UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

[UNDER SEAL],	Case No.
Plaintiffs,	COMPLAINT
vs.	
[UNDER SEAL],	FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)
Defendants.	

DOCUMENT TO BE KEPT UNDER SEAL

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UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* AMANDA CASHI, PLAINTIFFS, *v.* FOXHOLLOW TECHNOLOGIES, INC.; ev3 INC.; and DOES 1 - 200, DEFENDANTS.	CIVIL ACTION NO. FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2) JURY TRIAL DEMANDED

COMPLAINT

Qui tam plaintiff and relator Amanda Cashi, through her attorneys, on behalf of the United States of America, for her Complaint against FoxHollow Technologies, Inc., ev3 Inc., and Doe Defendants 1 – 200 (collectively, "Defendants"), 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 Defendants, their agents, employees and/or co-conspirators in violation of the Federal False Claims Act, 31 U.S.C. §3729 et seq.

2. The Defendants in this case caused, and conspired to cause, the submission of false and fraudulent claims for reimbursement to the Medicare program for medically unnecessary inpatient care. By reason of the Defendants' conduct, the United States has been damaged, and continues to be damaged, in a substantial amount.

3. Since 2004, FoxHollow Technologies, Inc., which later merged with ev3 Inc.

(collectively "FoxHollow"), has conducted an aggressive and unlawful marketing campaign to sell the company's SilverHawk Plaque Excision medical device ("the Silverhawk"), a device used in the removal of plaque in the arteries of patients suffering from peripheral artery disease. The medical term for this procedure is "atherectomy." An estimated 80 percent of all Silverhawk atherectomies are paid for by the federal Government through the Medicare program.

4. The Silverhawk atherectomy procedure, which is described in detail in paragraphs 55-59 below, is a minimally invasive procedure, typically performed under local anesthesia and with a very low complication rate. For the majority of patients, the procedure can safely be performed in an outpatient setting. Inpatient hospital care is only necessary when there are unexpected complications from the surgery or the patient has other medical conditions that require treatment or inpatient-level hospital care following the procedure.

5. After the introduction of the Silverhawk to the market in 2004, the largest obstacle that FoxHollow faced to increasing sales was the high price of the device relative to the Medicare reimbursement available to hospitals when the procedure was performed in an outpatient setting. Medicare reimbursement for an outpatient Silverhawk procedure averaged approximately $3,000, and at that amount hospitals were often losing money on the procedure. Medicare reimbursement for an inpatient procedure, however, averaged approximately $10,000, and at that level the hospitals could made a profit of several thousand dollars on short-stay patients (*i.e.*, at the hospital for a day or less).

6. In response to this situation, FoxHollow initiated a coordinated nationwide marketing strategy to encourage physicians and hospitals to admit Medicare patients undergoing the Silverhawk procedure to inpatient status – usually for a one-night stay – even though medical necessity only supported outpatient treatment in the majority of these cases.

7. The purpose of this strategy was to spur increasing sales of the Silverhawk device. FoxHollow believed – quite correctly, as it turned out – that if hospitals made a sizeable profit off of the Silverhawk procedure, they would encourage use of the procedure and this would spur sales.

8. A number of hospitals were influenced by FoxHollow's strategy and admitted their Silverhawk patients to clinically unnecessary inpatient stays in order to increase the hospitals' Medicare reimbursements. In the jargon of FoxHollow's sales representatives, these hospitals "drank the kool-aid" – a reference to the followers of James Jones – and admitted all or nearly all of their Silverhawk patients to inpatient status regardless of medical necessity.

9. FoxHollow's marketing strategy was particularly successful with hospitals that are physician-owned, since the operating physicians at these hospitals have a stake in the hospital's profits and therefore have a direct financial self-interest in treating Silverhawk patients on an inpatient basis.

10. In contrast to the hospitals that were influenced by FoxHollow's strategy, there are many other hospitals nationwide that when faced with the same temptation did not succumb to greed and continued to treat the majority of their Silverhawk patients on an outpatient basis.

11. FoxHollow's marketing strategy of encouraging inpatient admission of all Silverhawk patients contributed to strong sales of the Silverhawk device between 2004 and 2007. This in turn made FoxHollow into an attractive acquisition target for ev3 Inc, which acquired FoxHollow in October 2007 for $780 million in stock and cash. This acquisition produced substantial profits for FoxHollow's officers, managers and early investors.

12. As a result of the conduct alleged in this complaint, Defendants have knowingly submitted, or caused the submission, of thousands of claims for Medicare reimbursement for

clinically unnecessary inpatient hospital treatment for Silverhawk atherectomy procedures. These claims should have been billed as less expensive outpatient procedures. Claims for unnecessary inpatient treatment are false and fraudulent claims within the meaning of the False Claims Act ("the FCA").

13. The FCA was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, and further amended in 2009 by the Fraud Enforcement and Recovery Act of 2009. Congress enacted these 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.

14. The FCA provides, inter alia, that any person who: (i) knowingly presents, or causes to be presented, false or fraudulent claims for payment or approval to the United States Government; (ii) knowingly makes, uses, or causes to be made or used a false record or statement material to a false or fraudulent claim; (iii) conspires to commit a violation of the FCA; or (iv) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government; 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 Government.

15. The FCA allows any person having information about false or fraudulent claims to bring an action for himself and the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the

defendants during that time) to enable the United States (a) to conduct its own investigation without the defendants' knowledge, and (b) to determine whether to join the action.

16. Based on these provisions, *qui tam* Plaintiff and Relator Amanda Cashi seeks through this action to recover all available damages, civil penalties, and other relief for violations of the FCA alleged herein, in every jurisdiction to which Defendants' misconduct has extended.

II. PARTIES

17. Plaintiff/relator Amanda Cashi ("Relator") is a resident of Louisiana. Relator was employed by FoxHollow from January 2006 until April 30, 2008, primarily as a District Sales Manager. As District Sales Manager, Relator implemented corporate strategies to promote the Silverhawk device to key surgeons and hospital administrators in her region, which covered South Central Louisiana. Relator's employment with FoxHollow ended in April 2008 as a result of a company-wide downsizing that followed the acquisition of FoxHollow by ev3 Inc. Prior to being employed by FoxHollow, Relator worked in other sales positions in the pharmaceutical industry.

18. Defendant FoxHollow Technologies, Inc. is a Delaware corporation with headquarters in Redwood City, California. FoxHollow is a wholly-owned subsidiary of defendant ev3 Inc. FoxHollow designs, develops, manufactures and sells medical devices primarily for the treatment of peripheral artery disease. FoxHollow's first product was the Silverhawk device. FoxHollow markets the Silverhawk through its direct sales force in the United States primarily to interventional cardiologists, as well as to vascular surgeons and interventional radiologists. FoxHollow's sales representatives conduct business throughout the United States, including in this judicial district. During the time period covered by this Complaint, FoxHollow had one or more sales representatives employed full-time in this judicial

district. FoxHollow also paid one or more physicians in this judicial district to speak on behalf of the company at events designed to promote the Silverhawk device.

19. Defendant ev3 Inc. ("ev3") is a Delaware corporation with U.S. headquarters in Plymouth, Minnesota. ev3 is a global medical device company focused on technologies for the treatment of vascular diseases and disorders. On October 4, 2007, ev3 completed a merger with FoxHollow and acquired all of the outstanding shares of FoxHollow common stock, resulting in FoxHollow becoming a wholly owned subsidiary of ev3. Collectively, ev3 and FoxHollow are referred to in this Complaint as "FoxHollow."

20. Doe Defendants 1-200 are various hospitals and physicians that knowingly submitted, caused to be submitted, or conspired to submit, false and/or fraudulent claims for medically unnecessary inpatient Silverhawk atherectomy procedures to the Medicare program. Relator has not, as yet, ascertained the names of the individuals and entities sued as Does 1-200, and therefore sues these defendants by fictitious names.

III. JURISDICTION AND VENUE

21. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331, 28 U.S.C. §1367, 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. To the extent that there has been a public disclosure unknown to Relator, Relator is the original source of the information under 31 U.S.C. § 3730(e)(4). Relator has direct and independent knowledge of the information on which the allegations are based and voluntarily provided the information to the Government before filing this *qui tam* action based on that information.

22. This Court has personal jurisdiction over the Defendants pursuant to 31 U.S.C. §3732(a) because that section authorizes nationwide service of process and because the Defendants have at least minimum contacts with the United States. Moreover, one or more defendant can be found in, resides in, transacts or has transacted business in, or has conspired with persons who have taken substantial overt actions in furtherance of their illegal conspiracy in this judicial district.

23. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because one or more of the Defendants can be found in, resides in, transacts or has transacted business in, or has conspired with persons who have taken substantial overt actions in furtherance of their illegal conspiracy in this judicial district. In addition, statutory violations, as alleged herein, occurred in this judicial district.

IV. APPLICABLE LAW

A. The Medicare Program

1. General Program Features

24. According to FoxHollow reimbursement materials, Medicare is the single largest payer for atherectomy procedures and pays for approximately 80% of all Silverhawk procedures.

25. 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 is the nation's largest health insurance program. It provides health insurance to people age 65 and over, those who have end-stage kidney failure, and certain people with disabilities.

26. The Medicare program has four parts: Part A, Part B, Part C and Part D. Medicare Part A covers the cost of hospital inpatient stays and post-hospital nursing facility care. Medicare Part B covers the costs of physician services, certain pharmaceutical products,

diagnostic tests and other medical services not covered by Part A. Medicare Part C covers certain managed care plans, and Medicare Part D provides subsidized prescription drug coverage for Medicare beneficiaries.

27. The Medicare program is administered through the Department of Health and Human Services ("HHS"), Centers for Medicare and Medicaid Services ("CMS").

28. 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 the remainder of claims for reimbursements under Medicare Part B.

2. Medicare Payment System for Inpatient and Outpatient Procedures

29. Under Medicare rules, different settings of care have different payment systems. In the hospital inpatient setting, the payment amount is determined by the Diagnosis Related Group ("DRG") that describes the case. DRGs are groups of clinically similar diagnoses and/or procedure codes, which are presumed to have similar resource utilization.

30. Medicare pays a fixed amount per case for each DRG. Except in exceptional circumstances, a DRG's pre-determined reimbursement rate is paid to the hospital regardless of how long the patient stays in the hospital or the number of services provided.

31. On discharge of Medicare beneficiaries from a hospital, the hospital submits claims for reimbursement on a Form CMS UB-92.

32. Payments for outpatient hospital services are also based on a bundled, per-case payment system. Hospitals use Ambulatory Payment Classification ("APC") codes to bill for

costs associated with outpatient services. Medicare reimburses hospitals for outpatient services through standardized payments determined by the APC to which the claim is assigned.

33. Hospitals submit claims for outpatient services on the UB-92 claim form. Each claim is assigned one or more APCs based on the procedure codes (i.e., HCPCS code, as described below) included on that form. Unlike inpatient DRG payments, where the hospital generally receives only one DRG payment per case, hospitals can receive multiple APC payments for the same outpatient case, depending on the nature of the services provided.

34. Physician services provided to either inpatients or outpatients are billed and reimbursed separately from the hospital's DRG or APC-based payment. Physician services are reimbursed through a payment system called Resource Based Relative Value Scale ("RBRVS"). In the RBRVS system, payments for services are determined by the resource costs needed to provide them. Payments are calculated by multiplying a standardized measure of the amount of resources the procedure is expected to require (Resource Based Relative Value Units or RBRVUs) by a region-specific payment rate (conversion factor).

35. RBRVS payments are 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, those Federal programs tie levels of reimbursement to standardized codes.

36. The Current Procedural Terminology ("CPT") codes are a subset of the HCPCS codes (called Level I codes) and are published and updated annually by the American Medical

Association ("AMA").

37. 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.

38. Physicians typically submit claims for professional services on Form CMS-1500. The claim form sets forth the diagnostic code describing the patient's presenting condition and the procedural codes. On the claim form, the physician certifies that the services were "indicated and necessary to the health of the patient . . . ."

3. Medicare Reimbursement Rates for the Silverhawk Procedure

39. Medicare reimbursement rates for the Silverhawk procedure are significantly higher when the procedure is performed as an inpatient rather than an outpatient procedure. The following chart provides the average Medicare DRG and APC reimbursement rates for the Silverhawk procedure between 2005 and 2008:

MEDICARE REIMBURSEMENT RATES (NATIONAL AVERAGE)

Year	Avg. Inpatient Reimbursement	Avg. Outpatient Reimbursement
2005	DRG 478 (Other Vascular Procedures w/ Complications and Co-Morbidities): $14,100 DRG 479 (Other Vascular Procedures w/o Complications and Co-Morbidities): $ 7,160	APC 0081 (Non-coronary angioplasty or atherectomy): $1,886
2006	DRG 479: $ 7,437 DRG 553 (old 478 w/ Major Cardiovascular Diagnoses): $15,949 DRG 554 (old 478 w/o Major Cardiovascular Diagnoses): $10,676	APC 0081: $2,515
2007	DRG 479: $ 7,645 DRG 553: $15,965 DRG 554: $11,018	APC 0081: $2,640
2008	DRG 252 (old 553): $14,849 DRG 253 (old 554): $12,140 DRG 254 (old 479): $ 9,043	APC 0082 (old 0081): $5,664

40. One reason that the inpatient reimbursement is so much higher than the outpatient reimbursement is that the DRGs that cover the Silverhawk procedure include a number of "other vascular procedures," most of which consume substantial hospital resources over the course of multiple days, due to the nature of the care required. The reimbursement levels for these DRGs were set based on the expectation of a several-day hospital stay. By persuading hospitals to admit Silverhawk patients for one-night inpatient stays, FoxHollow sought to maximize reimbursement for hospitals by exploiting the high reimbursement rate under these DRGs.

B. Medical Providers Have a Duty To Submit Truthful Claims, and To Correct Any Known Prior False Claims Statements

41. Federal law 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).

42. Similarly, Federal law requires providers who discover material omissions or errors in claims submitted to Medicare or other Federal health care programs to disclose those omissions or errors to the Government. See 42 U.S.C. § 1320-a-7b(a)(3).

43. The requirement that providers be truthful in submitting claims for reimbursement is a precondition for participation in the Medicare program and other Federal health care programs. See, *e.g.*, 42 CFR §§ 1003.105, 1003.102(a)(1)-(2).

C. The Federal Anti-Kickback Statute Prohibits Medical Device Manufacturers from Offering Remuneration To Induce Purchases of Their Products

44. 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, 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 overutilization or poor quality of care. Compliance with the Anti-Kickback statute is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicare and other federal health care programs.

45. 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 manufacturers may not offer or pay any remuneration, in cash or kind, directly or indirectly, to induce physicians or

hospitals to order or recommend medical devices 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 financial inducement by a company that has as one of its purposes the inducement of a medical provider to utilize the company's products.

46. In May 2003, the Inspector General of HHS released a formal guidance to pharmaceutical manufacturers, identifying several marketing practices that constitute "kickbacks and other illegal remuneration" infecting federal health care programs. OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 5, 2003). Although the guidance is intended for drug manufacturers, the principles it articulates apply equally to device manufacturers.

47. The 2003 Guidance cautions manufacturers against engaging in the practice of "marketing the spread." The "spread" refers to the difference in value between what a provider pays for an item and the reimbursement that the provider receives from government health insurance for that item. The greater the difference between provider cost and program reimbursement, the greater the "spread" -- and the greater the provider profit.

48. The guidance states that the Anti-Kickback Act is triggered when the manufacturer induces purchases by "marketing the spread" between the actual, discounted price and the higher federal reimbursement amount since this constitutes the equivalent of offering purchasers an illegal inducement to purchase the product. It observes that "active marketing of the spread is strong evidence of the unlawful intent necessary to trigger the anti-kickback statute." 68 Fed. Reg. at 23736-37.

49. As explained below, FoxHollow induced purchases of its Silverhawk device by "marketing the spread" between the price of its Silverhawk device and the Medicare

reimbursement for one-night stays, which are reimbursed under DRGs designed for procedures typically requiring much longer hospital stays

V. BACKGROUND

A. Treatment of Peripheral Artery Disease with the Silverhawk Device

50. Peripheral arterial disease (PAD) occurs when leg arteries become narrowed or blocked by plaque. Plaque build-up in the leg arteries is also known as atherosclerosis or arteriosclerosis. Plaque is made up of deposits of fats, cholesterol and other substances.

51. When leg arteries are hardened and clogged by plaque, blood flow to the legs and feet is reduced. This can cause pain, changes in skin color and temperature, sores or ulcers and difficulty walking. Left untreated, PAD increases the risk of heart attack, stroke, leg amputation or death.

52. According to the American Heart Association (AHA), PAD affects approximately 8 to 12 million people in the United States. PAD becomes more common with age and, according to the AHA, and affects up to 20% of the U.S. population over 70. Growth in the prevalence of diabetes and obesity, both of which are risk factors for PAD, is also contributing to an increase in the prevalence of PAD.

53. Treatment for patients diagnosed with PAD depends on the severity of the disease. Physicians typically treat patients with mild to moderate PAD through non-invasive management, including lifestyle changes and drug treatment. If symptoms worsen, the traditional treatments for moderate to severe PAD are interventional procedures, which can include balloon angioplasty, stent placement, surgical bypass, or in extreme cases, amputation.

54. FoxHollow's Silverhawk device provides a different approach to the treatment of PAD called atherectomy. Atherectomy is a procedure that removes plaque within the artery.

55. The Silverhawk device is a battery-powered catheter (a thin, soft, flexible tube) ending in a cutting apparatus, consisting of a tiny rotating blade the size of a grain of rice and a nosecone designed to collect the long strips of plaque.

56. Under local anesthesia, the Silverhawk device is inserted through a tiny incision in the skin into the arterial system, typically through the femoral artery, and is moved through the artery to the site of the blockage. As the cutting tool moves up and down the artery, it shaves away very small layers of plaque. The plaque collects in the tip of the device and is then removed from the patient. Typically the surgeon will make several passes with the device before emptying the catheter. By removing plaque from the artery, the Silverhawk device restores the interior diameter of the artery to a size that allows normal blood flow without stretching the artery. Stenting, in contrast, expands the artery by pushing the plaque into the artery wall.

57. The Silverhawk procedure is considered minimally invasive because it can be done under local anesthesia, involves only a minor incision, and is of relatively short duration. The need for post-operative, inpatient level care is generally small. The most common complications occur because of perforation of the arterial wall. These events are very rare.

58. A number of published and peer reviewed articles have documented a very low complication rate with the Silverhawk device, less than five percent. *See, e.g.,* Zeller, *et al.*, "Midterm Results After Atherectomy-Assisted Angioplasty Of Below-Knee Arteries With Use Of The Silverhawk Device," 2004 J Vasc Interv Radiol., 15(12): 1391-7; McKinsey, *et al.*, "Novel Treatment of Patients With Lower Extremity Ischemia: Use of Percutaneous Atherectomy in 579 Lesions," Annals of Surgery - Abstract: Volume 248(4), October 2008 pp. 519-528; Mureebe and McKinsey, "Infrainguinal Arterial Intervention: Is There a Role for an Atherectomy Device?," 2006 Vascular14(5):313-318; Wilusz and Pupp, "Can Endovascular

Atherectomy Be Beneficial In Diabetic Limb Salvage?," Podiatry Today, Vol 19, No. 11, Nov. 1, 2006, reprinted at www.podiatrytoday.com/article/6301; Sarac, *et al.*, "Midterm Outcome Predictors for Lower Extremity Atherectomy Procedures," Nov. 8, 2006, SAVS Annual Meeting 2007 Abstracts.

59. FoxHollow also documented a low complication rate for the Silverhawk procedure in a clinical study it sponsored called the TALON study. The TALON study involved several hundred patients, and the Silverhawk procedure had a complication rate of less than five percent.

60. FoxHollow has competed with several other manufacturers that market different types of atherectomy devices. These include (1) an "Orbital" atherectomy device called the "Diamondback," manufactured by Cardiovascular Systems, Inc.; (2) a "x" atherectomy device manufactured by Spectranetics; and (3) a "Rotational" atherectomy device called the "Rotablator," manufactured by Boston Scientific.

B. Medicare Rules on Medical Necessity and Site of Service

61. As a condition of coverage, Medicare requires that services be "reasonable and necessary for the diagnosis or treatment of illness or injury." 42 U.S.C. § 1395y(a)(1)(A). Medicare will not pay for services that are not "medically necessary."

62. Providers who wish to participate in the Medicare program must ensure that their services are provided "economically and only when, and to the extent, medically necessary." 42 U.S.C. §1320c-5(a).

63. A provider may be excluded from participation in the Medicare program if that provider bills Medicare for medically unnecessary items or services. See 42 CFR § 1003.102.

64. The medical necessity requirement applies not only to the performance of specific procedures (such as atherectomy) but also to the general level of hospital services provided. The

general level of hospital services includes the "site of service" – either inpatient or outpatient.

65. Medicare rules provide that, as a general matter, an inpatient site of service is appropriate for a patient who is "admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services." See Medicare Benefit Policy Manual ("MBPM") Ch. 1 § 10. "Generally, a patient is considered an inpatient if formally admitted as an inpatient with the expectation that he or she will remain at least overnight . . . ." *Id.*

66. The Medicare rules further provide that when a hospital, through its credentialing committee, makes the decision to allow patients to be admitted to the hospital, the hospital should consider: (1) the severity of the signs and symptoms exhibited by the patient, (2) the medical predictability of something adverse happening to the patient, (3) the need for diagnostic studies that appropriately are outpatient services (*i.e.*, their performance does not ordinarily require the patient to remain at the hospital for 24 hours or more) to assist in assessing whether the patient should be admitted; and (4) the availability of diagnostic procedures at the time when and at the location where the patient presents. *Id.*

67. The rules further provide that "[p]hysicians should use a 24-hour period as a benchmark, *i.e.*, they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis." *Id.* (emphasis added).

68. This 24-hour benchmark is not a fixed rule, however. Medicare rules specifically provide that the overnight stay and 24 hour benchmarks do not, themselves, justify inpatient status. In other words, the rules require more than that the patient simply spend a certain amount of time in a hospital bed. In order to qualify for an inpatient "site of service," the patient must require an inpatient level of care (*e.g.*, nursing care, access to diagnostic or therapeutic equipment, etc.) for the 24-hour period. *Id.*

69. If a patient requires hospital level services for only several hours, then the patient may not be classified as an inpatient. Instead, the patient should be classified as an outpatient in "observation" status until a determination can be made as to whether inpatient admission is necessary. See MBPM Ch. 6 § 20.6(A) (defining observation services).

70. This rule applies with particular force to cases where a patient undergoes a scheduled surgical procedure that does not generally require a long inpatient convalescent period. With respect to such situations, the Medicare rules provide:

> Minor Surgery or Other Treatment - When patients with known diagnoses enter a hospital for a specific minor surgical procedure or other treatment that is expected to keep them in the hospital for only a few hours (less than 24), they are considered outpatients for coverage purposes regardless of: the hour they came to the hospital, whether they used a bed, and whether they remained in the hospital past midnight.

MBPM Ch. 1 § 10 (emphasis added).

71. In such situations, coverage of services on an inpatient or outpatient basis is not determined "solely on the basis of length of time the patient actually spends in the hospital." *Id.* In fact, Medicare will pay for a patient to remain in observation status for up to 48 hours. See MBPM Ch. 6 § 20.6(A). If the physician would like to observe the patient for several hours after a surgical procedure to ensure that no complications develop, then that justifies observation status and not an inpatient stay.

72. The Medicare rules emphasize the strict requirements for inpatient site of service in the regulations used by organizations tasked with reviewing the medical necessity of Medicare claims. The Medicare Quality Improvement Organization ("QIO") Manual provides that patients may only be classified as an inpatient if the patients "demonstrate signs and/or symptoms severe enough to warrant the need for medical care and must receive services of such intensity that they can be furnished safely and effectively only on an inpatient basis." See QIO Manual § 4110.

73. The QIO Manual further provides: "Inpatient care rather than outpatient care is required only if the patient's medical condition, safety, or health would be significantly and directly threatened if care was provided in a less intensive setting." *Id.*

D. Under Medicare Rules on Medical Necessity and Site of Service, the Majority of Silverhawk Cases Should Be Treated as Outpatient Cases in Observation Status Not as Inpatient Cases

74. The patient population suffering from PAD and who are candidates for the Silverhawk procedure can be placed on a continuum ranging from the relatively healthy to the very sick.

75. At the one end of the continuum are patients who are healthy, other than suffering from PAD, and who have few or no comorbidities. (A "comorbidity" is a medical condition existing simultaneously with the condition being treated.) At the other end of the continuum are patients who are quite frail and suffer from a number of serious comorbidities, such as leg or foot ulcers, diabetes, gangrene, coronary artery disease, lung disease, or neurological disease. When these comorbid conditions are present, the patient may require a higher level of care in order to monitor the comorbid condition during post-operative recuperation. For ease of reference, the patients who are relatively healthy and suffer few or no comordities will be referred to herein as "routine" Silverhawk cases.

76. As alleged in section VI below, FoxHollow persuaded a number of hospitals to admit all or almost all of their routine Silverhawk patients to short inpatient stays in order to obtain lucrative inpatient reimbursement from Medicare. Under Medicare rules on medical necessity and site of service, explained above, these patients should have been treated as outpatient cases in observation status, and reimbursed at the outpatient level of reimbursement.

VI. FOXHOLLOW KNOWINGLY PROMOTED MEDICALLY UNNECESSARY INPATIENT ADMISSION FOR MEDICARE PATIENTS UNDERGOING THE SILVERHAWK PROCEDURE

77. In June 2003, the U.S. Food and Drug Administration granted FoxHollow clearance to market the Silverhawk in the United States for treatment of atherosclerosis in the peripheral vasculature. FoxHollow commenced full commercial introduction of the Silverhawk in the United States in January 2004.

78. The original Silverhawk device came in four sizes, corresponding to the arteries in which the device is used. Newer innovations to the original device include the development of smaller sizes. The original device and newer innovations will collectively be referred to herein as the "Silverhawk."

79. After launching the Silverhawk device in 2004, FoxHollow devised a marketing strategy to persuade hospitals and physicians to treat routine Silverhawk atherectomies as inpatient admissions even though – as FoxHollow, the hospitals and physicians knew – inpatient admissions are medically unnecessary in most routine cases.

80. The purpose of the strategy was to take advantage of the fact that short inpatient stays would be reimbursed under DRG codes designed for much longer hospital stays. The average inpatient reimbursement for a one-night stay was approximately $10,000 compared to approximately $3,000 for an outpatient procedure.

81. By appealing to the medical providers' financial self-interest, FoxHollow intended to, and did, induce these providers to perform Silverhawk procedures as expensive and clinically unnecessary inpatient procedures. If properly handled as outpatient services, Medicare would have paid substantially less for these services.

82. The FoxHollow employee who was on the frontlines of this strategy was Stephanie

Corley, hired as a reimbursement specialist in March 2006 and promoted to Director of National Reimbursement in August 2006. Ms. Corley summed up FoxHollow's marketing strategy for the Silverhawk in an email to the sales and marketing departments on April 26, 2006: "Focus on moving the patient to inpatient from outpatient. Let this be your song." Corley warned the recipients of the email: "**Do not distribute externally! This is for internal use only.** That means do not email or print off to give to anyone outside of the company." (Bold in original).

83. To implement this unlawful strategy, FoxHollow employed a number of methods, including those described below.

A. FoxHollow Trained Its Sales Representatives To Promote the Reimbursement Advantages of Inpatient over Outpatient Treatment of Silverhawk Patients To Induce Physicians and Hospitals to Perform the Procedure on an Inpatient Basis Only

84. FoxHollow's sales and marketing efforts are undertaken through regions, each of which is organized into numerous sales territories. The regions are directed by Regional Sales Managers. The sales representatives, called District Sales Managers, report to the Regional Managers.

85. For most of her tenure at FoxHollow, Relator was a District Sales Manager whose sales territory covered Southwestern Louisiana. One of the sales representatives in this judicial district, whose territory included Buffalo General Hospital, was Michael Jerome.

86. While Relator was employed by FoxHollow, the company trained its sales representatives, including Relator, to emphasize to physicians and hospitals the large differential, averaging over 300 percent, between outpatient and inpatient reimbursement for the Silverhawk atherectomy procedure.

87. A July 2005 email from FoxHollow sales trainer Sara Jay to the entire sales force explained the company's strategy: "[W]e cannot get too involved in the process of telling them

[the medical providers] to change their current [admission] patterns but try to make them aware of the differences in payment . . . ." In other words, instead of directly telling medical providers to switch outpatients to inpatient, FoxHollow's strategy was to accomplish this end *indirectly* by marketing the spread (stressing the financial advantages of inpatient treatment).

1. FoxHollow Trained its Sales Representatives To Use an Economic Model Called "The Proforma" To Demonstrate the Financial Advantages of Inpatient Admission

88. Beginning sometime in 2005, FoxHollow began providing its sales force with a custom economic modeling tool to help them explain to physicians and hospitals the economic advantages of performing the Silverhawk procedure on an inpatient basis. The company internally referred to this tool by various names, such as the "Profit Analysis," "Cost-Benefit Analysis," or "Proforma" (hereafter referred to as the "Proforma").

89. The Proforma was designed to show the average profit or loss that a hospital could expect to receive by performing the Silverhawk procedure on an inpatient versus outpatient basis. The Proforma demonstrated that hospitals would lose money on the Silverhawk procedure if performed on an outpatient basis but that they would make money if performed as a short-stay inpatient procedure.

90. The Proforma was in the form of a spreadsheet. All of the numbers on the spreadsheet were variables based on assumptions that could be changed in order to recalculate the estimated profit or loss of the average inpatient or outpatient procedure.

91. The Proforma was divided into two sections, one for inpatient and one for outpatient procedures. Each section had two components, a "Cost" component and a "Reimbursement" component. The Cost component for inpatient procedures calculated the average cost for a one-night stay Silverhawk procedure, which included the device, laboratory

and operating room costs. The Cost component for outpatient procedures calculated the average cost for a typical Silverhawk procedure in an outpatient setting.

92. The Reimbursement component of the Proforma calculated the Medicare reimbursement for the average case. For inpatient procedures, this is a blended average based upon the percentage of cases falling into each DRG category. For the outpatient procedure, the Proforma used the applicable APC code and its associated Medicare reimbursement payment. The Proforma also failed to include any payment that the hospital might receive for other APCs.

93. The last column of the Proforma showed the hospital's estimated average profit per Silverhawk case. FoxHollow updated the Proforma periodically to include recent changes in the cost or reimbursement data.

94. Every Proforma that FoxHollow provided to the sales force showed that a hospital would make a profit of several thousand dollars on the average Silverhawk inpatient procedure because of the relatively high DRG reimbursement rate for inpatient procedures, and would sustain a loss on the average outpatient procedure because of the relatively low reimbursement for outpatient procedures.

95. FoxHollow encouraged its sales representatives to use the Proforma on sales calls in order to show physicians and hospitals that the Silverhawk procedure would be profitable if performed as an inpatient procedure. FoxHollow instructed its sales representatives, however, not to leave a copy of the Proforma in the providers' offices.

96. In a February 2, 2006 email, sales trainer Sara Jay forwarded a Proforma to the sales force and described the Proforma as "a great way to show a hospital the PROFIT they can make by doing these procedures." (All capitals in original.) Ms. Jay went on to explain, "I just used this to present to an OR [operating room] committee - so I thought I would share rather than

have everyone rewrite the same info . . . ." This particular Proforma showed the estimated average profit was $5,603 per inpatient case.

97. In a December 1, 2006 email, Heather Cowan, a FoxHollow Regional Sales Manager, recounted her experience selling the reimbursement advantages of inpatient admission at Austin Heart Hospital: "Kudos to the hawk [*i.e.*, Silverhawk] & all the stellar reimbursement info we have to support inpatient admissions that Austin Heart admits that they make a nice profit off of the hawk."

2. FoxHollow Trained its Sales Representatives To Organize "Reimbursement Meetings" with Physicians and Hospital Staff To Promote the Reimbursement Advantages of Inpatient Admission

98. FoxHollow trained its sales representatives to organize "reimbursement meetings" and conference calls with physicians and hospital staff to discuss various reimbursement issues, including the economic advantages of inpatient admission.

99. Stephanie Corley, FoxHollow's leading reimbursement specialist, participated in person or by phone in many of these meetings. One typical example was a reimbursement conference call in March 2006 with the staff at Alliance Medical Center in Austin, Texas. Two FoxHollow sales representatives also participated. The focus of the conference call was on one particular physician who had been treating 50% of his patients on an outpatient basis. From FoxHollow's perspective, this was a problem since the hospital was losing money on the outpatient procedures, which FoxHollow feared would lead the hospital to discourage use of the device. On the call were hospital coders and billers, as well as the coder from the physician's office.

100. In an email to the sales force summarizing the call, Ms. Corley reported what she learned during the call: "The physician was not writing admit to floor to move the 50%

outpatient's to inpatient status (**Difference in $3000 – 6000/patient. . . .unbelievable.)"** (Bold in original.) Ms. Corley ended the email by stating that she would follow up the call by contacting the physician directly to discuss ways to move these patients to inpatient.

101. The reimbursement meetings and conference calls were very successful in terms of influencing the admitting practices of the treating physicians and hospitals. For example, in an email on June 2, 2006, a FoxHollow District Sales Manager from the Midwest Region explained to the entire sales force that after Ms. Corley had a conference call with interventional radiologists in his district, "It did wonders and they inpatient most all patients. . . . Our call got them on track."

102. As another example, a sales representative based in Corpus Christi, Texas sent an email on July 8, 2006 describing a visit by Ms. Corley to Shoreline Cath Lab in his territory. The parent hospital of the Lab was upset because it was losing money on the Silverhawk procedure as an outpatient procedure. According to the sales representative's email, during Ms. Corley's visit the hospital CFO was told "that if they admit these Pts under DRGs 479, 553 and 554 . . . . they will be making several thousand on each case. Stephanie then walks him through the details. He seems shocked but happy . . . ." The CFO was apparently shocked but happy with the profits that could be made going forward. The sales representative concluded the email by stating, "Getting reimbursement right at every level completely changes the game for us with a hospital."

103. In internal communications, FoxHollow sales and marketing personnel routinely referred to hospitals with a large percentage of outpatient claims as a "problem" that could be "corrected" or "fixed" by converting the claims to inpatient claims. The emphasis was entirely on the economics of the problem and not on whether inpatient admission was medically justified.

104. For example, on June 1, 2006, Ms. Corley sent an email to the sales force

explaining the following "problem" that she could "fix":

> The majority of the facilities utilizing IRs [interventional radiologists] for SH [Silverhawk] are losing money on every case because these facilities do all the cases on an outpatient basis. I can discuss this with each hospital and correct the problem. Hospitals will begin their budgetary process from July to the end of September. This is when the profitability of SH will be thoroughly examined and your sales team will be asked to decrease the respective ASP [average selling price] if they are losing money. Some will limit catheter usage and others may consider discontinuing SH procedures.
>
> I can fix this nightmare and have been successful in several hospitals in which the DSMs [District Sales Manager] have brought this to my attention. Let's be the hero now before the budget process begins.
>
> * * * * *
>
> - Ask your DSMs to contact me immediately by email to set up a conference call with the facility to fix this problem.

105. The "fix" was convincing the facilities of the reimbursement advantages of inpatient admission.

106. As another example, on July 10, 2006, a FoxHollow District Sales Manager in the St. Louis, Missouri area sent an email to the sales force recounting his experience with a new medical facility in his district. He explained:

> After a review of the first 10 hawk cases… a few were coded as outpatient…How?….we discovered that when the LPN from the doc's office scheduled the case for the lab they said it was an outpatient procedure….Incredible! Easy fix….Now when LPN calls and schedules them all as inpatient then if only diagnostic they go home and are switched to outpt….

107. In other words, the sales representative convinced the medical facility that instead of scheduling some of the patients as outpatient as was medically appropriate, all of the patients would henceforth be scheduled as inpatient for purely economic reasons, except in those instances where the procedure was purely diagnostic.

C. FoxHollow Promoted the Reimbursement Advantages of Inpatient Admission at FoxHollow-Sponsored Conferences and Physician Training Events

108. In addition to reimbursement meetings and face-to-face sales calls, FoxHollow used company-sponsored conferences and physician training events to promote the reimbursement advantages of inpatient admission for Silverhawk patients. FoxHollow sponsored many such events each year, including national and regional conferences for vascular surgeons and interventional cardiologists, training courses on specific procedures, clinical investigators' meetings, and "Thought Leader Forums."

109. These events were typically one or two days in length and were held at expensive hotels in various locations throughout the United States, such as the Sheraton New Orleans, Ritz-Carlton in Phoenix, Grand Hyatt Denver, Chicago Downtown Marriott, Le Parker Meridien in New York City, among others. Admission was by invitation, and FoxHollw paid the attendees' round-trip airfare, ground transportation, accommodations, and meals. Speakers at these events were FoxHollow employees as well as outside doctors paid a speaking fee by FoxHollow. One doctor that FoxHollow paid to speak at many of these events was Dr. Sonya Noor, a vascular surgeon who practices at Buffalo General Hospital and other hospitals in this judicial district.

110. Relator attended several of the FoxHollow-sponsored events, and she received written materials concerning other events that she did not attend. At most of these events, FoxHollow organized presentations on reimbursement issues pertaining to the Silverhawk device. The reimbursement presentations were typically conducted by Stephanie Corley or another member of FoxHollow's reimbursement department and stressed the reimbursement advantages of inpatient admission over outpatient treatment.

111. For example, following is a one-sentence summary of Ms. Corley's presentation to a FoxHollow-sponsored conference of vascular surgeons in May 2006, written in an email by a FoxHollow sales representative to his colleagues:

"Outpatient procedures the hospital will loss [sic] $2,500....Inpatient, Hospitals will make on the average $3,500.... Any questions contact Stephanie"

112. Reimbursement Director Corley was known within the company as being the most effective speaker at these events, because of her ability to persuade providers to switch patients from outpatient to inpatient based on profitability. Following are excerpts of emails describing Ms. Corley and her impact at these events:

- "Once again Stephanie Corley proves she is money in the bank!" (Email of September 16, 2006, referring to Corley's appearance at a 2006 Below The Knee (BTK) conference).
- "[The doctors] drink from Momma Corley's reimbursement Kool-Aid." (Email of May 3, 2007, making allusion to the Jonestown massacre.)
- "Stephanie 'Cha Ching' Corley." (Email of September 6, 2006, referring to the expected impact of Corley's presentation at the upcoming 2006 BTK conference.)
- "[A]udience [is] hanging on every word . . . . [Corley] is talking them through their future cash cow." (Email of September 13, 2007, recounting Corley's presentation at a 2007 BTK conference).
- "First up today at the BTK, our reimbursement goddess, Stephanie Corley." (Email of September 15, 2007, referring to a 2007 BTK conference.)

113. FoxHollow closely tracked the "Return on Investment" (ROI) of its sponsored events by comparing the cost of the event with the increased sales attributable to the event. Following FoxHollow's Second National Conference of Vascular Surgeons (internally referred to as "VS2") in 2006, FoxHollow's Market Development Manager wrote an email stating: "The ROI analysis for VS2 showed that physicians who attended VS2 had 25% greater sales volume post meeting compared to physicians who didn't attend!!!"

114. Likewise, following a "Below The Knee" conference sponsored by FoxHollow in Scottsdale, Arizona in January 2007 (called "BTK 6"), a FoxHollow Regional Sales Manager stated: "[T]he impact from our BTK6 was huge to say the least. These programs take it to the next level with a guaranteed ROI if proper targets selected[.] [C]annot wait to hear about the patients treated and watching the ROI roll in."

D. FoxHollow Coached Physicians and Hospitals on How To Avoid Medicare Rejection of an Inpatient Claim for the Silverhawk Procedure

115. FoxHollow provided advice to physicians and hospitals on how to avoid rejection by Medicare and the Medicare Fiscal Intermediaries of an inpatient claim for the Silverhawk procedure due to lack of medical necessity.

116. One way in which this advice was communicated was through coding and documentation "tips" that FoxHollow representatives gave to physicians and hospitals. For example, a FoxHollow training manual for sales representatives provides these "tips":

Tips for changing Inpatient/Outpatient Case Mix

- Educate the physicians on common comorbidities and documentation
- Place the list of comorbidities in dictation station
- Develop standard post procedure orders with inpatient versus outpatient admission choices

117. Notably absent from the discussion of "tips" in the training manual is any discussion of whether inpatient admission is medically necessary.

118. Another FoxHollow "tip" was to inform hospitals that under the guidelines followed by Medicare, the site of service determination was "subjective," and therefore Medicare would not likely question a decision to admit an atherectomy patient.

119. Medicare provides overall rules governing whether a particular hospital case should be classified as inpatient or outpatient. Medicare allows hospitals to establish their own policies on how to apply those rules to individual cases. Rather than assess every procedure or category

of medical care themselves, most hospitals use commercially available sets of "criteria" to determine whether a case should be classified as inpatient. These criteria generally base the determination of the appropriate site of service on an assessment of a combination of factors, including the severity of the patient's illness, and the intensity of services the patient receives.

120. One common set of guidelines used by many hospitals (and often by Medicare Intermediaries as well) are the "Interqual" guidelines published by McKesson.

121. In communications with the FoxHollow sales force, Reimbursement Director Stephanie Corley stressed the "subjective" nature of the Interqual criteria. In an email on July 23, 2007, for example, Corley informed the sales force that "[o]ne of the issues with Interqual criteria is that it can be subjective – depending on how the hospitals case management department interprets the criteria." By this comment, Ms. Corley sought to give assurances that the provider's site of service decision would not likely be second-guessed in a Medicare audit.

122. In an email to the sales force on July 8, 2007, Ms. Corley addressed the common question, "How long must a patient stay in the hospital to qualify as an 'inpatient'?" Ms. Corley answered by stating that the key factor for inpatient admission was the "expectation" that a patient would remain overnight, regardless of whether the patient actually remained overnight. She stated:

> Answer: Medicare guidelines do not specify a time requirement; rather they base inpatient status as meeting Interqual-based guidelines and an expectation that the patient will need acute care overnight. Therefore, even if the patient is admitted to the inpatient unit after a SH procedure and discharged the same day, they would still be considered an inpatient by Medicare.

The clear implication of this explanation was that hospitals could game the Medicare reimbursement system by classifying Silverhawk patients as inpatient based on an "expectation" of an overnight stay, thus qualifying for higher reimbursement, but discharging the patients later

the same day.

123. Stephanie Corley provided this advice at a number of FoxHollow-sponsored conferences. For example, at the Third Vascular Surgeons ("VS3") conference held in Nashville, Tennessee on April 19-21, 2007, Ms. Corley was given three speaking slots devoted to reimbursement issues. (Dr. Sonya Noor, vascular surgeon at Buffalo General Hospital and other hospitals in this judicial district, was also one of FoxHollow's paid speakers at this conference.) One of Ms. Corley's sessions was a two hour talk entitled, "Reimbursement Basics: Increasing Cash Flow." Another was entitled, "Power Coding for Silverhawk." One FoxHollow sales representative in attendance at the conference emailed his colleagues the following summary of the latter presentation by Ms. Corley:

> PowerCoding for Silverhawk: Stephanie Corley
> - 50% of the audience thinks you must keep a patient in the hospital 24 hrs in order to bill as an in-patient. Uh…wrong!

As this summary shows, Ms. Corley told the conference of vascular surgeons that patients could be handled as inpatient for reimbursement purposes without keeping the patients in the hospital for even 24 hours.

124. Communicating this message was a key part of FoxHollow's strategy to induce providers to improperly admit all Silverhawk patients. After this message was communicated to the surgeons that attended a FoxHollow-sponsored conference called the "Gateway Summit" in April 2006, one District Sales Manager wrote the following email to his sales colleagues:

> I met with Dr. Maxen AbuAwad this am at St. Anthony's (St. Louis, MO) to discuss reimbursement (inpt vs. outpt). Mazen said they changed from 23hr admit to inpatient (admit to follow) and discharge the next day. . . .after the Gateway Summit . . . . Another ROI on the summit with Dr. Mendez and Dr. AbuAwad in attendance! Maxen stated they are admitting, billing, and coding correctly and the hospital is very happy.

In other words, following the reimbursement advice provided at the Gateway Summit, this

physician changed his practice of keeping the patients in outpatient observation status ("23hr admit") to admitting the patients to inpatient status. Clearly, this change was based strictly on reimbursement considerations, not medical necessity.

125. FoxHollow also coached physicians on what to include in the patient's records to support inpatient admission. Physicians were told that it was easier to justify inpatient admission if they wrote "Admit to Inpatient" *after* the procedure, not before. This advice was discussed in an email to the sales force on April 8, 2006: "physician must write ADMIT on the orders after the case never before. They can stay 10 or 24 hours as long as the patient is admitted after the procedure [and then] they qualify for large DRG's."

E. FoxHollow Perpetuated this Scheme Through Bonus Incentives Given to Sales Representatives

126. FoxHollow paid its Silverhawk sales representatives an annual salary plus a bonus. The bonus was based on Silverhawk sales in the representative's territory and whether the representative met certain sales quotas.

127. FoxHollow set high sales quotas for its Silverhawk sales representatives. This was driven in part by the company's desire to show strong top line revenue in order to make the company into an attractive candidate for acquisition, which ultimately occurred. One of the company's top performers in terms of sales was Michael Jerome, a sales representative whose territory covered Buffalo General Hospital and other hospitals in this judicial district.

128. Relator and other sales representative knew, based on their experience, that hospitals that lost money on the Silverhawk procedure were reluctant to order the device or allow the Silverhawk procedure at their hospital. The sales representatives believed that the only way that they could achieve their quotas was by adopting the company's strategy of encouraging inpatient admissions, regardless of medical necessity.

129. In August 2006, a shockwave went through the company when it learned of a federal investigation of another medical device company, Kyphon, Inc., for engaging in a very similar practice to that of FoxHollow. News stories announced that the federal government was investigating Kyphon for encouraging unnecessary overnight hospitalization for procedures involving a medical device manufactured by Kyphon in order to increase providers' Medicare reimbursement and thereby induce more purchases of Kyphon's device.

130. On August 30, 2006, shortly after learning about the Kyphon investigation, the General Counsel of FoxHollow, Mark Meltzer, sent an email to the entire company making it appear as if FoxHollow had a vigorous policy against encouraging unnecessary hospitalization of Silverhawk patients. Mr. Meltzer's email stated:

> The FBI is currently investigating a well known surgical device maker for possible violations of law regarding Medicare reimbursement. The investigation is centered on allegations that the company helped customers to overbill Medicare by using certain billing codes and encouraging overnight hospitalization when it was not medically necessary.
>
> It is essential that FoxHollow reps never engage in or suggest such practices. We should never advocate any practice that has a goal of increasing the cost of treatment. We share Medicare's interest in obtaining safe and effective medical treatment at the lowest possible price. Physicians and hospitals should make their own billing decisions without any advocacy from us. All coding and reimbursement inquiries from FHT customers should be directed to our reimbursement department, attention Stephanie Corley.
>
> The legal consequences of violating the law in this area are severe for both the individuals and for the company and can result in criminal charges and civil liability.

131. This email created an "official" policy for the company to hide behind, while the company did as little as possible to actually enforce the policy. The practices described in this Complaint continued as usual.

132. Upon information and belief, no FoxHollow employee was ever disciplined or terminated for encouraging inpatient admission of Silverhawk patients when it was not medically

necessary, even though this conduct was widespread and ostensibly in violation of the above-stated "policy."

F. Foxhollow Promoted the Extra Money a Physician Could Make from Additional Visits Surrounding an Inpatient Procedure as a Way To Persuade Physicians To Perform the Silverhawk Procedure on an Inpatient Basis Regardless of Medical Necessity

133. Medicare reimburses the operating physician the same base amount whether the procedure is performed inpatient or outpatient. However, an inpatient procedure affords more opportunities for physician visits, which are separately reimbursed. FoxHollow stressed this fact to physicians to encourage inpatient admissions.

134. Under Medicare guidelines, the Silverhawk procedure has no "global days" for the physician performing the procedure. "Global days" are the non-payment days before and after a procedure, *i.e.*, the days for which physician visits cannot be separately billed because the visits are included in the Medicare DRG payment for the procedure. Because the Silverhawk procedure has no global days, FoxHollow sales representatives emphasized to physicians that they could bill for the following visits surrounding a one-night inpatient admission:

- Office visits prior to the procedure
- Hospital daily visits one day following the procedure
- Hospital discharge visit
- Follow up physician office visits

135. Because each of the physician visits is reimbursed in the $80 to $100 range, the additional visits represented significant additional revenue for the physicians. FoxHollow used this as a selling point to induce physicians to opt for unnecessary inpatient admission of Silverhawk patients.

G. Foxhollow Encouraged Physicians and Hospitals To Split Up Multiple Silverhawk Procedures into Surgeries on Different Days To Maximize Reimbursement Even Though Performing All Procedures at the Same Time Is Safer and Less Expensive

136. A separate Silverhawk device is required for each artery from which plaque is removed. When plaque is removed from two arteries during the same surgery, Medicare reimburses the first procedure at 100% and the second at 50% of the applicable reimbursement rate. When the two procedures are performed during different surgeries, however, Medicare reimburses each procedure at 100%.

137. FoxHollow encouraged physicians and hospitals performing multiple procedures on a patient to perform the procedures on different days, since they would make more money that way.

138. For example, in an email to the Sales Department on March 29, 2006, Stephanie Corley offered this advice to sales representatives who encounter physicians that are going to perform procedures in two different arteries:

> If I were you, I would recommend that the doctor not do both legs at the same time. The hospital will lose way too much money and he and SH could be banned from the facility. Just a suggestions [sic] for the future job security of you and the MD.

139. This advice is reiterated in a FoxHollow training manual for sales representatives, which provides the following advice to a hypothetical doctor handling a case involving multiple procedures: "You perform one leg on Monday[,] discharge the patient and the other on Thursday = 100% payment x 2."

140. Sending Medicare patients home and bringing them back later for a second procedure subjects the patients to the risks associated with anesthesia and surgery two times, when they should have been subjected to those risks only once. In addition, Medicare is

damaged by this practice by being required to pay for two days of surgery instead of one.

VII. FOXHOLLOW'S MARKETING PRACTICES INDUCED NUMEROUS PROVIDERS TO ADMIT SILVERHAWK PATIENTS FOR MEDICALLY UNNECESSARY INPATIENT STAYS

141. FoxHollow made sales calls on every hospital in the country that performed atherectomy procedures. In this judicial district, one of the FoxHollow sales representatives was Michael Jerome. Mr. Jerome was frequently among the top performers in the company in terms of sales volume.

142. Because FoxHollow made sales calls on every hospital that performed atherectomy procedures, FoxHollow employees had numerous interactions with doctors and staff at the hospitals and multiple opportunities to promote the reimbursement advantages of inpatient admission of Silverhawk patients.

143. At FoxHollow's urging, a number of hospitals -- denominated in this Complaint as Doe Defendants 1-200 -- admitted all or nearly all of their Silverhawk patients to short inpatient stays, even though inpatient treatment was medically unnecessary in the large majority of these cases. In this manner, FoxHollow caused these hospitals to overbill Medicare for inpatient atherectomy claims that should have been billed as less expensive outpatient procedures, all in violation of the False Claims Act.

VIII. DAMAGES TO THE GOVERNMENT DUE TO UNNECESSARY INPATIENT TREATMENT

144. From 2004 to the present, Defendants have submitted or caused the submission of thousands of claims for Medicare reimbursement for clinically unnecessary inpatient hospital stays for Silverhawk atherectomy procedures. Under Medicare rules, these patients should have been treated as outpatients.

145. Claims for unnecessary inpatient admissions are false and fraudulent claims within

the meaning of the False Claims Act.

146. On average, Medicare paid approximately $7,000 more per case for each unnecessary inpatient case than if the procedure had been performed on an outpatient basis.

147. Accordingly, from 2004 to present, Medicare paid tens of millions of dollars for medically unnecessary inpatient hospital services due to Defendants' fraudulent conduct.

IX. FOXHOLLOW VIOLATED THE ANTI-KICKBACK STATUTE BY PROVIDING ILLEGAL FINANCIAL INDUCMENTS TO PROVIDERS

148. The federal Anti-Kickback Statute ("AKS"), 42 U.S.C. §1320a-7b(b), is designed to ensure that physicians make clinical decisions based upon informed, impartial medical judgment – judgment unaffected by personal financial motives. FoxHollow knowingly and routinely violated that fundamental principle by corrupting the medical judgment of physicians across the country by giving medical providers inducements to use FoxHollow's device. These inducements include but are not limited to the following:

149. Marketing the Spread. As noted in the Applicable Law section above, the AKS is violated when a device manufacturer induces purchases of its device by "marketing the spread" between the cost of the device and the federal reimbursement for the device, since the spread is a financial inducement to purchase the device. FoxHollow's practice of promoting the reimbursement advantages of inpatient admission was a form of marketing the spread. The practice was intended to, and did, induce providers to use the device because of the profit they could make off of the device, and as such violated the AKS.

150. Payments to Host "Silverhawk Training" Events. FoxHollow paid doctors to hold so-called "Silverhawk Training" events that were a pretext to pay doctors for using the device over competing products. These events involved the presentation of several live Silverhawk cases to onlookers that needed to be trained on the procedure. Often, however, only a

FoxHollow employee would be in attendance. Typically the treating doctor would schedule several Silverhawk procedures on the day of the training, which meant that several Silverhawk devices would be used. Although ostensibly a training event, FoxHollow used the event as a financial inducement to persuade the "trainer" to treat his or her patients with the Silverhawk device over competing devices.

151. Providing Shares in FoxHollow to Clinical Investigators. FoxHollow provided physicians shares in the company in exchange for participating as Investigators for clinical trials of the Silverhawk device. Relator is informed and believes that a number of physician-investigators made huge sums of money when they cashed in these shares.

152. Speaker Honoraria and Related Fees. FoxHollow paid fees to high volume users of the Silverhawk device for speaking on behalf of the company and for related services, such as acting as Course Directors at symposiums, presenters of live Silverhawk cases for audiences, and acting as "preceptors" to FoxHollow employees and other doctors. Relator is informed and believes that one purpose of these fees was to induce the high volume users to continue using the Silverhawk device or to reward them for their past use of the device.

153. Relator is informed and believes that these and other inducements were intended to and did influence the recipients of these inducements to use the Silverhawk device in circumstances where the recipients would not have used the device had there been no financial inducements. In this manner, these practices violated the AKS. The recipients of these financial inducements are included among the defendants denominated as Doe Defendants 1-200 in this Complaint.

154. Claims submitted for services tainted by illegal kickbacks are ineligible for reimbursement by the Medicare Program, or other federal health care programs. Defendants

have submitted or caused others to submit such kickback-tainted claims in violation of the False Claims Act. As a consequence, the United States has been damaged in significant amount.

COUNT I
False Claims Act
31 U.S.C. §3729(a)(1)

155. Relator realleges and incorporates by reference the allegations in paragraphs 1-154.

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

157. Through the acts described above, Defendants have knowingly presented, or caused to be presented, false or fraudulent claims to the United States Government for payment or approval.

158. Through the acts described above, Defendants knowingly made, used, or caused to be made or used a false record or statement material to a false or fraudulent claim.

159. Through the acts described above, Defendants have conspired amongst themselves, and with various other individuals to commit a violation of the False Claims Act.

160. Through the acts described above, Defendants have knowingly made, used, or caused to be made or used a false record or statement material to an obligation to pay or transmit money or property to the Government, and knowingly concealed, avoided, or decreased an obligation to pay or transmit money or property to the Government.

161. The United States, unaware of the falsity or fraudulence of the statements, records or claims made or submitted by Defendants, their 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.

162. By reason of the Defendants' acts, the United States has been damaged, and

continues to be damaged, in a substantial amount yet to be determined.

Prayer

WHEREFORE, Relator prays for judgment against the Defendants as follows:

1. that Defendants cease and desist from violating 31 U.S.C. §3729 et seq.;

2. that this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. §3729;

3. that Relator be awarded the maximum amount allowed pursuant to §3730(d) of the False Claims Act;

4. that Relator be awarded all costs of this action, including attorneys' fees and expenses; and

5. that the United States and Relator recover such other and further relief as the Court deems just and proper.

Demand for Jury Trial

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

Dated: December 16, 2009

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