IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA
TAMPA DIVISION

UNITED STATES OF AMERICA; and
THE STATE OF FLORIDA,

ex rel. JON SCHIFF,

PLAINTIFF AND RELATOR,

v.

BLACKSTONE MEDICAL, INC.; ORTHOFIX INTERNATIONAL, N.V.; MARK BLAIR; FLORIDA IOM; NORTH BREVARD HOSPITAL DISTRICT, d/b/a, PARRISH MEDICAL CENTER; ARA JASON DEUKMEDJIAN; MILLENIUM MEDICAL MANAGEMENT, LLC, d/b/a, DEUK SPINE INSTITUTE; SUN DEUKMEDJIAN and BHARAT C. PATEL,

DEFENDANTS.

CIVIL ACTION NO.

FALSE CLAIMS ACT COMPLAINT AND DEMAND FOR JURY TRIAL

FILED IN CAMERA AND UNDER SEAL

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I. BACKGROUND

Jon Schiff ("Relator") brings this action on behalf of the United States of America ("United States") for treble damages and civil penalties arising from the conduct of Defendants Blackstone Medical Co. ("Blackstone"); Orthofix International, N.V. ("Orthofix"); North Brevard Hospital District ("NBHD"); d/b/a Parrish Medical Center ("PMC"); Florida IOM ("FIOM"); Mark Blair ("Blair"); Ara Jason Deukmedjian ("Deuk"); Millennium Medical Management, LLC ("MMI") d/b/a The Deuk Spine Institute ("Deuk SI"); Sun Deukmedjian ("Sun"); and Bharat C. Patel (Patel) [collectively referred to as "Defendants"] in violation of the Federal Civil False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA") and Stark Law, 42 U.S.C.§1395nn. The violations arise out of false claims for payment made to Medicare,

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Medicaid, TRICARE, Federal Employees' Health Benefits Program and other federally funded government healthcare programs (hereinafter, collectively referred to as "Government Healthcare Programs").

1. This action is also brought under the respective *qui tam* provisions of the Florida False Claims Act on behalf of the State of Florida. The State of Florida and the United States are hereafter collectively referred to as the Government.

2. As alleged herein, beginning as early as in or about 2002, Defendants Blackstone Medical, Inc. ("Blackstone"), Orthofix International, N.V. ("Orthofix"), Mark Blair ("Blair"), North Brevard Hospital District d/b/a Parrish Medical Center ("NBHD"), Florida IOM ("FIOM"), and later Defendants Deuk, Deuk SI and Patel, caused thousands of false claims to be made on federal and state health care programs. Defendants accomplished this by (a) engaging in a systematic program of "kickbacks" to doctors to entice them to use Blackstone's services through Blair and FIOM and their companies as the providers of Intraoperative Neurophysiological Monitoring ("IOM"); (b) billing for the services of uncertified and inadequately or untrained "technicians"; (c) billing for services which were not provided at all but identified as IOM type services; (d) fraudulent billing for the provision of off-site IOM reading services by physicians where the technology was not provided by the hospital; (e) fraudulent billing for reading of IOM data by physicians who claimed they were reading the data in real-time, but technology made real-time reading impossible; (f) hospitals billed for surgical procedures for which component parts, including IOM services, were never provided and therefore the billings were fraudulent, and; (g) billing and comingling in violation of the Stark Law between financially related physicians and entities.

3. These illegal actions and resulting false claims caused the federal and state governments to pay out funds that they otherwise would not have paid and unlawfully enriched Defendants.

4. Blackstone (later purchased and now owned by Orthofix) in particular has engaged in similar kickback schemes to promote its surgical hardware products, and is and has been the subject of federal indictments, plea agreements and other Qui Tam litigation (unrelated to the IOM kickbacks and frauds committed here). Mark Blair, as an agent and employee of Blackstone/Orthofix, has been personally involved in delivering cash payments and other forms of kickbacks to doctors including Deuk, and through him, Deuk SI, MMI and Sun.

II. FEDERAL JURISDICTION AND VENUE

5. The acts proscribed by 31 U.S.C. § 3729 *et seq.* and 42 U.S.C. § 1395nn, and complained of herein occurred in the Middle District of Florida and elsewhere, as Blackstone/ Orthofix does business in the Middle District of Florida and throughout the United States. Defendants NBHD, Deuk SI, FIOM and MMI are located in the Middle District of Florida and Blair, Deuk, Sun, and Patel are residents of the State of Florida and reside in the Middle District of Florida. Therefore, this Court has jurisdiction over this case pursuant to 31 U.S.C. § 3732 (a), as well as under 28 U.S.C. § 1345. This Court has supplemental jurisdiction over this case for the claims brought on behalf of the State of Florida, pursuant to 31 U.S.C. §3732(b) and/or 28 U.S.C. § 1367, inasmuch as recovery is sought on behalf of said State which arises from the same transactions and occurrences as the claims brought on behalf of the United States.

6. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391 because Blackstone/Orthofix and Florida IOM do business in Florida, Defendant NBHD is located in Florida and Blair, Deuk, Deuk SI, MMI, Sun and Patel are residents of the State of Florida. The corporate Defendants transact business and the individual defendants reside and

conduct business in Florida and one or more of the acts proscribed by section 31 U.S.C. §3729 occurred in this State.

7. This court has jurisdiction of the subject matter of this action pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1331 and has personal jurisdiction over defendants because they and each of them do business, and the individual defendants reside, in the Middle District of Florida.

8. The facts and circumstances alleged in this complaint have not been publicly disclosed in a criminal, civil or administrative hearing, nor in any congressional, administrative, or government accounting office report, hearing, audit investigation, or in the news media.

9. Relator is an "original source" of the information upon which this complaint is based, as that term is used in the False Claims Act.

III. PARTIES

10. The United States funds the provision of medical care, including surgical procedures and surgical monitoring services, for eligible citizens through Government Healthcare Programs such as Medicare, Medicaid, Federal Employees' Health Benefits Program, TRICARE/CHAMPUS, CHAMPVA, and other agencies and programs, acting through the Centers for Medicare & Medicaid Services ("CMS") within the U.S. Department of Health and Human Services ("HHS"), the Department of Defense, and other federal agencies.

11. Relator Jon Schiff is a citizen of the United States and a resident of the State of Texas. As described in further detail below, as a result of being solicited by NBHD to provide a contract offer for the provision of Intraoperative Neurophysiological Monitoring services, Schiff was provided access to information unavailable to the public and specifically information that forms the basis of this Complaint. He is the original source of the facts and information hereinafter set forth concerning the illegal activities of the Defendants.

12. Relator Schiff is an Electroneurodiagnoisic Technician and member of Synaptic Resourses, LLC, an Oklahoma limited liability company, and Synaptic Resources of Austin, LLC, a Texas limited liability company. (These two limited liability companies are collectively referred to as "SR.") SR was formed in 2005 and is headquartered in Tulsa, Oklahoma with operations in Oklahoma, Texas and Florida. Schiff resides in Austin, Texas. He received his Bachelor of Science (B.S.) degree in Multi-National Business from Florida State University in 1987 and is a Certified Neurophysiologic Intraoperative Monitoring Technologist. SR, of which Schiff is a founding member, is a Joint Commission accredited organization. The Joint Commission (JC) is an independent, not-for-profit organization that accredits and certifies more than 19,000 health care organizations and programs in the United States. JC accreditation and certification is recognized nationwide as a symbol of quality which reflects an organization's commitment to meeting certain performance standards with regard to quality and safety. Its mission is to continuously improve health care for the public, in collaboration with other stakeholders, by evaluating health care organizations and inspiring them to excel in providing safe and effective care of the highest quality and value.

13. Defendant Blackstone Medical, Inc. was the largest and fastest-growing privately-held spinal implant company in the world before it was purchased in 2006 by Defendant Orthofix International, N.V. (an international conglomerate based in Italy). Blackstone has a long and controversial history of government investigations into its business practices, including the alleged payment of kickbacks to induce doctors to use its surgical hardware. Blackstone's principal place of doing business is McKinney, Texas. Orthofix is a publicly traded company (NASDAQ exchange "OFIX") with corporate affiliates and subsidiaries in many states and one of its principal places of doing business in Texas.

14. Mark Blair is an employee of the Blackstone Company located in Florida, known as Florida IOM. Blair is both the sales representative for the company's surgical hardware and the technologist purportedly providing technical IOM services during surgical procedures for which government health care programs are billed. He has worked with doctors at and with NBHD for about thirteen (13) years and with doctor Deuk for more than seven (7) years. Blair is not certified by either of the two most respected certifying agencies, the American Society for Electroneurodiagnostic Technologists (ASET) or the American Board of Neurophysiologic Monitoring (ABNM), nor registered with the respected American Society of Neurophysiologic Monitoring or the American Society of Electrodiagnostic Technologists.

15. North Brevard Hospital District does business as Parrish Medical Center. PMC provides medical, surgical and related services to three of the largest communities in Florida and has operated for more than 16 years. NBHD has previously been investigated by the federal government for billing misconduct in regard to pneumonia services and, in 2000, NBHD entered into a "Corporate Integrity Agreement." Such an agreement generally provides for the [hospital] to engage in significant compliance efforts over a period of years, with independent review organizations conducting audits and reviews of the hospitals' inpatient coding, laboratory billing, hospital outpatient billing and financial relationships with physicians.

16. Ara Jason Deukmedjian is a physician with privileges at NBHD and other Florida hospitals. Deuk is a Board Certified Neuro-Spine Surgeon and founder, CEO and Medical Director of the *Deuk Spine Institute* according to the website for Deuk SI. In fact, Deuk SI is a fictitious name for Millennium Medical Management, LLC, a Florida limited liability company, whose members (owners) include Deuk and his wife, Sun Deukmedjian. *The Deuk Spine Institute* has two locations: 8043 Spyglass Hill Road, Melbourne, FL 32940; and 836 Century Medical Drive Titusville, FL 32796. In addition to NBHD, Dr. Deuk also performs spinal

surgery at other hospitals, including Weusthoff Medical Center in Melbourne, Florida. Dr. Deuk states on his website that he has personally performed thousands of spine surgeries.

17. Significantly, Deuk is also the Surgery Chair of the PMC Medical Credentialing Committee. In that capacity, Deuk (and Deuk SI) has (have) the ability to deny credentials to companies, groups or physicians who refuse to use Blackstone IOM technicians or refuse to accept Patel as the "reader" of IOM data. Deuk, through the use of the PMC Medical Credentialing Committee, has barred competitors to Blair and FIOM and other legitimate providers of IOM services and reading neurologists from practicing at PMC or providing services to PMC or NBHD, which has resulted in the continuation of fraudulent practices at this and other hospitals.

18. Sun is the wife of Deuk and is the managing member of MMI responsible for Deuk SI and the employer of Patel. She is also a member of other limited liability companies created by Deuk relating to his practice of medicine and medical billing.

19. Bharat C. Patel is a physician who has privileges to practice at NBHD and other hospitals in Florida, including the Weusthoff Medical Center. Patel is the only physician Deuk will allow to "read" the IOM data in procedures performed by him and other physicians and, not coincidentally, Patel is employed at and named the Director of Interventional Pain Management at the Deuk Spine Institute. Patel is board certified in physiatry, pain medicine, electrodiagnostic medicine and interventional pain management. He is also an Assistant Professor of Physical and Rehabilitation Medicine at the University of Central Florida's College of Medicine.

20. Wuesthoff Medical Center-Melbourne, Inc., now known as SCHF Medical Center – Melbourne, Inc. ("WMC") is a Florida non-profit corporation that operates a medical hospital in Melbourne, Florida. Deuk and Patel have hospital privileges at WMC and Relator believes that Blair serves as both sales representative for Blackstone and the technologist purportedly

providing IOM services during surgical procedures at the hospital. WMC allows Deuk and other surgeons to use Patel to purportedly read IOM data while Blair is in the operating room.

21. At all times relevant hereto, the corporate defendants acted through their/its agents and employees and the acts of defendants' agents and employees were within the scope of their agency and employment. The policies and practices alleged in this Complaint were, on information and belief, set or ratified at the highest corporate levels of these defendants.

IV. INDIVIDUAL PARTICIPANTS

22. Kenneth Jones was Vice-President of ambulatory care for PMC and worked with Schiff to contract for IOM services for the hospital. As Vice-President for ambulatory care, Jones oversaw perioperative services, including operating room services and special procedures. He was also responsible for planning, organizing and directing PMC's ambulatory care centers and providing operational oversight and patient care coordination in accordance with healthcare reform.

23. Fran Gerett is the Materials Manager for PMC.

24. Matthew Graybill is the Perioperative and Patient Care Coordinator for PMC. He is knowledgeable about the people, procedures and equipment utilized in the operating room.

25. George Mikitarian is PMC President and CEO.

26. Timothy Skeldon is PMC's Chief Financial Officer.

27. William K. Osmond is the Chief Executive Officer and managing member of SR.

28. Rich Manabel is President of Neuromonitoring Technologies, a firm akin to SR in Glenwood, Maryland, who has experienced similar fraudulent conduct in Maryland.

29. Shawn Anderson is the owner and founder of Northwest Neurodiagnostics, an IOM company in the State of Washington. Northwest Neurodiagnostics, a locally owned and operated IOM company, has been in business since 1992. It has the largest staff of board

certified technologists in the Pacific NW and provides online, real-time oversight by licensed neurologists. Like Schiff, Shawn Anderson has had similar Blackstone "kickback" directed interference with his business.

30. Joe Knight is the area sales manager for Cadwell Laboratories. He is familiar with the equipment available and used by Blair at all relevant times. He also observed Blair making a bribe-kickback payment to Deuk. Joe Knight was also familiar with the inability of Blair to communicate and share data with Patel in real-time during surgeries in the operating rooms of PMC when IOM was supposed to be available and for which it was billed.

31. Rod Hillis is a neurologist who works for the Lee Memorial Health System in Ft. Meyers, Florida. He was a former employee of the Deuk Spine Institute and was a "reading" doctor for Deuk's surgeries as well as other surgeries monitored by Blair. Hillis told Schiff there were never any "real-time" IOM reads done on Deuk surgeries or surgeries monitored by Blair.

V. THE FALSE CLAIMS ACT

32. The False Claims Act (hereinafter referred to as "FCA"), 31 USC § 3729, was originally enacted in 1863, and was substantially amended in 1986 by the False Claims Amendments Act, Pub.L. 99-562, 100 Stat. 3153. The FCA was further amended in May 2009 by the Fraud Enforcement and Recovery Act of 2009 ("FERA") and again in March 2010 by the Patient Protection and Affordable Care Act ("PPACA"). 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 fraud 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. The FCA was further amended in May 2009 by the Fraud Enforcement and Recovery Act of 2009 ("FERA")

and again in March 2010 by the Patient Protection and Affordable Care Act ("PPACA"). Both FERA and PPACA made a number of procedural and substantive changes to the FCA in an attempt to ease the burden on the government and Relators in investigating and prosecuting *qui tam* suits under the FCA.

33. The False Claims Act generally provides that any person who knowingly 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 material to a false claim, or conspires to engage in such conduct, 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.

34. The Act 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. Based on these provisions, Relator seeks, through this action, to recover all available damages, civil penalties, and other relief for state and federal violations alleged herein.

VI. FEDERAL HEALTHCARE PROGRAMS

35. In 1965, Congress enacted Title XVIII of the Social Security Act (known as "Medicare" or the "Medicare Program") to pay for the cost of certain medical services and care. Entitlement to Medicare is based on age, disability or affliction with certain diseases. See 42 U.S.C. §§1395 to 1395ccc. Outpatient prescription drugs are covered under Parts A-D of the Medicare Program.

36. In 1965, the Federal Government also enacted the Medicaid program. Medicaid is the nation's medical assistance program for the needy, the medically-needy aged, blind, and disabled and families with dependent children. 42 U.S.C. §§ 1396-1396v. Medicaid is largely administered by the states and funded by a combination of federal and state funds. The majority

of Medicaid funding, however, is provided by the Federal Government. Among other forms of medical assistance, the Medicaid programs cover outpatient prescription drugs. 42 U.S.C. §§ 1396a (10)(A) and 1396d (a)(12).

37. Medicare is the nation's health program for persons over 65 and the disabled. Medicare is funded by the Federal Government. Medicare Part B has long covered outpatient prescription drugs that are provided to a patient "incident to" a physicians' services, and drugs that are required for the effective use of durable medical equipment. 42 U.S.C. § 395x(s)(2)(A).

38. The Federal Employees' Health Benefits Program (FEHB) is a health care program for federal employees, retirees and their families. It is codified in 5 U.S.C.A. §8901 *et seq.* The fund is administered by the Treasury through the Federal Employee Health Benefit Fund (FEHBA). 5 U.S.C.A. §§8906, 8909. The program itself is administered by the Office of Personnel Management.

39. TRICARE Management Activity, formerly known as CHAMPUS, is a program of the Department of Defense that helps pay for covered civilian health care obtained by military beneficiaries, including retirees, their dependents, and dependents of active-duty personnel. 10 U.S.C. §§ 1079, 1086; 32 C.F.R. Part 199. TRICARE contracts with fiscal intermediaries and managed care contractors to review and pay claims, including claims submitted for surgical procedures.

40. The Department of Veterans Affairs ("VA"), through programs such as CHAMPVA and other programs, provides medical assistance, including surgical coverage, for discharged veterans as well as the spouses and children of deceased and disabled veterans.

41. Under the Medicare Act, 42 U.S.C. § 1395y(a)(1)(A), there is an express fundamental condition of payment: "no payment may be made [under the Medicare statute] for any expenses incurred for items or services which . . . are not reasonable and necessary for the

diagnosis or treatment of illness or injury." This condition links each Medicare payment to the requirement that the particular item or service be "reasonable and necessary." Medicaid, TRICARE, EHBP and other federally funded programs restrict coverage under the same principle.

42. Hospitals and doctors and other service providers participating in the Medicare, Medicaid and other federally funded Government Healthcare programs are required to comply with regulations promulgated by the government, including proper "coding" which is a billing standard explaining the nature of the charge. Standards for the provision of IOM services mandate that IOM be undertaken in an inpatient setting only. As the level of anesthesia may significantly impact the ability to interpret intraoperative studies, continuous communication between the anesthesiologist and the monitoring physician is expected when medically indicated. It is also expected that a specifically trained technician, preferably registered with one of the credentialing organizations such as the American Society of Neurophysiologic Monitoring or the American Society of Electrodiagnostic Technologists, will be in continuous attendance in the operating room, with either the physical or electronic capacity for real-time communication with the reading neurologist or other physician trained in neurophysiology.

43. Medicare and the other federally funded programs do not permit operating surgeons to submit claims under the IOM code. This is because a surgeon cannot perform the surgery while, at the same time, monitoring patients' data in real-time. Monitoring (also referred to as "reading") may be performed from a remote site, if a trained technician will be in continuous attendance in the operating room, with either the physical or electronic capacity for real-time communication with the reading physician. In addition technical criteria compliance is mandatory. This must include 16-channel monitoring and certain minimum real-time auditory capability connectivity between monitoring staff, operating surgeon and anesthesia. The

equipment must also provide for all of the monitoring modalities that may be applied with code 95920, which are auditory evoked response, electroencephalography/electrocorticography, electromyography and nerve conduction, and somatosensory evoked response.

44. There are separate components for the coded billing. When a provider submits a Medicaid or other governmental code billing which includes requests for payment for surgical or monitoring services that were not reasonable and necessary, were not provided at all, were not provided in the manner mandated by the government, or by persons not authorized to bill for the coded service or equipment, the claims for those expenses are legally false.

VII. THE ANTI-KICKBACK STATUTE

45. 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.

46. 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 or service for which payment may be made under a federally-funded health care program. 42 U.S.C. §1320a-7b (b). Under this statute companies and persons may not offer, pay or solicit to receive, any remuneration, in cash or kind, directly or indirectly, to induce hospitals, physicians or other health service providers to order, recommend or arrange for the purchase or lease of any item or service 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 request or bill for additional services or products provided by the company.

47. Violation of the Anti-Kickback statute subjects the violator to exclusion from participation in federal health care programs, civil monetary penalties, and imprisonment. 42 U.S.C. §§1320a-7(b)(7), 1320a-7a(a)(7).

48. Compliance with the Anti-Kickback law is a precondition to participation as a health care provider under the Medicare, Medicaid, FEHBP, CHAMPUS/TRICARE, and other federal health care programs. With regard to Medicaid, for example, each physician and hospital that participates in the program must sign a provider agreement with his or her state. Although there are variations in the agreements among the states, the agreement typically requires the prospective Medicaid provider to agree that he or she will comply with all Medicaid requirements, which include the anti-kickback and Stark Law provisions. In a number of states, the Medicaid claim form itself contains a certification by the provider that the provider has complied with all aspects of the Medicaid program, including compliance with Federal laws.

49. Likewise, with regard to Medicare, all providers and suppliers must complete a Medicare enrollment form before receiving payments from the programs. The following forms must be completed and submitted to the applicant's proper Medicare Contractor in their given region: (a) provider entities complete the CMS Form 855A to enroll in Medicare Part A; (b) supplier entities (*e.g.*, clinics and group practices) complete the CMS Form 855B to enroll in Medicare Part B; and (c) individuals (*e.g.*, physicians and other practitioners) complete CMS Form 855I. All three CMS 855 forms contain a materially identical certification that the applicant agrees to abide by all Medicare laws, including the anti-kickback statute and that payment is conditioned upon compliance with these statutes and regulations. The Certifications specifically state: "I understand that payment of a claim by Medicare is conditioned upon the

claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark Law), and on the provider's compliance with all applicable conditions of participation in Medicare." *See* CMS 855A at 37; 855B at 30; 855I at 25.

50. In sum, either pursuant to provider agreements, claims forms, or other appropriate 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 and the Stark Law.

51. Any party convicted under the Anti-Kickback statute must be excluded (i.e., not allowed to bill for services rendered) from federal health care programs for a term of at least five years. 42 U.S.C. §1320a-7(a)(l). Even without a conviction, if the Secretary of 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).

52. The enactment of these various provisions and amendments demonstrates Congress' commitment to the fundamental principle that federal health care programs will not tolerate the payment of kickbacks. Thus, compliance with the Anti-Kickback statute is a prerequisite to a provider's right to receive or retain reimbursement payments from Medicaid and other federal health care programs. Reimbursement is also prohibited by the general legal principle that providers who are corrupt or unethical or violate the integrity of a government program involving government funds are not entitled to payment from the public treasury for the resulting claims.

VIII. SUBSTANTIVE CLAIMS

A. Background.

53. IOM is used to identify compromise to the nervous system during certain surgical procedures. Neurodiagnostic tests such as evoked responses, EEG, EMG and TCMEP (transcranial motor evoked potential) are monitored for changes that could imply damage to the nervous system. The purpose of this monitoring is to immediately alert the surgeon so the surgical procedure may be altered to avoid permanent neurological damage. Such impairments may be due to correctable factors such as circulatory disturbance, excess compression from retraction, bony structures or hematomas, or mechanical stretching. Monitoring can also identify new systemic impairment; identify or separate nervous system structures, e.g., around or in a tumor; and demonstrate which tracts or nerves are still functional.

54. Health insurance programs, both government and private, recognize the value of IOM to reduce surgical morbidity and mortality and to help reduce the incidence and severity of medical malpractice lawsuits. The IOM monitoring and records provide evidence that there were no changes to a patient's neurological status related to surgical manipulation thereby preventing unwarranted litigation as well as significantly benefitting the surgical patient.

55. Reimbursement requirements for IOM are described in CMS national coverage policies and in Local Coverage Determination (LCD) – such as L 26800 for Trailblazer Health Enterprises – the Texas Medicaid contractor. This LCD is identical to the federal regulation, as are the LCD's in other states throughout the country.

56. Medicare and similar government health program regulations outline the procedures for which reimbursement will be authorized or coverage provided for intraoperative neurophysiological monitoring during surgery. The list contains some of the most delicate and detail oriented surgeries, including:

- Surgery of the aortic arch, its branch vessels or thoracic aorta, including internal carotid artery surgery, when there is risk of cerebral ischemia;
- Resection of epileptogenic brain tissue or tumor;
- Protection of cranial nerves, including:
  - Resection of tumors involving the cranial nerves;
  - Microvascular decompressive surgeries (i.e., trigeminal neuralgia surgery);
  - Skull base surgery in the vicinity of the cranial nerves and surgeries of the foramen magnum;
  - Cavernous sinus tumors;
  - Oval or round window graft;
  - Endolymphatic shunt for Meniere's disease;
- Vestibular section for vertigo;
- Correction of scoliosis or deformity of spinal cord involving traction on the cord;
- Decompressive procedures on the spinal column or cauda equina performed for myelopathy or claudication where the function of spinal cord or spinal nerves is at risk;
- During placement of internal spinal fixation devices, i.e., pedicle screws where nervous system function is at risk;
- Spinal cord tumors and spinal fractures (with the risk of cord compression);
- Neuromas of peripheral nerves or brachial plexus when there is risk to major sensory or motor nerves;

- Surgery or embolization for intracranial Arterio-Venous Malformations (AVMs);
- Embolization of bronchial artery AVMs or tumors;
- Arteriography during which there is a test occlusion of the carotid artery;
- Circulatory arrest with hypothermia;
- Distal aortic procedures when there is risk of ischemia to spinal cord;
- Leg lengthening procedures when there is traction on the sciatic nerve;

57. IOM will also be considered for other procedures in which the nervous system is at risk for intraoperative injury with the submission of documentation supporting the medical necessity.

58. Due to the nature of these services and the potential for significant morbidity in some procedures requiring intraoperative monitoring, Medicare expects to see these services used in the inpatient setting only. As the level of anesthesia may significantly impact the ability to interpret intraoperative studies, ***continuous*** communication between the anesthesiologist and the monitoring (also referred to as "reading") physician is expected.

59. It is also expected that, if the reading-physician is not physically present in the operating room during surgeries, a specially trained technician be in continuous attendance in the operating room with the physical or electronic capacity for real-time communication with the reading physician who is normally a neurologist or physician trained in neurophysiology.

60. If a technician is responsible for the operating room monitoring and communication, it is preferable that he be registered with one of the credentialing organizations such as the American Society of Neurophysiologic Monitoring or the American Society of Electrodiagnostic Technologists.

61. The billing for the IOM procedure involves the hospital, technician, equipment for communicating the data and the physician reading that data in real-time. There are also document maintenance requirements of government health care programs mandating that these materials remain available for government inspection for a number of years following the surgical monitoring.

62. Due to the potential risk for morbidity with many of the above-noted surgeries and the need for explicit and focused attention to both the monitoring and the procedure, Medicare does not allow operating surgeons to submit claims for this code.

63. Monitoring may be performed from a remote site as long as a trained technician is in continuous attendance in the operating room, with either the physical or electronic capacity for real-time communication with the reading physician. Technical criteria are mandatory and currently include 16-channel monitoring and minimum real-time auditory capacity with the possible addition of video connectivity between monitoring staff, operating surgeon and anestheologist. The equipment must also provide for all of the monitoring modalities that may be applied with code 95920, which are auditory evoked response, electroencephalography /electrocorticography, electromyography and nerve conduction, and somatosensory evoked response. Undivided attention to a unique patient during the critical part of the surgery requiring the neuromonitoring is expected.

64. Although IOM has become the *de facto* standard of care for many surgeries, it is not a mandatory part of the surgical procedure but rather must be prescribed by the doctor performing the surgery. If IOM services are available, however, most hospitals will routinely approve the surgeon's request. The surgeon normally completes an IOM request form when scheduling the procedure which asks the hospital to provide IOM and that all modalities performed be interpreted in real-time by a reading neurologist via a secure high-speed internet

data and audio capability. The IOM provider bills the hospital a set fee for each surgery monitored pursuant to a negotiated contract.

65. Blair, through FIOM, Blackstone and Orthofix had been providing IOM services to NBHD, WMC and (upon belief) other facilities for years.

66. When Kenneth Jones was hired by NBHD, he was concerned about the high cost to NBHD for IOM monitoring by Blackstone/Blair/FIOM. In his prior experience with St. Vincent's Healthcare, in Jacksonville, Florida, where he was director of neuroscience, orthopedics, and surgical services, Jones was aware of the requirements for proper IOM monitoring and cost of these services when provided by quality companies and technologists such as SR and Schiff.

67. Under the IOM provider agreement with Blackstone/Blair/FIOM, NBHD was billed and paid approximately one-thousand dollars ($1,000) per surgical procedure monitored. This was in addition to funds paid for the services of other billing parties. Blair, who has been providing these services for about ten years, has billed for thousands of surgical monitoring procedures.

68. The hospitals, surgeons and reading neurologists each use separate Current Procedural Terminology (CPT) codes and bill their charges directly to the appropriate government or private sector health care insurer. CPT codes describe the specific procedures and services performed by physicians and other health care providers. In order to obtain reimbursement, the reading doctor cannot also be the operating surgeon. There are a variety of CPT codes utilized for IOM monitoring, including: Intraoperative Neurophysiology **95920**: This code is used by the reading doctor and is billed ***per hour***. It provides for ongoing electrophysiologic testing and monitoring performed during surgical procedures and cannot be billed by itself, but must be used as an add-on code with the primary surgical procedure. There

are additional codes which are added to **95920** and charged for the various modalities that the reading doctor claims to have been monitoring.

69. It is not uncommon for the reading doctor to charge between six hundred and eight hundred dollars per hour, resulting in billing to governmental or private health care programs of several thousand dollars *per surgical procedure*. As discussed above, to bill for any of these procedures, Medicaid and Medicare regulations uniformly require that the reading doctor be monitoring the data from the operating room in real-time.

70. North Brevard Hospital District, which does business as Parrish Medical Center, makes extensive use of IOM during surgical procedures.

71. On or about January 31, 2011, Schiff was asked by Kenneth Jones, to provide a proposal to provide IOM services at PMC. Jones had previously contracted with Schiff to provide IOM at St. Vincent's and consequently was familiar with the quality service provided by SR. PMC was concerned about the high rate being charged for IOM services by the current provider – Mark Blair.

72. In order to provide PMC with the contract proposal that Jones requested, on or about January 31, 2011, Schiff conducted a review of the current IOM procedures, provider and the equipment being used in the operating room. This investigation was authorized and permitted by Kenneth Jones.

73. In making his due diligence/pre-contract investigation, Schiff was shocked to discover that the monitoring equipment used by Blair and PMC for the previous decade – was an Axon Sentinel – equipment that was developed in 1992.

74. The model of Axon Sentinel at PMC was so outdated it could not make a real-time internet connection. Because the equipment could not send any signals from the Operating Room to a remote site for real-time reading, no physician could have been monitoring the data in

real-time, unless he or she had been physically present in the operating room. As will be explained below, no "reading" physician was in the operating room nor able to read the IOM data, in real-time, for the entire period that Blair was serving as the "technician" for IOM procedures. As a result, literally thousands of fraudulent IOM billings were submitted to Medicare / Medicaid and other government programs by the Defendants, including and especially the "reading doctor," in most instances, Patel.

75. In addition, the old equipment was so large and bulky that it was basically a permanent fixture in the Operating Room, a constant reminder and notification to hospital administration of the outdated and obsolete equipment purportedly being used by Blair and Patel.

76. Shortly after Schiff learned about the obsolete equipment, he recognized the false billing implications. He had a meeting with Kenneth Jones about the situation, revealing the information he had obtained. Also present at this meeting were Fran Gerrett, Materials Manager; Tina Spangler, Operations Manager; and Matthew Graybill, Perioperative and Patient Care Coordinator.

77. It was evident that NBHD had knowledge of the fraud. Graybill told Schiff that Blair never speaks to any patients, does not get patient consent to monitor their surgical procedures and Graybill has never seen Blair fill out any IOM patient reports.

78. Graybill also admitted to Schiff that he believed that Blair was/is paying-off Deuk and possibly another physician at the hospital, Dr. Joseph E. Rojas, to monitor their surgical procedures. Rojas has privileges at NBHD and is an orthopedic surgeon.

79. Graybill's observations and statements confirmed that the billing of all procedures by Blair purportedly "read" by Patel were fraudulent. Graybill, who was in the position to know, stated to Schiff that he had never seen Dr. Patel set foot in the hospital, nor had he ever seen Blair call Patel from the operating room during any surgical procedure.

80. Deuk, Deuk SI and Sun have effectively prevented other neurologists from reading IOM data at these hospitals.

81. Using the obsolete equipment available, the thousands of IOM procedures billed to governmental agencies by Defendants are false claims. There was no real-time reading of IOM data, Blair did not communicate telephonically with Patel from the operating room and Patel was not present at the hospital to read the IOM data in person.

82. Rod Hillis is a neurologist who works for the Lee Memorial Health System in Ft. Meyers, Florida. He was a former employee of the Deuk Spine Institute and was a "reading" doctor for Deuk's surgeries as well as other surgeries monitored by Blair. On July 27, 2011, Dr. Hillis told the Relator that he left the Deuk Institute several years ago "because he had issues with Dr. Deuk's antics." Hillis told Schiff there were never any "real-time" reads done on Deuk surgeries or surgeries monitored by Blair. All of the IOM data on these operations were read as "paper reads" after the surgeries were completed.

B. Blackstone, Orthofix, FIOM and Blair Paid Kickbacks to Physicians to Induce them to Use, Order, Recommend and Arrange for their IOM Products and Services Which were Billed to Government Programs.

83. In March 2010 or thereabouts, Blair was observed to pass Deuk an envelope filled with cash. This payoff occurred shortly before a surgical procedure in which Dr. Deuk was involved that was set to begin at PMC.

84. Joe Knight, who witnessed the payoff, is an IOM equipment salesman for Cadwell Laboratories, a manufacturer of the equipment for IOM. Joe Knight knew Blair because Blair had discussed purchasing equipment from Cadwell.

85. As Blair passed the payoff to Deuk, Mr. Knight overheard Blair say to Deuk, "Here's the amount that we agreed upon." Later Blair admitted to Knight that he had made the

payment to Deuk, bragging that "it cost me over 20K to get Deuk's business—but it was worth it."

86. The kickback paid by Blair to Deuk, his observations and what he heard and had been told were disturbing to Joe Knight. When he attended the March 5, 2010 American Society of Neurophysiological Monitoring (ASNM) meeting in Clearwater, Florida shortly after the kickback revelations, he recounted what he had heard and seen to Joe Melvin, SR's manager and a close colleague of Schiff.

87. Deuk has refused to work with any other technologist except Blair and, as chair of the Medical Credentialing Committee at PMC, has prevented any other technologist from conducting IOM processes at the hospital. Similarly, Deuk would only allow Patel to "read" IOM data purportedly obtained by Blair and read in real-time. Deuk mandated that doctors at PMC utilize Patel who also "reads" IOM data for other doctors and at other hospitals, likely under the same fraudulent conditions.

88. During Schiff's negotiations with NBHD and, after he disclosed the results of his investigation and concerns about billing to Kenneth Jones and others present at the meeting, NBHD hired two additional neurologists who would be available to read IOM data. One of the "new" doctors, Vesna Micik, introduced herself to Deuk and was shocked at how rudely he treated her. Deuk advised Micik that he would not allow her to do any IOM readings for him. Deuk has also rebuffed all attempted contacts by SR and told Schiff he would not allow SR to monitor his surgical procedures. All of this information was relayed to Jones.

C. Deuk, Deuk SI, MMI, Sun and Patel Solicited and Received Bribes/Kickbacks for Using Blair's Intraoperative Neurophysiological Monitoring Services.

89. Blair's statement to Deuk as he handed over cash outside the operating room of Parrish Medical Center shows that Deuk not only received the bribe, but negotiated with Blair as to the amount.

90. NBHD was aware of the bribery but failed to report it, failed to stop it and continued to bill for services knowing they were fraudulent. PMC's high level employee, Graybill, who may never have seen the cash payment from Blair to Deuk outside the PMC operating room, told Schiff that he (and therefore the hospital) knew of the kickback scheme. Graybill even implicated another doctor at the hospital, Rojas, in the scheme. Relator has no knowledge relating to Rojas aside from statements made by Graybill.

91. Soliciting the bribes and kickbacks and allowing the systematic payments to be made in exchange for services fraudulently charged to the United States and the State of Florida violates the False Claims Act and the Kickback provisions of law.

D. The Defendants Knowingly Billed the Government and Collected Funds for Services Never Performed or Performed in Knowing Violation of Medicaid Regulations.

92. Throughout the past nine to ten years, NBHD has charged the United States and the State of Florida for surgical services that it knew were not being provided, indeed, were impossible because of the lack of communication capacity of the IOM equipment purportedly used by Blair to communicate data, *in real-time* to a physician who was at a "remote" location. Further, Blair, the surgeons requesting authorization for using the IOM, including Deuk, Deuk SI, MMI and Sun and the purported "reading" physician, Patel, were involved in the scheme and, as each billed Medicaid and other federal programs, every claim submitted was a "false claim" under the act.

93. Further proof was obtained by Schiff that Patel did not read IOM data that NBHD, Blair and other defendants charged to the government. During the contract negotiations between SR and Kenneth Jones for NBHD and, as a result of the information Schiff disclosed, Jones asked Dr. Patel to produce records for the most recent thirty (30) patients whose surgical procedures were ostensibly "read" by him. Patel is required to keep these records for a minimum of seven years or until the patient is eighteen years old, whichever is longer. Jones had to make this demand three times before Patel produced any documents. When he finally did produce some documents, they were evidently forged, and not well forged at that.

94. Jones told Schiff that Patel's records appeared to be identical photocopied reports with only the patient name changed. These photocopies did not provide the information mandated by Medicaid and other government agencies or the standard of the industry. Each document merely reflected that IOM has been performed. Patel, Deuk SI, Sun and MMI could not produce the read-out charts or other detailed information that IOM reports routinely contain, such as: type of IOM equipment utilized; a history of the patient's illness; diagnosis; type of surgical procedure; date of surgery; time surgery started; modalities tested (EEG,EMG, SSEP, TCMEP, etc.); time of first incision; time surgery ended; specific information about the type of surgical procedure performed; the modalities monitored; and the chat log documenting the conversation between the technologist and the reading doctor which is typed into the computer during the procedure.

95. The value of the IOM monitoring is, in its simplest terms, to inform the surgeon of neurological incidents to avoid, in real-time, as the surgery is underway, and to make a record that can be used after the surgery to prove that neurological damage was not the result of the surgery.

96. Patel, through his employer and likely record keepers, Deuk SI, MMI and Sun, was unable to produce routinely kept records of his purported neurological "reading" services.

97. As a result, Relator believes that all bills submitted to Medicare and other government programs by Patel (or the other defendants on his behalf) for real-time reading of surgical procedures at PMC are false claims. Upon information and belief, Patel is also the reading doctor for other surgeons at PMC and for surgical procedures at other hospitals throughout the region such as Weusthoff Medical Center in Melbourne, Florida. Patel has submitted false claims to Medicare and other governmental health care programs for the professional component of IOM services in thousands of surgical procedures.

98. The remaining Defendants induced the false claims through a scheme to prevent competition by neurologists and other physicians who would have actually provided these services, by paying kickbacks to Deuk and doctors throughout the State of Florida and other states.

99. In or about 2010, Blair and his employers became aware of increasing scrutiny and so Blair arranged to purchase a newer model of the Cadwell equipment. Blair was aware of his improper billings and, as a result, purchased a new machine with real-time monitoring capability from Cadwell Laboratories in 2010. This machine was ostensibly to replace the equipment at PMC.

100. Blair told Knight that he needed to buy the new monitoring equipment so he "could get online." Joe Knight, the area sales representative for Cadwell -- a maker of state of the art IOM equipment -- had three models to offer Blair: the Cascade, Cascade Elite and Cascade Pro. All of the models had built-in remote monitoring capability, giving the remote neurologist the ability to view data in real-time. Each model required the reading physician to

log on with a unique, secure, individual pass code. According to Knight, Patel never logged on to the new model purchased by Blair.

101. The hospital had internet available in the operating room which required authorized access. Although Blair purchased a real-time capable system in 2010, the hospital never provided internet access for the IOM equipment until on or after April 2011. There was no other means of "hooking up" the new equipment in the operating room to allow real-time monitoring and, as indicated above, Patel never logged on to the new equipment.

102. In March of 2011, after Blair learned that NBHD was attempting to replace him, he made frantic efforts to bring the new monitoring equipment on-line. By then, NBHD knew that others, including Schiff, were aware that IOMs were being fraudulently billed to the government.

103. Deuk also knew that NBHD had entered into a contract with SR to provide IOM services to the hospital and planned to exclude Patel from reading data output. It was during this time that Deuk used the hospital's credentialing committee, of which he was the chair, to coerce NBHD to void the contract with SR.

104. Although Blair purchased the Cascade model from Knight, the equipment was never used until Relator exposed the real-time monitoring problem. Despite trying on several occasions to train Blair on the operation of the new equipment, Knight advised Schiff that Blair never mastered the necessary training. In addition, although Knight loaded the software necessary for remote reading onto Patel's computer, Patel neither requested nor activated the software security code necessary to establish a remote connection. Each computer code is unique and documents each time the computer is logged on to read IOM signals. As a result, even if Blair was able to operate the new monitoring equipment, Patel still did not receive any signals and therefore never read any IOM data in real-time.

105. Patel's computer is likely the property of Deuk, Deuk SI, MMI and Sun and each of these Defendants was aware that the access to real-time communication had not been activated. Blair and his employers were also aware. Nonetheless, Patel and these defendants continued to bill government agencies for reading services by Patel and the hospital(s) allowed this charade to continue.

106. Knight stated that the new monitoring machine has been in use only since April, 2011. The old Axon equipment was still being "used" during surgical procedures before that time.

107. NBHD is designated as a "Disproportional Share Hospital" which treats significant populations of Charity, Medicaid and Medicare patients. Relators believe that, about 80% of the surgical procedures performed at NBHD are billed to Medicare and that NBHD, Deuk and Patel have billed the federal health care program for thousands of improper surgical procedures. Any bills that may have been submitted by NBHD to Medicare for these surgical procedures that included reimbursement of IOM charges are arguably false claims as well. NMHD knew that the services provided by its subcontractor, Blackstone / Blair, did not meet the requirements for real-time reading necessary for Medicare reimbursement.

108. The scheme to bribe surgeons and "reading" physicians by paying kickbacks is a common method of operation for Blackstone. Illustrative is a similar scheme in Maryland[1] and Washington and possibly other states.[2] Rich Mathabel, President of Neuromonitoring Technologies in Glenwood, Maryland, who is a competitor and professional colleague of

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[1] This information may be sufficient to allege a claim under Maryland's False Health Claims Act of 2010, § 2-602 and Relator reserves the right to amend the complaint to include said claim.

[2] The pattern identified by Relator provides evidence that false claims induced or made by Defendants have been submitted in additional States.

Relator, has had a similar experience dealing with a Blackstone company – Maryland IOM. Mathabel's company had provided IOM services for two Maryland hospitals, Montgomery General in Olney and Good Samaritan in Baltimore for more than a decade. Mathabel was suddenly told in August, 2010, that Montgomery General would no longer utilize Neuromonitoring Technologies for IOM services at the hospital. Good Samaritan followed suit and terminated its long-term relationship with Neuromonitoring Technologies on or about January 1, 2011. Administrators at both hospitals were seemingly disconcerted by the decision and would only say they were changing to Blackstone Medical for IOM services at the request of their surgeons, such as Navinder Sethi, MD. It is revealing that, at both hospitals, only the surgeons using Blackstone surgical hardware demanded the change. Less than a year later, however, Good Samaritan requested that Mathabel's company return to the hospital to provide IOM services for all of its surgical procedures. Montgomery General also rehired Neuromonitoring Technologies, but only for Medicare procedures. Relator believes these decisions were the result of enhanced kickback enforcement from Medicare regulators against companies like Blackstone. Upon information and belief, Blackstone may currently be under investigation by the United States Attorney's office in Boston.

109. Another colleague of Schiff's was also the target of Blackstone's scheme. Shawn Anderson, the owner and founder of Northwest Neurodiagnostics, had a nearly identical experience. Northwest Neurodiagnostics, a locally owned and operated IOM company located in the state of Washington, has been in business since 1992 with no history of malpractice. It had the largest staff of board certified technologists in the Pacific NW and provided online, real-time oversight by licensed neurologists. In October, 2010, Anderson was told by Auburn Regional Medical Center that his company was being replaced by NW Monitoring, LLC, a Blackstone company. Anderson's company had provided IOM services at Auburn Regional for many years

and the Blackstone company was neither cheaper nor more experienced. Consistent with the pattern in Florida and Maryland, the Washington hospital administrators were opposed to the change but would only say that the "surgeons" insisted on Blackstone.

E. Fraudulent Billings Violated the Stark Law.

110. Deuk refers all of his surgical patients to Patel in violation of the Stark Law. He reiterated this position to neurologists retained by NBHD to provide IOM reading services under the SR contract, including Dr. Vesna Micik. When Dr. Micik approached Deuk, after being retained by NBHD to read IOM data in conjunction with the SR contract, Deuk advised her that he would not allow her to read any IOM data for his patients. Deuk has insisted that only Patel read IOM data for his surgical patients.

111. Other Deuk SI physicians refer their surgical patients to Patel in violation of the Stark Law.

112. Patel, as an employee of Deuk SI, comingled funds that he had been paid by Medicaid and other governmental payors with Deuk, Deuk SI, MMI, and Sun for IOM "reading" for surgeries performed by Deuk and other physicians employed by Deuk SI, and as a result he and each of them have violated the Stark Act.

113. NBHD was aware of the relationship between Deuk and Patel and authorized this unlawful referral of services between the surgeon (Deuk) and reading physician (Deuk). Indeed, by allowing Deuk to chair the surgical Medical Credentialing Committee of the hospital, NBHD gave Deuk the authority to effectively exclude other neurologists from reading IOM data during surgical procedures.

114. Deuk, Deuk SI and the other Defendants failed to report the referral relationship as required by the Stark Law.

COUNT I

FALSE CLAIMS ACT
31 U.S.C. §3729(a)(1)(A) and (C) (2010)

115. Relator repeats and realleges each allegation contained in paragraphs 1 through 114, above as if fully set forth herein.

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

117. Defendants, individually and by and through its officers, agents, employees, related companies, subsidiaries and holding companies, knowingly presented, or caused to be presented, a false or fraudulent claim for payment or approval in violation of 31 U.S.C. § 3729(a)(1)(A)(2010).

118. As set forth in the preceding paragraphs, Defendants conspired with each other and others in paying and receiving illegal kickbacks, billing for IOM services that were not provided or provided in violation of governmental regulations, and, in a campaign to defraud the United States by getting false and/or fraudulent Medicare, Medicaid, FEHB, TRICARE and other Government health care claims paid in violation of 31 U.S.C. § 3729(a)(1)(C) (2010).

119. Defendants, individually and by and through its officers, agents, and employees, authorized and encouraged the actions of its various officers, agents, and employees to take the actions set forth above.

120. As a result of the acts of Defendants, the United States Government reimbursed physicians and hospitals for IOM procedures that it otherwise would not have paid.

121. Each IOM procedure approved by NBHD or other hospitals as described herein, and billed by NBHD or the other the hospital(s), Blair, Deuk, Deuk SI, MMI, Sun, Patel and

other physicians who were bribed by Defendants represents a false or fraudulent record or statement.

122. Every IOM billed by Blair, PMC, Patel, Deuk SI, MMI and Sun for reading of IOM data by Patel submitted to a federal health insurance program represents a false or fraudulent claim for payment.

123. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid for thousands of IOM procedures for surgeries conducted by Deuk and Deuk SI employees and read by Patel that they otherwise would not have paid for but for Defendants' fraudulent and illegal conduct. These IOM procedures which were incapable of providing a benefit to the patients as there was no real-time reading of the data, and the corresponding claims to federally funded health care programs were a foreseeable and intended result of Defendants' illegal acts.

124. As set forth in the preceding paragraphs, Defendants have knowingly violated 31 U.S.C. § 3729 *et seq.* and have thereby damaged the United States Government. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500 and not more than $11,000 for each false claim paid or approved.

WHEREFORE, Relator respectfully requests this Court enter judgment against Defendants, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.* provides;

(b) That civil penalties of $11,000 be imposed for each and every false claim that Defendant caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT II

FALSE CLAIMS ACT
31 U.S.C. §3729(a)(1)(B) and (C) (2010)

125. Relator repeats and realleges each allegation contained in paragraphs 1 through 114, above as if fully set forth herein.

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

127. Defendants, individually and by and through its officers, agents, employees, related companies, subsidiaries and holding companies, knowingly made, used, or caused to be made or used, false records or statements material to a false or fraudulent claim in violation of 31 U.S.C. § 3729(a)(1)(B) (2010).

128. As set forth in the preceding paragraphs, Defendants conspired with each other and private physicians, health care providers, and other third-party interests who assisted Defendants in perpetuating its fraudulent conduct of IOM procedures which were being conducted using equipment unable to transmit in real-time, were not monitored in person or in

real-time and otherwise conducted in a manner unacceptable and in violation of Medicaid and related government regulations to defraud the United States by getting false and/or fraudulent Medicare, Medicaid, FEHB, TRICARE and other Government health care claims paid in violation of 31 U.S.C. § 3729(a)(1)(C) (2010).

129. Defendants, individually and by and through its officers, agents, and employees, authorized and encouraged the actions of its various officers, agents, and employees to take the actions set forth above.

130. As a result of the acts of Defendants, the United States Government reimbursed physicians and hospitals for procedures that it otherwise would not have paid had Defendants not given kickbacks and other inducements to physicians and had Defendants not presented false or misleading information to promote the exclusive use of Blair and other Blackstone unqualified IOM technicians and physician "readers."

131. Every billing for IOM services as a result of Defendants' illegal conduct and/or illegal inducements represents a false or fraudulent record or statement. Each claim for reimbursement for such, submitted to a federal health insurance program, represents a false or fraudulent claim for payment.

132. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in substantial amount to be determined at trial. Federal health insurance programs have paid numerous claims for IOM and related services billed by hospitals, Blair, Deuk, Deuk SI, MMI, Sun, Patel and others for IOM services that were not provided or provided on equipment unable to provide transmission capacity and therefore not "read" in real-time, services for which they otherwise would not have paid for but for Defendants' fraudulent and illegal conduct. These false claims to federally funded health care programs were a foreseeable and intended result of Defendants' illegal acts.

133. As set forth in the preceding paragraphs, Defendants have knowingly violated 31 U.S.C. § 3729 *et seq.* and have thereby damaged the United States Government. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not less than $5,500 and not more than $11,000 for each false claim paid or approved.

WHEREFORE, Relator respectfully requests this Court enter judgment against Defendants, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the U.S. because of the false claims alleged within this Complaint, as the Federal Civil False Claims Act, 31 U.S.C. § 3729 *et seq.* provides;

(b) That civil penalties of $11,000 be imposed for each and every false claim that Defendant caused to be presented to the Government Healthcare Programs under the Federal False Claims Act;

(c) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(d) That the Relator be awarded the maximum amount allowed pursuant to the Federal False Claims Act; and

(e) That the Court award such other and further relief as it deems proper.

COUNT III

STARK LAW
42 U.S.C. §1395nn(a)(1)

134. Relator repeats and realleges each allegation contained in paragraphs 1 through 114, above as if fully set forth herein.

135. This is a claim for treble damages and penalties under the Stark Law, 42 U.S.C. § 1395nn, *et seq.*, as amended.

136. Defendants, individually and by and through their officers, agents, employees, related companies, subsidiaries and holding companies, knowingly made prohibited referrals to related physicians and entities for the furnishing of designated health services and presented claims or bills for designated health services in violation of 42 U.S.C. § 1395nn (2010).

137. Defendants, individually and by and through its officers, agents, and employees, authorized and encouraged the actions of its various officers, agents, and employees to take the actions set forth above.

138. As a result of the acts of Defendants, the United States Government reimbursed physicians and hospitals for procedures that it otherwise would not have paid had Defendants properly reported their relationship.

139. Every billing for IOM services as a result of Defendants' illegal conduct represents a prohibited referral. Each claim for reimbursement for such, submitted to a federal health insurance program, represents an unlawful billing or claim.

140. By reason of Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial. Federal health insurance programs have paid numerous claims for services provided by related physicians and entities

prohibited by the Stark Law. These prohibited claims to federally funded health care programs were a foreseeable and intended result of Defendants' illegal acts.

141. As set forth in the preceding paragraphs, Defendants have knowingly violated 42 U.S.C. § 1395nn *et seq.* and have thereby damaged the United States Government. The United States is entitled to three times the amount by which it was damaged, to be determined at trial, plus a civil penalty of not more than $15,000 for each prohibited claim paid or approved, and not more than $100,000 for each arrangement or scheme.

142. As set forth in the preceding paragraphs, Defendants have knowingly violated 42 U.S.C. § 1395nn (f) *et seq.* by failing to report information require by law and thereby damaged the United States Government. The United States is entitled to $10,000 per day for each day for which reporting was required.

WHEREFORE, Relator respectfully requests this Court enter judgment against Defendants, as follows:

(a) That the United States be awarded damages in the amount of three times the damages sustained by the U.S. because of the prohibited referral and claims alleged within this Complaint, as the Stark Law, 42 U.S.C. § 1395nn *et seq.* provides;

(b) That civil penalties of $15,000 be imposed for each and every prohibited bill or claim that Defendants caused to be presented to the Government Healthcare Programs under the Stark Law;

(c) That other civil sanctions and penalties including reimbursement for all payments made in violation of the Stark Law, $100,000 for the scheme and $10,000 per day for failure to report;

(d) That pre- and post-judgment interest be awarded, along with reasonable attorneys' fees, costs, and expenses which the Relator necessarily incurred in bringing and pressing this case;

(e) That the Relator be awarded the maximum amount allowed pursuant to the Stark Law and Federal False Claims Act; and

(f) That the Court award such other and further relief as it deems proper.

COUNT IV

FLORIDA FALSE CLAIMS ACT

143. Relator repeats and realleges each allegation contained in paragraphs 1 through 114, above as if fully set forth herein.

144. This is a *qui tam* action brought by Relator on behalf of the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

145. Fla. Stat. § 68.082(2) mandates liability for any person who:

(a) knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;

(c) conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid.

146. In addition, Fla. Stat. § 409.920 makes it a crime to: (c) knowingly charge, solicit, accept, or receive anything of value, other than an authorized copayment from a Medicaid recipient, from any source in addition to the amount legally payable for an item or service provided to a Medicaid recipient under the Medicaid program or knowingly fail to credit the agency or its fiscal agent for any payment received from a third-party source;... (e) knowingly, solicit, offer, pay or receive any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for referring an individual to a person for the furnishing of any item or service for which payment may be made, in whole or in part, under the Medicaid program, or in return for obtaining, purchasing, leasing, ordering, or arranging for or recommending, obtaining, purchasing, leasing, or ordering any goods, facility, item, or service, for which payment may be made, in whole or in part, under the Medicaid program.

147. Fla. Stat. §456.054(2) also prohibits the offering, payment, solicitation, or receipt of a kickback to a healthcare provider, whether directly or indirectly, overtly or covertly, in cash or in kind, in exchange for referring or soliciting patients.

148. Defendants violated Fla. Stat. § 409.920(c) and (e) and §456.054(2) by engaging in the conduct described herein.

149. Defendants further violated Fla. Stat. § 68.082(2) and knowingly caused false claims to be made, used and presented to the State of Florida by deliberate and systematic violation of federal and state laws, including the FDCA, federal Anti-Kickback Act, Fla. Stat. § 409.920(c) and (e) and §456.054(2) and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government-funded healthcare programs.

150. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers, physicians and third party payers in connection therewith.

151. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was a condition of payment of claims submitted to the State of Florida in connection with Defendants' conduct. Compliance with applicable Florida statutes, regulations and requirements was also a condition of payment of claims submitted to the State of Florida.

152. As a result of the acts of Defendants, the State of Florida reimbursed physicians, hospitals and others for treatments that it otherwise would not have paid had Defendants not engaged in the conduct described herein, had Defendants not given kickbacks and other inducements to themselves and other physicians and hospitals.

153. Each charge for IOM services that was submitted as a result of Defendants' illegal practices, reporting or failure to report and/or illegal inducements represents a false or fraudulent record or statement. Each claim for reimbursement for such claims submitted to the State of Florida for reimbursement represents a false or fraudulent claim for payment.

154. As a result of Defendants' violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged.

155. Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who has brought this action pursuant to Fla. Stat. § 68.083 (2) on behalf of himself and the State of Florida.

156. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relator respectfully requests this Court to award the following damages to the following parties and against Defendants:

To the State of Florida:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of Defendants' conduct;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim which each Defendant caused to be presented to the State of Florida;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To Relator:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses which Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States and the State of Florida, and on his own behalf, demands judgment against Defendants, and each of them, as follows:

A. That Defendants cease and desist from violating 31 U.S.C. §3729 *et seq.* and the equivalent provisions of the state statutes set forth above;

B. That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $11,000 for each false claim, together with the costs of this action, with interest, including the cost to the United States Government for its expenses related to this action;

C. That this Court enter judgment against Defendants, and each of them, for the maximum amount of actual damages and civil penalties permitted under the false claims statutes of the State of Florida;

D. That this Court enter judgment against the Defendants in an amount equal to three times the amount of damages the United States Government has sustained because of Defendants' actions, plus a civil penalty of $15,000 for each bill or claim submitted in violation of the Stark Law, together with the costs of this action, with interest, including the cost to the United States Government for its expenses related to this action;

E. That this Court enter judgment against Defendants, and each of them, for $100,000 for devising and participating in the scheme;

F. That this Court enter judgment against the Defendants in an amount equal to $10,000 per day for every day Defendants failed to report as required by the Stark Law, together with the costs of this action, with interest, including the cost to the United States Government for its expenses related to this action;

G. That Relator be awarded all costs incurred, including his attorneys' fees;

H. That, in the event the United States Government subsequently intervenes in this action, Relator be awarded 25% of any proceeds of the claim and that, in the event the United States Government does not intervene in this action, Relator be awarded 30% of any proceeds;

I. That Relator be awarded the maximum percentage of any proceeds of the claim permitted under the Florida False Claims Act, Fla. § 68.085.

J. That the United States and Relator receive all relief, both in law and in equity, to which they are entitled.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of Federal Rules of Civil Procedure, Plaintiffs and Relator hereby demand a trial by jury.

Dated: October 24, 2011

Respectfully submitted,

Mark Schlein, **Trial Counsel**
Florida Bar No. 0000700
Diane Marger Moore
Florida Bar No. 268364
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
12100 Wilshire Blvd., Suite 950
Los Angeles, CA 90025
Tel: 310-207-3233 Fax: 310-207-4204
mschlein@baumhedlundlaw.com

Attorneys for Relator, Jon Schiff

JS 44 (Rev. 12/07)

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON THE REVERSE OF THE FORM.)

I. (a) PLAINTIFFS

United States of America, et al., ex rel. Jon Schiff

(b) County of Residence of First Listed Plaintiff _____
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorney's (Firm Name, Address, and Telephone Number)

Mark Schlein, Baum Hedlund Aristei & Goldman, 12100 Wilshire Blvd., #950, Los Angeles, CA 90025 (310) 207-3233

DEFENDANTS

Blackstone Medical, Inc.,; Orthofix International, N.V.; Mark Blair; Florida IOM; North Brevard Hospital District, d/b/a

County of Residence of First Listed Defendant Collin County, TX
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE LAND INVOLVED.

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question (U.S. Government Not a Party)
- ☐ 2 U.S. Government Defendant
- ☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)
(For Diversity Cases Only)

	PTF	DEF		PTF	DEF
Citizen of This State	☐ 1	☐ 1	Incorporated or Principal Place of Business In This State	☐ 4	☐ 4
Citizen of Another State	☐ 2	☐ 2	Incorporated *and* Principal Place of Business In Another State	☐ 5	☐ 5
Citizen or Subject of a Foreign Country	☐ 3	☐ 3	Foreign Nation	☐ 6	☐ 6

IV. NATURE OF SUIT (Place an "X" in One Box Only)

CONTRACT	TORTS		FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES
☐ 110 Insurance	PERSONAL INJURY	PERSONAL INJURY	☐ 610 Agriculture	☐ 422 Appeal 28 USC 158	☐ 400 State Reapportionment
☐ 120 Marine	☐ 310 Airplane	☐ 362 Personal Injury - Med. Malpractice	☐ 620 Other Food & Drug	☐ 423 Withdrawal 28 USC 157	☐ 410 Antitrust
☐ 130 Miller Act	☐ 315 Airplane Product Liability	☐ 365 Personal Injury - Product Liability	☐ 625 Drug Related Seizure of Property 21 USC 881	PROPERTY RIGHTS	☐ 430 Banks and Banking
☐ 140 Negotiable Instrument	☐ 320 Assault, Libel & Slander	☐ 368 Asbestos Personal Injury Product Liability	☐ 630 Liquor Laws	☐ 820 Copyrights	☐ 450 Commerce
☐ 150 Recovery of Overpayment & Enforcement of Judgment	☐ 330 Federal Employers' Liability	PERSONAL PROPERTY	☐ 640 R.R. & Truck	☐ 830 Patent	☐ 460 Deportation
☐ 151 Medicare Act	☐ 340 Marine	☐ 370 Other Fraud	☐ 650 Airline Regs.	☐ 840 Trademark	☐ 470 Racketeer Influenced and Corrupt Organizations
☐ 152 Recovery of Defaulted Student Loans (Excl. Veterans)	☐ 345 Marine Product Liability	☐ 371 Truth in Lending	☐ 660 Occupational Safety/Health		☐ 480 Consumer Credit
☐ 153 Recovery of Overpayment of Veteran's Benefits	☐ 350 Motor Vehicle	☐ 380 Other Personal Property Damage	☐ 690 Other	LABOR	☐ 490 Cable/Sat TV
☐ 160 Stockholders' Suits	☐ 355 Motor Vehicle Product Liability	☐ 385 Property Damage Product Liability		☐ 710 Fair Labor Standards Act	☐ 810 Selective Service
☐ 190 Other Contract	☐ 360 Other Personal Injury			☐ 720 Labor/Mgmt. Relations	☐ 850 Securities/Commodities/ Exchange
☐ 195 Contract Product Liability				☐ 730 Labor/Mgmt.Reporting & Disclosure Act	☐ 875 Customer Challenge 12 USC 3410
☐ 196 Franchise				☐ 740 Railway Labor Act	☒ 890 Other Statutory Actions
REAL PROPERTY	CIVIL RIGHTS	PRISONER PETITIONS		☐ 790 Other Labor Litigation	☐ 891 Agricultural Acts
☐ 210 Land Condemnation	☐ 441 Voting	☐ 510 Motions to Vacate Sentence		☐ 791 Empl. Ret. Inc. Security Act	☐ 892 Economic Stabilization Act
☐ 220 Foreclosure	☐ 442 Employment	Habeas Corpus:		IMMIGRATION	☐ 893 Environmental Matters
☐ 230 Rent Lease & Ejectment	☐ 443 Housing/ Accommodations	☐ 530 General		☐ 462 Naturalization Application	☐ 894 Energy Allocation Act
☐ 240 Torts to Land	☐ 444 Welfare	☐ 535 Death Penalty		☐ 463 Habeas Corpus - Alien Detainee	☐ 895 Freedom of Information Act
☐ 245 Tort Product Liability	☐ 445 Amer. w/Disabilities - Employment	☐ 540 Mandamus & Other		☐ 465 Other Immigration Actions	☐ 900Appeal of Fee Determination Under Equal Access to Justice
☐ 290 All Other Real Property	☐ 446 Amer. w/Disabilities - Other	☐ 550 Civil Rights			☐ 950 Constitutionality of State Statutes
	☐ 440 Other Civil Rights	☐ 555 Prison Condition			

FEDERAL TAX SUITS
☐ 870 Taxes (U.S. Plaintiff or Defendant)
☐ 871 IRS—Third Party 26 USC 7609

V. ORIGIN (Place an "X" in One Box Only)

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from another district (specify) ☐ 6 Multidistrict Litigation ☐ 7 Appeal to District Judge from Magistrate Judgment

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity):
31 U.S.C. 3729, et seq.

Brief description of cause:
False Claims Act (false claims for payments made by Medicare, etc.)

VII. REQUESTED IN COMPLAINT: ☐ CHECK IF THIS IS A CLASS ACTION UNDER F.R.C.P. 23 DEMAND $ CHECK YES only if demanded in complaint: JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY (See instructions): JUDGE _____ DOCKET NUMBER _____

DATE 10/25/2011 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG. JUDGE _____