

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

United States Courts
Southern District of Texas
FILED

AUG 21 2007

Michael N. Milby, Clerk of Court

UNITED STATES OF AMERICA
[UNDER SEAL],

PLAINTIFF,

v.

[UNDER SEAL],

DEFENDANT.

CIVIL ACTION NO.

H 07-2702

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

COMPLAINT

UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

UNITED STATES OF AMERICA <i>EX REL.</i>)	CIVIL ACTION NO.
)	H 07-2702
ELAINE BENNETT)	FILED UNDER SEAL
)	PURSUANT TO
PLAINTIFF,)	31 U.S.C. § 3730(b)(2)
)	
v.)	JURY TRIAL DEMANDED
)	
ATRICURE, INC.,)	
)	
DEFENDANT.)	

COMPLAINT

Plaintiff and qui tam relator Elaine Bennett, through her attorneys Sanford, Wittels & Heisler, LLP, for her Complaint against Atricure Inc. (hereinafter “Defendant”) alleges as follows:

I. INTRODUCTION

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

2. This qui tam case is brought against Defendant for conducting a fraudulent marketing and inducement campaign that foreseeably caused false or fraudulent claims for procedures performed using Defendant’s bipolar ablation products to be presented to the Medicare program. As a direct result of Defendant’s improper practices, the Federal Treasury has been damaged in a substantial amount yet to be determined.

3. Since the introduction of their radio-frequency surgical ablation products, one of the

largest obstacles Defendant has faced in selling its products is that the only use is for the off-label treatment of atrial fibrillation. Defendant has initiated a coordinated nationwide sales campaign (including the use of illegal kickbacks and other improper means) to entice physicians and hospitals to use their surgical ablation products for off-label purposes.

4. Upon information and belief, Relator alleges that there have been a number of deaths caused by Defendant's off-label procedure for the treatment of atrial fibrillation. These deaths provide disturbing evidence of the dangerous risks associated with Defendant's off-label procedure.

5. For the majority of patients, cardiac ablation can be more safely performed, at a lower cost, as an outpatient procedure performed by an electrophysiologist ("EP") in a catheterization lab. EPs are specialized cardiologists. In a catheter ablation procedure, the patient is awake with less anesthesia (under conscious sedation), experiences fewer side effects, and will go home the same day of the procedure. Inpatient admission is not medically necessary. However, through their aggressive off-label marketing campaign, Defendants have induced hospitals to use their cardiac surgical ablation procedures, which are performed by cardiothoracic surgeons and billed as inpatient procedures.

6. Defendant has promoted its products to hospitals by highlighting the high spread between Medicare reimbursement for procedures performed with Defendant's products and the relatively low cost of those procedures. Defendant has encouraged cardiothoracic surgeons to perform procedures using Defendant's products as a means of winning business for those surgeons.

7. Defendant has done more than just talk to physicians and hospitals about off-label uses for Defendant's products. In order to bolster this off-label marketing campaign, Defendant has given both hospitals and physicians kickbacks and other inducements to encourage them to buy and

use Defendant's Bipolar ablation products.

8. Defendant's sales representatives also provide free equipment to hospitals to induce them to purchase a specified quantity of Defendant's products. Free equipment, in effect, increases the hospital's reimbursement for the procedure as it reduces hospital costs. By increasing the hospital's revenues, providing free equipment creates an additional inducement to perform an increased number of surgical ablation procedures.

9. Defendant also offers price discounts to induce hospitals to "lock-in" to a market share commitment to buy Defendant's cardiac ablation products. When entering into these agreements, the hospitals agree to allow Defendant to confiscate all competitors' products and equipment from the hospital vicinity to ensure that the hospitals will use only Defendant's products. These market-share commitments interfere with the discretion of the physicians to use the treatment that is in the best interest of each particular patient.

10. Defendant also provides cardiothoracic surgeons free advertising, marketing and referral services in exchange for the surgeon's agreement to use Defendant's products. Such services are particularly valuable to those surgeons because, in recent years, they have been faced with declining case volumes due to the rise of cardiac stents and catheter-based, outpatient procedures used by EPs, cardiologists, to treat cardiac illnesses and due to the decline of coronary artery bypass graft surgery. Defendant thus pitches its products (and the attendant procedures) to cardiothoracic surgeons as a way to win back market share (i.e., by giving cardiothoracic surgeons a "cutting edge" new surgical treatment that only they can offer to patients).

11. Recognizing this market opportunity (i.e., that cardiothoracic surgeons were losing market share), Defendant offered the surgeons kickbacks in the form of free advertising, press, and

referral services to bring in more patients and business to the surgeons and to promote the surgeons as eminent physicians that provide this new cutting edge procedure. This in-kind marketing support by sales representatives includes marketing directly to patients as well as marketing to other physicians (i.e. electrocardiologists, cardiologists, primary care physicians, family practitioners) who can directly refer those newly diagnosed atrial fibrillation patients to the cardiothoracic surgeons for surgery as a treatment option, thus eliminating the cardiologist, whose normal protocol for the treatment of atrial fibrillation is drug therapy and catheter ablation -- all done as outpatient procedures. Defendant has attempted to change the normal course of referral patterns by advising patients that they can then be referred for surgical ablation as a first line therapy instead of the outpatient therapy option that a cardiologist would provide for that same patient. These referral services provide an extremely valuable benefit for the surgeons in marketing their practice. This marketing support also promotes performance of additional surgical ablation procedures and the purchase of more of Defendant's products.

12. The decline of cardiothoracic surgery has also caused many cardiothoracic surgeons to seek training for new treatments. Another in-kind benefit Defendant provides to physicians is direct, extensive training by sales representatives to teach the surgeons how to perform surgical ablation for the off-label treatment of atrial fibrillation. In order to obtain this surgeon training, hospitals or physicians must agree to lock-in to an agreement to purchase and utilize Defendant's products.

13. As a result of Defendant's off-label marketing and illegal kickbacks campaign, a substantial number of patients have undergone more intensive, inpatient surgical ablation procedures, where less intensive, outpatient catheter ablation procedures (or other treatments) should have been performed instead. The Medicare program has faced substantial increased costs for these

inappropriate inpatient surgical procedures.

14. The FCA was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub. L. 99-562, 100 Stat. 3153. Congress enacted the 1986 amendments to enhance and modernize the Government's tools for recovering losses sustained by frauds against it after finding that federal program fraud was pervasive. The amendments were intended to create incentives for individuals with knowledge of Government frauds to disclose the information without fear of reprisals or Government inaction, and to encourage the private bar to commit resources to prosecuting fraud on the Government's behalf.

15. The Act provides that any person who presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government, or knowingly makes, uses, or causes to be made or used false records and statements to induce the Government to pay or approve false and fraudulent claims, is liable for a civil penalty ranging from \$5,500 up to \$11,000 for each such claim, plus three times the amount of the damages sustained by the federal Government.

16. The Act allows any person having information about false or fraudulent claims to bring an action for herself 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 defendant during that time). Based on these provisions, qui tam plaintiff and relator, Elaine Bennett, seeks through this action to recover damages and civil penalties arising from the Defendant's knowing fraud on the U.S. Government.

II. PARTIES

17. Elaine Bennett is a resident of Saint Louis County, Missouri. Ms. Bennett was

employed by Boston Scientific from June 12, 2006 to September 28, 2006 as a Sales Representative specializing in the marketing of ablation products for the treatment of atrial fibrillation. She worked in the Midwest region in Central and Southern Illinois and Central and Southern Missouri. As a former sales representative that was trained to market ablation products for the treatment of atrial fibrillation, Ms. Bennett has specialized knowledge of industry-wide practices, including the improper marketing, billing and coding practices at Atricure.

18. Defendant Atricure is headquartered in West Chester, Ohio. Atricure develops, manufactures, and markets surgical devices designed to create precise lesions, or scars, in cardiac and soft tissues. Hospitals and surgeons have used Atricure's ablation system to treat atrial fibrillation in over 30,000 patients. Atricure's ablation system has been used as a sole-therapy minimally invasive treatment on more than 2,000 patients. A substantial majority of Atricure's revenues are generated through the non-FDA-approved, or off-label, use of its system to treat atrial fibrillation. Atricure has been violating the False Claims Act by causing the submission of fraudulent Medicare claims to promote the off-label use of its ablation system to treat atrial fibrillation.

III. JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action pursuant to both 28 U.S.C. §1331 and 31 U.S.C. §3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§3729 and 3730. Under 31 U.S.C. §3730(e), there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint.

20. This Court has personal jurisdiction over the Defendant pursuant to 31 U.S.C. §3732(a), because that section authorizes nationwide service of process and because the Defendant

has at least minimum contacts with the United States. Moreover, the Defendant can be found in and transacts – or has transacted – business in the Southern District of Texas.

21. Venue is proper in this District pursuant to 31 U.S.C. §3732(a), because the Defendant can be found in and transacts – or has transacted – business in the Southern District of Texas.

IV. BACKGROUND

A. THE MEDICARE PROGRAM

22. Medicare is a federally funded health insurance program primarily benefiting the elderly. Medicare was created in 1965 when Title XVIII of the Social Security Act was adopted. Medicare, the nation's largest health insurance program, provides health insurance to people age 65 and over, those who have end-stage kidney failure, and certain people with disabilities.

23. Medicare Part A (the Basic Plan of Hospital Insurance) covers the cost of hospital inpatient stays and post-hospital nursing facility care. Medicare Part B (the Voluntary Supplemental Insurance Plan) covers the costs of physician services, certain pharmaceutical products, diagnostic tests, and other medical services not covered by Part A.

24. The Centers for Medicare and Medicaid Services (CMS) administers Medicare but much of the daily administration and operation of the Medicare program is managed through contracts with private insurance companies that operate as Fiscal Intermediaries. Fiscal Intermediaries are responsible for accepting claims for reimbursements under Medicare Part A (and some claims under Part B), and making payments for such claims. “Medicare Carriers” are responsible for accepting and paying claims for reimbursements under Medicare Part B.

1. Medicare Payments to Hospitals

25. Medicare pays hospitals different amounts for various services based, in part, on the setting (e.g., inpatient or outpatient) where the services were performed. Hospitals are generally reimbursed for inpatient services on a “per case” basis. In other words, each inpatient hospitalization is assigned a Diagnosis Related Group (“DRG”) based on the nature and severity of the patient’s diagnosis and the services performed. Medicare then pays the hospital a pre-determined reimbursement rate based on the DRG. The pre-determined DRG reimbursement rate is paid to the hospital regardless of how long the patient is admitted or the number of services provided.

26. DRGs are assigned to a case through a process called “grouping.” A “grouper” is a type of software that reviews various data related to the hospitalization (especially the patient’s diagnosis and the procedures performed) to determine the appropriate DRG for the treatment.

27. In most cases, the procedure performed by the hospital is one of the most significant, if not the determinative, data point affecting the DRG grouper’s decision. These procedures are classified and reported using International Classification of Diseases, Ninth Revision, Clinical Modification (“ICD-9-CM”) system, established by CMS and the National Center for Health Statistics. These codes are commonly referred to as “ICD-9 procedure codes.”

28. Payments for hospitals in the outpatient setting also bundle items and services so that hospital providers are paid for the procedures performed, including the cost of equipment. Hospitals use APC Codes (Ambulatory Payment Classifications) to bill for costs associated with outpatient services.

2. Medicare Payments to Physicians

29. Physician services provided in conjunction with a procedure performed at a hospital (on either an inpatient or outpatient basis) are billed and reimbursed separately from the hospital's DRG or APC payment.

30. Like hospital reimbursement, Medicare bases physician reimbursement on the assumption that similar types of procedures consume a similar amount of resources, and thus deserve similar reimbursement. Accordingly, Medicare reimburses physicians based on standardized procedure codes – HCPCS and CPT codes, as described below.

31. Each procedure code is assigned a weight or value (called a Resource Based Relative Value Unit or “RBRVU”), as determined by the Resource-Based Relative Value Scale (“RBRVS”). The payment level for any given procedure is then determined by multiplying the RBRVU value for the code times a conversion factor (which takes into account regional and other variable cost factors).

32. The RBRVS system is based on the Healthcare Common Procedure Coding System (HCPCS). HCPCS is a standardized coding system designed to ensure that Medicare, Medicaid, and other federal health care programs pay for services rendered to patients by attending physicians and other healthcare professionals in accordance with payment schedules tied to the level of professional effort required to render specific categories of medical care. To ensure normalization of descriptions of medical care rendered and consistent compensation for similar work, both programs tie levels of reimbursement to standardized codes.

33. Current Procedural Terminology (“CPT”) codes are Level I HCPCS codes and are published and updated annually by the American Medical Association (“AMA”).

34. Base CPT codes are five-digit numbers organized in numeric sequences that identify both the general area of medicine to which a procedure relates (such as “Evaluation and Management,” “Anesthesiology,” “Surgery,” “Radiology,” or general “Medicine”) and the specific medical procedures commonly practiced by physicians and other health care professionals working in that field.

35. The instructions that accompany the CPT manual direct providers “not [to] select a CPT code that merely approximates the service provided.” Rather, when none of the standard CPT codes provides an accurate description of the services provided or procedure performed, providers are instructed to “report the service using the appropriate unlisted procedure or service code” (i.e., the special CPT codes provided for use when none of the standard CPT codes reasonably and adequately describes the specific procedure or service provided).

36. Codes listed after each subsection in the CPT Manual and ending in -99 are “unlisted” codes. When a provider submits a claim with a “99” code, it must also provide supplemental information describing the procedure performed so that the carrier may determine the appropriate reimbursement. Correct code assignment occurs after this extra documentation for the claim is reviewed by the carrier.

37. Physicians typically submit claims for professional services on Form CMS-1500. This claim form sets forth the diagnostic code describing the patient’s presenting condition and the procedure codes. On the claim form, the physician certifies that the services were “medically indicated and necessary to the health of the patient”

3. Other Rules Governing Payments to Both Hospitals and Physicians

38. In addition to compliance with other national or local coverage criteria, Medicare requires, as a condition of coverage, that services be reasonable and medically necessary. 42 U.S.C. § 1395y(a)(1)(A). Providers must provide economical medical services and, then, provide such services only where medically necessary. 42 U.S.C. § 1320c-(a)(1). Providers must provide evidence that the service is medically necessary and appropriate. 42 U.S.C. § 1320c-5(a)(3). Providers must ensure that services provided are not substantially in excess of the needs of such patients. 42 U.S.C. § 1320a-7(b)(6)&(8).

39. Federal law also specifically prohibits providers from making “any false statement or representation of a material fact in any application for any . . . payment under a Federal health care program.” See 42 U.S.C. § 1320-a-7b(a)(1). Similarly, Federal law requires providers who discover material omissions or errors in claims submitted to the Medicare to disclose those omissions or errors to the Government. See 42 U.S.C. § 1320-a-7b(a)(3). The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program. See, e.g., 42 CFR §§ 1003.105, 1003.102(a)(1)-(2).

40. It is unlawful for a physician to make a referral that will lead to a claim being submitted to Medicare for services or products supplied by an entity (such as a medical device company) with which the physician has a financial relationship. See 42 U.S.C. § 1395nn(a)(1).

B. THE ANTI-KICKBACK STATUTE

41. The federal health care Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b), arose out of Congressional concern that payoffs to those who can influence health care decisions will result in goods and services being provided that are medically unnecessary, are of poor quality, or even

harmful to a vulnerable patient population. To protect the integrity of federal health care programs from these difficult to detect harms, Congress enacted a prohibition against the payment of kickbacks in any form, regardless of whether the particular kickback actually gives rise to over-utilization or poor quality of care.

42. The Anti-Kickback Statute prohibits any person or entity from making or accepting payment to induce or reward any person for referring, recommending, or arranging for the purchase of any item for which payment may be made under a federally funded health care program. 42 U.S.C. §1320a-7b(b). Under this statute, medical device companies may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or others to order or recommend products or procedures that may be paid for by a federal health care program. The law not only prohibits outright bribes and rebate schemes, but also prohibits any payment by a company that has, as one of its purposes, inducement of a physician to perform additional procedures using the company's products.

43. Violation of the Anti-Kickback Statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment of up to five years per violation. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

44. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider in federal health care programs. Either pursuant to provider agreements, claims forms, or other manner, hospitals and physicians who participate in a federal health care program generally must certify that they have complied with the applicable federal rules and regulations, including the Anti-Kickback law.

45. Any party convicted under the Anti-Kickback Statute must be excluded from federal health care programs (i.e., not allowed to bill for services rendered) for a term of at least five years. 42 U.S.C. §1320a-7(a)(1). Even without a conviction, if the Secretary of the Department of Health and Human Services (“HHS”) finds administratively that a provider has violated the statute, the Secretary may exclude that provider from the federal health care programs for a discretionary period (in which event the Secretary must direct the relevant state agency(ies) to exclude that provider from the state health program), and may consider imposing administrative sanctions of \$50,000 per kickback violation. 42 U.S.C. §1320a-7(b).

C. TREATMENT OF ATRIAL FIBRILLATION, WITH AND WITHOUT ABLATION

46. Atrial fibrillation is a very fast and irregular beating of the atria. Atrial fibrillation is the most prevalent type of arrhythmia leading to hospital admission. Over 2.2 million Americans suffer from atrial fibrillation, and approximately 160,000 new cases are diagnosed every year.

1. Treatment of Atrial Fibrillation without Ablation

47. Treatment with antiarrhythmic drugs and anticoagulation is considered first-line therapy in patients with symptomatic atrial fibrillation.

48. The cardiac “Maze” procedure is a form of open-heart surgery used to treat atrial fibrillation with strategic placement of incisions in both atria. Since its introduction, the Maze procedure has undergone three iterations: Maze I, II, and III, which all involve cut and sew techniques used during open-heart procedures. Despite its high success rate, the Maze operation has not been widely adopted except for patients undergoing cardiac surgery because of the need for cardiopulmonary bypass, the morbidity and complication rates, and because it is a difficult and very

challenging procedure for the surgeon to perform.

2. Treatment of Atrial Fibrillation with Ablation

49. In recent years, physicians have begun to try to treat atrial fibrillation by ablating – i.e., removing or destroying – certain heart tissue with various forms of energy (e.g., radio frequency, microwave). In general, physicians have experimented with two types of ablation procedures: (1) catheter ablation and (2) surgical ablation.

a. Catheter Ablation

50. Catheter ablation is a minimally invasive procedure that involves the use of a catheter which is threaded through the leg and into the heart. The catheter is equipped with a device that delivers radiofrequency waves to the arrhythmia source.

51. Catheter ablation is an outpatient procedure, performed by an electrophysiologist (“EP”) in a catheterization lab. EPs are specialized cardiologists. In a catheter ablation procedure, the patient is generally awake with less anesthesia (under conscious sedation), or in some cases under general anesthesia, experiences fewer side effects, and will go home within one day of the procedure.

52. Catheter ablation has recently gained recognition as an effective procedure to treat atrial fibrillation. A large number of studies have reported high rates of successful treatment and a low incidence of complications with the catheter ablation techniques.

53. The American College of Cardiology, the American Heart Association Task Force on Practice Guidelines, and the European Society of Cardiology Committee for Practice are the premier medical societies that establish “standards of care” and treatment protocols for patients with cardiac conditions. In 2006, the Guidelines for patients with atrial fibrillation were updated to include

catheter-based ablation as a third-tier treatment option, following drug therapy and cardioversion. This is the first time catheter-based ablation was included as a standard of care, because, until this time, catheter-based ablation had been considered experimental. Catheter-based ablation has been used in practice for a much longer period of time (around 5 years) than surgical ablation, which is why surgical ablation is still considered experimental, and was not added to the recommended practices, or considered a “standard of care”.

b. Surgical Ablation

54. Surgical ablation is a surgical procedure performed in the operating room with the patient under general anesthesia. The procedure is a derivative of the Maze procedure using radio frequency (or other) energy to create lesions, rather than a cut and sew technique.

55. Surgical ablation procedures are generally performed by cardiothoracic surgeons. Unlike catheter ablation procedures, which are performed on an outpatient basis, surgical ablation procedures are generally performed on an inpatient basis, requiring the patient to stay in the hospital.

56. There is not yet any study assessing the safety and efficacy of using radio frequency surgical ablation or any other energy source to perform surgical ablation for the treatment of atrial fibrillation.

57. Surgical ablation may be performed as either an open-heart procedure (often in conjunction with another open-heart procedure) or as a “minimally invasive” “sole-therapy” procedure.

58. A wide variety of minimally invasive forms of surgical ablation, including thoracoscopic epicardial ablation, are currently being investigated as potential forms of treatment for atrial fibrillation. Because the efficacy and safety of thoracoscopic surgical ablation are still under

investigation, the procedure is considered more experimental and is less accepted than either catheter ablation or the Maze surgical procedure.

59. At the AATS (American Association of Thoracic Surgeons) Society meeting in May, 2007, several surgeons, including Dr. J. Crayton Pruitt, reported that efficacy rate of surgical ablation was lower than 50% in clinical studies.

60. The Heart Rhythm Society (HRS), European Hearth Rhythm Association (EHRA), and European Cardiac Arrhythmia Society (ECAS) have recently released their Expert Consensus Statement regarding surgical ablation for atrial fibrillation (AF). The Expert Consensus Statement set forth that “prospective multicenter clinical trials are needed to better define the relative safety and efficacy of surgical [ablation] tools and techniques.” The Statement also revealed that “[t]he true success rates of these procedures are likely to be lower than has been reported.”

61. A stand-alone, minimally invasive surgical ablation procedure – unlike traditional heart surgery – does not require opening the thoracic cavity to expose the heart and lungs and does not require putting the patient on a heart-lung bypass machine to stop the heart. Patients treated with the minimally invasive, closed-chest procedure generally recover faster than those treated with procedures that require open heart access.

c. Surgical Ablation with Defendant’s Bipolar Surgical Ablation System

62. Defendant’s bipolar ablation system consists of a radio-frequency power generator known as an ablation sensing unit, or ASU, and several radio-frequency ablation clamps that connect to the ASU.

63. Defendant’s bipolar ablation system can be used either in conjunction with open heart surgery or as a sole-therapy, minimally invasive procedure.

64. A sole-therapy, minimally invasive procedure, unlike traditional heart surgery, does not require opening the thoracic cavity to expose the heart and lungs and does not require a heart-lung machine. When using the minimally invasive, closed-chest, procedure, surgeons insert a lighted scope and other instruments through small incisions in the patient's chest. A heart-lung bypass machine is not necessary, and the entire procedure takes two to three hours.

D. MEDICARE COVERAGE OF ABLATION PROCEDURES

65. Typically, catheter ablation and surgical ablation are recommended as treatment for atrial fibrillation only when the patient is either intolerant of or resistant to drug therapy.

66. There is no National Coverage Determination for reimbursement for radio frequency surgical ablation. Accordingly, the Medicare Carrier in each state or region determines the conditions for coverage and reimbursement of physician charges for surgical cardiac ablation.

67. Defendant has directed substantial effort to obtain coverage for radio frequency surgical cardiac ablation procedures through the Medicare Carriers.

68. As alleged herein, Defendant developed a marketing scheme to exploit high reimbursement under DRG 108 for the stand-alone surgical ablation procedure using their product to persuade hospitals to purchase their products. Under DRG 108, hospitals obtain an average reimbursement of \$28,000 to \$30,000. Because the average total cost to the hospital for use of Defendant's sole-therapy, minimally invasive products is only \$10,650, hospitals make a substantial profit whenever such a procedure is performed. Defendant heavily promotes this fact as part of its campaign to get hospitals to perform surgical ablation procedures using Defendant's products.

69. Defendant also coaches hospitals to “upcode” the minimally invasive, closed-chest, procedure to a procedure code for open-heart DRG 108 to take advantage of the Medicare care system and obtain an over-reimbursement of approximately \$20,000 per a procedure.

V. ALLEGATIONS

A. DEFENDANT ILLEGALLY MARKET THEIR PRODUCTS TO HOSPITALS AND PHYSICIANS

70. Since 2000, Defendant has aggressively marketed its surgical ablation products to induce hospitals and physicians to purchase their products and use them specifically (and only) for off-label treatment of atrial fibrillation.

71. In large part due to that aggressive and improper off-label marketing campaign, Defendant’s surgical ablation product has been used to treat atrial fibrillation in more than 2,000 sole therapy, closed-chest, thoracoscopic ablation procedures and more than 20,000 concomitant procedures (i.e., open-heart ablation procedures done in conjunction with another open-heart procedure).

72. Since approximately 2002, Defendant devised a strategy to further expand such off-label use of their product. This strategy involves marketing their minimally invasive, stand-alone products by advising hospitals to take advantage of the Medicare system to obtain over-reimbursement for such procedures.

1. **Defendant Aggressively (and Exclusively) Promote Their Product for Off-label Treatment of Atrial Fibrillation**

73. Although Defendant’s surgical ablation system is not FDA-approved for the treatment of atrial fibrillation, Defendant specifically markets it for that use. In fact, that is the only practical use for their product and the only use for the product that Defendant promotes.

74. Defendant's surgical ablation system is categorized as a Class II device, which, pursuant to 42 C.F.R. 405.201, "require special controls, such as performance standards or postmarket surveillance, to provide a reasonable assurance of safety and effectiveness."

75. The indicated use of surgical ablation that was approved by the FDA in Defendant's 510(k) premarket notification was for *general use* "to ablate cardiac tissue during cardiac surgery."

76. When a device is approved by the FDA for a general use, a specific indication for use can become a new intended use that requires submission of an additional 510(k) approval to establish the safety and effectiveness of the device.

77. The FDA has determined that the use of Defendant's product to treat atrial fibrillation is a specific indication for a new intended use, which requires an additional pre-market approval, due to considerations of safety and effectiveness.

78. There is not yet a study assessing the safety and efficacy of using Defendant's product to treat atrial fibrillation.

79. Defendant has not received FDA clearance or 510(k) approval supporting the specific use of surgical ablation to treat atrial fibrillation.

80. The FDA has three times denied Defendant specific approval for the use of surgical ablation to treat atrial fibrillation.

81. Notwithstanding the absence of specific approval, the only real-world, actual use of Defendant's surgical ablation system is to treat atrial fibrillation.

82. Thus, all current uses of the bipolar surgical ablation system are off-label. Moreover, the underlying purpose of all of Defendant's training and marketing of their ablation system is to promote the off-label treatment of atrial fibrillation.

83. A disturbing sequence of deaths has been caused by the use of Defendant's procedure

for the off-label treatment of atrial fibrillation. At least four of these deaths have occurred in Texas in the past year. One death occurred at Lubbock Heart Hospital in Lubbock, Texas in June 2007.

84. Defendant's procedure has also caused patients severe life-threatening injuries. In July 2007, another patient treated off-label for atrial fibrillation with Defendant's procedure at Lubbock heart hospital was critically injured and nearly died. The patient was hospitalized in the intensive care unit for two weeks or longer. Defendant's procedure also caused severe injuries to a patient at Memorial Hospital in Springfield, Illinois in 2007. The patient was hospitalized for an extensive period. Another patient at St. John's Hospital in Springfield, Illinois was also injured in 2007 by Defendant's off-label procedure for the treatment of atrial fibrillation.

85. All of Defendant's sales activities, including promotion of high reimbursements, upcoding, kickbacks such as free products, free advertising, and referrals, are for the off-label promotion of Defendant's products to treat atrial fibrillation, which is experimental and not approved by the FDA.

86. Defendant's sales representatives also promote the off-label use of Defendant's product by directly training doctors to use Defendant's ablation system to treat atrial fibrillation.

87. Defendant's new hires were not taught to treat any condition other than atrial fibrillation with Defendant's product.

88. Multiple conflicts of interest also affect the members of Defendant's corporate governance structure, some of whom use their financial ties and leadership positions to further promote investments in Defendant's off-label procedure and maximize their own financial interest. More specifically, some members of Defendant's Board of Directors have simultaneously served on the Boards of Directors of clinics and hospitals that have invested in Defendant's procedure for the off-label treatment of atrial fibrillation. For example, one of Defendant's directors, Alan L.

Kaganov, who served as a director of Atricure from May 2001 to June 2006, also served as a board member for St. Francis Medical Center, from June 1999 through November 2006. Mr. Kaganov was also a shareholder of both companies. St. Francis Medical Center has invested in Defendant's products and its surgeons have treated patients with atrial fibrillation off-label with Defendant's procedure. St. Francis Medical Center also promotes Atricure's Wolf Mini-Maze procedure on its website.

2. Defendant "Markets the Spread" – Emphasizing the High Reimbursement to Cost Ratio for Off-label Use of Their Product – As Part of Their Aggressive Off-Label Pitch to Hospitals

89. Defendant aggressively promotes the off-label use of its product to hospitals by "marketing the spread" between the high DRG reimbursement for atrial fibrillation procedures using their products and the low cost of those procedures. (The details of Defendant's "marketing the spread" scheme are somewhat different than the practice as executed in the pharmaceutical industry, because Defendant does not have the same level of control over the reimbursement for their products as pharmaceutical companies do. In this case, however, Defendant's conduct has the same practical effect – namely, encouraging hospitals to purchase their product simply because of the high profit margin the hospital will realize. Moreover, Defendant's aggressive promotion of the high profit margin hospitals can expect to see when Defendant's products are used to treat atrial fibrillation demonstrate that Defendant is aggressively promoting the use of their product for that one specific off-label use. Defendant also offers hospitals kickbacks and volume discounts that effectively reduce hospital costs and increase the hospitals' profit margins when they use Defendant's inpatient procedures).

90. Defendant's promotional literature and sales presentations to hospitals emphasize favorable reimbursement from Medicare as the central marketing theme used to induce hospitals and

surgeons to purchase and use their products off label. Defendant advises hospitals that they can obtain \$28,067 for the closed-chest, sole-therapy procedure by using the procedure code 37.33, which is a code designated for open-heart surgery.

91. Defendant has also established a “reimbursement hotline . . . to help educate the [hospital or physician’s] coding specialist and fight denials.” Defendant promotes its reimbursement hotline as a resource to help health care providers “navigate” the “reimbursement landscape” and obtain advice regarding “Physician coding considerations, Hospital coding considerations, Coverage decisions, Technology assessments, and Reimbursement experiences, especially denials”

92. Defendant further states: “Our independent reimbursement expert is available at 888-347-6403 ext. 5338, or call directly to 513.755.5338. Your call will be returned within one business day.”

93. Defendant’s sales representatives are instructed to promote the use of Defendant’s bipolar ablation system to treat atrial fibrillation by advising hospitals and doctors that they can obtain substantially higher reimbursements from Medicare by using their products.

94. Atricure’s hired staff of medical professionals are required to accompany new surgeons into the operating room to provide the new surgeons with detailed instructions regarding how they can administer Defendant’s product to treat Medicare patients with atrial fibrillation.

95. Atricure also provides free advertising services for surgeons that promote its procedure by paying for the design, publication, and marketing of brochures, including camera-ready art work, that advertise the surgeon’s name and explain that the surgeon treats atrial fibrillation by using Defendant’s ablation system.

3. Defendant Provides Improper Remuneration (Kickbacks) to Physicians and Hospitals To Induce Them To Purchase, Perform and Use Its Products for Off-label Procedures

96. As set forth below, Defendant routinely provides illegal kickbacks to physicians to induce them to perform procedures using Defendant's products, and to hospitals to induce them to buy Defendant's products and to promote their use by physicians who practice at the hospital.

97. Because compliance with the Anti-Kickback Statutes is a condition of payment, claims for reimbursement for procedures performed by a physician who has received a kickback or at a hospital that has received a kickback from Defendant are not eligible for reimbursement by Medicare.

98. Accordingly, kickback-tainted claims for reimbursement are false claims within the meaning of the Federal False Claims Act.

a. Defendant Provides Improper Kickbacks, in the Form of Free Marketing and Promotional Services, to Physicians to Induce them to Perform Procedures Using Defendant's Products

99. Defendant provides physicians with tangible and in-kind services to induce performance of procedure and sales of their product. Some of the valuable in-kind services provided include marketing, advertising, and referral services.

100. Defendant's marketing campaign specifically targets cardiothoracic surgeons, who, in recent years, have been losing business because of the increasing popularity of outpatient catheter ablation procedures. Defendant promotes surgical ablation procedures as a marketing tool for cardiothoracic surgeons – i.e., telling the surgeons that they could advertise their proficiency in this cutting edge, high profile new treatment for atrial fibrillation, and by telling surgeons that they can make them look like heroes by training them to perform a procedure that will yield hospitals the highest margins of profitability.

101. As part of this effort – and in recognition of the cardiothoracic surgeons’ need to promote themselves to counter the rise of catheter-based treatment options – Defendant provides both marketing assistance and referral services to cardiothoracic surgeons when they agree to perform procedures using Defendant’s product. These services are valuable, and thus constitute remuneration for purposes of the Anti-Kickback Statute.

102. Similarly, Defendant directly drums up potential candidates for surgical ablation, and refers those potential patients to cardiothoracic surgeons who have agreed to use Defendant’s product. Defendant sponsors community symposiums to screen for patients who are good candidates for their surgical ablation procedures.

103. During the community symposiums, Defendant misrepresents the treatment options for atrial fibrillation and presents surgical ablation, catheter ablation and cardioversion all as first-line therapy for the treatment of atrial fibrillation. Defendant then focuses on the risks associated with drug therapy and catheter ablation and misrepresents that the success rate for catheter ablation is less than that for surgical ablation—Defendant states that the success rate for catheter ablation is “30%-80%” and that the sole-therapy, Mini-Maze “may eliminate Afib about 85%-91% of [the] time.”

104. Defendant then directly refers the screened patients who attend the community symposiums for “medical consultations” with cardiothoracic surgeons who have agreed to use Defendant’s procedure. Defendant continues to track these patients to determine whether they received treatment with its off-label procedure.

105. Defendant also helps cardiothoracic surgeons who have agreed to use their product to increase surgeons’ patient pool by providing free advertising services. Defendant pays for the design, publication, and marketing of brochures – including camera-ready art work – that advertise

the surgeon's name, promote the surgeon as an excellent physician, and explain that the surgeon treats atrial fibrillation by using Defendant's surgical ablation system.

106. Defendant also provides grants to surgeons who promote the procedure performed with their product. These grants are used to fund the training of new surgeons to use Defendant's product to treat atrial fibrillation.

b. Defendant Provides Free Equipment and Special Discounts to Hospitals to Induce Them to Purchase Defendant's Products, and to Discourage the Use of Competitor's Products

107. Defendant routinely provides kickbacks to hospitals in the form of free products or the free use of equipment, disguised in the form of discounts or equipment loans. Often these improper inducements are given on the explicit condition that the hospital will predominantly (or exclusively) use Defendant's products.

108. Defendant routinely provide hospitals with free products, including: (a) generators used to power Defendant's disposable equipment; and (b) disposable equipment used to perform surgical ablations. These gifts are given in exchange for the hospital's agreement not only to buy a targeted volume of Defendant's products, but also to give Defendant's products preferred status.

109. By receiving free products, hospitals reduce costs and increase reimbursement on each procedure performed. Because the DRG-based reimbursement to the hospital is fixed, the hospital pockets 100% of these "discounts."

110. Although these free gifts are often described in the contracts and invoices as simply "discounted" items, they do not comply with the Medicare anti-kickback safe harbor for legitimate discounts.

111. Furthermore, these "discount" arrangements with hospitals routinely require the hospitals to ensure that Defendant's products are used in a certain percentage (often 80% or more) of

all surgical ablation procedures performed at the hospital. In such cases, any offered discounts are explicitly conditioned on the hospital's commitment to "lock in" a certain market share for Defendant's products.

112. Often, as part of these "lock in" arrangements, Defendant requires the hospitals to turn over to Defendant all competitors' products and equipment from the hospital vicinity to ensure that the hospitals will use only Defendant's products. In some cases, Defendant's sales representatives disable the generators used to power the competitor's products (e.g., by taking the power cords and adaptors) to ensure that the hospital does not allow surgeons to use those competitor's products during surgical ablation.

113. Defendant also offers bundling incentives to hospitals such that if a hospital buys three scopes, it will get one scope for free.

114. Defendant uses these purported "discounts" (actually gifts of free goods – which result in higher profits for the hospitals) as leverage to induce the hospitals to buy more of Defendant's products, regardless of whether another surgical ablation product (or a procedure other than surgical ablation) would have been more appropriate. Thus, these market-share commitments interfere with the discretion of the physicians to use the treatment that is in the best interest of each particular patient.

4. Defendant Coaches Hospitals to Upcode and Overcharge Medicare for Closed-Chest, Stand-alone Procedures

115. Starting in approximately 2002, Defendant's sales and marketing departments trained their sales representatives to market their closed-chest, sole-therapy, minimally invasive procedure by advising hospitals that they could obtain an over-reimbursement through billing Medicare with a DRG and procedure code for open-heart surgery.

116. Specifically, Defendant's managers trained typical sales representatives to make sales to hospitals on the basis of pointing out the potential profit to be derived by billing Medicare DRG 108 with procedure code 37.33 (which is a code for open-heart surgery) for closed-chest, stand-alone procedures. DRG 108 and procedure code 37.33 are incorrect codes to use for sole-therapy, closed-chest procedures.

117. Defendant instructs hospitals to designate treatment of atrial fibrillation with their product under ICD-9 procedure code 37.33 (excision or destruction of other lesion or tissue of heart, open approach).

118. Defendant instructs hospitals and surgeon that perform "a sole therapy" procedure "to use the ICD-9 procedure code 37.33," which "falls into DRG 108." Defendant emphasizes that "right now, just as a reference point, Medicare's national average payments is \$28,067" but that it will vary depending on locale.

119. ICD-9 procedure code 37.33 designates the use of "open chest" approaches, including the Maze procedure. Defendant's surgical ablation system, used as a sole-therapy procedure, does not involve an open approach, and is in fact a minimally invasive closed-chest approach.

120. Because Defendant's sole-therapy procedure is closed-chest, the hospital expenses associated with the procedure are significantly less than the hospital expenses for open-heart surgery.

121. The DRG code associated with procedure code 37.33, the code for open-heart surgery, is DRG 108, which reimburses hospitals an average of \$28,067.52, according to Atricure's estimates.

The average length of hospital stay for patients who require procedures that qualify under DRG 108 is seven to twelve days. In contrast, Defendant's closed-chest, stand-alone procedure requires hospitalization for an average of only two to three days. Moreover, the average cost of Defendant's closed-chest, stand-alone procedure is only \$10,650, approximately one-third of the average cost of

procedures billed under DRG 108.

122. By promoting and encouraging the use of procedure code 37.33, which is designated for open-heart surgery, Defendant coaches hospitals to obtain an over-reimbursement of more than \$17,000, or 260% higher than the hospital cost of the procedure, each time Defendant's surgical ablation system is used as a stand-alone procedure.

123. Because there is no specific procedure code that provides reimbursement for the minimally invasive, closed-chest surgical ablation procedure, which is still considered an experimental and investigational procedure, a more appropriate code for the procedure would be procedure code 37.99 (other operations on heart and pericardium). Procedure code 37.99 is assigned to DRG 111 (Major Cardiovascular Procedures without Complications and Comorbidities) and DRG 110 (Major Cardiovascular Procedures With Complications and Comorbidities). DRG 111 would be the more appropriate of the two DRG codes for purposes of coding Defendant's stand-alone, minimally invasive procedure because the average length of hospital stay under DRG 111 is 3.43 days, whereas, the average length of hospital stay under DRG 110 is 8.4 days. The average Medicare reimbursement under DRG 111 is \$12,954, which corresponds more closely with the hospital costs of Defendant's minimally invasive, closed-chest procedure.

124. Defendant's sales representatives are instructed that they should promote Defendant's surgical ablation system to treat atrial fibrillation by advising hospitals and doctors that if they use procedure code 37.33 and DRG 108 for the use of Defendant's product as a stand-alone procedure, they can obtain higher reimbursements from Medicare.

5. Specific Cases Of Fraudulent Claims Submitted To Medicare For The Off-Label Treatment Of Atrial Fibrillation

125. During the period from July 1, 2006 through December 31, 2006, Dr. Dale Geiss treated patients with atrial fibrillation at St. Francis Medical Center in Peoria, Illinois, using Atricure's RF Surgical Ablation System, as a stand-alone procedure. One of Defendant's Board directors, Alan L. Kaganov, who has served as a director of Atricure from May 2001 to June 2006, also served as a board of director for St. Francis Medical Center, from June 1999 through November 2006. Mr. Kaganov was also a shareholder of both companies, indicating a conflict of interest. During the surgeries that occurred at St. Francis Medical Center, Atricure's sales representative were present to observe the use of the RF Surgical Ablation System. Upon completion of the procedure, St. Francis Medical Center filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospital to receive reimbursements of approximately \$30,000 for each stand-alone use of Defendants' RF Ablation System.

126. During the period from July 1, 2006 through December 31, 2006, Dr. Scott Cook, MD, PhD, and Dr. Michael Colla, MD, treated patients at Carle Clinic Association in Urbana, Illinois. Dr. Cook and Dr. Colla administered Defendant's RF Surgical Ablation System, as a sole therapy procedure to treat patients with atrial fibrillation. Defendant's Sales Representative was present during the procedures to observe the use of Defendant's RF Surgical Ablation System. Upon completion of the procedure, Carle Clinic Association filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospital to receive reimbursements of

approximately \$30,000 for each stand-alone use of Defendant's RF Ablation System, which is a minimally invasive procedure.

127. During the period from July 1, 2006 through December 31, 2006, Dr. Mark Barnett, MD and Dr. James Levett, MD treated patients at St. Luke's Hospital in Cedar Rapids, Iowa. Dr. Barnett and Dr. Levett administered Defendant's RF Surgical Ablation System, as a stand-alone procedure to treat patients with Atrial Fibrillation. Atricure's Sales Representative was present during the procedures to observe the use of the Defendant's RF Surgical Ablation System. Upon completion of the procedure, St. Luke's Hospital filed claims for Medicare reimbursement and used the ICD-9 procedural code 37.33 (excision or destruction of other lesion or tissue of heart, open approach) and the related DRG code 108, which allowed the hospital to receive reimbursements of approximately \$30,000 for each stand-alone use of Defendants' RF Ablation System.

128. Based upon information and belief, Defendant is carrying out similar fraudulent activities in the Southern District of Texas because it employs sales representatives, conducts sales and promotions of its product and facilitates trainings for the off-label use of its procedure in this district.

COUNT I

False Claims Act

31 U.S.C. §3729(a)(1)-(2), (7)

129. Plaintiff realleges and incorporates by reference the allegations in paragraphs 1-128.

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

131. As described above, Defendant has, through their off-label marketing campaign and the use of illegal kickbacks, caused physicians and hospitals to perform an increased number of

costly inpatient surgical ablation procedures in cases where less costly and less invasive treatments would otherwise have been performed.

132. Through the acts described above, Defendant knowingly presented and caused to be presented to the United States fraudulent claims, records, and statements in order to obtain reimbursement for surgical ablation services performed with Defendant's surgical ablation products.

133. Through the acts described above, Defendant knowingly made, used, and caused to be made and used false records and statements in order to obtain reimbursement from the United States for surgical ablation services performed with Defendant's surgical ablation products.

134. The United States, unaware of the falsity or fraudulence of the statements, records, or claims made or submitted by Defendant, its agents, and employees, approved, paid, and continues to approve and pay claims that otherwise would not have been approved or paid, and has not recovered funds that would otherwise have been recovered.

135. Through the acts described above, Defendant knowingly presented, or caused to be presented, false or fraudulent claims to the United States Government in order to obtain government reimbursement for health care services provided under Medicare.

136. As a result of these false claims, the United States has been damaged and continues to be damaged in an amount yet to be determined.

Prayer

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

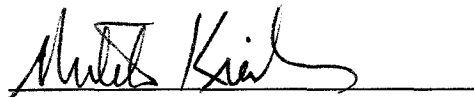
1. that Defendant cease and desist from violating 31 U.S.C. §3729 et seq.;
2. that this Court enter judgment against Defendant in an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty of not less than \$5,500 and not more than \$11,000 for each violation of 31 U.S.C. §3729;
3. that Plaintiff be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;
4. that Plaintiff be awarded all costs of this action, including attorneys' fees and expenses;
5. that the United States and Plaintiff recover such other and further relief as the Court deems just and proper; and,
6. that Plaintiff be awarded relief pursuant to Texas Public Policy to make her whole for the damages and financial losses suffered, including punitive and compensatory damages.

Demand for Jury Trial

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

Dated: August 21, 2007

Respectfully submitted:



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