UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA *ex rel.* CHARLES BIRCHALL, Jr., JOHN MILLER, and WALTER BENNETT, Plaintiffs, v. SPINEFRONTIER, INC., IMPARTIAL MEDICAL EXPERT, LLC, KIC MANAGEMENT GROUP, INC., KICVENTURES, LLC, KINGSLEY CHIN, M.D., ADITYA HUMAD, and VANESSA DUDLEY, Defendants.	No. 15cv12877-RWZ No. 15cv12908-RWZ **JURY TRIAL DEMANDED**

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U.S. DISTRICT COURT
DISTRICT OF MASS.

UNITED STATES' COMPLAINT IN INTERVENTION

Introduction

1. The United States of America ("United States") brings this Complaint in Intervention against SpineFrontier, Inc. ("SpineFrontier"), Impartial Medical Expert, LLC[1] ("IME"), KIC Management Group, Inc. ("KIC Management"), KICVentures LLC ("KICVentures"), Kingsley Chin, M.D. ("Chin"), Aditya Humad ("Humad"), and Vanessa Dudley ("Dudley") (collectively, the "Defendants") to recover treble damages, restitution, and civil penalties under the False Claims Act, 31 U.S.C. §§ 3729-33 ("FCA"), and under the common law.

[1] The State of Delaware's Division of Corporations identifies the company's name in public filings as "Impartial Medical Expert, LLC." However, the Defendants promoted and marketed the company in the plural as "Impartial Medical Experts, LLC."

2. From at least March 2013 through December 2018 (the "Relevant Period"), SpineFrontier, and later IME, at the direction of their owners and principals, KICVentures, KIC Management, Chin, Humad, and Dudley, paid, and conspired to pay, millions of dollars in sham "consulting" fees to surgeons to induce them to use SpineFrontier's medical devices during spine surgeries, in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b). The Defendants' illegal conduct caused the submission of false claims for payment to federal health care programs in violation of the FCA.

3. The Defendants paid surgeons to induce them to use SpineFrontier's medical devices over competitors' medical devices. The Defendants attempted to hide the true nature of the payments by characterizing them as fees for evaluations of SpineFrontier medical devices and other consulting activities. In reality, the Defendants paid surgeons based on the volume and value of SpineFrontier medical devices the surgeons used. The surgeons often performed little or no actual consulting work in exchange for these "consulting" payments. When certain surgeons did, on occasion, perform consulting work, the Defendants paid the surgeons for significantly more time than they actually had spent consulting, and without regard for the quality or quantity of any feedback the surgeons provided. Often, SpineFrontier paid surgeons for time spent merely using SpineFrontier medical devices during spine surgeries, including procedures reimbursed by federal health care programs.

4. The Defendants knew that their "pay-to-play" payments violated the law. To evade detection, the Defendants created a sham company, IME, to pay the surgeons. The Defendants told prospective "consultant" surgeons that if they consulted for SpineFrontier through IME, then government regulators would not scrutinize the payments.

5. To give IME a veneer of legitimacy, the Defendants falsely marketed IME as a separate referral company through which physicians could perform consulting and expert witness services, ostensibly for a variety of clients. In reality, Chin controlled both IME and SpineFrontier. After SpineFrontier began using IME as a vehicle to process purported consulting payments, IME served only one client—SpineFrontier.

6. The Defendants placed no limit or cap on the number of times SpineFrontier and IME paid a surgeon ostensibly to "evaluate" a particular SpineFrontier medical device. The Defendants marketed the absence of such a cap to prospective surgeons in order to convince them to become consultants and use SpineFrontier's medical devices. In many instances, the same surgeon received multiple, and in some cases dozens of, payments for purportedly evaluating the same medical device. To the extent these surgeons provided any consulting feedback at all through these repetitive "evaluations," the feedback was duplicative and unnecessary, and SpineFrontier largely ignored it.

7. SpineFrontier, via IME, paid over $8 million in kickbacks through sham consulting fees to approximately 35 surgeons. (A spreadsheet reflecting these payments is attached as Exhibit A). Through their use of SpineFrontier medical devices in spine surgeries, these "consulting" surgeons generated more than $100 million in revenue for SpineFrontier. Indeed, these surgeons generated the vast majority of SpineFrontier's total domestic sales of medical devices during the Relevant Period.

Jurisdiction and Venue

8. This Court has subject matter jurisdiction over the FCA claims pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and over the common law claims pursuant to 28 U.S.C. § 1345.

9. This Court may exercise personal jurisdiction over the Defendants pursuant to 31 U.S.C. § 3732(a), as all the Defendants transact business in this District.

10. Venue lies in this District pursuant to 31 U.S.C. § 3732(a), because all of the Defendants transact business in this District, where SpineFrontier, KICVentures, and KIC Management are headquartered. Furthermore, defendant Humad resides in this District.

Parties

11. Plaintiff is the United States of America, acting on behalf of the United States Department of Health and Human Services ("HHS") and the Centers for Medicare and Medicaid Services ("CMS"), which administers the Health Insurance Program for the Aged and Disabled established by Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq*. ("Medicare"), and the Department of Defense ("DoD"), including DoD component the Defense Health Agency ("DHA"), which administers the TRICARE program ("TRICARE").

12. Relator Charles Birchall, Jr., resides in Ohio.

13. Relator John Miller resides in Ohio.

14. Relator Walter Bennett resides in Virginia.

15. SpineFrontier is a Delaware corporation with a principal place of business at 350 Main Street, Malden, MA 02148. It manufactures, designs, markets, and sells spinal medical devices, including in the District of Massachusetts. Surgeons use these medical devices in spine surgeries that federal health care programs pay for throughout the United States.

16. KICVentures is a Delaware corporation with a principal place of business at 350 Main Street, Malden, MA 02148. KICVentures is a private investment holding company that owns and operates multiple businesses, including SpineFrontier and IME. KIC, LLC owns KICVentures, and Chin owns KIC, LLC.

17. KIC Management is a Delaware corporation with a principal place of business at 350 Main Street, Malden, MA 02148. KIC Management manages both SpineFrontier and IME. Chin owns KIC Management.

18. IME is a Delaware corporation and identifies its business address as 3296 N. Federal Highway #11631, Fort Lauderdale, Florida, which is a post office box. IME's website states that it "is a premier consultant referral firm that connects its Clients to leading medical and surgical specialists with extensive, real-world experience in healthcare services, medical device and instruments design and evaluations, lectures, didactic skills training, and expert witness and litigation support." https://impartialmedicalexperts.com/ (last visited February 27, 2020). KICVentures and KIC Management jointly own IME.

19. Chin, a resident of Florida, is the founder and principal owner of SpineFrontier, KICVentures, and KIC Management. He graduated from medical school in 1996, and practices as a surgeon in and around Hollywood, Florida. Chin is married to defendant Dudley.

20. Humad, a resident of Massachusetts, has served as the Chief Financial Officer of KICVentures since November 2009, and as the Chief Financial Officer of SpineFrontier since July 2011. Since June 2014, Humad has also served as the President of SpineFrontier. Humad was employed as SpineFrontier's Director of Finance and Business Relations between July 2010 and July 2011 and as its Vice President of Business Development between July 2011 and June 2014.

21. Dudley, a resident of Florida, has served as IME's Business Administrator since IME's inception in or around May 2012, and is IME's sole employee. Dudley married Chin in 2015.

Legal and Factual Background

I. THE FALSE CLAIMS ACT AND THE ANTI-KICKBACK STATUTE

22. The FCA establishes liability to the United States for any individual or entity that "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A), or "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," 31 U.S.C. § 3729(a)(1)(B), or "conspires to commit a violation" of the above, 31 U.S.C. § 3729(a)(1)(C). The FCA defines "knowingly" to include actual knowledge, reckless disregard, and deliberate indifference. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

23. The AKS makes it illegal for individuals or entities knowingly and willfully to "offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person . . . to purchase . . . order, or arrange for or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2)(B). For example, the AKS prohibits a medical device company from knowingly and willfully paying doctors directly or through a third party to induce the doctors to use the company's medical devices in surgeries or other medical procedures for which federal health care programs provide reimbursement. A violation of the AKS is a felony punishable by fines and imprisonment, 42 U.S.C. § 1320a-7b(b)(2), and can also result in exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7(b)(7).

24. The AKS arose out of congressional concern that remunerative inducements may corrupt patient and professional health care decision-making, impose higher costs on federal health care programs, and divert federal funds towards goods and services that are medically

unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect federal health care programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form. First enacted in 1972, Congress strengthened the statute in 1977 and 1987 to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient Program Protection Act of 1987, Pub. L. No. 100-93.

25. In 2010, Congress amended the AKS to provide that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). Congress added this provision to confirm "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the [FCA], even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854 (Oct. 28, 2009).

26. The HHS Office of Inspector General ("HHS-OIG") has promulgated "safe harbor" regulations that identify payment practices not subject to AKS enforcement because such practices are unlikely to result in fraud or abuse. *See* 42 C.F.R. § 1001.952. Safe harbor protection is afforded only to those arrangements that meet all of the specific conditions set forth in the regulations. The Defendants' conduct does not fall within any regulatory safe harbor.

II. REQUIRED DISCLOSURES OF MANUFACTURER PAYMENTS TO PHYSICIANS

27. As of March 31, 2013, a covered manufacturer (such as SpineFrontier) must disclose to CMS any payment or transfer of value made to a physician or hospital, as well as any physician ownership or investment in the covered manufacturer. *See* 42 U.S.C. § 1320a-7h(a)(1)(A) (formerly known as the "Sunshine Act" and hereinafter referred to as the "Open

Payments program"). The Open Payments program also makes this information available to the public. *See* 42 U.S.C. § 1320a-7h(c)(1)(A)(ii).

III. 2013 HHS-OIG GUIDANCE ON SPINAL MEDICAL DEVICES

28. On March 26, 2013, HHS-OIG issued a Special Fraud Alert concerning physician-owned entities, particularly physician-owned distributorships ("PODs"). *See* HHS-OIG, *Special Fraud Alert: Physician-Owned Entities*, 78 Fed. Reg. 19271-3 (Mar. 26, 2013) ("POD Special Fraud Alert"). HHS-OIG detailed its concern that the "financial incentives PODs offer to their physician-owners may induce the physicians both to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices." *Id.* at 19272. HHS-OIG expressed particular concern "about the presence of . . . financial incentives in the implantable medical device context because such devices typically are 'physician preference items,' meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital . . . where the procedure is performed." *Id.*

IV. MEDICARE

29. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act through Title XVIII of the Social Security Act. 42 U.S.C. §§ 1395 *et seq*. ("Medicare"). A person's age, disability, or affliction with end-stage renal disease determines his or her entitlement to Medicare benefits. *See* 42 U.S.C. §§ 426 to 426-1.

30. Medicare is a "Federal health care program" for purposes of the AKS. *See* 42 U.S.C. § 1320a-7b(f).

31. CMS, an agency of HHS, administers the Medicare program. For purposes of this action, there are two primary components to the Medicare Program: Part A and Part B. Medicare Part A authorizes payment for institutional care, including inpatient hospital services, skilled nursing facilities, and home health care. *See* 42 U.S.C. §§ 1395c to 1395i-5. Medicare Part B is a federally subsidized, voluntary insurance program that covers a percentage of the fee schedule for physician services, as well as for a variety of "medical and other services." *See* 42 U.S.C. §§ 1395j to 1395w-6.

32. To participate in Medicare, a health care provider must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The provider agreement requires compliance with the requirements that the Secretary deems necessary for participation and payment. The provider agreement specifically requires compliance with the AKS.

A. Medicare Part A

33. Medicare Part A authorizes payment for institutional care, including hospitalization, for eligible patients. Under Medicare Part A, hospitals enter into an agreement with Medicare to provide health care items and services to treat Medicare patients. The hospital, also called a "provider," may then bill Medicare for that treatment.

34. During the Relevant Period, CMS reimbursed hospitals for inpatient Part A services through Medicare Administrative Contractors ("MACs").

35. MACs are private insurance companies that are responsible for determining the amounts Medicare owes to providers. *See* 71 Fed. Reg. 67960, 68181 (Nov. 24, 2006). Under their contracts with CMS, MACs review, approve, and pay providers' Medicare bills, called "claims," using federal funds. *See* 42 C.F.R. § 421.5(b).

36. Since 2007, in order to receive Medicare reimbursement for providing patient care, a hospital must complete and submit a claim for payment on a CMS 1450 form (also known as UB-04). This form contains patient-specific information, including a provider's diagnosis and provision of services to a Medicare patient. Medicare relies upon the accuracy and truthfulness of the CMS 1450 forms to determine whether the service is payable and how much to pay the provider.

37. In addition, at the end of each fiscal year, a hospital submits to the MAC a form referred to as a "cost report," which may identify any outstanding costs that the hospital claims for reimbursement for that year. By auditing and reviewing cost reports, Medicare ensures the accuracy of previously submitted claims and can make adjustments when there is a discrepancy between the hospital's costs and Medicare's reimbursements. Medicare relies upon the accuracy and truthfulness of a hospital's cost report to determine what amounts, if any, Medicare either owes or overpaid the hospital during the year.

38. In 1983, Congress established the prospective payment system ("PPS") as the system by which Medicare reimburses hospitals for inpatient hospital costs. Under PPS, the amount Medicare pays a hospital for treating an inpatient Medicare beneficiary is based on a variety of factors, including the particular condition that led to the patient's hospital admission or that the hospital principally treated.

39. Under PPS, the hospital inputs information regarding a patient's illness or condition into a software program called the "grouper." The grouper uses a classification system called a diagnostic related group ("DRG") to categorize the patient's illness or condition. Medicare uses the DRG information to determine the level of reimbursement the hospital receives for the expected costs related to a beneficiary's hospitalization, including the cost of

medical devices and surgical equipment used to care for the beneficiary. Medicare payments to a hospital under PPS "are payment in full for all inpatient hospital services," 42 C.F.R. § 412.50(a), including the "[d]rugs, biologicals, supplies, appliances, and equipment" furnished to an inpatient. 42 C.F.R. § 409.10(a)(5). Such supplies, appliances, and equipment include "item[s] . . . that the beneficiary must continue to use after he or she leaves the hospital[,]" including implanted spinal devices. 42 C.F.R. § 409.14(b)(1).

40. For spinal surgeries, hospitals often treat medical devices as "physician preference" items, meaning surgeons select the type of medical devices to be purchased and used for their surgeries. A hospital may require a device manufacturer to execute a pricing agreement before the hospital permits an operating surgeon to exercise his or her preference to use that manufacturer's device in a surgery. Regardless, a hospital purchases each medical device a surgeon uses during spinal surgery from the manufacturer or distributor of that medical device, and Medicare reimburses the hospital for the cost of the medical device as part of the applicable DRG.

B. Medicare Part B

41. Eligible individuals who are 65 or older, or disabled, may enroll in Medicare Part B to obtain benefits in return for payments of monthly premiums. Medicare Part B reimburses the cost of medically necessary physician services, including spine surgery procedures, rendered to Medicare Part B beneficiaries. MACs are responsible for processing the payment of Medicare Part B claims to providers on behalf of CMS.

42. The vast majority of health care providers elect to enter into Medicare participation agreements, which allow them to bill Medicare Part B for their professional services. If a surgeon has entered into a Medicare participation agreement, the surgeon may bill

Medicare Part B directly for each procedure he or she performed on a Medicare beneficiary. In order to bill Medicare, a surgeon must submit an electronic or hard-copy claim form called a CMS 1500 form to the MAC. When the surgeon submits the claim, he or she certifies that the surgeon knows Medicare's requirements and that the claim complies with applicable laws and regulations, including the AKS.

43. A surgeon wishing to submit the CMS 1500 form electronically must also submit a provider enrollment form. The provider enrollment form requires surgeons to certify their understanding 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, 42 U.S.C. § 1320a-7b(b))."

44. For a claim to be eligible for payment by Medicare Part B, the claim must identify each service the surgeon rendered to the patient. The surgeon identifies the service performed by using a corresponding code from the American Medical Association's Current Procedural Terminology ("CPT") Manual. The CPT Manual is a systematic list of codes for procedures and services, including spinal surgery procedures, that physicians perform or direct. The CPT Manual identifies each procedure or service using a five-digit CPT code.

V. TRICARE

45. TRICARE (formerly known as CHAMPUS) is a health care program administered by DHA. TRICARE provides health care insurance for active duty military personnel, military retirees, and military dependents.

46. TRICARE is a "Federal health care program" for purposes of the AKS. *See* 42 U.S.C. § 1320a-7b(f).

47. A physician seeking reimbursement from TRICARE must comply with TRICARE's anti-fraud and abuse provisions, and medical providers seeking payment from TRICARE have a duty to familiarize themselves with program requirements. 32 C.F.R. § 199.9(a)(4). TRICARE regulations identify kickbacks between suppliers and providers as presumptively fraudulent. *Id.* § 199.9(c)(12).

48. In order to bill TRICARE, a surgeon must submit an electronic or hard-copy claim using the same CMS 1500 form the surgeon uses to submit a claim to Medicare. When a surgeon submits a claim to TRICARE using the CMS 1500 form, the surgeon certifies that he or she knows TRICARE's requirements and that the claim complies with applicable laws and regulations, including the AKS.

VI. SPINAL MEDICAL DEVICES

A. Spinal Surgery

49. There are four regions of the spine: the cervical, thoracic, lumbar, and sacral regions. The cervical spine consists of seven vertebrae in the neck region; the thoracic spine consists of twelve vertebrae in the mid-back region; and the lumbar spine consists of five vertebrae in the lower back region. The sacral region of the spine is below the lumbar region and consists of additional fused (*i.e.*, non-articulating) vertebrae.

50. Spinal implants may be used to help stabilize the spine and facilitate fusion. Cervical fusion surgeries are surgical procedures that surgeons perform to join or fuse two or more vertebrae in the cervical spine region. Surgeons perform lumbar fusion surgeries in a number of different ways. A procedure in which the surgeon accesses the lumbar spine region through an incision in the back is called a posterior fusion. A procedure in which the surgeon accesses the lumbar spine region through an abdominal incision is called an anterior fusion. A

procedure in which the surgeon accesses the lumbar spine region through an incision in the psoas muscle—which is located at the side of the lumbar region and extends into the pelvis—is often called an XLIF (or extreme lateral interbody fusion). A procedure in which the surgeon approaches through both the abdomen and the back is called a 360-degree fusion.

B. Types of Spinal Devices

51. During the Relevant Period, SpineFrontier sold, among other things, the types of medical devices described below.

52. A "cage" is a medical device, typically made of polyetheretherketone plastic ("PEEK"), which a surgeon may implant during a cervical or lumbar fusion surgery to maintain space between vertebral segments. SpineFrontier's cages included Arena-C, Arena-L, A-CIFT, A-LIFT, E-LIFT, LES P-LIFT, S-LIFT, and T-LIFT.

53. A "pedicle screw" is a medical device, typically made of titanium, which a surgeon implants into the bones of the spine to facilitate the fixation of spinal vertebrae. A surgeon implants a pedicle screw into two or more adjacent spinal segments to anchor "rods" or "plates." SpineFrontier's pedicle screws included FacetFuse, PedFuse REspond, PedFuse REmind, PedFuse REset, PedFuse REturn, and MISquito.

54. A "rod" is a medical device, anchored by pedicle screws, which a surgeon places longitudinally along the back of the lumbar and thoracic spine. SpineFrontier's rods—including Rod SP (straight and lordotic), Rod (straight, lordotic, and straight bulleted), and CoCr rods (straight and lordotic)—are part of the PedFuse pedicle screw system.

55. A "plate" is a medical device that a surgeon anchors with screws and places longitudinally along the front of the cervical spine. SpineFrontier's plates included Invue, Invue Inset, Invue MAX, InSpan, and InSpan-SLIM, with four levels of plates offered for purchase.

56. A percutaneous sacroiliac ("SI") screw is a medical device that a surgeon implants in connection with an SI joint fusion.

57. Biologics and allografts are materials that attract cells to increase bone formation in spinal fusion procedures. SpineFrontier's biologics included DBMForm, DBMPure Micro, DBMPure Macro, Cancellous Chips, DBMPutty, and DBM Crunch.

Factual Allegations

I. THE DEFENDANTS' KICKBACK SCHEME

58. The Defendants paid surgeons for their use of SpineFrontier's medical devices in spine surgeries, rather than for actual consulting work. The Defendants told surgeons that, under the guise of paying "consulting fees" for product evaluations, SpineFrontier would pay the surgeons every time they used one of SpineFrontier's medical devices. The Defendants sought to have surgeons sign up as "consultants" as soon as they began using SpineFrontier medical devices.

59. When determining how much to pay a surgeon in a given period, the Defendants did not assess or review the surgeon's evaluative feedback—indeed, the surgeon's feedback was often minimal or nonexistent. Nor did the Defendants assess whether the hours a surgeon submitted accurately accounted for how much consultative work he or she had performed. Instead, the Defendants ensured that each surgeon's "consulting" fees corresponded, as closely as possible, to the volume and value of SpineFrontier medical devices the surgeon had used in spine surgeries during a given period. The Defendants did so by (a) instructing surgeons to submit "consulting hours" to IME that were in reality based on the number and type of spine surgical procedures the surgeon had performed with SpineFrontier medical devices, and (b) reviewing submitted hours to ensure the surgeons had followed that instruction.

60. Numerous surgeons followed the Defendants' instruction, and the Defendants in turn paid them for supposed consulting hours that far exceeded the time the surgeons had engaged in any consultative activities. Indeed, the Defendants often paid surgeons "consulting" fees when the surgeons had done no consulting work at all.

61. While purporting to pay consulting fees, the Defendants actually paid surgeons kickbacks, typically $500 to $1,000 for each procedure where a surgeon implanted a SpineFrontier medical device in a patient.

II. SPINEFRONTIER AND THE SPINAL MEDICAL DEVICE BUSINESS

62. Chin, a surgeon, founded SpineFrontier in 2006, and he serves as its CEO and Director. KICVentures and KIC Management, both of which Chin owns and operates, principally own SpineFrontier and IME.

63. SpineFrontier develops, markets, and sells medical devices for spinal surgeries, including cages, pedicle screws, plates, rods, and biologics. During the Relevant Period, SpineFrontier was one of approximately 250 competing spinal medical device manufacturers in the United States.

64. Hospitals purchased SpineFrontier medical devices from one of two sources: either directly from SpineFrontier, or indirectly through a distributor that purchased medical devices from SpineFrontier.

65. Although hospitals purchased the medical devices, SpineFrontier understood that operating surgeons generally decided which medical devices they used in surgeries. Accordingly, SpineFrontier focused most of its sales and marketing efforts on persuading surgeons to use its medical devices over competitors' medical devices.

III. THE ORIGINS OF IME AND THE IME CONSULTING AGREEMENTS

66. Prior to September 2013, SpineFrontier directly contracted with numerous surgeons as consultants. Pursuant to these direct "consulting" agreements, SpineFrontier agreed to pay the surgeons for, *inter alia*, supposed feedback on SpineFrontier's medical devices, discussion time with SpineFrontier employees and third parties pertaining to SpineFrontier's medical devices, and other miscellaneous consulting services.

67. Similarly, prior to September 2013, SpineFrontier offered investment opportunities to surgeons who used SpineFrontier medical devices.

68. The 2013 announcements of the Open Payments program and HHS-OIG's POD Special Fraud Alert caused the Defendants to reconsider their practice of offering direct "consulting" agreements and investment opportunities to surgeons. As a result of these announcements, SpineFrontier, Chin, and Humad knew that SpineFrontier's direct "consulting" agreements and direct investment opportunities with surgeons would engender increased government scrutiny. SpineFrontier, Chin, and Humad also believed, however, that SpineFrontier needed to continue paying surgeons to induce them to use SpineFrontier's medical devices over competitors' medical devices.

69. In an attempt to conceal their kickbacks, as well as to sidestep the Open Payments program and potential government scrutiny of PODs, the Defendants decided to create and use IME as a pass-through vehicle for SpineFrontier's illegal payments to surgeons.

70. SpineFrontier presented IME to prospective "consulting" surgeons as a separate third-party entity, and attempted to camouflage IME's true nature when touting its alleged benefits. As a SpineFrontier sales representative wrote to a prospective surgeon in March 2014:

> We have recently partnered with a new company, IME, to help us with this agreement. Basically what it is, is a 3rd party company that we hired to help find

> surgeons willing to help us with consulting. Therefore, it eliminates the need for a surgeon to get paid directly from the manufacturer and shields them from OIG, sunshine act [*i.e.*, the Open Payments program], and kickback concerns.

71. In reality, IME was not separate from SpineFrontier, Chin, Humad, KICVentures, or KIC Management. The Defendants did not inform prospective "consulting" surgeons that KICVentures and KIC Management, which own and manage SpineFrontier, jointly own IME. Chin is the owner and operator of KICVentures and KIC Management, and Dudley (Chin's wife) is IME's only employee. Humad has served as the President of SpineFrontier, as well as the Chief Financial Officer for KICVentures, since 2014, and frequently performed various services on IME's behalf, including determining how much to pay each surgeon for their purported consulting.

72. SpineFrontier and IME sent coordinated communications to surgeons with direct consulting agreements explaining SpineFrontier's rationale for "outsourc[ing]" consulting arrangements to IME. For example, in a document entitled "Memo: Changes in Consulting Agreements" dated September 26, 2013, Humad told potential "consulting" surgeons that SpineFrontier "recognizes and understands the evolving compliance environment in lieu of the Physician Payments Sunshine Act [*i.e.*, Open Payments program], Anti-Kickback Statute [*i.e.*, AKS] and the Stark Law" and is "taking the step to remove direct consulting relationships with surgeons to lessen the potential risks of conflict. We have chosen to outsource all related consulting services to [IME]."

73. Also in the fall of 2013, Dudley, IME's Business Administrator and sole employee, sent a letter to prospective consulting surgeons stating:

> We believe government oversight of the industry will continue, as demonstrated by recent press related to investigations of [PODs] by [HHS-OIG]. IME understands the compliance issues facing its clients and consultants, and has positioned itself to enable its consultants to provide services at fair market hourly

> rates in a statutorily compliant manner with respect to the Physician Payment Sunshine Act [*i.e.*, Open Payments program], Anti-Kickback Statute [*i.e.*, AKS] and the Stark Law as outlined in the enclosed legal opinion letter from our attorney.

(A copy of this letter is attached as Exhibit B). Dudley attached two documents to this letter. One was a form consulting agreement ("IME consulting agreement") stating that "IME manages a referral service providing product consulting and expert witness assignments to certain technology companies, law firms, insurance companies, and other interested parties ('Clients')." (A copy of the IME consulting agreement is attached as Exhibit C). In reality, SpineFrontier was always IME's only "client." The IME consulting agreement did not disclose KICVentures', KIC Management's, or Chin's ownership and control of IME. *See* Exhibit C. The other document that Dudley attached to her letter was a legal opinion from Peter J. Baxter of Strong & Hanni, P.C. ("Strong & Hanni), a law firm in Salt Lake City, Utah. (A copy of this opinion is attached as Exhibit D). The one-page opinion stated that Strong & Hanni, acting as counsel "only for IME," had reviewed the proposed IME consulting agreement and concluded that it complied with the Open Payments program and the AKS. Exhibit D. The opinion expressly assumed that IME would pay compensation "*for bona fide services* by the Consultant consistent with fair market value, in arms'-length transactions[,] and . . . *will not be determined in a manner that takes into account the volume or value of any referrals or business.*" *Id.* (italic emphasis added). Neither of these express assumptions was true in practice.

IV. THE IME CONSULTING AGREEMENT AND PRODUCT "EVALUATIONS"

74. The arrangement described in the IME consulting agreement was a fiction. The Defendants did not enforce the IME consulting agreement as written and ignored many of its provisions in practice. Nor did the Defendants operate and manage IME and SpineFrontier as separate entities, despite expressly describing them as such.

75. The IME consulting agreement described how IME ostensibly would compensate surgeons to "provide real-time evaluations of medical products . . . ." Exhibit C at 1. In a section titled "2.1.1. Medical Product and System Services ($250-500 per hour)," it stated:

> It is expected that a cervical spinal product/construct evaluation is conducted within approximately 30-60 minutes, and a lumbar spinal product/construct evaluation is conducted within approximately 1-2 hours. **This will not include surgical time spent utilizing and/or implanting spinal products.**
>
> You agree to document and submit any time related to product/construct evaluation, training, research or discussions on a monthly basis through a Product/System Services Form provided by IME.... The attached Exhibit...is the IME recommended format of a Product/System Services Form, however a Client may change this format to match Client requirements. All Product/System Services Forms provided by IME and completed by the Consultant will be submitted directly to IME.

Id. at 2 (bold emphasis added; underline in original).

76. The attached exhibit to the IME consulting agreement, titled "Spine Technology Services - Form A" ("Form A"), shown below, did not provide any space for medical device feedback:

IMPARTIAL Medical EXPERTS

SPINE TECHNOLOGY SERVICES – FORM A

Phone: 1-855-411-0453
Email: info@call-ime.com

IME Consultant:	Client:

CHECK ALL THAT APPLY

	Submitted time	Approved time
☐ Cervical Product/Construct Evaluation		
☐ Lumbar Product/Construct Evaluation		
☐ Assist in training with respect to Client products		
☐ Assist with research or papers related to Client products		
☐ Discussions with Client regarding industry trends		
☐ Completed Monthly Review with CTO/Engineer for comprehensive feedback on Client's technology portfolio.	TOTAL TIME	TOTAL TIME

CHECK ALL THAT APPLY
CLIENT SYSTEMS EVALUATED:

Cervical: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

Lumbar: ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐

determined the value of the cases for SpineFrontier) that the surgeons performed using SpineFrontier medical devices.

78. The IME consulting agreement described the invoicing process that IME and SpineFrontier ostensibly instructed surgeons to follow in order to be paid for "consulting" time spent evaluating SpineFrontier medical devices:

> Each invoice shall include an itemization of the activities performed, the amount of time spent (rounded to the nearest 30 minute increment) on each activity, and the date on which such activity was performed. For Medical Product/System Services, each Form [A] should be completed and signed for the month in which Services were provided with the amount of time spent on each activity.

See Exhibit C at 3. As indicated above, the Defendants subsequently replaced the hardcopy Form A with the IME Product/Systems Services Form to permit surgeons to submit their hours through an on-line web portal.

79. In practice, no one at IME or SpineFrontier conducted a review of itemized "consulting" activities to determine the amount of payment due.

80. The IME consulting agreement expressly stated that consulting time "will not include surgical time spent utilizing and/or implanting spinal products." Exhibit C at 2. On December 9, 2013, Humad confirmed to a "consulting" surgeon that the IME consulting agreement "excludes surgical time in implantation of products (Section 2.1.1)."

81. In practice, the Defendants assured surgeons that the time they spent in surgery using SpineFrontier medical devices constituted "consulting" time for which SpineFrontier would pay, and the Defendants instructed surgeons to bill on a per-case basis when they used a SpineFrontier medical device in surgery.

82. SpineFrontier managed IME's consulting agreements, and IME played a minimal role apart from creating a false impression of independence. Although Dudley sent surgeons the

initial IME paperwork, she ceased doing substantive legitimate work once a surgeon had signed up through IME's website. As Dudley explained in an e-mail to a new SpineFrontier sales support manager: "Now that we have moved to URLs [*i.e.*, the IME Product/Systems Services Form] and added a few positions in the Sales Dept at [SpineFrontier], my role is minimal. I primarily deal with surgeons who signed up pre-URL and field questions from any surgeon/rep/distributor that gets my number. I do also have the ability to monitor the electronic tracker for consulting hours at www.spinefrontier.com/ime."

83. The Defendants knowingly took steps to create the false appearance that IME was separate from SpineFrontier, Chin, and Humad. On April 21, 2014, Dudley wrote an e-mail to Humad, Chin, and others agreeing with the premise that "IME needs its own website link, not a subset of [SpineFrontier]," "if we are trying to create separation between entities."

84. In a further attempt to create the illusion of a bona fide separate company from SpineFrontier, IME "kept" a 5% administrative fee on all "consulting" fees it paid to surgeons for SpineFrontier. *See* Exhibit C at 3. As set forth in the IME consulting agreement: "[Consulting f]ees will be paid by IME, net of a 5% processing fee for IME administrative costs as well as the time expended and expenses incurred in the presentation of consulting opportunities to Consultant." *Id.* In reality, IME incurred virtually no administrative costs. The Defendants did not procure a physical office or business space for IME, apart from obtaining a post office box located in Fort Lauderdale, Florida. IME has only ever had one employee, Dudley.

85. SpineFrontier employees performed work on behalf of IME and other companies under the KICVentures and KIC Management umbrella. The Defendants commingled funds between the companies under the KICVentures and KIC Management umbrella, including

SpineFrontier and IME. SpineFrontier and KICVentures paid the "consulting" fees to the surgeons through IME, drawing on SpineFrontier revenues and funds from other companies the Defendants owned and controlled.

V. THE DEFENDANTS BASED PAYMENTS TO SURGEONS ON THE SURGEONS' USE OF SPINEFRONTIER'S MEDICAL DEVICES.

86. The Defendants, and others they employed and directed, informed surgeons that they could bill SpineFrontier, via IME, for consulting on a per-surgical-case basis, rather than based on their actual consulting time. That is, the Defendants directed surgeons to disregard how much time they truly spent consulting and to instead use a predetermined formula that would create the appearance that they had done work. Most commonly, the Defendants told surgeons that they could bill one hour for each cervical case, and two hours for each lumbar case.[2] In reality, the surgeons' time submissions did not matter to the Defendants: the Defendants paid surgeons based on how many surgeries they did with SpineFrontier products,[3] not the quality or usefulness of the surgeons' feedback or the actual time the surgeons devoted to evaluating products.

87. The Defendants, including Chin, Humad, and Dudley, provided prospective "consulting" surgeons with an "IME surgeon payout example" that demonstrated how the surgeons could make predetermined amounts of money by using SpineFrontier medical devices in their procedures:

---

[2] The Defendants sometimes varied the instruction from one surgeon to another. For example, they told some surgeons they could bill thirty minutes for each cervical case and told others they could bill sixty minutes. In all events, the instruction disregarded how much time (if any) the surgeon actually spent consulting.

[3] At times the Defendants were short on cash, and thus did not always timely pay their "consultants," and did not always pay in full.

Illustrative Example for Surgeon Compensation with Impartial Medical Experts (IME)*:

Medical Spine Product Evaluation Services: $500/hour

Hypothetical Example of a week:	# Evaluations	Estimated Hours / Evaluation	Total Hours	
Cervical Product Evaluations/Feedback	3	1 hours	3 hours	$1,500
Lumbar Product Evaluations/Feedback	3	2 hours	6 hours	$3,000
Weekly Total				**$4,500**
Monthly Total (assuming same weeks)				$18,000
Training efforts in month			3 hours	$1,500
Strategic Discussions in month			1 hours	$500
Estimated Monthly Product Evaluation Services				**$20,000**

The "# [of] Evaluations" shown in the above example correlated to the number and type of surgical spine cases a prospective "consulting" surgeon could perform using SpineFrontier medical devices in a week. The "Estimated Hours/Evaluation" shown in the above example identified the pre-determined formula commonly marketed to surgeons: one hour for each cervical case, and two hours for each lumbar case. The "Total Hours" column reflected the "# [of] Evaluations" multiplied by the pre-determined formula set by the Defendants as shown in the "Estimated Hours/Evaluation" column. The Defendants then multiplied the "Total Hours" by an hourly "consulting" rate ($500 per hour in this example) to determine how much the Defendants would pay the surgeons. As described below, the Defendants provided other instructions to surgeons that made clear these sums were not in truth "estimates" of legitimate time surgeons would engage in consultative activities, but rather a roadmap to the per-surgical-case fees the Defendants paid.

88. The Defendants directed SpineFrontier sales personnel to market these per-surgical-case fees. For example Chin, copying Humad, wrote the following direction to a SpineFrontier employee in an e-mail dated September 6, 2013:

> Here is an email you could customize and send
>
> Dear Dr[.]
>
> I want to followup [sic] on our discussion yesterday.
>
> I value your evaluation of our products as we compete to make each product the best in class. If surgeons like you keep working together into [sic] SpineFrontier Inc [sic] I expect this company to move to the front for innovative products.
>
> It seems you want to test things out with us first so I propose that you start by evaluating each product in the cervical spine and lumbar spine and **we compensate you for each case** that you consult with us on purely to evaluate the products and instruments.
>
> **We propose $250 - 500 for a cervical construct and $500-1000 per lumbar construct depending on what you evaluate.** This makes it easy to track and over time you can go to a more general consulting agreement or be involved with the company with your ideas. **So you evaluate a [sic] 100 lumbar constructs we compensate you a $100,000 and so forth.**
>
> If this can work we can send you an official letter.

(Bold emphasis added). Likewise, On May 2, 2015, Chin wrote an e-mail to Dudley, Humad, and six SpineFrontier employees. The subject line of the e-mail was "Evaluating our products in surgery," and it stated, in relevant part:

> Team
>
> To clarify how our advisors should bill for this service
>
> Cervical
> Anticipate 1 hour of evaluation
>
> Lumbar
> Anticipate 2 hours[.]

In reality, this was more than an "anticipation." As described below, the Defendants provided instruction to surgeons to bill set amounts of time for every surgery, and the Defendants frequently "corrected" hourly submissions when surgeons did otherwise. Consistent with Chin's direction, on September 27, 2013, a SpineFrontier sales representative wrote an e-mail to a

prospective "consulting" surgeon stating that the surgeon would be "compensated for the evaluations of our products **on a per case basis** ($500/cervical and $1000/lumbar) . . . ." (Bold emphasis added).

89. Chin, Humad, and Dudley closely supervised and directed negotiations with prospective "consulting" surgeons. For example, Chin agreed to a surgeon's request for a higher fee per case in exchange for the surgeon's agreement to use more SpineFrontier medical devices. A SpineFrontier sales representative wrote an e-mail to the surgeon on February 26, 2014 stating:

> I have talked to Dr. Chin and he in turn has been negotiating with IME. We have come to an agreement for you to be able to bill at $1000/hour per case evaluated.... For example, **if you were to do 2 cervical cases** [at SprineFrontier's pre-set formula of 1 hour per cervical case] **and 2 lumbar cases** [at 2 hours per lumbar case] **a week at the average time of surgery, that would be an additional $6K a week, or more than $300K annually**.... Considering Spine Frontier has negotiated a higher than normal rate for you as a consultant, they are wanting you to be a lead consultant.... **Basically, what that means is that they are asking for you to do all your cases with Spine Frontier products to justify that rate.**

(Bold emphasis added).

90. The Defendants further promised prospective "consulting" surgeons that the Defendants would not cap or limit the amount of money the Defendants would pay, so long as the surgeons continued using SpineFrontier medical devices in spine surgeries. For example:

- On October 30, 2013, a SpineFrontier Senior Sales Representative sent the following e-mail to a prospective "consulting" surgeon:

> For this evaluation of our current products and in helping us make these the best in class products **we are willing to compensate you $500 per cervical construct and $1000 per lumbar construct**.... As we discussed, there is no quota and no non compete clause within this agreement. **Also, there is no cap on how much you are able to consult with us**. This is run through a consulting firm called IME and therefore you would be receiving everything from them, and not from any manufacturing company, including us. That makes this really appealing to

> most surgeons considering the Sunshine Act [*i.e.*, Open Payments program] and OIG. You would be contracted to IME, consulting on behalf of [SpineFrontier], based on the rate we have discussed with them that I have passed on to you. You will also find an attorney opinion letter in the documents that I gave you validating this agreement.
>
> (Bold emphasis added).

- On December 2, 2013, a SpineFrontier Senior Sales Representative followed up by e-mail with a prospective "consulting" surgeon and stated as follows:

> I just wanted to highlight some of the features for you to think about when making your decision between us and the other opportunity you have mentioned looking at.
>
> - SF pays the highest rate of anyone in the market for product evaluation **(flat rate per case)**
> **- No caps on the amount of consulting you can do or the money you can earn**
> - No non-compete clause
> - Works with a 3rd party to protect you from OIG or sunshine act [*i.e.*, Open Payments program] . . . .
>
> (Bold emphasis added).

91. Once a surgeon signed an IME consulting agreement, the Defendants paid that surgeon based on the number and type of surgical spine cases he or she performed using SpineFrontier medical devices, not for the time, if any, spent evaluating the medical devices (whether in the operating room, which the IME agreement prohibited, or elsewhere).

92. On a monthly basis, the Defendants tracked the number of surgical spine cases each IME "consulting" surgeon performed using SpineFrontier medical devices, the sales generated by those cases, and the number of "consulting" hours submitted by the surgeon. The Defendants entered this information into a monthly spreadsheet titled "Total Number of Surgeon Cases & Sales." (An exemplar of such a spreadsheet is attached as Exhibit E).

93. To determine how much to pay a "consulting" surgeon, the Defendants did not assess the value of the surgeon's feedback and did not attempt to confirm how much time the

surgeon had actually engaged in consultative work. Instead, Humad gathered the monthly spreadsheet described above, and then frequently applied a formula of one hour for each cervical case and two hours for each lumbar case. Humad did not review surgeons' consulting feedback (to the extent any existed) when applying this formula. Humad sometimes delegated the task of reviewing the monthly spreadsheet to a "Junior Financial Analyst" at SpineFrontier, who similarly did not review surgeons' consulting feedback (to the extent any existed) when calculating how much to pay a surgeon for purported consulting. Humad instructed the Junior Financial Analyst to review and approve so-called consulting time by looking only to the volume of medical devices the surgeon had used. In an e-mail on February 12, 2015, Humad directed the Junior Financial Analyst "to review reports with me of hours submitted against the monthly sheet you prepare for all surgeons showing total cases and total sales and the[n] we review monthly so you can approve final hours online[.]"

94. On occasion, Humad and others acting at his direction would approve consulting hours that did not perfectly align with the Defendants' predetermined formulas.[4] But at no point did Humad, or anyone acting at his direction, review, assess, or otherwise consider any consulting feedback when determining how many hours to approve, or make any inquiry into how much time a surgeon had actually spent doing consulting work. In some instances, as discussed below, Chin and Humad told surgeons they could get more consulting hours approved overall if the surgeons used more, or more expensive, SpineFrontier medical devices during spine surgeries.

[4] In some instances, SpineFrontier and IME paid less than the formula dictated due to inability to pay at the time.

95. Dudley, in her capacity as IME's sole employee, knew that SpineFrontier encouraged and informed surgeons to bill for "consulting" hours based on the number of spine surgical cases in which they used SpineFrontier medical devices rather than on the actual time (if any) spent consulting. Dudley monitored the hours surgeons submitted each month against the formula of one hour for each cervical case and two hours for each lumbar case performed. If Dudley identified a discrepancy where a surgeon reported more hours than the predetermined formula yielded, she reported that discrepancy to Humad and Chin.

96. When a surgeon submitted "consulting" hours that exceeded the predetermined ratio of cases to hours, the Defendants frequently reduced the hours to bring them into conformity with the per-surgical-case formula. For example:

i. On April 7, 2014, Chin wrote an e-mail to Humad, IME [*i.e.*, Dudley], and SpineFrontier employees, entitled "Reconciling IME hours with payments" that stated:

> The surgeons made a great point that we should manually reconcile their final payments with their IME numbers. So if they bill 14 hours and we pay for 10 hours we should change their online numbers to the 10 hours and not leave a discrepancy.

ii. On October 14, 2014, Dudley wrote an e-mail to Humad and another SpineFrontier employee which stated that a surgeon "seemed to have discrepancies in his hours before where he had more hours than cases I believe. . . . Would like to monitor this."

iii. On April 16, 2015, Chin wrote an e-mail to Humad, surgeon Dr. John Atwater, Dudley, and two other SpineFrontier employees:

> Aditya[,] Please call Dr[.] Atwater to discuss his consulting hours that is [*sic*] submitted online and how it matches up[.]
>
> This process is one of the easiest I am aware among spine companies being online. Because we provide our own input to sign off it completes the circle to make it true consulting activity by the paying company SpineFrontier. IME being the independent vehicle. **If there is no oversight then we all can be accused of a sham system to pay surgeons for business.**

(Bold emphasis added). That same day, Humad spoke with Dr. Atwater and they agreed to reduce the 21.5 hours of time Dr. Atwater had submitted to 9 hours "for the 5 case evaluations done with IME for February," in order to bring the total into alignment with the Defendants' predetermined ratio of cases to hours. Humad summarized this conversation in a subsequent e-mail to Chin, Dr. Atwater, IME [*i.e.*, Dudley], and three SpineFrontier employees. Dudley responded by e-mail to Humad: "Good Job Aditya."

97. By instructing surgeons to submit hours on a per-case basis, and by enforcing pre-determined formulas when reviewing surgeons' submissions, the Defendants ensured they would pay consulting fees based on the volume and value of SpineFrontier medical devices the surgeons used during spine surgeries—without regard for the actual time the surgeons spent in consultative work (if any) or the utility of the surgeons' feedback.

VI. SURGEONS OFTEN PERFORMED LITTLE OR NO WORK IN EXCHANGE FOR "CONSULTING" FEES.

98. The Defendants paid many surgeons for "consulting" work even when they had not performed any such work or communicated any evaluation of SpineFrontier medical devices.

99. The IME Product/System Services Form, which replaced Form A, permitted surgeons to input their "consulting" hours and provide written feedback on SpineFrontier's medical devices via an on-line web portal. The Defendants paid surgeons for purportedly consulting on a SpineFrontier medical device even when surgeons submitted multiple hours to IME using the Product/System Services Form, but left no written medical device feedback at all. For example:

i. Dr. Atwater entered no comments into the IME Products/Systems Services Form on six occasions over 20 months, but SpineFrontier/IME paid him for approximately 10.5 aggregate hours of cervical time and for 39 aggregate hours of lumbar time for those occasions;

ii. Dr. Francis Paul DeGenova entered no comments into the IME Product/System Services Form on 12 occasions over 16 months, but SpineFrontier/IME paid him

for approximately 64.5 aggregate hours of cervical time and for 230 aggregate hours of lumbar time for those occasions;

iii. Dr. Agha Khan entered no comments into the IME Product/System Services Form on six occasions over 24 months, but SpineFrontier/IME paid him for approximately six aggregate hours of cervical time and for 24 aggregate hours of lumbar time for those occasions;

iv. Dr. Michael Murray entered no comments into the IME Product/System Services Form on 12 occasions over 28 months, but SpineFrontier/IME paid him for approximately 24 aggregate hours of cervical time and 36 aggregate hours of lumbar time for those occasions; and

v. Dr. Joseph Shehadi entered no comments into the IME Product/System Services Form on eight occasions over 14 months, but SpineFrontier/IME paid him for approximately 15 aggregate hours of cervical time and for 62.5 aggregate hours of lumbar time for those occasions.

100. In other instances, the Defendants paid surgeons for purportedly consulting on a SpineFrontier medical device when they submitted multiple hours to IME using the Product/System Services Form but left sparse, repetitive, or trivial comments, sometimes wholly unrelated to any medical device they supposedly evaluated. For example:

i. Dr. Atwater entered the comment "Excited to continue to work with Spine Frontier" for the period July 1, 2015 to August 11, 2015 in the IME Product/System Services Form. SpineFrontier/IME paid him for approximately eight and a half hours of lumbar time for that period;

ii. Dr. DeGenova entered "March 2015," "April 2015," and "May" on three consecutive monthly forms between March 1, 2015 and May 20, 2015 in the IME Product/System Services Form. SpineFrontier/IME paid him for approximately 15 aggregate hours of cervical time and for 107 aggregate hours of lumbar time for these occasions;

iii. Dr. Khan entered "will continue to evaluate products" and "will continue to evaluate and use products" on 18 occasions over 24 months in the IME Product/System Services Form. SpineFrontier/IME paid him for approximately 10 aggregate hours of cervical time and 24 aggregate hours of lumbar time for these occasions; and

iv. Dr. Shehadi entered "[t]here were 9 cases this month. Not 7" for the period November 1, 2014 to December 4, 2014 in the IME Product/System Services Form. SpineFrontier/IME paid him for approximately one hour of cervical time and nine hours of lumbar time for that period. He also entered "12 cases in total"

for the period December 1, 2014 to January 4, 2015 in the IME Product/System Services Form. SpineFrontier/IME paid him for approximately two hours of cervical time and 12 hours of lumbar time for that period.

101. Even when surgeons provided some substantive feedback, the Defendants showed no interest in it. When a surgeon commented on a SpineFrontier medical device using the IME Product/System Services Form, IME did not share the feedback with SpineFrontier and its engineers—the SpineFrontier employees who supposedly needed to review the feedback in order to modify or improve SpineFrontier's medical devices. Thus, on December 10, 2015, a SpineFrontier sales representative wrote an e-mail to a SpineFrontier mechanical engineer observing that "no one was paying attention" to the feedback offered by a surgeon in the IME Product/System Services Form.

102. Some surgeons gave in-person verbal feedback on SpineFrontier medical devices to SpineFrontier's sales representatives and engineers. Even in these instances, however, the hours these surgeons submitted often far exceeded whatever actual time they spent consulting or providing feedback to SpineFrontier sales representatives and engineers. Humad, and others working at his direction, did not seek confirmation from the SpineFrontier's sales representatives and engineers as to whether the surgeons provided any verbal feedback, let alone whether the hours the surgeons submitted properly corresponded to the time the SpineFrontier sales representative or engineer spent receiving verbal feedback from the surgeon regarding the medical devices. Moreover, the Defendants did not require SpineFrontier sales representatives and engineers to report the time they spent with surgeons receiving verbal feedback on the medical devices.

103. The Defendants paid many surgeons for evaluating the same SpineFrontier medical device on numerous occasions, even when the device was simple, stable, or relatively rudimentary, *e.g.*, a pedicle screw used in lumbar or cervical spine surgeries. For example:

- Dr. DeGenova "evaluated" more than 100 PedFuse REmind pedicle screws in 2014, and more than 255 of the same screws in 2015, in addition to several other SpineFrontier products. In 2014 and 2015 combined, the Defendants paid Dr. DeGenova $243,110 in "consulting" fees for 80.5 hours of cervical product evaluation time and 367 hours of lumbar product evaluation time. Dr. DeGenova, however, did minimal or no consulting work for IME and/or SpineFrontier in exchange for these payments.

- Dr. Shehadi "evaluated" approximately 96 PedFuse REset pedicle screws in 2014 and 58 in 2015, in addition to several other SpineFrontier products. In 2014 and 2015 combined, the Defendants paid Dr. Shehadi $61,037.50 in "consulting" fees for 18 hours of cervical product evaluation time, and 106 hours of lumbar product evaluation time. Dr. Shehadi, however, did minimal or no consulting work for IME and/or SpineFrontier in exchange for these payments.

104. None of the Defendants followed up with the SpineFrontier sales representatives, SpineFrontier engineers, or the surgeons themselves to determine whether any of the hours the surgeons submitted to IME captured the time the surgeons *actually* spent consulting or evaluating SpineFrontier medical devices. Rather, as described above, the Defendants reviewed the surgeons' number of surgical spine cases using SpineFrontier medical devices (and the total sales generated by those cases) against the number of hours submitted to determine how much to pay the "consulting" surgeons.

VII. EXAMPLES OF DEFENDANTS' KICKBACK-TAINTED RELATIONSHIPS WITH SURGEONS

105. Based on guidelines that SpineFrontier, Chin, and Humad communicated to them, Drs. Atwater, DeGenova, Khan, Murray, and Shehadi admit to reporting consulting hours to IME materially in excess of the number of hours they actually spent engaged in consultative activities, and that the Defendants paid each for consulting hours he did not work. (Settlement Agreements

between the United States of America and Drs. Atwater, DeGenova, Khan, Murray, and Shehadi, respectively, attached as Exhibits F, G, H, I, & J). Drs. Atwater, DeGenova, Khan, Murray, and Shehadi further admit that SpineFrontier, Chin, and Humad, respectively, told them that they could bill a per-case rate, usually (although not always) one hour whenever they used any SpineFrontier cervical spine medical device, and usually (although not always) two hours whenever they used any SpineFrontier lumbar spine medical device, ostensibly for "evaluations" of those medical devices, but regardless of the actual amount of hours (if any) they spent consulting. *Id.* SpineFrontier and IME paid Drs. Atwater,[5] DeGenova,[6] Khan,[7] Murray,[8] and Shehadi[9] even when they provided only minimal or no substantive feedback to SpineFrontier. *Id.*

106. These physicians also admit that the Defendants never asked them to provide more consultative work or expressed any dissatisfaction with their performance as consultants, even when SpineFrontier paid for product evaluations that contained minimal or no substantive content.

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[5] SpineFrontier paid Dr. Atwater $13,775 in consulting fees between January 1, 2014 and December 31, 2014.

[6] SpineFrontier paid Dr. DeGenova $243,200 in consulting fees between January 1, 2014 and July 31, 2015.

[7] SpineFrontier paid Dr. Khan $146,925 in consulting fees between March 15, 2013 and December 31, 2017.

[8] SpineFrontier paid Dr. Murray $86,925 in consulting fees between July 1, 2013 and December 31, 2017.

[9] SpineFrontier paid Dr. Shehadi $61,037.50 in consulting fees between June 1, 2014 and December 31, 2015.

A. Dr. John Atwater

107. Dr. John Atwater is an orthopedic surgeon who is currently practicing in Florida and who previously practiced in Illinois.

108. During June 2013, SpineFrontier and Dr. Atwater discussed a direct consulting agreement under which SpineFrontier would have paid Dr. Atwater at a rate of $500 per hour. Before the parties executed such an agreement, SpineFrontier informed Dr. Atwater that it had "outsourced" its consulting services to IME, and IME and Dr. Atwater entered into a consulting agreement on or about October 17, 2013.

109. According to data that the Defendants submitted to the Open Payments program,[10] between January 1, 2014, and December 31, 2014, SpineFrontier paid Dr. Atwater through IME, a total of approximately of $13,775 in purported consulting fees. During this time, Dr. Atwater used SpineFrontier medical devices in surgical procedures reimbursed by Federal health care programs, including Medicare.

110. Humad informed Dr. Atwater that he could bill SpineFrontier, via IME, a flat rate of one hour whenever he used a SpineFrontier cervical medical device and two hours whenever he used a SpineFrontier lumbar medical device.

111. Dr. Atwater did as Humad instructed. Based upon Humad's guideline, Dr. Atwater billed SpineFrontier for consulting hours materially in excess of the number of hours in which he actually performed consultative activities.

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[10] Humad oversaw SpineFrontier's submission of data to the Open Payments Program with respect to every doctor to whom SpineFrontier made payments, including Drs. Atwater, DeGenova, Khan, Murray, and Shehadi.

112. The Defendants paid Dr. Atwater consulting fees even when Dr. Atwater provided minimal or no consulting feedback on SpineFrontier's products. Furthermore, the Defendants never communicated to Dr. Atwater that his purported consulting work was unsatisfactory, even when SpineFrontier paid Dr. Atwater for medical device evaluations with minimal or no substantive content. The Defendants' decision to pay Dr. Atwater even though he submitted hours that frequently reflected no consulting work was consistent with Humad's instruction to Dr. Atwater that SpineFrontier would pay Dr. Atwater based on the number and type of cases he performed.[11]

B. Dr. Francis Paul DeGenova

113. Dr. Francis Paul DeGenova is a surgeon based in Columbus, Ohio.

114. On February 14, 2013, SpineFrontier and Dr. DeGenova entered into a direct consulting agreement. On October 3, 2013, SpineFrontier informed Dr. DeGenova that it was "outsourcing" its consulting agreement to IME based on concerns regarding the Open Payments program and HHS-OIG's POD Special Fraud Alert; however, Humad also told Dr. DeGenova that SpineFrontier decided to change from SpineFrontier's direct consulting agreement to the IME consulting agreement because of an accounting or bookkeeping issue. In late 2013, IME and Dr. DeGenova entered into a consulting agreement.

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[11] SpineFrontier, acting via Chin and Humad, also paid Dr. Atwater a kickback to another entity he owned, known as Your Extra Hands Surgical Services, LLC ("YEHSS"). Pursuant to a sham agreement between SpineFrontier and YEHSS, SpineFrontier paid YEHSS $3,200 a month between March and October 2014. Dr. Atwater admits that YEHSS did not provide services worth $3,200/month to SpineFrontier; that SpineFrontier was aware YEHHS was not providing such services; and that SpineFrontier nevertheless did not communicate any dissatisfaction with YEHSS. *See* Exhibit F.

115. According to data that the Defendants submitted to the Open Payments program, between January 1, 2014 and July 31, 2015, SpineFrontier paid Dr. DeGenova, through IME, a total of $243,200 in purported consulting fees. During this time, Dr. DeGenova utilized SpineFrontier products, including in surgical surgeries reimbursed by Federal health care programs, including Medicare.

116. Chin and Humad told Dr. DeGenova that he could bill one hour of consulting time for a cervical surgery using SpineFrontier medical devices and two hours of consulting time for each lumbar procedure using SpineFrontier medical devices.

117. Dr. DeGenova did as Chin and Humad instructed. Based upon the guideline that Chin and Humad gave him, Dr. DeGenova billed SpineFrontier for consulting hours materially in excess of the number of hours in which he actually performed consultative activities. As a general matter, in calculating his purported consulting hours, Dr. DeGenova tallied the number of cervical and lumbar procedures he performed each month using SpineFrontier medical devices and multiplied those numbers according to the Defendants' formula—one hour for cervical, two hours for lumbar—to calculate the "consulting" time he submitted to IME using the IME Product/System Services Form each month.

118. The Defendants paid Dr. DeGenova consulting fees even when Dr. DeGenova provided minimal or no consulting feedback on SpineFrontier's medical devices. Furthermore, the Defendants never communicated to Dr. DeGenova that his purported consulting work was unsatisfactory, even when SpineFrontier paid Dr. DeGenova for medical device evaluations with minimal or no substantive content. The Defendants' decision to pay Dr. DeGenova even though he submitted hours that frequently reflected no consulting work was consistent with Chin and

Humad's guideline to Dr. DeGenova that SpineFrontier would pay Dr. DeGenova based on the number and type of cases he performed.

C. Dr. Agha Khan

119. Dr. Khan is a neurosurgeon practicing in Maryland.

120. On or about March 15, 2013, SpineFrontier and Dr. Agha Khan entered into a direct consulting agreement. Pursuant to the March 15, 2013 consulting agreement, SpineFrontier agreed to pay Dr. Khan at a rate of $500 per hour.

121. On or about October 4, 2013, SpineFrontier informed Dr. Khan that it had "outsourced" its consulting services to IME. On or about April 1, 2014, IME and Dr. Khan signed an IME consulting agreement.

122. According to data that the Defendants submitted to the Open Payments program, between March 15, 2013, and December 31, 2018, SpineFrontier paid Dr. Khan directly, and indirectly through IME, a total of $146,925 in purported consulting fees. During this time, Dr. Khan used SpineFrontier medical devices in surgical procedures reimbursed by Federal health care programs, including Medicare.

123. SpineFrontier informed Dr. Khan that he could bill SpineFrontier, via IME, a flat rate of one hour whenever he used a SpineFrontier cervical device and two hours whenever he used a SpineFrontier lumbar device.

124. Dr. Khan did as SpineFrontier instructed. Based upon the SpineFrontier guideline, Dr. Khan billed SpineFrontier for consulting hours materially in excess of the number of hours in which he actually performed consultative activities

125. SpineFrontier assured Dr. Khan that it was simply paying him in line with the agreed-upon ratio of payments to SpineFrontier medical devices used. For example, on or

around January 24, 2016, SpineFrontier's Chief Sales Officer wrote an e-mail to Humad regarding "Dr. Khan IME 2014 & 2015" which stated:

> It looks like you are correct that Dr[.] Khan is submitting too many hours relative to the number of cases that he is doing, as you can see in my attached analysis. I ran a scenario assuming that he might have done an average of 1.5 hours of consulting per case. Even thought [sic] the two are not related**, its [sic] the only proxy I can use for his level of activity**. Based on that assumption, we would owe him for about 54 hours or $25,650.
>
> I will make sure that Dr[.] Khan understands how the consulting works so that he doesn't continue to submit too many hours moving forward.

(Bold emphasis added). The "attached analysis" demonstrated that the Defendants determined Dr. Khan's "consulting" fees by comparing the number of cases in which he used SpineFrontier medical devices against his submitted hours, and only "approved" hours for payment in line with the agreed-upon ratio—and not based on any consulting work that Dr. Khan did (or did not) do.

126. The Defendants paid Dr. Khan consulting fees even when Dr. Khan provided only minimal or no substantive feedback to SpineFrontier. Furthermore, the Defendants never communicated to Dr. Khan that his purported consulting work was unsatisfactory, even when they paid Dr. Khan for medical device evaluations with minimal or no substantive content. The Defendants' decision to pay Dr. Khan even though he submitted hours that frequently reflected no consulting work was consistent with SpineFrontier's guideline to Dr. Khan that it would pay Dr. Khan based on the number and type of cases he performed.

D. Dr. Michael Murray

127. Dr. Michael Murray is an orthopedic surgeon practicing in New York.

128. On or about July 1, 2013, SpineFrontier and Dr. Michael Murray entered into a direct consulting agreement. Pursuant to the July 1, 2013 agreement, SpineFrontier agreed to pay Dr. Murray at a rate of $500 per hour.

129. On or about October 5, 2013, SpineFrontier informed Dr. Murray that it had "outsourced" its consulting services to IME, and IME and Dr. Murray entered into an IME consulting agreement on or around February 2014.

130. According to data that the Defendants submitted to the Open Payments program, between July 1, 2013 and December 31, 2017, SpineFrontier paid Dr. Murray directly, and indirectly through IME, a total of $86,925 in purported consulting fees. During this time, Dr. Murray used SpineFrontier medical devices in surgical procedures reimbursed by Federal health care programs, including Medicare.

131. SpineFrontier informed Dr. Murray that he could bill SpineFrontier, via IME, a flat rate of one hour whenever he used a SpineFrontier cervical device and two hours whenever he used a SpineFrontier lumbar device.

132. Dr. Murray did as SpineFrontier instructed. Based upon that guideline from SpineFrontier, Dr. Murray billed SpineFrontier for consulting hours materially in excess of the number of hours in which he actually performed consultative activities

133. The Defendants paid Dr. Murray consulting fees even when Dr. Murray provided only minimal or no substantive feedback to SpineFrontier. Furthermore, the Defendants never communicated to Dr. Murray that his purported consulting work was unsatisfactory, even when they paid Dr. Murray for medical device evaluations with minimal or no substantive content. The Defendants' decision to pay Dr. Murray even though he submitted hours that frequently reflected no consulting work was consistent with SpineFrontier's guideline to Dr. Murray that it would pay Dr. Murray based on the number and type of cases he performed.

E. Dr. Joseph Shehadi

134. Dr. Joseph Shehadi is a neurosurgeon practicing in Ohio.

135. Dr. Shehadi first heard about SpineFrontier from a colleague in Ohio in early 2014. After IME sent him an invitation to become a consultant, IME and Dr. Shehadi signed an IME consulting agreement on or about June 1, 2014. Under the June 1, 2014, agreement, the Defendants agreed to pay Dr. Shehadi at a rate of $500 per hour.

136. According to data that the Defendants submitted to the Open Payments program, between June 1, 2014 and December 31, 2015, SpineFrontier paid Dr. Shehadi, through IME, a total of $61,037.50 in purported consulting fees. During this time, Dr. Shehadi used SpineFrontier medical devices in surgical procedures reimbursed by Federal health care programs, including Medicare.

137. Humad informed Dr. Shehadi that he could bill SpineFrontier, via IME, a flat rate of one to one-and-a-half hours whenever he used a SpineFrontier cervical device and two hours whenever he used a SpineFrontier lumbar device.

138. Dr. Shehadi did as Humad instructed. Based upon the guideline that Humad gave him, Dr. Shehadi billed SpineFrontier for consulting hours materially in excess of the number of hours in which he actually performed consultative activities

139. At certain times, the Defendants did not pay Dr. Shehadi for the full amount of hours he submitted to IME via the Product/Systems Services Form. In response to Dr. Shehadi's inquiries concerning why that had happened, Humad told him that he did not use enough of SpineFrontier's products to justify his consulting hours. Humad further communicated to Dr. Shehadi that, if Dr. Shehadi used more SpineFrontier products, then SpineFrontier could pay him more "consulting" fees.

140. The Defendants paid Dr. Shehadi consulting fees even when Dr. Shehadi provided only minimal or no substantive feedback to SpineFrontier. Furthermore, the

Defendants never communicated to Dr. Shehadi that his purported consulting work was unsatisfactory, even when they paid Dr. Shehadi for medical device evaluations with minimal or no substantive content. The Defendants' decision to pay Dr. Shehadi even though he submitted hours that frequently reflected no consulting work was consistent with Humad's guideline to Dr. Shehadi that SpineFrontier would pay Dr. Shehadi based on the number and type of cases he performed.

VIII. THE DEFENDANTS KNOWINGLY AND WILLFULLY PAID AND CONSPIRED TO PAY SURGEONS TO INDUCE THEIR USE OF SPINEFRONTIER DEVICES IN SPINE SURGERIES THAT FEDERAL HEALTH CARE PROGRAMS REIMBURSED.

141. The Defendants intended their "consulting" payments, including those through IME, to induce spine surgeons to use SpineFrontier medical devices during spine surgeries, thereby increasing sales.

142. Humad directly and indirectly told surgeons that more "consulting" hours would be approved for payment if the surgeons used more (or more expensive) SpineFrontier medical devices—regardless of any "consulting" work or feedback.

143. For example, Humad told Dr. Murray that he would be a more "valuable" consultant if he used more expensive SpineFrontier medical devices, such as the InSpan—one of SpineFrontier's most expensive devices. At various times, Humad also separately told Drs. Murray and Shehadi that their respective usage of SpineFrontier's medical devices did not support the consulting hours they submitted through IME. Humad informed both Drs. Murray and Shehadi that, if they used more SpineFrontier medical devices, then SpineFrontier could pay more in "consulting" fees. *See, e.g.,* Exhibit J.

144. The Defendants reviewed documents that listed each surgeon's surgical spine cases using SpineFrontier medical devices against that surgeon's submitted "consulting" hours.

The Defendants did so in order to ensure that the kickbacks produced the desired effect: an increase in SpineFrontier's sales revenues.

145. The Defendants internally touted that their kickbacks successfully induced surgeons to use SpineFrontier medical devices. The Defendants understood that the additional income surgeons received from SpineFrontier gave the company an advantage over its competitors. Moreover, the Defendants knew that their sham consulting payments were a driving factor in the surgeons' use of SpineFrontier medical devices. For example, the Defendants created a spreadsheet, entitled the "WHY Report," which detailed that "consulting" was a primary reason for many surgeons' use of the company's medical devices:

Surgeon	Hospital	Why do they use us?
Jeffrey Carlson, M.D.	Bon Secours Mary Immaculate	**Consulting**, told him we would develop his ideas. Wanted to be a part of something bigger, grass roots effort
Jeffrey Moore, D.O.	Bon Secours Mary Immaculate	**consulting.**
Paul DeGenova, D.O.	Grant Medical Center	**consulting**. also wants to teach other surgeons
Joseph Shehadi, M.D.	Grant Medical Center	**Consulting**, wants to be involved with surgeon network
Mike Murray, M.D.	Lawrence Hospital Center	**consulting**, and Dan Ullman is a veteran
Vivek Kushwaha, M.D.	Houston Orthopedic and Spine Hospital	**Consulting**, value of growth, equity
Jason Tinley, M.D.	USMD Ft. Worth	**consulting** and business growth potential.
Jason Montone, D.O.	North Ks. City Hospital	**Consulting**
Bonaventure Ngu, M.D.	Indirect	converted from alphatec. **consulting**. Outreach work in Africa and support while he brings his business to the surgery center
Matthew Wasserman, M.D.	Memorial Hermann Katy	**Consulting**, teaching opportunities
Jacob Rosenstein, M.D.	USMD Arlington	Was looking for a new cervical plate option. Scott Autrey cold called and discovered that need. Dr. Rosenstien was eager to work with our design team to create an ideal multi-level cervical plate. **Consulting revenue was also very appealing to him**. He liked our one-level cervical plate and we promised to make him a TLIF inserter and to design a multi-level cervical plate

John Atwater, M.D.	0	**consulting**, said we would use his neural monitoring company and Kyle Black's PA-on-demand service
Agha Khan, M.D.	Maryland General Hospital	**consulting** opportunities. Told him we'd host 5 labs per year at his facility. Also told him we'd help him bring better surgical care to Africa
Dhruv Pateder, M.D.	Reston Medical Center	**consulting opportunities**

(Bold emphases added; excerpts from original).

146. The Defendants imposed no substantive qualifications or prerequisites before a surgeon could sign up as a consultant; rather, the Defendants encouraged all surgeons who used SpineFrontier's medical devices to be "consultants." Far from seeking expert consulting feedback only from accomplished and experienced surgeons, the Defendants even discussed offering IME consulting agreements to medical school residents in an effort to expand SpineFrontier's revenue possibilities once the residents graduated.

147. The Defendants were well aware of the relevant health care laws, and referenced those laws in pitch materials they distributed to prospective consultants. The cover letter IME sent to surgeons along with the IME consulting agreement stated: "IME understands the compliance issues facing its clients and consultants, and has positioned itself to enable its consultants to provide services at fair market hourly rates in a statutorily compliant manner with respect to the Physician Payment Sunshine Act [*i.e.*, the Open Payments program], Anti-Kickback Statute [*i.e.*, AKS] and the Stark Law as outlined in the enclosed legal opinion letter from our attorney." Exhibit B.

148. The Defendants knew that the law prohibited them from paying "consulting" surgeons merely for using SpineFrontier's medical devices in a surgical spine case. For instance, on April 16, 2015, Chin wrote an e-mail to Humad, Dr. Atwater, Dudley, and two other SpineFrontier employees:

> Aditya[,] Please call Dr[.] Atwater to discuss his consulting hours that is [*sic*] submitted online and how it matches up[.]
>
> This process is one of the easiest I am aware among spine companies being online. Because we provide our own input to sign off it completes the circle to make it true consulting activity by the paying company SpineFrontier. IME being the independent vehicle. **If there is no oversight then we all can be accused of a sham system to pay surgeons for business.**

(Bold emphasis added). In reality, as described above, there was no "oversight" of the Defendants' sham system to pay surgeons for business, apart from the Defendants' efforts to ensure that surgeons used enough SpineFrontier medical devices in spine surgeries.

149. Moreover, the Defendants knew that the law prohibited them from paying their consulting surgeons based on the value or volume of referrals, *i.e.*, how many, and what type of, SpineFrontier medical devices the "consulting" surgeons used during spine surgeries. The Defendants also knew that the law required them to pay for actual consulting work at a fair market value rate. The opinion letter that Defendants obtained from Strong & Hanni expressly stated that the "compensation agreed upon and actually paid to the Consultant by IME <u>will not be</u> determined in a manner that takes into account the volume or value of any referrals or business." Exhibit D. Likewise, in a letter written by Humad and SpineFrontier's General Counsel, the Defendants assured surgeons that the IME consulting agreements would pay consulting surgeons "at a **fair market rate** of up to $500 per hour[.]" (Bold emphasis added).

150. Notwithstanding their knowledge of the law and relevant regulations, the Defendants acted contrary to Strong & Hanni's opinion letter and repeatedly disregarded concerns raised by surgeons—and attorneys representing certain surgeons—that IME's "consulting" payments ran afoul of the AKS. Instead, the Defendants falsely assured surgeons that the IME consulting arrangement complied with the law.

151. The Defendants knew that their representations regarding the IME consulting arrangement's compliance with the law were false. The Defendants paid surgeons based on their use of SpineFrontier's medical devices, and they disregarded safeguards expressly set forth in the IME consulting agreement.

IX. DEMONSTRATIVE CLAIMS TO FEDERAL PROGRAMS

152. The Defendant's kickbacks caused the submission of false claims resulting in tens of millions of dollars of damages to the government.

153. Specific examples of false claims the Defendants caused to be submitted to Medicare and TRICARE as a result of conduct alleged herein are attached as Exhibit K.

COUNT I
(Against SpineFrontier, IME, Chin, Humad, and Dudley)
False Claims Act, 31 U.S.C. § 3729(a)(1)(A)
Presenting and Causing False Claims to Be Presented for Payment

154. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

155. SpineFrontier, IME, Chin, Humad, and Dudley knowingly caused third-party facilities including but not limited to hospitals, ambulatory surgery centers, physician practices, and physicians to submit claims for payment to federal health care programs for surgeries and related services that were false or fraudulent, and not payable, because SpineFrontier, IME, Chin, Humad, and Dudley knowingly and willfully offered and paid remuneration in violation of the AKS to induce surgeons to order, arrange for, and recommend the purchase of SpineFrontier medical devices for which payment was made in whole or in part by federal health care programs, including Medicare and TRICARE.

156. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

COUNT II
(Against SpineFrontier, IME, Chin, Humad, and Dudley)
False Claims Act, 31 U.S.C. § 3729(a)(1)(B)
Use of False Statements

157. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

158. SpineFrontier, IME, Chin, Humad, and Dudley knowingly made or used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted to the United States, and the United States' payment of those false and fraudulent claims was a reasonable and foreseeable consequence of SpineFrontier's, IME's, Chin's, Humad's, and Dudley's statements and actions.

159. These false records and statements included false certifications on provider enrollment forms and false and misleading representations on claim forms that the claims to federal health care programs for spinal surgeries using SpineFrontier medical devices complied with the AKS, when in fact those claims violated the AKS.

160. SpineFrontier, IME, Chin, Humad, and Dudley made or used, or caused to be made or used, such false records or statements with actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false or fraudulent.

161. By virtue of these false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

COUNT III
(Against All Defendants)
False Claims Act, 31 U.S.C. § 3729(a)(1)(C)
Conspiracy to Submit False Claims

162. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

163. The Defendants entered into an unlawful agreement to cause the presentation of false or fraudulent claims to the United States, and performed acts in furtherance of this conspiracy. The Defendants created and used IME as a vehicle through which to offer and pay surgeons prohibited remuneration in violation of the AKS in order to induce them to use SpineFrontier medical devices, including in procedures reimbursed by federal health care programs, including Medicare and TRICARE. Furthermore, the Defendants used and directed the use of personnel and assets from SpineFrontier, IME, KICVentures, and KIC Management to effectuate those unlawful payments.

164. By virtue of the resulting false or fraudulent claims, the United States suffered damages in an amount to be determined at trial.

COUNT IV
(Against All Defendants)
Unjust Enrichment

165. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

166. This is a claim for the recovery of monies by which all Defendants have been unjustly enriched.

167. By directly or indirectly obtaining from the United States, through federal health care programs, funds to which they were not entitled, Defendants were unjustly enriched, and are liable to account and pay such amounts, or the proceeds therefrom, which are to be determined at trial.

COUNT V
(Against All Defendants)
Payment by Mistake

168. The United States incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

169. This is a claim for the recovery of monies the United States paid directly or indirectly to Defendants as a result of mistaken understandings of fact.

170. The United States' mistaken understandings of fact were material to its decisions to pay claims the Defendants caused to be submitted to federal health care programs for spinal surgeries using SpineFrontier medical devices.

171. The United States, acting in reasonable reliance on the truthfulness of the claims to federal health care programs for spinal surgeries using SpineFrontier medical devices, paid monies directly or indirectly to Defendants to which they were not entitled. Thus, the United States is entitled to recoup such monies, in an amount to be determined at trial.

PRAYER FOR RELIEF

The United States requests that judgment be entered in its favor and against defendants as follows:

(a) On Counts I, II, and III (False Claims Act), for treble the United States' damages, together with the maximum civil penalties allowed by law;

(b) On Count IV (Unjust Enrichment), in the amount the Defendants were unjustly enriched;

(c) On Count V (Payment by Mistake), in the amount the Defendants illegally obtained and retained; and

(d) For pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38, the United States requests a trial by jury.

Date: March 5, 2020.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing document was served by first-class mail on:

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Pursuant to 31 U.S.C. § 3730(b)(2), no service was made upon the Defendant because this case is still under seal.

Dated: March 5, 2020

By: _____
STEVEN SHAROBEM
Assistant United States Attorney