UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA ex rel. SUSAN HUTCHESON and PHILIP BROWN,

BRINGING THIS ACTION ON BEHALF OF THE UNITED STATES OF AMERICA,

Plaintiffs and Relators,

v.

BLACKSTONE MEDICAL, INC. and ORTHOFIX INTERNATIONAL N.V.,

Defendants.

06 CA 11771 MEL

Civil Action No. _____

Judge _____

Filed Under Seal Pursuant to 31 U.S.C. Section 3720(b)(2) and Local Rule 7.2

MAGISTRATE JUDGE Bowler

DO NOT SERVE

COMPLAINT FOR VIOLATIONS OF THE FALSE CLAIMS ACT

I. INTRODUCTION

1. Qui Tam Relators Susan Hutcheson and Philip Brown bring this action on their own behalf and on behalf of the United States of America to recover damages and penalties under the False Claims Act, 31 U.S.C. § 3729 *et seq.*, against Defendants Blackstone Medical, Inc. and its successor corporation, Orthofix International N.V. The violations arise out of Defendants' actions to cause the submission of false claims for payment to Medicaid, Medicare, TRICARE, and other federally-funded government healthcare programs for spinal surgeries involving Defendants' device, implantation, and instrumentation products.

2. This complaint details fraudulent schemes employed by Defendants to increase the market share of its products by systematic payment of kickbacks to physicians throughout the United States in the form of sham consulting agreements, research grants, entertainment, travel, and other illegal incentives in order to induce

those physicians and other health care providers to use their surgical devices, implants, and instrumentation products.

II. JURISDICTION AND VENUE

3. This action arises under the United States Civil False Claims Act, 31 U.S.C. § 3729 *et seq*.

4. The Court has subject-matter jurisdiction pursuant to 31 U.S.C. § 3732 (a) and 28 U.S.C. § 1331, and has personal jurisdiction over the defendants because the defendants do business and are located in this District.

5. Venue lies under 28 U.S.C. 1391 (b), (c) and 31 U.S.C. 3732 (a) because Defendant Blackstone Medical Inc. operates and transacts business within this district.

6. The allegations of this complaint have not been publicly disclosed in a criminal, civil, or administrative hearing, nor in any congressional, administrative, or General Accounting Office report, hearing, audit, or investigation, nor in the news media.

7. Each Relator is an original source of the information upon which this complaint is based, as that phrase in used in the False Claims Act and other laws at issue herein.

8. Relators provided disclosure of the allegations of this complaint to the United States prior to filing.

III. PARTIES

10. The real party in interest to the claims set forth herein is the United States of America.

11. Relator Susan Hutcheson is a resident of Florida and a citizen of the United States. Relator Hutcheson was employed as a Regional Manager by Blackstone Medical Inc. from January 2004 until she was fired in January 2006. She now works for spinal implant and instrumentation manufacturer Custom Spine.

12. Relator Philip Brown is a resident of Florida and a citizen of the United States. Relator Brown was hired as an independent distributor for Blackstone Medical Inc. in 3004. He currently distributes surgical products for another manufacturer.

13. Defendant Blackstone was created in 1996 and is headquartered in Springfield, Massachusetts. The company was formed by Mike Lyons, Matt Lyons, and Bill Lyons. Prior to the recent acquisition by Orthfix, BMI developed, manufacturered, and sold numerous spinal fixation devices, implants, and instrumentation.

14. Defendant Orthofix is a global company founded in Verona, Italy in 1980. Orthofix designs, develops, manufactures, markets, and distributes medical equipment used principally by musculoskeletal medical specialists for orthopedic applications. Orthofix is headquartered in Netherlands and the United States corporate administrative offices are located in Huntersville, North Carolina. Orthofix acquired Blackstone in August 2006 for $333 million. Defendants Blackstone and its successor Orthofix shall be collectively referred to herein as Blackstone.

IV. THE STATUTORY AND REGULATORY ENVIRONMENT

15. BMI illegally induced physicians to utilize its spinal surgery products through payment of illegal kickbacks. As a result of BMI's illegal inducements, physicians performed surgeries using BMI products on Medicare and Medicaid patients admitted at healthcare facilities around the country. By so doing, BMI caused hospitals to submit false

claims for payment of these surgeries performed in violation of the Anti-Kickback Act.

A. THE ANTI-KICKBACK ACT

16. Pursuant to the Anti-Kickback Act, 42 U.S.C. Section 1320a-7b(b), it is unlawful to knowingly offer or pay any remuneration in cash or in kind in exchange for the referral of any product for which payment is sought from any federally-funded health care program, including Medicare, Medicaid, and Tricare.

17. The Anti-Kickback Act is designed to, *inter alia*, ensure that patient care will not be improperly influenced by inappropriate compensation from the healthcare industry.

18. Each of the federally-funded health care programs requires every provider who seeks payment from the program to promise and ensure compliance with the provisions of the Anti-Kickback Act and other federal laws governing the provision of health care services in the United States.

19. The Anti-Kickback Act prohibits medical device manufacturers and suppliers from compensating, in cash or in kind, a physician when a purpose of the payment is to influence the physician's use of its product over the product of any competitor.

20. Examples of activities prohibited by the Anti-Kickback Act include without limitation payments for sham consulting services, illusory training sessions, bogus research and educational grants, bogus speaking fees, lavish entertainment, travel and lodging expenses, expensive meals and wine, and other gifts and discounts. These activities are particularly suspect if the medical device supplier selects the physician

based upon perceived ability or potential to prescribe the company's products rather than professional qualifications or services actually rendered to the company.

B. REIMBURSEMENT BY GOVERNMENT-FUNDED HEALTH CARE PROGRAMS.

21. The Health Insurance for the Aged and Disabled Program, popularly known as the Medicare program, was created in 1965 as part of the Social Security Act (SSA). The Secretary of HHS administers the Medicare Program through CMS, a component of HHS.

22. The Medicare program consists of two parts. Medicare Part A authorizes the payment of federal funds for hospitalization and post-hospitalization care. 42 U.S.C. § 1395c-1395i-2 (1992). Medicare Part B authorizes the payment of federal funds for medical and other health services, including without limitation physician services, supplies and services incident to physician services, laboratory services, outpatient therapy, diagnostic services, and radiology services. 42 U.S.C. § 1395(k), 1395(i), 1395(s).

23. Reimbursement for Medicare claims is made by the United States through the Department of Health and Human Services (HHS). The Centers for Medicare and Medicaid Services (CMS) is an agency of HHS and is directly responsible for the administration of the Medicare Program. CMS, in turn, contracts with private insurance carriers to administer and pay claims from the Medicare Trust Fund. 42 U.S.C. § 1395u. In this capacity, the carriers act on behalf of CMS. 42 C.F.R. § 421.5(b) (1994). These entities are called fiscal intermediaries.

24. Under the Medicare Program, CMS makes payments retrospectively (after the services are rendered) to hospitals for inpatient services. Medicare enters into

provider agreements with hospitals in order to establish the hospitals' eligibility to participate in the Medicare Program. However, Medicare does not prospectively contract with hospitals to provide particular services for particular patients. Any benefits derived from those services are derived solely by the patients and not by Medicare or the United States.

25. As detailed *infra*, BMI illegally induced physicians to perform surgeries at healthcare facilities using its medical devices, implants, and instrumentation. In so doing, BMI caused hospitals to submit false claims for surgical services rendered Medicare, Medicaid and other federal program beneficiaries admitted for surgeries.

26. Hospitals submit claims for interim reimbursements for these services delivered to specific Medicare beneficiaries during their hospital stays. 42 C.F.R. §§ 413.1, 413.60, 413.64. Hospitals submit patient-specific claims for interim payments on a Form UB-92.

27. As a prerequisite to payment, CMS requires hospitals to submit annually a form CMS-2552, commonly known as the Hospital Cost Report. Cost Reports are the final claim that a provider submits to the fiscal intermediary for items and services rendered to Medicare beneficiaries.

28. Every Hospital Cost Report contains a "Certification" that must be signed by the chief administrator of the provider or a responsible designee of the administrator.

29. The Hospital Cost Report certification page includes the following notice:

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

> where otherwise illegal, criminal, civil and administrative action, fines and/or imprisonment may result.

30. And, the responsible hospital provider official is required to certify, in pertinent part:

> To the best of my knowledge and belief, it [the Hospital Cost Report] is a true, correct and complete statement prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provisions of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

31. As a result of its systematic payment of kickbacks to physicians to utilize its spinal surgery products, BMI caused hospitals to submit false certifications to the United States. Claims submitted as a result of illegally-induced surgeries were false claims.

V. ALLEGATIONS OF FACT

32. BMI engaged in a scheme to secure the use of its products in spinal surgeries by paying remuneration, in cash and in kind, to physicians.

33. Medicare, Medicaid and other federal program beneficiaries represent a significant percentage of the patient population for spinal surgeries.

34. BMI paid remuneration in excess of fair market value in such forms as, *inter alia,* sham consulting agreements; paid development projects; research grants; royalties; exorbitant and sometimes illicit entertainment expenses; high-end travel and accommodations; speaking engagements and seminars, and other illegal incentives.

35. BMI targeted surgeons with high volumes of surgical business.

36. BMI's primary business model was to engage surgeons to be members of its Medical Advisory Board ("MAB") and then pay the MAB surgeons pursuant to consultant agreements.

37. The consulting agreements provided that the physicians would be "engaged" for a certain number of hours per month to consult on "projects" for BMI spinal products.

38. The majority of the physicians did not in fact perform services for the engaged number of hours.

39. The services solicited by physicians were not legitimate and necessary and did not serve a commercially-reasonable business purpose.

40. Rather, the actual purpose of the consulting agreement was to secure the physician's business.

41. Under the agreements, the physicians were paid a monthly stipend, ranging in numbers from $1,666 per month to $8,000 per month.

42. The remuneration paid to the physicians pursuant to consulting agreements (hereinafter referred to as "MAB doctors") was, in most cases, not commercially reasonable and was above fair market value for the services rendered.

43. The MAB doctors included, without limitation, the following physicians:

Bajares
Benalcazar, Hugo
Blumenthal, Scott
Booth, Kevin
Bosita, Renato
Bradley
Capen, Daniel
Chan, Patrick
Childs

Ciacci, Joseph
Chicago Spinal Consultants
Davis, Randy
Dunlap, Janet
Esses, Stephen
Eubanks
Fitzpatrick
Garber, Jason
Grant, Joseph
Grover, Jaswinder
Hall, Ronjon
Hill, Michael
Gregory Hoffman
Huntsman, Kade T.
Ibrahim, Kamil
Jordan, Richard
Kabins
Keller, Paul
Kilian
Kim, Kee
Kozak
Kravetz, Phillip
Lanman, Todd
Letellier, Marc
Lewis, Adam
Linovitz, Ray
Lorenz, Mark
Mason, Michael
Mastrodimos
McGee
Mekhail, Anis
Nelson, Russell
Nicolakis
O'Neill, James
Olson, James
Ozuna, Richard
Pacheco, Helson
Peppers, Timothy
Raben, Tony
Rappaport, James
Reed, Michael
Reichman, Howard
Reing, Michael
Rimoldi, Reynold
Rovner, Robert

Sethi, Navinder
Shadeed
Shelokov
Shively
Stephens, Susan
Thomas, Harvey
Villanueva
Watkins, Robert, Jr.
Watters
Weller, Simcha
Westerlund, Erik
Williams, John
Zindrick, Michael

44. Relator Hutcheson believes that improper remuneration was paid to approximately three-quarters of MAB physicians, and that BMI paid MAB physicians without regard to whether they provided services or not. Put another way, it was entirely up to the individual physician whether or not she or he provided services.

45. BMI closely tracked its monthly sales volume to each MAB doctor.

46. In fact, in initial visits, BMI sales representatives were told to distribute "Surgeon Visit Questionnaires" to potential MAB doctors prior to meeting with BMI senior management. These questionnaires had entries for the surgeon's "Annual Sales with Blackstone Medical."

47. BMI regional and other managers and officers regularly discussed, including at the sales-managers' meetings, that additional MAB doctors needed to be recruited. Sales managers and representatives clearly understood that the policy and practice of the company was that a paid arrangement was necessary to secure the business of high-volume surgeons.

48. Internal communications and reports reflect this policy and practice. For example, in a November 23, 2005 email, BMI's Vice President of Sales, Paul Sendro,

directed BMI managers to come up with a plan to present to BMI owners "for hitting the sales number given to your region for 2006 . . . . This plan should include the number of MAB's, number of new product sets, etc. . . . needed to achieve the goal."

49. After a meeting with BMI's President, Andrew Janiak circulated the following "action item" to meet the goals spelled out by Mr. Lyons: "1)Add 3 MAB's from list provided to Fred and you; 2) Place 1-2 surgeons from the region on 'motion preservation project'..."

50. Regional Sales Managers regularly were instructed to provide lost revenue reports to BMI senior management. As reflected in a November 2, 2005 email from Eric Hansen, these reports tracked:

> 1. Lost revenue from not signing MAB surgeons or inability to provide research/education projects.
>
> * * *
>
> 3. Lost revenue due to late MAB payment or nondelivery of contracts.
>
> This should be broken down by surgeon or facility then show the dollar figure in lost revenue.
>
> **Example**
>
> Surgeon A=$50,000 in lost revenue.

51. All MAB doctors recruited were approved by senior management of BMI. MAB contracts were negotiated by Robert Hastings, Vice President of Technology Development and Professional Relations. On information and belief, MAB contracts were signed by BMI President Matt Lyons.

52. If an MAB doctor stopped using BMI products, he was reprimanded. BMI also terminated MAB contracts when an MAB doctor failed to use BMI products.

53. By way of example, the MAB agreement with Dr. Michael Reed was terminated after he began using a competitor's products.

54. Internal communications and reports regularly reflected that MAB doctors were not "engaged" for the number of contract hours each month. Emails were routinely circulated looking for additional engagements for MAB doctors and for additional hours to report for each MAB doctor.

55. BMI did not properly document the number of hours "engaged" by any MAB doctor. In fact, many of its representatives were asked to "write up" descriptions regarding interactions with MAB doctors and email it to Professional Relations. By information and belief, the Professional Relations Department would transform these emails into allegedly supporting documentation for MAB doctor hours. Sales manager Brian Dukate sent the following email to VP Paul Sendro in response to an internal request for "more hours" for MAB Doctor Hoffman:

> Paul,
>
> This is ridiculous! This is sucking up all of my time to the point that I cannot get anything else done!! Why are the other departments not engaging the MAB's. I cannot just make things up out of thin air and my reps getting back to me makes it even more impossible. We have gone from this being to write up a conversation you or a rep had with a surgeon to we don't have enough hours. Help! Vivian please make sure Paul gets this.
>
> Brian

56. In November 2005, BMI Vice President Bob Hastings held a "Medical Advisory Board Consulting Training" session with BMI employees and discussed its inadequate documentation practices. According to bullet points in a PowerPoint

training document used in the meeting, reporting "accuracy" was necessary because of, among other things, the "Justice Department" and "Exposure."

57. As a result, BMI attempted to pay physicians for the hours they actually expended under their MAB agreements. This change substantially reduced the amounts which the MAB physicians were paid. Resulting complaints by MAB physicians caused BMI to instruct sales-force personnel to begin "documenting" MAB physician hours by sales-force personnel.

58. BMI offered paid arrangements other than MAB contracts with physicians in order to secure their business.

59. BMI also regularly offered to pay surgeons for research projects or educational grants. These payments did not have commercially reasonable parameters and were above fair market value. Rather, the primary purpose of these arrangements was to secure their business.

60. For example, on April 7, 2004, BMI committed to Dr. Stewart Eidelson to pay an "unrestricted education grant" of $18,000 to support "your research of our product."

61. By way of another example, and upon information and belief, when MAB Doctor Jordan indicated his intent to discontinue his relationship with BMI, BMI attempted to incentivize Dr. Jordan to continue using BMI products by offering him cash payments as well as payments for the two research studies at $50,000/per study.

62. BMI also offered other illegal incentives to induce physicians to use its products in spinal surgeries.

63. BMI managers and representatives were expected to do "whatever it takes" to make a surgeon happy and to secure that surgeon's business. BMI managers and representatives provided exorbitant meals and entertainment for surgeons, including taking them to strip clubs and arranging for prostitutes.

64. Ms. Hutcheson was advised on or about September 29, 2006 by BMI distributor Lance Cochran that in one case, a female BMI sales manager in Dallas, Texas took two surgeons to a strip club and, at the physicians' urging, joined strippers on the stage, disrobed, and engaged with them in sex acts. BMI's reaction upon learning of the incident was to demote the manager to a sales-representative position.

65. BMI knowingly engaged in a pervasive practice of providing kickbacks to surgeons in order to secure their business. BMI knew that the payment of these kickbacks resulted in the use of its products in spinal surgeries performed on Medicare, Medicaid and other federally-funded patients.

66. Relators know that BMI's illegal remuneration of physicians occurred nationwide. As a regional manager, Ms. Hutcheson had contact with other regional managers regarding the practices discussed in this complaint, and participated in national meetings of regional managers at which the MAB system was discussed in substantial detail.

67. In September 2006, Ms. Hutcheson was shown documents provided by BMI to a licensed practical nurse, Jeff Yielding, in which BMI offered Mr. Yielding substantial compensation, to include a commission, $1,000 per day in expenses, and two $50,000 "unrestricted grants" if Mr. Yielding would tout BMI products to physicians with whom he had professional relationships. Mr. Yielding declined BMI's offer.

68. Relator Hutcheson was advised on or about September 28, 2006, by BMI distributor Lance Cochran, that, probably in late summer 2006, St. Dominic's Hospital in Jackson, Mississippi, asked BMI to provide details about its relationship with Dr. Adam Lewis, a physician on St. Dominic's staff. When BMI refused, St. Dominic's reportedly terminated Dr. Lewis's privileges and contacted FBI agents regarding its suspicions. Mr. Cochran, the BMI distributor responsible for St. Dominic's, advised Ms. Hutcheson that he was "shredding documents 24 hours a day."

69. BMI knowingly caused the submission of false claims to the United States for spinal surgeries performed on Medicare, Medicaid and other federally-funded patients.

70. As to each of the above factual allegations, Defendants acted with actual knowledge of this information, in deliberate ignorance of the truth or falsity of this information and/or in reckless disregard of the truth or falsity of this information. Defendants knowingly violated the False Claims Act as that term is defined in 31 U.S.C. § 3729(b).

71. The scheme to cause the filing of false claims described herein was pervasive and nationwide and took place for many years.

COUNT I: VIOLATIONS OF THE UNITED STATES CIVIL FALSE CLAIMS ACT

72. The allegations of paragraphs 1-71 are realleged as if fully set forth herein.

73. The False Claims Act, 31 U.S.C. § 3729(a)(1) and (2), imposes liability upon, *inter alia*, those who knowingly cause to be presented to an officer or employee

of the United States false claims for payment or approval. It also imposes liability on those who conspire to get false claims paid. 31 U.S.C. § 3729(a)(3).

74. Defendants deliberately engaged in a concerted, vigorous, and cynical campaign to induce physicians to utilize its medical products by paying illegal kickbacks.

75. Claims for payment to federally-financed healthcare systems, to include at least Medicaid, Medicare, and Tricare, which resulted from Defendants' knowingly-illegal kickback campaign were false claims.

76. The false claims referenced in the foregoing paragraph were caused to be presented by Defendants, in violation of 31 U.S.C. §3729(a)(1).

77. Defendants' kickbacks to physicians and others were intended to, and did, cause the submission of false claims, in violation of 31 U.S.C. § 3729(a).

78. Defendants conspired with others, to include physicians who accepted kickbacks, to defraud the United States by getting false claims allowed and paid.

79. Because the United States would not have paid for services which it knew to have been the result of illegal kickbacks, the United States has been harmed in an amount equal to the value paid by the United States.

80. The United States Government has been damaged as a result of Defendants' conduct in violation of the False Claims Act in an amount to be determined at trial.

COUNT II: RETALIATION AND WRONGFUL DISCHARGE

81. The allegations of paragraphs 1-80 are realleged as if fully set forth herein.

82. Relator Hutcheson repeatedly questioned her supervisors about BMI's business practices, including whether BMI was buying the business of physicians. She also objected to other practices at BMI, including the policy and practice of entertaining the physicians in whatever manner they requested, including arranging for strippers and prostitutes and having female BMI representatives act provocatively and "party" with the male physicians. Relator Hutcheson refused to entertain the physicians in this manner. As a result, Relator Hutcheson was wrongfully discharged in January 2006.

83. As a result of the actions of BMI in discharging Relator Hutcheson in violation of 31 U.S.C. § 3730(h), Relator Hutcheson is entitled to all relief necessary to make her whole, including two times the amount of back pay, interest on the back pay, and compensation for special damages sustained as a result of the discrimination, including litigation costs and reasonable attorneys fees.

PRAYER FOR RELIEF

WHEREFORE, Relators requests:

1. That the Court enter judgment against 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 action in violation of 31 U.S.C. § 3729, and the costs of this action, with interest, including the costs to the United States Government for its expenses related to this action;

2. That in the event that the United States Government intervenes in this action, Relators be awarded 25% of the proceeds of the action or the settlement of any such claim;

3. That in the event that the United States Government does not proceed with this action, Relators be awarded 30% of the proceeds of this action or the settlement of any such claim;

4. That on Count II, Relator be awarded all relief necessary to make her whole, including two times the amount of back pay, interest on the back pay, and compensation for special damages sustained as a result of the discrimination.

5. That Relators be awarded all costs, attorneys' fees, and litigation expenses;

6. That the United States Government and Relator receive all relief, both at law and in equity, to which they may reasonably appear entitled.

Dated: September 29, 2006

Respectfully submitted,

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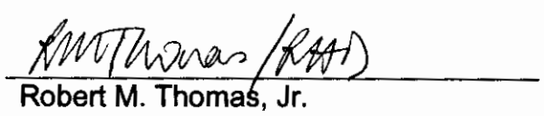

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THIS COMPLAINT MAY NOT BE SERVED UNTIL SERVICE IS ORDERED BY THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS