Inc., which manufactured and sold the defibrillators and pacemakers in question and, in many cases, improperly provides free services to various Defendants as an illegal inducement for increased sales of its devices.

B. The Implantation of Defibrillators and BiVentricular Pacemakers.

13. In 1985, the Food and Drug Administration ("FDA") approved implantable defibrillators—also known as Automatic Implantable Cardioverter-Defibrillators ("AICD")—for the treatment of irregular heartbeat and fibrillation which usually are associated with heart failure. The implantation of AICDs is indicated in patients with an ejection fraction of less than 35 percent, a family history of sudden death, irregular ventricular rhythm, and, in some patients, a structural heart abnormality.

14. In 2001, the Food and Drug Administration ("FDA") approved biventricular pacemakers, also known as cardiac resynchronizaton devices or CRT pacemakers ("CRT Pacemakers"), for the treatment of medically refractory heart failure. The indications for implanting such devices are Class 3 or 4 heart failure (in patients with maximum medical therapy), a prolonged QRS duration as measured on an electrocardiogram ("EKG"), and an ejection fraction of less than 35 percent.

15. In 2002, the FDA approved implantable combination CRT pacemaker-defibrillators ("CRT-D"), which largely supplanted the need for CRT Pacemakers alone. In addition to the features offered by CRT Pacemakers, the CRT-D devices also feature the ability

to terminate malignant ventricular tachycardia and ventricular fibrillation (in layman's terms, to stop a potentially fatal irregular heartbeat and restart a heart after it stops beating) thereby dramatically reducing the risk of sudden and fatal cardiac arrest (also commonly and simply known as "sudden death").

16. Most hospitals in the United States do not allow general cardiologists to implant defibrillators unless those cardiologists obtain additional credentials. Rather, it is only appropriate for defibrillators to be implanted by board-certified cardiac electrophysiologists (a sub-specialty among cardiac physicians).

17. General cardiologists may, however, implant CRT Pacemakers without the additional credentials needed to implant defibrillators.

18. As such, Dr. Gandhi—a general cardiologist—was qualified to implant CRT Pacemakers, but not CRT-D devices, between 2001 and 2005.

19. Beginning in 2002, prevailing medical literature explained that CRT Pacemakers were obsolete in the face of the new devices. Indeed, the overwhelming weight of authority and research studies in leading medical journals was that it would be unethical for a physician *not* to offer his patients a CRT-D device instead of a CRT Pacemaker, since patients who were candidates for the pacemaker were almost always at high risk for sudden death and would, therefore, benefit tremendously from the more recent and efficacious device.

20. Within the Hospital and its sister hospitals, more than a dozen cardiac electrophysiologists (sub-specialist cardiologists with special training and credentials necessary to implant CRT-D devices) on staff had begun implanting CRT-D devices as early as 2002.

21. Notwithstanding their obsolescence by 2002, between 2001 and 2005, Dr. Gandhi and other general cardiologists in the Group implanted countless CRT Pacemakers in patients.

Dr. Gandhi, who is not a cardiac electrophysiologist, deprived these patients of any option to be treated by electrophysiologists who could have implanted CRT-D devices instead of CRT Pacemakers because doing so would have deprived Dr. Gandhi and the Group of the substantial income they earned for several years' worth of CRT-Pacemaker implantations.

22. Conversely, in cases where neither a pacemaker nor a defibrillator is indicated, the implantation of such a device can doom a patient to a lifetime of debilitating follow-up procedures and limitations on activity that can materially and dramatically diminish the patient's quality of life. The management of these patients requires additional training in electrophysiology as complex life-changing decisions must be made which are beyond the expertise of a general cardiologist.

C. Dr. Gandhi's Pacemaker Practice

23. Despite the documented indication and medical need in hundreds of his patients for implantable defibrillators (which he was unqualified to implant), Dr. Gandhi instead implanted CRT Pacemakers in all of them but one. The one patient between 2001 and 2005 whom Dr. Gandhi referred to a cardiac electrophysiologist for the implantation of a defibrillator was a wealthy member of the Hospital's board of directors.

24. Indeed, due to the incredibly high volume of procedures by Dr. Gandhi and others in the Group, by 2004 the Hospital had the highest volume of CRT pacemaker implantations in the United States—because most hospitals across the country had dramatically scaled back or eliminated the implantation of such pacemakers after the advent of implantable defibrillators.

25. Dr. Gandhi and the other physicians at the Group exclusively implanted devices manufactured by Medtronic Corporation.

26. In exchange for their high volume of implantations (which led to millions of dollars in sales to Medtronic at the rate of approximately $20,000 per device), Dr. Gandhi and the Group demanded concessions and gratuities from Medtronic.

27. To maintain its sales through Dr. Gandhi and the Group in a highly competitive environment (Guidant Corporation, now a part of Boston Scientific, aggressively markets its own devices), Medtronic acquiesced to the doctors' demands and provided gratuities to Dr. Gandhi and the Group including (but not limited to):

a. Direct cash payments under the guise of "consulting" or "training" honoraria;

b. Furnishing Medtronic employees as de facto employees of the Group for months at a time. These personnel worked practically full-time at the Group at no cost to the Group, checking patients' pacemakers in person and performing transtelephonic checks on pacemakers as well. These Medtronic employees also performed procedures on pacemaker patients such as echo guided atrial ventricular optimizations—without physician guidance—and then made medical judgments on the appropriate settings for pacemakers. (Dr. Gandhi requires all of his pacemaker patients to have these painful optimization procedures done every three months, although the appropriate standard of care is to perform optimizations only on non-responding devices.)

28. Making matters worse, Dr. Gandhi systematically billed patients and payors, including the Medicare program operated by the Government—without using appropriate CPT code modifiers—for the free and improper services and procedures that the Medtronic employees had performed on his patients. These improper billings, standing alone, amount to hundreds of thousands of dollars in false claims.

29. When confronted by a Medtronic employees about the inappropriate nature of those charges, Dr. Gandhi threatened to have the Medtronic employee fired, and kept billing as he had done before.

30. These threats were, no doubt, serious. Indeed, on a separate occasion Dr Gandhi asked a research coordinator employed by their group to falsify documentation on a patient involved in a carotid stent research study. When the employee refused to do so, she was similarly threatened by Dr. Gandhi. When she persisted in her refusal to falsify the documentation, she was terminated from employment.

31. Indeed, Medtronic—as well as Guidant/Boston Scientific—participated knowingly in the defibrillator implant fraud at the Hospital. Both entities were eagerly seeking to provide the implants for Dr. Gandhi's practice.

32. Both companies have intimate knowledge of the requirements for implantation of all of their devices, and in fact provide extensive training on this topic to physicians, nurses, coders and anyone else associated with these procedures. They are, in fact, looked to as the experts on these topics.

33. Both companies failed to address obvious failures to meet criteria for implantation in Dr. Gandhi's (and other cardiologists) patients and continued to promote their practices.

34. Medtronic representative Bob Knopik pressured cardiologists at the Hospital to use Medtronic products by falsely stating that the Hospital had an exclusive business arrangement with Medtronic.

35. Mr. Knopik (and others at his direction) provided free TTM boxes (devices used to remotely check the function of pacemakers via telephone lines) to cardiologists who implanted

Medtronic pacemakers. These TTMs were issued to patients by the cardiologists and then used by the cardiologists to perform remote pacemaker checks that were billed by the cardiologists.

36. The TTM devices were being purchased by the Hospital and placed on patient bills. This issue was reported to John Gorski on multiple occasions. Mr. Gorski's response was "Leave it alone, I made an agreement with the cardiologists to do this." After the issue was reported to the Hospital's Corporate Compliance, the practice was finally stopped.

37. Mr. Knopik was actually observed accessing the medical records of patients that had been implanted with devices from his competition (Guidant/Boston Scientific) in order to learn who the referring and implanting physicians were. With this information Mr. Knopick then pressured these physicians to use Medtronic products. Mr. Knopik was banned from Hospital as a result of this practice, but after Dr. Gandhi threatened that he would take his referrals elsewhere if Mr. Knopik were not allowed to resume activities at the Hospital, Mr. Knopik was reinstated six months later.

38. In addition, Medtronic employees also falsified consent forms on behalf of patients who were not competent to consent to procedures (such as Alzheimer's and Dementia sufferers).

D. The Hospital Willingly Turns a Blind Eye.

39. After receiving a number of complaints from electrophysiologists about Dr. Gandhi's implantation of CRT Pacemakers between 2002 and 2005 when CRT-D devices—not CRT Pacemakers—were medically indicated, the Hospital's Quality Assurance ("QA") committee investigated Dr. Gandhi's practices.

40. Through this investigation, the Hospital's own QA committee discovered that approximately *75 percent* of Dr. Gandhi's CRT Pacemaker implantations were inappropriate.

41. One of the members of the QA committee vocally opposed allowing Dr. Gandhi to continue implanting pacemakers under the circumstances. That member was quickly and quietly removed from the QA committee.

42. Additionally, several local cardiac electrophysiologists reported to the Hospital's medical staff that it was inappropriate for Dr. Gandhi to be implanting CRT pacemakers in patients who were indicated for the more efficacious CRT-D devices.

43. The Hospital refused to take any action and the concerns were swept under the rug.

44. By 2005, Dr. Gandhi turned his attention to obtaining a share of the even more lucrative defibrillator market.

45. Although Dr. Gandhi was not an electrophysiologist, he sought permission from the Hospital to implant defibrillators in its Cath Lab, where he had been implanting pacemakers for years.

46. At the time, Mr. Decker was the administrative director of the Hospital's Cath Lab.

47. In response to Dr. Gandhi's efforts to obtain credentials that would allow him to implant defibrillators in patients at the Hospital's Cath Lab, Hospital administrators sought Mr. Decker's opinion on the matter.

48. Mr. Decker provided the Hospital's administrators with information about the guidelines promulgated by the North American Society for Pacing and Electrophysiology

("NASPE") (now renamed the "Heart Rhythm Society") for ~~credentialing~~ non-electrophysiologists for the implantation of defibrillators.

49. NASPE's guidelines provide that a general cardiologist not trained in electrophysiology (like Dr. Gandhi) should *only* receive credentials to implant defibrillators if:

a. There is a shortage of electrophysiologists in the area and patients are being underserved;

b. The cardiologist completes an examination given by NASPE;

c. The cardiologist completes a training course on defibrillator implantation;

d. The cardiologist is proctored/trained in defibrillator implantation by a qualified electrophysiologist.

50. At all times, there have been enough cardiac electrophysiologists in Northwest Indiana to meet patients' needs. Indeed, there are numerous fellowship-trained and board-certified cardiac electrophysiologists on staff at the Hospital who have been performing such implantations for years. There has never been a case of a patient being unable to obtain a defibrillator implantation at the Hospital due to the lack of available cardiac electrophysiologists to perform the procedures.

51. Dr. Gandhi attempted to take the NASPE exam in Miami, Florida (with his costs paid by Medtronic), but did not pass.

52. Dr. Gandhi repeatedly asked local cardiac electrophysiologists to proctor him for CRT-D Device implantation. All of them refused. As such, Dr. Gandhi was never proctored by an electrophysiologist.

53. Although Dr. Gandhi attended a training course on implantation, he did not meet any of the other three criteria.

54. Therefore, Dr. Gandhi was unqualified to implant defibrillators and was not entitled to privileges to do so.

55. Based on the NASPE guidelines, and in response to information provided by cardiac electrophysiologists on staff at the Hospital, the Hospital's board initially was hesitant to allow Dr. Gandhi to implant defibrillators at its Cath Lab.

56. In response, Dr. Gandhi repeatedly stated that he would get defibrillator privileges, and that no one could stop him.

57. To overcome the hospital's initial reluctance, Dr. Gandhi embarked on a plan to manipulate the Hospital's credentialing system. He did so by taking advantage of his position as co-chair of the Hospital's cardiology subcommittee to change a rule that prohibited a doctor from being proctored by a member of his own medical practice. Using his influence on that committee, Dr. Gandhi forced the passage of a new rule that would allow such incestuous proctoring to take place.

58. Once the cardiology subcommittee approved the rule, it was then considered by the Hospital's medical executive committee. That committee was chaired by Dr. Gandhi's partner and co-owner of the Group, Dr. Makam. Not surprisingly, the executive committee approved the new rule.

59. Dr. Makam's misconduct extends beyond his role on the medical executive committee. He used his influence for personal profit in other ways, as well. For example, the Hospital formed a cardiovascular research foundation as an opportunity for the Hospital's cath lab physicians to participate in research projects on various devices/procedures. The captive nature of the patients in a community hospital environment, as opposed to a tertiary care center such as a University setting, provided a great opportunity for follow-up. The large volume of

patients seen in the CH cath lab provided a huge patient base from which to select appropriate study participants.

60. Dr. Makam was named director of research and appointed chairman of the research committee. From this position, Dr. Makam controlled selection of studies that would be done.

61. Initially, Dr. Makam was paid for filling this role by the Hospital. Not surprisingly, the selection of studies and primary investigators was slanted toward Dr. Makam and the Group. Dr. Makam's focus in his role of research director was clearly to enrich himself. This focus became a daily pursuit for Dr. Makam.

62. Indeed, Dr. Makam (or others on his behalf) routinely asked all of the vendors who visited the cath lab about the possibility of providing Dr. Makam with research "opportunities." The standard approach by Dr. Makam was " I will use your product if you will pay me to be involved in research for your company, if not, I will not use your product". The implication was that Dr. Makam could and would use his influence to bring products into use at Hospital.

63. The best example of this blatant abuse of position was when Ron Becker, a new representative for the peripheral vascular product line of Guidant/Boston Scientific, sought out Mr. Decker and confided that Dr. Makam had approached him in the manner described above for research projects. Mr. Becker stated that he "just had something happen that I have never before experienced, Dr. Makam asked me for a paying research project and told me that he would only use Guidant/Boston Scientific products if he got one, usually the doctors at least pretend that they are interested in the research itself."

64. Similarly, Dr. Makam owns a restaurant called Boston's that is located near the Hospital. He requires all vendors who perform in-service seminars for Hospital staff to purchase all food to be served at such events to be purchased from Boston's.

65. Meanwhile, another of Dr. Gandhi's partners in the Group, Dr. Bhagwat, also applied for privileges at the Hospital to implant defibrillators. In his application, Dr. Bhagwat implied that he already had such privileges at St. Margaret Mercy Hospital.

66. Dr. Bhagwat did not have such privileges. Nevertheless, the Hospital believed that he did and granted him reciprocal privileges at the Hospital to implant defibrillators at its Cath Lab.

67. Once the rules change that Dr. Gandhi pushed through the Hospital's committees went into effect, and once Dr. Bhagwat gained privileges to implant defibrillators at the Hospital, it was a simple matter for Dr. Bhagwat—who had never been trained, let alone board certified, as a cardiac electrophysiologist—to proctor his partner, Dr. Gandhi.

68. Notwithstanding its initial—and appropriate—unwillingness to allow Dr. Gandhi to perform defibrillator implantations at its facility, and notwithstanding Dr. Gandhi's failure to comply in numerous respects with controlling NASPE guidelines, because of his relationship with the Hospital and its board—and the huge income Dr. Gandhi generates for the Hospital through his exclusive use of the Hospital and its facilities for his device implantations, cardiac catheterizations, coronary interventions and other admissions—in January 2005 the Hospital granted Dr. Gandhi credentials to implant defibrillators in his patients based on Dr. Bhagwat's having proctored him and sponsored his application for implantation privileges.

69. Over time, Dr. Gandhi then did for some of his other partners what Dr. Bhagwat had done for him, proctoring and sponsoring the other physicians in the Practice for defibrillator implantation privileges notwithstanding their clear lack of qualifications.

70. As another example of the Hospital's willingness to acquiesce to the desires of Dr. Gandhi and his colleagues to increase referrals to the Hospital, the Hospital provided free office space in exchange for referrals to the Hospital. To conceal the nature of the transaction, an entire two-story office building owned by the Hospital was leased to Dr. Gandhi's group, although the group only occupied the first floor. Dr. Gandhi then sub-leased the second floor back to the Hospital at a cost at least equal to the total rent being charged to Gandhi's Group under the primary lease. The net effect was that the Hospital's sublease payments amounted to a reimbursement of Gandhi's rent or a below-market rate rental agreement.

71. The financial transactions described above were not the only cases where the Hospital improperly subsidized the practice of physicians who referred patients to the Hospital or its affiliates. For example, the Hospital has routinely provided payments entitled "Practice Support" to physicians ranging from $100,000.00 to $150,000.00 per year.

72. The purpose of the "Practice Support" payments was to entice the recipient physicians to send patients to the Hospital or its affiliates.

73. Officially, the "Practice Support" payments to the physicians were in the form of loans that the physicans were to repay. But the Hospital routinely canceled or otherwise wrote-off these debts, meaning that the physicians never were required to repay them. For example, in the case of a physician who practiced primarily at Methodist Hospital in Merrillville, the Hospital advanced him sums to pay off a malpractice loan under the guise of Practice Support. The

physician then moved his practice from Methodist to the Hospital. The Hospital later forgave this physician's debt.

74. In yet another example of the Hospital's willingness to violate ethics in the interest of generating revenue from cardiologist referrals, all patients receiving outpatient diagnostic procedures, were routinely upgraded to inpatient status when an interventional procedure was also done.

75. This upgrade was accomplished by a checkbox on the post intervention order set. This checkbox was routinely filled in by the nurse in the cath lab.

76. Only after Mr. Decker asked for a review of the process did a change occur. The Hospital's Utilization Review department thereafter assigned an reviewer to look at each intervention to determine if it could be reflected as an inpatient. The qualifying factors for change to inpatient status were: meeting Interqual criteria for inpatient admission, and a physician's order for inpatient admission being present.

77. Conversely, the Hospital put improper pressure on other physicians to coerce them to refer patients only to its home-health and rehabilitation services, although physicians are required to provide their patients with a choice of available home-health and rehabilitation providers. Indeed, Dr. Jayakar was among the physicians pressured by Hospital administrators to stop advising patients of the availability of alternative providers in this regard.

78. Similarly, the Hospital used its own security personnel to intimidate "dissident" physicians, going so far as to monitor groups of doctors meeting at restaurants and to use connections within the Munster Police Department to "run" the license plates of the cars in the restaurant parking lot to confirm the identity of the attendees.

E. The Start of Dr. Gandhi's Defibrillator Practice

79. Once Dr. Gandhi was credentialed to implant defibrillators, he stopped implanting CRT Pacemakers altogether in favor of the more lucrative CRT-D Devices. (CRT pacemakers cost approximately $10,000 each—one-third of the cost of a CRT-D Device.)

80. Dr. Gandhi continued to use the Hospital's Cath Lab as the exclusive location for his procedures.

81. To launch his new defibrillator practice, Dr. Gandhi brought his surviving CRT Pacemaker patients back into the Hospital's Cath Lab to replace their CRT Pacemakers with the very CRT-D Devices that had been medically necessary and more appropriate than CRT Pacemakers when the CRT Pacemakers had been installed in the first place, but were not installed at the time because Dr. Gandhi was not able to reap the profits from doing so. Dr. Gandhi euphemistically referred to such CRT-D Device implantations as "upgrades," as if he were installing a bigger hard drive or more memory in a computer.

82. As but one of many examples of Dr. Gandhi's "double-dipping," a patient who received a CRT Pacemaker from Dr. Gandhi in December 2004 was brought back into the Hospital's Cath Lab *only four months later* in March 2005, and given a CRT-D Device, although her condition had not changed in the meantime. Indeed, the only change was that Dr. Gandhi was now permitted by the Hospital to implant the defibrillator, meaning that the patient was forced to undergo two significant and risky cardiac procedures when only one was indicated, while Dr. Gandhi and the Hospital were permitted to charge enormous fees for both costly procedures.

F. Medically Unnecessary Implantations

83. In addition to replacing CRT Pacemakers with CRT-D Devices in patients where the CRT-D Devices had been indicated in the first place, to improperly maximize his income Dr. Gandhi also has implanted numerous defibrillators, CRT Pacemakers and/or CRT-D Devices in patients for whom such devices were clearly *not* indicated.

84. The indication criteria for implanting a prophylactic defibrillator are the combination of:

a. Class 3 or 4 heart failure after maximized medical therapy (meaning that all medical treatment options have been exhausted),

b. History of sudden cardiac death, or ventricular arrythmias, and

c. Ejection fraction less than 35 percent.

85. The indication criteria for implanting a CRT Pacemaker are the combination of:

a. Class 3 or 4 heart failure,

b. Maximized medical therapy, and

c. QRS duration greater than 120 milliseconds.

86. The indication criteria for implanting a CRT–D Device are the combination of:

a. Class 3 or 4 heart failure,

b. Maximized medical therapy,

c. QRS duration greater than 120 milliseconds, and

d. Ejection fraction less than 35%.

87. *All* of the criteria in each category must be present—the absence of any one of them rules out the implantation of the device.

88. In numerous documented cases, Dr. Gandhi has implanted defibrillators, CRT Pacemakers and/or CRT-D Devices in patients who should not have received them according to

the criteria set forth immediately above. For example, Dr. Gandhi routinely implanted CRT-D Devices in patients whose pre-operative EKG reports revealed QRS intervals of less than 120 milliseconds. This result alone demonstrated a lack of medical need for the devices and should have prevented Dr. Gandhi from going forward with the procedures. Sadly, Dr. Gandhi implanted the devices anyway.

89. To avoid quality assurance checks or audits of medical records that might reveal the lack of a medical need for implantation of one of these devices, Dr. Gandhi and his staff have systematically altered surgical reports to indicate a medical need that was, in fact, absent. In many cases, for example, the patients' EKG printouts reveal a QRS interval below 120 milliseconds that clearly indicates that the patient is not a good candidate for a CRT Pacemaker while the surgical report falsely reports a higher QRS interval of 120 milliseconds or greater.

90. In one such case, Dr. Gandhi or his agents falsified the surgical notes of a 25 year-old man (the average defibrillator patient is in his or her sixties) in whom he implanted a CRT-D Device with reference to a QRS interval that justifies such an implantation. But the QRS interval on his pre-operative EKG printout clearly revealed that he should not receive a CRT-D Device. Another cardiologist recommended that this patient receive treatment with medication for at least three months before reconsidering implantation of a device, in part because this patient suffered from an infection known as myocarditis, from which most patients recover fully without the need for implantation of any device. Nonetheless Dr. Gandhi implanted a CRT-D Device immediately and falsified the surgical report to indicate that the QRS interval was greater than 120 milliseconds.

91. Many other documented cases exist in which Dr. Gandhi's patients' EKG printouts revealed a QRS interval of less than 120 milliseconds, ruling them out as candidates for

this expensive procedure. Notwithstanding this disqualifying fact, Dr. Gandhi implanted a CRT-D Device in each patient and falsified all of the surgical reports (or instructed his agents to do so on his behalf) to indicate a sufficiently high QRS interval to justify the implantation of a CRT-D Device, thereby covering up the unnecessary procedure.

G. False Billings.

92. For each "upgrade" implantation of a CRT-D Device, Dr. Gandhi and/or the Group billed the patient and/or the patient's payor—often the Government's Medicare program—for the professional and related fees for two procedures when only one was medically indicated.

93. For each implantation in which Dr. Gandhi implanted a defibrillator and/or CRT Pacemaker and/or combination CRT-D Device that was medically unnecessary, including (without limitation) those where Dr. Gandhi or others on his behalf falsified records to suggest otherwise, Dr. Gandhi and/or the Group billed the patient and/or the patient's payor—often the Government's Medicare program—for good s and services that were not medically necessary.

94. Dr. Gandhi's and the Group's conduct set forth above was knowing and intentional, and was a part of an ongoing scheme to defraud payors, including the United States of America, out of millions of dollars in payments for unnecessary procedures, many of which Dr. Gandhi was not qualified even to perform in the first instance.

95. For each defibrillator implantation performed by Dr. Gandhi in the Hospital's Cath Lab, the Hospital also billed the patient's payors—often the Government's Medicare program—for its components of the charges related to the procedure.

96. In each case, the Hospital knew that the procedures in question were not medically necessary, or that Dr. Gandhi was unqualified to perform them, or both.

97. In each case set forth above, Dr. Gandhi, the Group, and/or the Hospital knowingly submitted or caused to be submitted false and fraudulent statements and claims in support of their requests for payments by the Government and its various agencies.

H. Community Cardiology Center, L.L.C.

98. Beginning in or around 2000, rumors circulated around the Hospital of a joint venture cardiac catheterization lab being proposed at the Illiana Surgery Center.

99. Illiana Surgery Center was located in close proximity to the Hospital, was interested in expanding, and was courting many of the most prolific admitters and procedural cardiologists on staff at the Hospital.

100. The rumored proposal involved the construction of a "Heart Hospital" that would provide a full range of cardiology and cardiac surgery services. The leadership at the Hospital was threatened by the rumored joint venture and the prospect of loss of procedures and revenue.

101. The Hospital administrators considered forming a joint venture of their own with the cardiologists on its staff, even though this would mean a loss of overall revenue to the hospital. The formation of this partnership was not seriously pursued until it became evident that Illiana was actually moving ahead with building a cath lab and forming a partnership of its own with staff cardiologists.

102. There was much discussion about the best way to structure the joint venture and how to operate it. The Hospital was already involved in a joint venture outpatient surgery center

("CSC") and decided that it was best to share some of the wealth with the cardiologists rather than lose all of it to the competition.

103. As the planning for a catheterization lab proceeded, two alternative plans were considered. One scenario called for a diagnostic-only CCC, while the other called for cardiac interventions to be done in the CCC.

104. It was clear that the best advantage to the hospital was for the CCC to do diagnostics only, with the patients coming to the hospital's cath lab on another day to receive elective coronary interventions. The Hospital administration favored the diagnostic only scenario.

105. As the planning phase progressed, the hospital expressed concern about availability of emergency surgical facilities for patients having coronary interventions in the CCC setting. But the physicians involved in the joint venture believed that since the CCC was to be constructed within the Medical Office Building (MOB) which was contiguous with the main hospital, that emergency cases could be transported easily to the CH surgery department.

106. The physicians resisted the diagnostic-only alternative, preferring to do elective interventions immediately as was their practice in the Hospital's cath lab. The hospital's practice had been to admit coronary intervention cases post procedure if they met Interqual criteria and a physician's order for admission was obtained. This standard of practice could not be maintained in an outpatient setting. The physicians wanted to maintain the same standard of practice used in the Hospital's cath lab. They cited time constraints and having to schedule the patient twice to accomplish the same work that they could accomplish in one visit to the Hospital cath lab.

107. The Hospital wanted to limit the number of cases done in the CCC to 5 per day in order to preserve an adequate volume of work in the Hospital's own cath lab.

108. The Hospital wanted to maintain control of the decision-making process in the CCC and retained controlling positions on CCC board of directors for Hospital representatives even though the investing physicians retained a majority partnership.

109. The issues raised in the planning phase of the project were resolved quickly once it became evident that the cardiologists were in serious negotiation with Illiana to invest in their "Heart Hospital."

110. It was agreed that coronary interventions that were not "complicated" could be performed at the CCC. Any complex or risky cases would be done in the Hospital's cath lab as it was in closer proximity to the surgery area.

111. A scheme was worked out to allow the same standard of practice to be maintained for coronary intervention patients in the CCC and the Hospital's cath lab. Coronary interventions done in the CCC were transferred post procedure to the Hospital's cath lab recovery area. The patients were charged by the Hospital as inpatients and a fee was paid back to the CCC for the diagnostic portion of the work. This arrangement was reviewed by hospital attorneys.

112. The Hospital acquiesced to the cardiologists and allowed unlimited numbers of cases to be performed in the CCC. The average daily procedure volume in the CCC was approximately ten within one month of opening. This volume was not new business, but was directly shifted from the Hospital cath lab procedure volume.

113. The joint venture cath lab was started on the sole basis of retaining referrals from cardiologists and preventing the competition from gaining these referrals.

114. The resources of the not-for-profit Community Hospital were provided free of charge to a for-profit entity (CCC) in order to decrease start-up costs and attract investors. These resources included, but were not limited to: financial planning, consulting services on

architectural design, equipment acquisition, vendor selection, oversight on equipment installation, and planning for staffing needs.

115. The venture capital for the CCC project was largely provided by the Hospital. A not-for-profit entity thus provided capital to a for-profit entity. Shares were held in favor of the investors, but the CCC board of directors was composed of two Hospital representatives and one member of the investor group to allow the Hospital to retain control.

116. CCC patients receiving coronary interventions were routinely transferred to the Hospital's cath lab recovery area and admitted as inpatients so that the more lucrative inpatient rate could be charged for the procedure. The CCC was paid a "kickback" for the referral/admission.

117. Compounding the abuses relating to the operation of the CCC is its relationship with the Community Surgery Center ("CSC"). The CSC is a for-profit joint venture owned by the Hospital and by a number of physicians. When the CSC was formed, its investors also included a number of Hospital administrators who were later forced to divest their ownership interest due to an apparent conflict of interest.

118. At the outset, the CSC was administered by the Hospital's director of surgery. Similarly, for many years, the not-for-profit Hospital shared its surgery department staff with the for-profit CSC. Relators allege, on information and belief, that the Hospital employees' services were never billed to the CSC.

119. Relators are further informed and believe that CSC cases have been billed to third-party payors, including Medicare and Medicaid, using the Hospital's facility number as an effort to improperly maximize reimbursement.

Count I: False Claims Act (31 U.S.C. 3729(a)(1))

120. Relators incorporate the allegations in paragraphs 1 – 119 above by reference as if separately repeated here.

121. This is a claim for treble damages and other relief under the Act, 31 U.S.C. § 3729 *et seq.*

122. Dr. Gandhi, the Group, and the Hospital have knowingly (as that term is defined in the Act) presented, or caused to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States false or fraudulent claims for payment or approval.

123. The Government has been severely damaged (in an amount to be determined at trial) as a result of these defendants' false and/or fraudulent statements and, therefore, by their violations of the False Claims Act.

Count II: False Claims Act (31 U.S.C. 3729(a)(2))

124. Relators incorporate the allegations in paragraphs 1 – 123 above by reference as if separately repeated here.

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

126. Dr. Gandhi, the Group, and the Hospital have knowingly (as that term is defined in the Act) made, used, or caused to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government.

127. The Government has been severely damaged (in an amount to be determined at trial) as a result of these defendants' false and/or fraudulent statements and, therefore, by their violations of the False Claims Act.

Count III: False Claims Act—Conspiracy (31 U.S.C. 3729(a)(3))

128. Relators incorporate the allegations in paragraphs 1 – 127 above by reference as if separately repeated here.

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

130. Dr. Gandhi, the Group, and the Hospital have knowingly (as that term is defined in the Act) conspired to defraud the Government by getting a false or fraudulent claim allowed or paid.

131. The Government has been severely damaged (in an amount to be determined at trial) as a result of these defendants' conspiracy and, therefore, by their violations of the False Claims Act.

Request for Relief

WHEREFORE, Relators request judgment against the Defendants, jointly and severally, as follows:

A. That Defendants cease and desist from violating 31 U.S.C. § 3729 and from making any further false claims or statements to the Government;

B. That this Court enter judgment against Defendants, jointly and severally, in an amount equal to three times the amount of damages the Government has sustained because of the Defendants' actions, plus a civil penalty of not less than $5,000 and not more than $10,000 for each violation of 31 U.S.C. § 3729;

C. That Relators be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

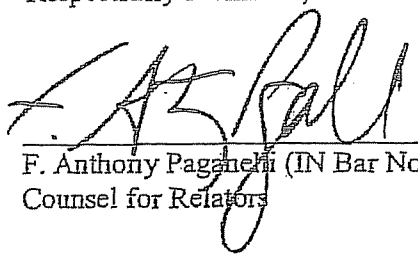
D. That Relators be awarded all costs and expenses of this action, including attorneys' fees; and

E. That Relators recover such other relief as the Court deems just and proper.

Jury Demand

Relators demand trial by jury of all causes of action so triable.

Respectfully submitted,



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CERTIFICATE OF SERVICE

I certify that a copy of the foregoing document was served on September 27, 2011 by Fed Ex Overnight upon the following persons:

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AUSA Wayne Ault
Office of the U.S. Attorney
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