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12 UNITED STATES DISTRICT COURT  
13 CENTRAL DISTRICT OF CALIFORNIA

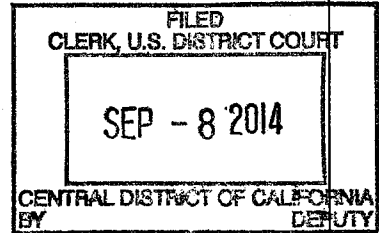
14 UNITED STATES OF AMERICA,  
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16 Plaintiff,  
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18 vs.  
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20 RELIANCE MEDICAL SYSTEMS, LLC,  
APEX MEDICAL TECHNOLOGIES,  
21 LLC, KRONOS SPINAL  
TECHNOLOGIES, LLC, BRET BERRY,  
22 JOHN HOFFMAN, ADAM PIKE, and  
23 ARIA O. SABIT, M.D.  
24

25 Defendants.  
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CV14-6979 *CAS PJW*

Case No.

UNITED STATES' COMPLAINT

1 The United States of America brings this action against Reliance Medical  
2 Systems, LLC, Apex Medical Technologies, LLC, Kronos Spinal Technologies,  
3 LLC, Bret Berry, John Hoffman, Adam Pike, and Aria O. Sabit, M.D.  
4

5 **NATURE OF ACTION**

6 1. This is an action to recover damages and civil penalties under the  
7 False Claims Act (FCA), 31 U.S.C. §§ 3729-33, and to recover money for common  
8 law or equitable causes of action for payment by mistake and unjust enrichment.  
9

10 The United States' claims arise out of an illegal scheme by the defendants to  
11 knowingly submit – and cause to be submitted – claims to the Medicare program  
12 for items and services that were tainted by kickbacks, were not reasonable and  
13 necessary, and were otherwise false and fraudulent.  
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16 2. At all relevant times, Reliance Medical Systems (Reliance) sold spinal  
17 implants in Southern California through distributorships that it controlled,  
18 including Apex Medical Technologies (Apex) and Kronos Spinal Technologies  
19 (Kronos). Drs. Aria Sabit and Sean Xie were physician-investors in Apex, and  
20 Drs. Gowriharan Thaiyananthan and Ali Mesiwala were physician-investors in  
21 Kronos.  
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24 3. The spinal fusion claims of Drs. Sabit, Xie, Thaiyananthan, and  
25 Mesiwala, were tainted by kickbacks that Reliance paid to them through Apex and  
26 Kronos. Consequently, the Medicare claims for spinal fusion surgeries that these  
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1 physicians submitted for the spinal fusion surgeries they performed using Reliance  
2 implants were false and not payable. The Medicare claims submitted by hospitals  
3 for the related hospital services also were tainted by kickbacks and, accordingly,  
4 were false and not payable. This action seeks to recover the money Medicare paid  
5 as a result of the false claims that Reliance, Berry, Hoffman, and Pike, through  
6 Apex, and Kronos, caused to be submitted by Drs. Sabit, Xie, Thaiyananthan, and  
7 Mesiwala, and by the hospitals where those physicians performed surgeries using  
8 Reliance implants.  
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12 4. In addition, certain of the spinal fusion surgeries performed by  
13 Reliance's physician-investors using Reliance implants were not medically  
14 necessary or were more extensive than what was necessary. The payments that  
15 Reliance made to physician-investors, through Apex and Kronos, caused them to  
16 perform surgeries using Reliance implants that were not medically necessary  
17 and/or were more extensive than what was necessary. This action also seeks to  
18 recover the money Medicare paid as a result of the false claims for medically  
19 unnecessary surgeries and related hospital services that Reliance, Berry, Hoffman,  
20 and Pike, through Apex and Kronos, caused to be submitted by Drs. Xie,  
21 Thaiyanantha and Mesiwala and the hospitals where those physicians performed  
22 unnecessary surgeries using Reliance implants.  
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**JURISDICTION**

5. This action arises under the FCA and under the common law.

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. § 1345 because the United States is the Plaintiff. In addition, the Court has subject matter jurisdiction over the FCA cause of action under 28 U.S.C. § 1331. The Court has personal jurisdiction over the defendants pursuant to 31 U.S.C. § 3732(a) because the defendants transact or transacted business in the Central District of California.

**VENUE**

7. Venue is proper in the Central District of California under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because the defendants conducted business in this district; Drs. Sabit, Xie, Thaiyananthan, and Mesiwala performed surgeries using Reliance implants in this district; and many of the events giving rise to these claims occurred in this district.

**PARTIES**

8. The United States of America is the Plaintiff. The United States brings this action on behalf of the United States Department of Health and Human Services (HHS), including HHS's component, the Centers for Medicare and Medicaid Services (CMS), which administers the Medicare and Medicaid Programs.

1           9.     Defendant Reliance Medical Systems, LLC (Reliance), is a Utah  
2 company. Reliance's mailing address is 1838 East 9800 South, Sandy, Utah,  
3 84092, and its principal place of business is 545 West 500 South, Bountiful, Utah,  
4 84010. At all relevant times, Reliance operated companies that had financial  
5 relationships with physicians who arranged for the hospitals in which these  
6 physicians worked to purchase Reliance spinal implants.  
7  
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9           10.    Defendant Apex Medical Technologies, LLC (Apex), is one such  
10 Reliance affiliate. Apex is a Florida company, which lists its street address as  
11 11313 Mandarin Ridge Lane, Jacksonville, Florida, 32258. Between 2010 and  
12 2012, Apex's conducted business in Southern California.  
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15           11.    At all relevant times, Apex derived revenues from the sale of spinal  
16 implants to the hospitals in which its two physician-investors – Drs. Aria Sabit and  
17 Sean Xie – performed surgeries.  
18

19           12.    Defendant Kronos Spinal Technologies, LLC (Kronos), is another  
20 Reliance affiliate. Kronos is a Florida company, which lists its street address as  
21 11313 Mandarin Ridge Lane, Jacksonville, Florida, 32258. At all relevant times,  
22 Kronos' principal place of business in Southern California.  
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25           13.    At all relevant times, Kronos derived revenues from the sale of spinal  
26 implants to the hospitals in which its physician-investors – including Drs. Ali  
27 Mesiwala and Gowriharan Thaiyananthan – performed surgeries.  
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1           14. Defendant Bret Berry is a resident of the state of Florida. Berry is a  
2 Reliance founder and owner and an investor in approximately twenty companies  
3 that distribute Reliance implants, including Apex and Kronos. His last known  
4 address is 514 Frank Shaw Road, Tallahassee, Florida, 32312.  
5

6           15. Defendant John Hoffman is a resident of the state of Texas. Hoffman  
7 is a distributor for Reliance and an investor in approximately five companies that  
8 distribute Reliance implants, including Apex and Kronos. His last known address  
9 is 6738 Manassas Drive, San Antonio, Texas, 78240.  
10

11           16. Defendant Adam Pike is a resident of the state of Utah. Pike is a  
12 Reliance founder and owner and an investor in approximately twenty companies  
13 that distribute Reliance implants, including Apex and Kronos. His last known  
14 address is 313 Pheasant Ridge Circle, Bountiful, Utah, 84010.  
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16           17. Defendant Aria Sabit, M.D. is a resident of the state of Michigan. Dr.  
17 Sabit was an Apex physician-investor from May 1, 2010, until August 10, 2012.  
18 Between April 2010 and June 2012, Dr. Sabit was an enrolled Medicare physician.  
19 Between June 2009 and December 2010, Dr. Sabit resided in Ventura, California,  
20 where he performed surgeries on Medicare beneficiaries. Dr. Sabit's last known  
21 address is 848 Ann Street, Birmingham, Michigan, 48009.  
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## BACKGROUND

### **I. THE MEDICARE PROGRAM**

18. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, known as the Medicare Program, to pay for the costs of certain health care services. 42 U.S.C. § 1395, *et seq.* Entitlement to Medicare benefits is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 to 426-1.

19. The Department of Health and Human Services (HHS) is responsible for the administration and supervision of the Medicare Program. The Centers for Medicare & Medicaid Services (CMS) is an agency of HHS and is directly responsible for the administration of 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 a variety of “medical and other services.” *See* 42 U.S.C. §§ 1395j to 1395w-5.

20. To participate in the Medicare Program, a health care provider must file a provider agreement with the Secretary of HHS. 42 U.S.C. § 1395cc. The

1 provider agreement requires compliance with the requirements that the Secretary  
2 deems necessary for participation in the Medicare Program and in order to receive  
3 reimbursement from Medicare. The provider agreement specifically requires  
4 compliance with the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b).  
5

6 21. Medicare reimburses only those services furnished to beneficiaries  
7 that are “reasonable and necessary for the diagnosis or treatment of illness or  
8 injury...” 42 U.S.C. § 1395y(a)(1)(A). In submitting claims for payment to  
9 Medicare, providers must certify that the information on the claim form presents an  
10 accurate description of the services rendered and that the services were reasonably  
11 and medically necessary for the patient.  
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15 **A. Medicare Part A**

16 22. Part A of the Medicare program authorizes payment for institutional  
17 care, including hospitalization, for eligible patients.  
18

19 23. Under Medicare Part A, hospitals enter into an agreement with  
20 Medicare to provide health care items and services to treat Medicare patients. The  
21 hospital, also called a “provider,” is authorized to bill Medicare for that treatment.  
22

23 24. During the relevant time period, CMS reimbursed hospitals for  
24 inpatient Part A services through Medicare Administrative Contractors (MACs).  
25

26 25. MACs are private insurance companies that are responsible for  
27 determining the amount of payments to be made to providers. *See* 71 Fed. Reg.  
28



1 67960, 68181 (Nov. 24, 2006). Under their contracts with CMS, MACs review,  
2 approve, and pay Medicare bills, called “claims,” received from hospitals. *See* 42  
3 C.F.R. § 421.5(b). Those claims are paid with federal funds.  
4

5 26. Since 2007, in order to get paid, a hospital must complete and submit  
6 a claim for payment on a Form UB-04. This form contains patient-specific  
7 information including the diagnosis and types of services that are assigned or  
8 provided to the Medicare patient. The Medicare program relies upon the accuracy  
9 and truthfulness of the UB-04 Forms to determine whether the service is payable  
10 and what amounts the hospital is owed.  
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13 27. In addition, and at the end of each fiscal year, a hospital submits to the  
14 MAC a form referred to as a “cost report,” which identifies any outstanding costs  
15 that the hospital is claiming for reimbursement for that year. The cost report serves  
16 as the final claim for payment that is submitted to Medicare. The Medicare  
17 program relies upon the accuracy and truthfulness of the cost report to determine  
18 what amounts, if any, the hospital is owed, or what amounts the hospital has been  
19 overpaid during the year.  
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23 28. In 1983, Congress established the prospective payment system (PPS)  
24 as the system by which hospitals are reimbursed for inpatient hospital costs. Under  
25 PPS, the amount Medicare pays a hospital for treating an inpatient Medicare  
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1 beneficiary is based in large part on the particular condition that led to the patient's  
2 admission to, or that was principally treated by, the hospital.

3           29. Under PPS, a patient's illness or condition is categorized under a  
4 classification system called a diagnostic related group (DRG). The DRG  
5 establishes how much the hospital will be paid under Medicare and reflects the  
6 resources the patient's condition or treatment typically requires. The MAC uses  
7 the patient specific information (for example, the diagnosis codes) submitted by  
8 the hospital on the UB-04 to determine what DRG is assigned to a certain claim,  
9 and hence, what amount will be paid.  
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13           30. The DRG is intended to reimburse the hospital for the expected costs  
14 of any items that it must purchase in connection with the hospitalization. The  
15 DRG is intended to compensate the hospital for any spinal implants, where those  
16 devices are appropriately used to treat a Medicare beneficiary.  
17  
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### 19           **B. Medicare Part B**

20           31. Medicare Part B is funded by insurance premiums paid by enrolled  
21 Medicare beneficiaries and by contributions from the Federal Treasury. Eligible  
22 individuals who are 65 or older, or disabled, may enroll in Medicare Part B to  
23 obtain benefits in return for payments of monthly premiums. Payments under  
24 Medicare Part B are typically made directly under assignment to service providers  
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1 and practitioners, such as physicians, rather than to the patient/beneficiary. In that  
2 case, the physician bills the Medicare Program directly.

3 32. The United States provides reimbursement for Medicare Part B claims  
4 from the Medicare Trust Fund through CMS. To assist in the administration of the  
5 Medicare Part B Program, CMS contracts with MACs. 42 U.S.C. § 1395u. MACs  
6 are responsible for processing the payment of Medicare Part B claims to providers  
7 on behalf of CMS.  
8

9 33. In order to bill Medicare, a physician must submit an electronic or  
10 hard-copy claim form called a CMS 1500 form to the carrier. When the CMS  
11 1500 is submitted, the physician certifies that he or she is knowledgeable of  
12 Medicare's requirements and that the services for which payment is sought were  
13 "medically indicated and necessary for the health of the patient."  
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16 34. Physicians wishing to submit the CMS 1500 electronically must  
17 submit a provider enrollment form.  
18

19 35. For a CMS 1500 claim to be paid by the Medicare Part B Program,  
20 the claim must identify each service rendered to the patient by the physician. The  
21 service is identified through a corresponding code that is listed in the American  
22 Medical Association (AMA) publication called the Current Procedural  
23 Terminology (CPT) Manual. The CPT is a systematic list of codes for procedures  
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1 and services performed by or at the direction of a physician. Each procedure or  
2 service is identified by a five-digit CPT code.

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4 36. In addition to the CPT Manual, the AMA publishes the International  
5 Classification of Diseases (ICD-9) Manual, which assigns a unique numeric  
6 identifier to each medical condition. In order to be payable by Medicare, the CMS  
7 1500 claim form must identify both the CPT code that the provider is billing for  
8 and the corresponding ICD-9 code that identifies the patient's medical condition  
9 that renders the provider's service medically necessary.  
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## 12 **II. SPINAL SURGERY**

13 37. There are four regions of the spine: the cervical, thoracic, lumbar, and  
14 sacral regions. The cervical spine consists of seven vertebrae in the neck region;  
15 the thoracic spine consists of twelve vertebrae in the chest region; and the lumbar  
16 spine consists of five vertebrae in the lower back region. The sacral region of the  
17 spine is below the lumbar region and consists of additional fused (or non-  
18 articulating) vertebrae.  
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22 38. Each vertebra of the spine is referred to by a letter and number  
23 denoting its region and location. From top to bottom, the seven vertebrae of the  
24 cervical spine are named C1-C7; the twelve vertebrae of the thoracic spine are  
25 named T1-T12; and the five vertebrae of the lumbar spine are named L1-L5. In  
26 addition, the vertebra of the sacral spine that adjoins the lumbar spine is named S1.  
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1           39.    A discectomy is a surgical procedure to remove a herniated,  
2    intervertebral disc.

3           40.    A laminectomy is a surgical procedure to remove the lamina, which is  
4    the back part of the vertebra.  
5

6           41.    A corpectomy is a surgical procedure to remove all or the majority of  
7    a vertebral body, which is the front part of the vertebra.  
8

9           42.    A spinal fusion is an invasive surgical procedure that is performed to  
10   join (or “fuse”) two or more vertebrae of the spine.  
11

12           43.    Lumbar fusion surgeries can be performed in a number of different  
13   ways. A procedure in which the surgeon accesses the spine through an incision in  
14   the back is called a posterior fusion. A procedure in which the surgeon accesses  
15   the spine through an abdominal incision is called an anterior fusion. A procedure  
16   in which the surgeon accesses the spine through an incision in the psoas muscle –  
17   which is located at the side of the lumbar region and extends into the pelvis – is  
18   often called an XLIF (or extreme lateral interbody fusion). A procedure in which  
19   the surgeon approaches through both the abdomen and the back is called a 360-  
20   degree fusion.  
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25           44.    Spinal implants may be used in connection with a fusion surgery to  
26   help stabilize the spine and facilitate fusion.  
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1           45. Physicians typically select the implantable device they use during  
2 surgical procedures. Hospitals typically purchase the selected devices directly  
3 from vendors.  
4

5           46. A spinal implant must be cleared by the Food and Drug  
6 Administration (FDA) before a vendor can market that implant in interstate  
7 commerce.  
8

9           47. Companies can bypass the FDA's premarket approval process if they  
10 can show that their proposed device is "substantially equivalent" to other  
11 commercially available devices. *See generally* 21 U.S.C. § 360e(b)(1); 21 CFR §  
12 814.1(c)(1).  
13

14           48. During the relevant period, the types of implants described below  
15 were generally commercially available.  
16

17           49. A "cage" is an implant that is typically made of polyetheretherketone  
18 (PEEK) plastic, and that may be used in a fusion surgery to maintain space  
19 between the vertebral segments.  
20

21           50. Through Apex and Kronos, Reliance charged hospitals as much as  
22 \$7,500 for each cage.  
23

24           51. A "pedicle screw" is a metal implant, typically made of titanium,  
25 which is implanted into the bones of the spine to facilitate the fixation of the spinal  
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1 vertebrae. Screws are implanted into two or more adjacent spinal segments, and  
2 used to anchor “rods” or “plates.”

3 52. Through Apex and Kronos, Reliance charged hospitals as much as  
4 \$2,400 for each screw.  
5

6 53. A “plate” is an implant that is used in connection with cervical  
7 procedures. A plate is anchored by screws and placed longitudinally along the  
8 front of the cervical spine.  
9

10 54. Through Apex and Kronos, Reliance charged hospitals as much as  
11 \$2,400 for each plate.  
12

13 55. A “rod” is an implant that is anchored by pedicle screws, and that is  
14 placed longitudinally along the back of the lumbar and thoracic spine.  
15

16 56. Through Apex and Kronos, Reliance charged hospitals as much as  
17 \$522.50 for each rod.  
18

19 57. A “crosslink” is an implant that can be used to establish a transverse  
20 connection between two rods.  
21

22 58. Through Apex and Kronos, Reliance charged hospitals as much as  
23 \$1,875 for each crosslink.  
24

### 25 **III. THE ANTI-KICKBACK STATUTE**

26 59. The Anti-Kickback Statute (AKS) prohibits any person or entity from  
27 knowingly and willfully offering, paying, soliciting, or receiving any remuneration,  
28

1 directly or indirectly, to induce or reward a person for, *inter alia*, purchasing,  
2 ordering, arranging for, or recommending the purchase or ordering of any goods or  
3 services for which payment may be made, in whole or in part, under a federal  
4 health program, including Medicare. 42 U.S.C. § 1320a-7b(b)(1),(2).

6 60. The AKS “seeks to ensure that referrals will be based on sound  
7 medical judgment and that providers will compete for business based on quality  
8 and convenience, instead of paying for ... [referrals].” OIG Advisory Op., No. 98-  
9 16 (Nov. 3, 1998). The AKS is intended to prevent arrangements that can lead to  
10 the distortion of medical decision-making, overutilization of services and supplies,  
11 increased costs to Federal health care programs, and unfair competition. *See* 65  
12 Fed. Reg. 59,434, 59,440 (Oct. 5, 2000).

16 61. For the purposes of the AKS, “remuneration” includes the transfer of  
17 anything of value, “directly or indirectly, overtly or covertly, in cash or in kind.”  
18 42 U.S.C. § 1320a-7b(b)(1). In addition to the more obvious types of remuneration  
19 (e.g., cash payments), the statute also prohibits less direct forms of payment, such  
20 as providing investment opportunities or equity interests, particularly under  
21 economic terms that make the investment extremely advantageous, or where the  
22 provider has a substantial financial interest in generating business for the company  
23 in which he or she invests. *See* OIG Advisory Op., No. 97-5 (Oct. 6, 1997); *see*  
24  
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1 also Special Advisory Bulletin: Contractual Joint Ventures, 68 Fed. Reg. 23,148,  
2 23,150 (Apr. 30, 2003).

3  
4 62. The AKS's legislative history confirms Congress's intent to interpret  
5 the term "remuneration" broadly. *See* 123 Cong. Rec. 30,280 (1977) (Statement of  
6 Rep. Rostenkowski), cited at 56 Fed. Reg. 35,952, 35,958 (July 29, 1991) (Final  
7 Rule regarding AKS Safe Harbors).

8  
9 63. The knowing and willful payment of remuneration to a physician – or  
10 the knowing and willful receipt of remuneration by a physician – violates the AKS  
11 when even one purpose of the transaction is to induce the referral – or generation –  
12 of federal health program-related business.

13  
14  
15 64. As codified in the Patient Protection and Affordable Care Act of 2010,  
16 the AKS provides that, "a claim that includes items or services resulting from a  
17 violation of [the AKS] constitutes a false or fraudulent claim for purposes of [the  
18 False Claims Act]." 42 U.S.C. § 1320-a-7b(g). This amendment to the AKS  
19 clarifies "that all claims resulting from illegal kickbacks are considered false  
20 claims for purposes of civil action under the False Claims Act." 155 Cong. Rec.  
21 S10854 (statement of Sen. Leahy).

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24 **A. AKS "Safe Harbors"**

25  
26 65. OIG has promulgated "safe harbor" regulations that define practices  
27 that are not subject to the AKS because such practices are unlikely to result in  
28

1 fraud or abuse. *See* 42 C.F.R. § 1001.952. The safe harbors set forth specific  
2 conditions that, if met, assure entities involved of not being prosecuted or  
3 sanctioned for the arrangement qualifying for the safe harbor. However, safe  
4 harbor protection is afforded only to those arrangements that precisely meet all of  
5 the conditions set forth in the safe harbor.  
6

7  
8 66. Under the safe harbor for investment interests, any payment to an  
9 investor that is a return on an investment does not constitute remuneration for  
10 purposes of the AKS if each of the safe harbor's eight requirements are satisfied.  
11  
12 *See* 42 C.F.R. § 1001.952(a).

13 67. The safe harbor for investment interests is narrowly tailored to prevent  
14 improper economic inducements from being disguised as ordinary investments.  
15 Among other things, the safe harbor for investment interests contains the following  
16 requirements:  
17

- 18
- 19 • The terms on which an investment interest is offered to an investor  
20 who is in a position to ... generate business for the entity must not be  
21 related to the previous or expected volume of referrals ... or the  
22 amount of business otherwise generated from that investor to the  
23 entity;
  - 24 • No more than 40 percent of the entity's gross revenue related to the  
25 furnishing of health care items and services in the previous fiscal year  
26 or previous 12 month period may come from referrals or business  
27 otherwise generated from investors;
  - 28 • No more than 40 percent of the value of the investment interests ...  
may be held in the previous fiscal year or previous 12 month period  
by investors who are in a position to make or influence referrals to,

1 furnish items or services to ... or otherwise generate business for the  
2 entity; [and]

- 3 • The amount of payment to an investor in return for the investment  
4 interest must be directly proportional to the amount of the capital  
5 investment (including the fair market value of any pre-operational  
6 services rendered) of that investor.

7 42 C.F.R. § 1001.952(a)(2)(i), (iii), (vi), (viii).

8 68. Reliance's PODs do not satisfy the requirements of the safe harbor for  
9 investment interests.

10 69. Bret Berry, John Hoffman, and Adam Pike were aware that Reliance's  
11 PODs do not satisfy the requirements of the safe harbor for investment interests.  
12

### 13 **B. OIG Advisory Opinions**

14  
15 70. Individuals and entities may seek an advisory opinion from the OIG to  
16 determine whether a specific business arrangement constitutes grounds for the  
17 imposition of sanctions under the AKS. *See* 62 Fed. Reg. 7350 (Feb. 19, 1997).  
18 Individuals and entities contemplating a business arrangement that could violate  
19 the AKS may avoid unnecessary risk by describing the arrangement and asking the  
20 OIG for an advisory opinion.  
21

22  
23 71. In one of the first advisory opinions issued, the OIG provided  
24 guidance to a radiology group and a hospital system contemplating a joint venture.  
25 OIG Advisory Opinion No. 97-5 (Oct. 6, 1997). The OIG cautioned that, "the  
26 major concern is that the profit distributions to investors in the joint venture, who  
27  
28

1 are also referral sources to the joint venture, may potentially represent  
2 remuneration for those referrals.” *Id.* at 7. Further,

3 even in situations where each party’s return is proportionate with its  
4 investment, the mere opportunity to invest (and consequently receive  
5 profit distributions) may in certain circumstances constitute illegal  
6 remuneration if offered in exchange for past or future referrals. Such  
7 situations may include arrangements where one or several investors in  
8 a joint venture control a sufficiently large stream of referrals to make  
9 the venture’s success highly likely ... or the financial investment  
required is so small that the investors have little or no real risk.

10 *Id.* at 10.

### 11 **C. OIG Special Fraud Alerts and Related Guidance**

12  
13 72. The OIG issues Special Fraud Alerts to discuss “trends of health care  
14 fraud and certain practices of an industry-wide character.” 59 Fed. Reg. 65,373  
15 (Dec. 19, 1994). The purpose of these alerts is “to provide general guidance to the  
16 health care industry” and to offer “additional insight to the Medicare carrier and  
17 fraud units in identifying health care fraud schemes.” *Id.* at 65,373.

18  
19  
20 73. In 1989, OIG issued a Special Fraud Alert on Joint Venture  
21 Arrangements. This Special Fraud Alert discussed arrangements that presented the  
22 strong potential for an AKS violation where a physician joint venture arrangement  
23 was “intended not so much to raise investment capital legitimately to start a  
24 business, but to lock up a stream of referrals from the physician investors and to  
25 compensate them indirectly for those referrals.” OIG, Special Fraud Alert: Joint  
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1 Venture Arrangements (OIG-89-4), *reprinted in* 59 Fed. Reg. 65,373 (Dec. 19,  
2 1994).

3           74. The 1989 Special Fraud Alert expressed OIG's concerns over joint  
4 ventures in which physicians could benefit financially from their own referrals.  
5 The 1989 Alert identified the following particular areas of concern, among others:  
6 (1) recruiting and retaining only physicians who are in a position to make referrals,  
7 (2) requiring only nominal physician investments and providing returns that are  
8 disproportionately large in relation to business risk, and (3) employing a "shell"  
9 structure that outsources business operations to an ongoing entity. *Id.*

10           75. In 2003, OIG reiterated the concerns expressed in the 1989 Special  
11 Fraud Alert in a 2003 Special Advisory Bulletin concerning the "proliferation of  
12 arrangements between those in a position to refer business, such as physicians, and  
13 those providing items ... for which Medicare ... pays." OIG, Special Advisory  
14 Bulletin on Contractual Joint Ventures, *reprinted in* 68 Fed. Reg. 23,148 (Apr. 30,  
15 2003).

16           76. In 2006, OIG repeated these concerns again, and stated that OIG's  
17 guidance in the 1989 Special Fraud Alert applies specifically to physician-owned  
18 medical device distribution companies. Such "physician owned distributorships"  
19 (PODs) are companies that derive revenue by selling implantable medical devices  
20 ordered by physician-investors for use in surgeries that they perform on their own  
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1 patients. The OIG warned that PODs in particular create “the strong potential for  
2 improper inducements” to physician-investors and “should be closely scrutinized  
3 under the fraud and abuse laws.” Letter from Vicki Robinson, “Response to  
4 Request for Guidance Regarding Certain Physician Investments in the Medical  
5 Device Industries” (Oct. 6, 2006).  
6

7  
8 77. In March 2013, OIG issued a Special Fraud Alert regarding PODs.  
9 See OIG Special Fraud Alert: Physician-Owned Entities (Mar. 26, 2013). The  
10 2013 Special Fraud Alert references prior OIG guidance about the legal issues  
11 under the AKS raised by physician-owned entities, and reiterates four long-  
12 standing AKS concerns associated with PODs, including: (1) the corruption of  
13 medical judgment, (2) overutilization, (3) increased costs of federal health care  
14 programs, and (4) unfair competition.  
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16

17  
18 78. The 2013 Special Fraud Alert concludes that PODs are “inherently  
19 suspect” under the AKS, and it reiterates OIG’s prior guidance that the opportunity  
20 for a referring physician to earn a profit, including through an investment return  
21 from an entity for which the physician generates business, could constitute illegal  
22 remuneration under the AKS. OIG identified the following four features, among  
23 others, that may render PODs particularly suspect: (1) selecting physicians based  
24 on their position to generate business through referrals, (2) requiring, pressuring, or  
25 actively encouraging its physician-investors to refer, recommend, or arrange for  
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1 the purchase of the POD's devices, (3) retaining repurchase rights for a physician-  
2 investor's failure or inability to arrange for the purchase of the POD's devices, and  
3 (4) operating through a "shell structure."  
4

5 79. The 2013 Special Fraud Alert also expresses concern over physicians  
6 concealing their financial interest in PODs from hospitals, or conditioning their  
7 referrals to a hospital on the hospital's agreement to purchase the POD's devices,  
8 and over a POD having a small number of physician-owners, such that the volume  
9 or value of a particular physician-owner's recommendations or referrals closely  
10 correlates to that physician-owner's return on investment.  
11  
12

13 80. On October 23, 2013, OIG issued a study on the impact of PODs on  
14 the market for spinal implants. The study concluded that surgeons performed more  
15 spinal surgeries at hospitals that purchased from PODs, and those hospitals  
16 experienced increased rates of growth in the number of spinal surgeries performed  
17 in comparison to the rate for hospitals that did not purchase from PODs. *See*  
18 Daniel R. Levinson, Spinal Devices Supplied By Physician-Owned Distributors:  
19 Overview of Prevalence and Use, OEI-01-11-00660, at 9 (Oct. 2013).  
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**FACTS**

**IV. DEFENDANTS' KICKBACK SCHEME**

**A. Reliance Medical Systems**

81. Bret Berry and Adam Pike formed Reliance on or about January 19, 2006.

82. Bret Berry and Adam Pike describe Reliance as their “holding company,” because Reliance controls its network of PODs and holds certain Food and Drug Administration (FDA) clearances to sell spinal implants to hospitals through its PODs.

83. From 2007 to the present, Bret Berry and Adam Pike owned and operated approximately fourteen PODs that were affiliated with Reliance and that had financial relationships with physicians that use Reliance’s implants, including Kronos and Apex.

84. During the relevant period, each of Reliance’s PODs, including Kronos and Apex, purchased Reliance implants at cost and then re-sold these implants to hospitals at a substantial mark-up for use in physician-investors’ surgeries.

85. Adam Pike has described Reliance’s PODs as his “money making compan[ies.]”



1           86. John Hoffman has described Reliance’s physician-investors as the  
2 “producers of the revenue stream.”

3           87. Reliance does not actually manufacture the implants for which it has  
4 obtained FDA marketing clearance. Instead, Reliance contracts with unaffiliated  
5 companies to manufacture the implants that Reliance sells to hospitals.  
6

7           88. Reliance does not seek intellectual property rights in the design of the  
8 implants it sells through its PODs.  
9

10           89. Reliance’s implants are indistinguishable in design to those of  
11 implants that were generally commercially available.  
12

13           90. Bret Berry has described Reliance certain products as being based on  
14 “knockoff[s]” of other companies’ designs.  
15

16           91. Before 2010, Reliance purchased most of the implants it distributed  
17 from Spinevision, a privately held spine device company headquartered outside of  
18 the United States.  
19

20           92. Prior to September 2007, Reliance did not have FDA clearance to sell  
21 its own PEEK cages.  
22

23           93. On September 27, 2007, Reliance obtained clearance through the  
24 FDA Premarket Notification process to sell PEEK cages, “which can be used to  
25 replace a portion of a collapsed, damaged, or unstable vertebral body.” This was  
26 Reliance’s first FDA clearance.  
27  
28

1           94.    Reliance represented to the FDA that its PEEK cage System is  
2 substantially equivalent to systems made by Medtronic and Synthes.

3           95.    Prior to March 2009, Reliance did not have FDA clearance to sell its  
4 own pedicle screw system.

5           96.    On March 26, 2009, Reliance obtained FDA clearance to sell a  
6 pedicle screw fixation system consisting of rods, screws, and crosslinks.  
7

8           97.    Reliance represented to the FDA that its pedicle screw system is  
9 substantially equivalent to systems made by Medtronic, Stryker, and Synthes.  
10

11           98.    Bret Berry and Adam Pike illegally expanded Reliance's business by  
12 offering investment opportunities in Reliance PODs, including Kronos and Apex,  
13 to physicians who agreed to use Reliance implants in their surgeries.  
14

15  
16                   **B. Kronos Spinal Technologies**

17           99.    Bret Berry, Adam Pike, and John Hoffman formed Kronos Spinal  
18 Technologies, LLC (Kronos) on or about February 27, 2007.  
19

20           100.   On or about June 2007, Berry, Pike, and Hoffman offered Dr. Ali  
21 Mesiwala and Dr. David Lundin the opportunity to invest in Kronos.  
22

23           101.   Drs. Mesiwala and Lundin initially shared a forty percent ownership  
24 interest in Kronos, through a company Dr. Mesiwala controlled called SoCal  
25 Medical Surgical (SMS).  
26  
27  
28

1           102. Drs. Mesiwala and Lundin paid nothing in exchange for their  
2 ownership interest in Kronos.

3           103. Between August 2007 and September 2008, Kronos paid SMS  
4 \$769,800.

5           104. Although Drs. Mesiwala and Lundin shared forty percent ownership  
6 of Kronos, Dr. Lundin was paid only approximately \$110,000 of the money  
7 Kronos paid to SMS between August 2007 and September 2007; Dr. Mesiwala was  
8 paid the remainder, approximately \$659,000.

9           105. Dr. Lundin surrendered his shares of Kronos in or about September  
10 2008.

11           106. Between October 2008 and November 2009, Dr. Mesiwala was  
12 Kronos' sole physician-investor. During this period, Dr. Mesiwala owned twenty-  
13 five percent of Kronos, and generated more than ninety-nine percent of Kronos'  
14 revenues.

15           107. In or about late-2009, Dr. Gowriharian Thaiyananthan was offered the  
16 opportunity to invest in Kronos.

17           108. On January 22, 2010, Dr. Thaiyananthan made a capital contribution  
18 of \$100,000 in exchange for a twenty percent ownership interest in Kronos.

19           109. On January 15, 2010, one week *before* Dr. Thaiyananthan made his  
20 capital contribution to Kronos, Kronos paid him \$79,000. On January 31, 2010,  
21

1 one week after he made his capital contribution, Kronos paid Dr. Thaiyananthan an  
2 additional \$69,400. Thus, in the same month Dr. Thaiyananthan purchased his  
3 shares of Kronos for \$100,000, Kronos paid him \$148,400.  
4

5 110. Between August 2007 and September 2012, Kronos paid its physician  
6 investors a total of \$4,941,390.  
7

8 111. Kronos' payments to its physician-investors were based on profits  
9 they generated through sales of implants to hospitals where the physician-investors  
10 performed surgeries using Reliance implants.  
11

12 112. There was a direct relationship between the volume or value of  
13 surgeries Kronos' physician-investors performed using Reliance implants and the  
14 amount Kronos paid them.  
15

### 16 **C. Apex Medical Technologies** 17

18 113. Bret Berry, Adam Pike, and John Hoffman formed Apex Medical  
19 Technologies, LLC (Apex) on or about September 15, 2008.  
20

21 114. In or about April 2010, Berry, Pike, and Hoffman offered Dr. Aria  
22 Sabit – along with Dr. Sean Xie, a neurosurgeon who trained with Dr. Sabit – the  
23 opportunity to invest in Apex.  
24

25 115. In May 2010, Berry, Pike, Hoffman, and Drs. Sabit and Xie each  
26 made a capital contribution of \$5,000 in exchange for which each received a one-  
27 fifth ownership stake in Apex.  
28

1           116. In May 2010, the same month in which Drs. Sabit and Xie made their  
2 initial capital contribution, Reliance – through Apex – paid them \$20,117 each,  
3 more than four times their initial capital contribution.  
4

5           117. Between approximately April 2010 and December 2010, Community  
6 Memorial Hospital in Ventura, California (Community Memorial), paid Apex  
7 \$1,421,484 for the cost of the Reliance implants that Dr. Sabit used in his  
8 surgeries.  
9

10           118. Between May 2010 and December 2010, Apex paid Dr. Sabit  
11 \$264,957.  
12

13           119. Reliance's payments to Dr. Sabit were based on profits he generated  
14 for Reliance through sales of implants to Community Memorial that were then  
15 used in Dr. Sabit's surgeries.  
16

17           120. There was a direct relationship between the number of surgeries Dr.  
18 Sabit performed using Reliance implants and the amount Reliance paid him  
19 through Apex.  
20

21           121. Prior to April 2010 – when Dr. Sabit agreed to invest in Apex – Dr.  
22 Sabit never used Reliance implants.  
23

24           122. After April 16, 2010, Dr. Sabit used Reliance implants in more than  
25 90 percent of his spinal fusion surgeries at Community Memorial.  
26  
27  
28

1 123. During the eight-months Dr. Sabit practiced at Community Memorial  
2 before he was offered an investment interest in Apex, he performed approximately  
3 64 instrumented fusion surgeries.  
4

5 124. In the eight-month period after he became a Reliance POD investor,  
6 Dr. Sabit performed approximately 130 instrumented fusion surgeries at  
7 Community Memorial, an increase of more than 100 percent.  
8

9 125. Dr. Sabit did not disclose his financial interest in Apex – or his  
10 financial relationship with Reliance – to his patients.  
11

12 126. Dr. Sabit denied his financial interest in Apex to staff at Community  
13 Memorial.  
14

15 127. On or about the summer of 2010, Dr. Sabit denied any financial  
16 relationship with Apex to his employer, Dr. Moustapha Abou-Samra.  
17

#### 18 **D. Dr. Sabit's Relocation to Michigan**

19 128. On or about April 2011, Dr. Sabit obtained temporary privileges at  
20 Detroit Medical Center, Doctor's Hospital of Michigan, and McLaren Lapeer  
21 Regional Medical Center (McLaren).  
22

23 129. On November 15, 2011, and May 21, 2012, Reliance submitted  
24 vendor profile forms to Detroit Medical Center certifying that no physician owned  
25 all or part of Apex. Reliance knew those certifications were false because Dr.  
26 Sabit remained an Apex investor until June 30, 2012.  
27  
28

1           130. After Dr. Sabit relocated to Michigan, Reliance, through Apex, paid  
2 him \$173,613. Reliance made its last payment to Dr. Sabit on June 30, 2012.

3           131. On several occasions, Dr. Sabit gave sworn testimony denying that he  
4 had a financial relationship with any medical device company. For example:  
5

- 6           • On November 12, 2012, Dr. Sabit testified that he never had been paid any  
7 compensation by a medical device manufacturer, and that he didn't know of  
8 any device company in Bountiful, Utah [where Reliance is based];
- 9           • On August 27, 2012, Dr. Sabit testified that he did not personally make any  
10 money depending on what instrumentation was being used, and that the  
11 company whose devices he used did not make any difference to him  
12 financially; and
- 13           • On September 9, 2013, Dr. Sabit testified that when he practiced in  
14 California, he did not make any additional money because of the hardware  
15 being used.

16           132. On September 10, 2013, Dr. Sabit had an in-person meeting with Dr.  
17 Michael McKenna, the Chief Medical Officer of McLaren. In the meeting, Dr.  
18 Sabit professed not to understand how Apex worked and stated that he had  
19 discontinued his financial relationship with Apex prior to acquiring staff privileges  
20 at McLaren.  
21

22           133. On January 30, 2014, Dr. Sabit gave sworn testimony in connection  
23 with the government's investigation. This time, Dr. Sabit invoked his rights under  
24 the Fifth Amendment of the Constitution and refused to answer any questions  
25 concerning his financial relationships with Apex and Reliance.  
26  
27  
28

1                   **V. ADDITIONAL EVIDENCE OF DEFENDANTS' UNLAWFUL**  
2                   **PURPOSE**

3                   134. At all relevant times, Bret Berry, John Hoffman, and Adam Pike were  
4 aware of, possessed, and discussed information about the AKS's prohibitions,  
5 including the OIG guidance that warned against offering investment opportunities  
6 to physicians to induce them to generate business.  
7

8                   135. Reliance's compliance manuals acknowledge the OIG guidance  
9 concerning the prohibition against offering remuneration to physicians to induce  
10 them to generate business.  
11

12                   136. On April 18, 2008, the law firm Thompson & Knight LLP advised  
13 Reliance that "[m]ultiple Federal courts have held that the [AKS] covers any  
14 arrangement where one purpose of that arrangement is to obtain money for the  
15 referral of services or to induce further referrals."  
16  
17

18                   137. On July 26, 2011, Adam Pike was recorded describing the purpose of  
19 Reliance's PODs as follows: "*I always scoff at someone I'm sitting with that says*  
20 *well it's really not about the money ah b\*\*\*s\*\*\*, it is about the money. We make a*  
21 *lot of money.*" (emphasis added). Bret Berry and John Hoffman were also present  
22 when Pike made this statement.  
23  
24

25                                   **A. Inducements to Physicians**

26                   138. Reliance did not allow physicians to become investors unless  
27 hospitals in which they performed surgeries agree to purchase Reliance devices.  
28



1           139. Bret Berry and John Hoffman have stated that Reliance does not offer  
2 investment interests to physicians who will not order a high volume of Reliance  
3 implants.  
4

5           140. On July 26, 2011, John Hoffman was recorded stating that a particular  
6 surgeon – a partner of Dr. Mesiwala – was not invited to become a Kronos investor  
7 because “he’s not busy at all.” Bret Berry and Adam Pike were also present when  
8 Hoffman made this statement.  
9

10           141. Bret Berry, John Hoffman, and Adam Pike expected physician-  
11 investors to regularly use Reliance implants.  
12

13           142. As stated by Adam Pike, Reliance expects physician-investors “to  
14 participate aggressively” in Reliance’s profitability by regularly using Reliance  
15 implants.  
16

17           143. On July 20, 2011, Dr. Mesiwala was recorded telling a potential  
18 Kronos investor that “the expectation is [that you] will be using your own stuff,”  
19 i.e. Reliance implants.  
20

21           144. In this same conversation, Dr. Mesiwala described Kronos as follows:  
22 “if you truly are in this to make money and you have a finite time limit to do it, I  
23 don’t know a better way to do it.”  
24

25           145. On July 26, 2011, Adam Pike was recorded telling a potential Kronos  
26 physician-investor,  
27  
28

1 [what] we've made ... ranged anywhere from probably the lowest  
2 being around thirty, probably thirty grand a month per owner. Uh  
3 upwards of eighty uh just depending on the ... business that month.  
4 Now, mind you this comes from very dedicated employees ... and *it's*  
5 *our job not to ever sign someone up unless they are that dedicated*  
6 *cause it doesn't work or improve ya understand so that's one of our*  
7 *criteria.*

8 (emphasis added). Bret Berry and John Hoffman were also present when Pike  
9 made this statement.

10 146. On July 26, 2011, Adam Pike was recorded telling a potential Kronos  
11 physician-investor, "We're interested in you growing ... your practice ... Grow it  
12 is fine. Grow it fine but *grow with us. Be dedicated and loyal to your company*  
13 *here.*" (emphasis added). Pike added, "We ... don't share this with everyone ...  
14 we handpick who we work with." Bret Berry and John Hoffman were also present  
15 when Pike made these statements.

16 147. On July 26, 2011, John Hoffman was recorded stating that certain  
17 physicians were not invited to invest because they would not be "loyal" to  
18 Reliance. Specifically, Hoffman stated, "Loyalty's a big factor. They ... have ten  
19 companies they work with and they're not gonna change that."

20 148. On July 26, 2011, Adam Pike was recorded stating that Reliance  
21 insisted on "evaluating" physicians before they could invest. Specifically, Pike  
22 stated: "we always start guys out with an evaluation period. We mandate that."

23 149. During this same meeting, Adam Pike was recorded stating,  
24  
25  
26  
27  
28

1 The evaluation phase is ... for a couple of reasons. It lets you get  
2 familiar with the product. It ... lets you get familiar with us as a  
3 company and vice-versa. We get familiar with you, we better  
4 understand your hospital. *We better understand your volume and your*  
5 *commitment* to it and then when we all agree and- and the signing date  
6 comes then it's we know what we got, everybody knows. There's no  
7 the ... question mark.

8 (emphasis added). Bret Berry and John Hoffman were also present when Pike  
9 made this statement.

10 150. During this same meeting, Adam Pike and Bret Berry were recorded  
11 making the following statements:

12 Pike: also [the evaluation period is] a nice buffer time for when  
13 the competitors come to you or the hospital staff comes to you  
14 and asks about this company you're not an owner.

15 Berry: You have no finances-

16 Pike: You ... *don't have to disclose anything.* (emphasis  
17 added).

18 151. Berry, Hoffman, and Pike promised their physician-investors that they  
19 would be paid their share of profits during their evaluation periods, during which  
20 time they were not technically investors in a Reliance POD.  
21

22 152. On July 26, 2011, Adam Pike was recorded telling a potential Kronos  
23 physician-investor "if you're the right guy for us and we're right for you then after  
24 you've evaluated for a month and you're like you know what this, I like it and ... I  
25 want to go forward and we're all agree then *there's no revenue loss ... you'll*  
26  
27  
28

1 *capture what you've worked for.*" (emphasis added). Bret Berry and John Hoffman  
2 were also present when Pike made this statement.

3 153. On July 26, 2011, Adam Pike was recorded stating that Reliance is  
4 interested in recruiting physicians who would "be appreciative of [Reliance] and  
5 not take it for granted and do it for years and years and raise those kids with this  
6 nice income and *[in] the first month or two go ahead and buy their college*  
7 *education ....*" (emphasis added). Bret Berry and John Hoffman were also present  
8 when Pike made this statement.

9 154. On at least one other occasion, in late 2010, Adam Pike promised  
10 potential physician-investors that Reliance would pay them enough to "put their  
11 kids through college."

12 155. On July 26, 2011, Adam Pike was recorded stating that the amount of  
13 money Reliance pays its physician-investors is "not a supplemental income. *It's*  
14 *likely to make you more money than your practice does.*" (emphasis added). Bret  
15 Berry and John Hoffman were also present when Pike made this statement.

## 16 **B. Physician-Investor Buy Outs**

17 156. Bret Berry and Adam Pike discouraged Reliance physician-investors  
18 from using a competitor's implants in their surgeries. By way of example:

- 19 • On May 27, 2008, Larry Sager – a part-owner of certain Reliance PODs –  
20 wrote to Berry and Pike to notify them that Dr. Erik Westerlund, who at the  
21 time was a Reliance physician-investor, had planned to use a competitor's

1           pedicle screws in a scheduled surgery; Berry responded by writing  
2           “WTF?!”; and

- 3           • On August 4, 2009, Sager wrote to Pike to notify him of “more concern”  
4           regarding Dr. Choll Kim, who at the time was a Reliance physician-investor.  
5           Sager’s “concern” about Dr. Kim was due to his failure to use Reliance  
6           interbody cages in one of his scheduled surgeries. In response, Pike  
7           instructed Sager “to [bring] this to the attention of the other partners.”

8           157. Both Dr. Westerlund and Dr. Kim surrendered their shares in their  
9           respective Reliance PODs shortly after Sager drafted the above-mentioned emails  
10           alerting Berry and Pike to his “concerns” about their implant selection.

11           158. Bret Berry, John Hoffman, and Adam Pike retained the right to  
12           repurchase the shares of Reliance’s physician-investors. Berry, Hoffman, and Pike  
13           exercised this right in circumstances where particular physician-investors failed to  
14           generate significant profits for their POD.  
15           generate significant profits for their POD.

16           159. Dr. David Lundin was one such physician who was forced to leave  
17           Kronos due to his failure to use Reliance implants in a significant number of his  
18           surgeries.  
19           surgeries.

20           160. Between August 2007 and September 2008, Dr. Mesiwala, the only  
21           other physician-owner of Kronos, pressured Dr. Lundin to increase Dr. Lundin’s  
22           volume of spinal fusion surgeries.  
23           volume of spinal fusion surgeries.

24           161. Between August 2007 and September 2008, Bret Berry, John  
25           Hoffman, and Adam Pike discouraged Dr. Lundin from using implants sold by  
26           Hoffman, and Adam Pike discouraged Dr. Lundin from using implants sold by  
27           Hoffman, and Adam Pike discouraged Dr. Lundin from using implants sold by  
28           Hoffman, and Adam Pike discouraged Dr. Lundin from using implants sold by

1 Reliance's competitors, and pressured Dr. Lundin to use a greater percentage of  
2 Reliance's implants in his surgeries.

3           162. On or about the Summer of 2008, Dr. Lundin announced his intention  
4 to leave Dr. Mesiwala's practice and to move to another geographical area. After  
5 Dr. Lundin announced his intention to leave Dr. Mesiwala's practice, Bret Berry,  
6 John Hoffman, and Adam Pike informed Dr. Lundin that he would be forced to  
7 surrender his shares in Kronos without compensation.  
8

9           163. Bret Berry, John Hoffman, and Adam Pike also forced Dr.  
10 Gowriharan Thaiyananthan to surrender his shares in Kronos without  
11 compensation.  
12

13           164. On July 26, 2011, Adam Pike was recorded stating,  
14

15           There's a plan for [Dr. Thaiyananthan] to get busier ... he's got some  
16 options ... in another market a little south of here ... and we'll work  
17 on those ... one of the things that we could do is we could buy Ty [Dr.  
18 Thaiyananthan] out and when he re-establishes himself in another  
19 market he could buy back in.  
20

21 Bret Berry and John Hoffman were also present when Pike made this statement.  
22

23           165. Adam Pike made the statement quoted above after Dr. Thaiyananthan  
24 made what he describes as a "paradigm shift" in his surgical practice, and began  
25 performing significantly fewer surgeries involving Reliance implants.  
26

27           166. On August 10, 2012, Reliance forced Dr. Thaiyananthan to return his  
28 shares in Kronos.

1           167. The document memorializing Reliance's re-acquisition of Dr.  
2 Thaiyananthan's shares characterizes the transaction as a "sale" of "ten  
3 membership units" in exchange for \$24,448. However, Kronos had already paid  
4 its investors \$24,448 as a monthly profit distribution for July 2012. Apart for the  
5 profit distribution that each Kronos investor received on July 31, 2012, Reliance  
6 paid Dr. Thaiyananthan *no money* in exchange for his shares.  
7  
8

9           168. By contrast, approximately one month later, on September 1, 2012,  
10 Reliance paid Dr. Ali Mesiwala for \$101,789 for ten membership units in Kronos.  
11

12           169. Reliance paid Dr. Mesiwala more than Dr. Thaiyananthan for the  
13 same number of Kronos membership units because Dr. Mesiwala was continuing  
14 to generate significant profits for the company by performing surgeries using  
15 Reliance implants.  
16

### 17                           **C. Foreseeability of Physician-Investor Overutilization**

18  
19           170. Reliance generated daily reports detailing the number and types of  
20 surgeries that its physician-investors performed using Reliance implants. Bret  
21 Berry and Adam Pike carefully reviewed these daily surgery reports.  
22

23           171. Adam Grant, a Reliance employee responsible for generating daily  
24 surgery reports, would regularly celebrate reports indicating that Reliance  
25 physician-investors were performing more (and more complicated) surgeries, and  
26  
27  
28

1 would lament reports indicating that Reliance physician-investors had not  
2 performed the expected number of surgeries using Reliance implants.

3  
4 172. By way of example:

- 5 • on October 31, 2012, Grant's email to Bret Berry and Adam Pike attaching  
6 daily surgery reports stated "New record for QSI [Quality Spinal  
7 Innovations, a Reliance POD] cases for a day. Woohoo";
- 8 • by contrast, on January 18, 2013, Grant's email attaching daily surgery  
9 reports stated, "There is a chain I've been hitting myself with, since that is  
10 what you'll want to do upon opening the attachment. Sorry."

11 173. Bret Berry and Adam Pike personally encouraged physician-investors  
12 to perform more (and more complicated) instrumented fusion surgeries. For  
13 example:

- 14  
15 • On May 17, 2007, in response to an inquiry from Dr. Erik Westerlund  
16 regarding a patient "that would ... consider heroic surgical measures," Adam  
17 Pike encouraged Dr. Westerlund to perform "a seven level fusion with  
18 interbody using EST [Embassy Spinal Technologies, a Reliance POD]";
- 19 • On August 28, 2007, in response to a Reliance distributor's report that a  
20 Reliance physician-investor had scheduled a T10-S1 [i.e. an eight-level]  
21 fusion, Bret Berry wrote, "That is awesome!! Is he using PEEK as well?"
- 22 • On October 18, 2007, in response to a Reliance distributor's report that Dr.  
23 David Greenwald "booked 5 cases today ... I LOVE IT!" Adam Pike wrote,  
24 "Please tell Dr. Greenwald to slow down. How dare he go crazy like this!  
25 PS. We are on it."
- 26 • In late-2007, Dr. Erik Westerlund wrote Bret Berry and Adam Pike to  
27 complain about "regular and incremental pressure" from Reliance, which  
28 "seems to have included subtle effects on my clinical volume."



1 174. As stated by Adam Pike, Reliance is “interested in [its physician-  
2 investors] growing ... [their] practice.”

3 175. After Drs. Sabit, Mesiwala, and Thaiyananthan invested in Apex and  
4 Kronos, the rate at which they billed Medicare for implanting PEEK cages  
5 increased dramatically.  
6

7 176. The seven months before Dr. Sabit agreed to invest in Apex, he billed  
8 Medicare for fifteen procedures involving the implantation of PEEK cages. By  
9 contrast, during the seven months *after* Dr. Sabit entered into a financial  
10 relationship with Reliance, he billed Medicare for forty-three such procedures, an  
11 increase of 287%.  
12  
13  
14

15 **VI. ADDITIONAL EVIDENCE OF DEFENDANTS’ WILLFULNESS**  
16

17 177. Bret Berry, John Hoffman, and Adam Pike were each personally  
18 aware of the AKS – and of OIG’s guidance concerning the AKS – when they  
19 formed Reliance and each of its distributorships, including Apex and Kronos.  
20  
21

22 178. On July 26, 2011, Adam Pike was recorded stating that he and Berry  
23 founded Reliance as part of a plan to “get around” the AKS. Specifically, Pike  
24 stated, “Bret and I started this coming out of MBA school together. We were we  
25 were aware of Stark and Anti-Kickback and *we knew those existed and we devised*  
26  
27  
28

1 *a plan around those.”* (emphasis added). Bret Berry and John Hoffman were  
2 present when Adam Pike made this statement.

### 3 **A. Concealment**

4  
5 179. Reliance attempted to “get around” the AKS by structuring its  
6 operations in a way that enabled it to hide its financial relationships with its  
7 physician-investors.  
8

9 180. On multiple occasions, Reliance, Berry, Hoffman, and Pike were  
10 advised by their attorneys that they should notify patients that physician-investors  
11 had a financial interest in Reliance’s distributorships.  
12

13 181. By way of example:

- 14
- 15 • On October 25, 2006, Reliance’s principal attorney, John S. Bradley, Esq.,  
16 advised Adam Pike: “I think you would ... want to notify the patients that  
17 the Dr. has a financial interest in the manufacturer of the device and that  
18 they may request another device be used if they desire.”
  - 19 • On April 17, 2007, Bradley wrote again to advise Reliance to “[d]isclose the  
20 physician investor’s financial interest ... in writing at the time that the  
21 referral ... is sought ... and advise all patients ... of other available  
22 alternatives that are comparable and competitive to the manufactured  
23 devices and supplies which the physicians have an ownership interest in....”

24 182. In spite of this advice, Reliance, Berry, Hoffman, and Pike did not  
25 disclose their financial relationships with physician-investors to patients, nor did  
26 they require physician-investors to disclose these relationships to their patients.

27 183. As explained by Bret Berry, Reliance’s principals did not want  
28 anyone to know who its physician-investors were. Specifically, on July 26, 2011,

1 Berry was recorded telling a potential physician-investor, "Our job is ... to let  
2 everybody outside ... of our group think that you're just using this product ... *We*  
3 *don't want anyone to know that you're an owner.*" (emphasis added).  
4

5 184. During this same meeting, Adam Pike was recorded telling the  
6 potential physician-investor, "so hypothetically ... you start u-utilizing Kronos  
7 products here and you're evaluating it and we ... arrive to a point where we wanna  
8 sign you up and everyone's happy um the hospital doesn't need to know that. *The*  
9 *community doesn't need to know that ... No one knows but our own circle.*"  
10  
11 (emphasis added).  
12

13 185. Reliance made a series of false statements to hospitals that inquired  
14 about Reliance's financial relationships with its particular physicians, including  
15 hospitals where Apex and Kronos physician-investors performed surgeries.  
16  
17

18 186. In September 2012, in response to an inquiry from a California  
19 hospital, Laurann Turner, Reliance's Vice President of Operations, wrote that Dr.  
20 Ali Mesiwala, "is not a distributor for Kronos Spinal Technologies, *nor has he*  
21 *received any payments or remunerations from Kronos Spinal Technologies as a*  
22 *consultant or investor*" (emphasis added). This statement was false because,  
23  
24 through Kronos, Reliance had paid Dr. Mesiwala more than \$3 million at the time  
25 it wrote this letter.  
26  
27  
28

1 187. On November 2011 and May 2012, Reliance certified to Detroit  
2 Medical Center that no “physicians licensed to practice medicine ... own all or part  
3 of [Apex].” At the time Reliance submitted these certifications, Dr. Sabit, who  
4 was on the hospital’s surgical staff, owned 20 percent of Apex.  
5

6 188. On multiple other occasions, Reliance submitted false or materially  
7 incomplete and misleading statements to hospitals concerning its relationships with  
8 particular physicians. Dates on which Reliance submitted false certifications to  
9 hospitals include:  
10

- 11 • 11/4/09 (national certification to Hospital Corporation of America);
- 12 • 6/7/10 (certification to Intermountain Health, in Salt Lake City, Utah);
- 13 • 10/13/10 (certification to St. Joseph Health System, in Los Angeles,  
14 California);
- 15 • 11/18/10 (national certification to Tenet Healthcare Corporation);
- 16 • 6/22/11 (certification to Mary Black Health System, in Spartanburg, South  
17 Carolina);
- 18 • 11/1/11 (national certification to Sharp HealthCare);
- 19 • 11/1/11 (certification to St. Bernadine Hospital, in Los Angeles, California);
- 20 • 12/2/11 (certification to Our Lady of the Lake Hospital, in Baton Rouge,  
21 Louisiana).
- 22
- 23
- 24
- 25
- 26
- 27
- 28

1 189. Adam Pike has also repeatedly made a series of false verbal  
2 statements to hospitals that inquired about Reliance's relationships with particular  
3 physicians.  
4

5 190. In a further effort to avoid disclosing their payments to physicians,  
6 Bret Berry and Adam Pike elected to buy-out Reliance's physician-investors in late  
7 2012.  
8

9 191. In December 2011, CMS announced proposed regulations  
10 implementing the Transparency Reports and Reporting of Physician Ownership or  
11 Investment Interests (the "Sunshine Act") section of the Patient Protection and  
12 Affordable Care Act. 76 Fed. Reg. 78,742 (Dec. 19, 2011). The regulations  
13 implementing the Sunshine Act require device manufacturers, including PODs, to  
14 report annually to CMS information regarding payments, ownership, investment  
15 interests, and other transfers of value to physicians. *Id.* at 78,751-52; *cf.* 78 Fed.  
16 Reg. 9,458, 9,493 (Feb. 8, 2013) (final rule).  
17  
18  
19

20 192. Reliance sought legal advice from John Bradley concerning the  
21 Sunshine Act.  
22

23 193. In an August 31, 2012 email between Bret Berry and Adam Pike,  
24 Berry acknowledged that, "[t]he whole point of looking at this [physician-  
25 employee] model was to avoid the sunshine act."  
26  
27  
28

## B. Minimal or Non-Existent Capital Contributions

194. Reliance, Berry, Hoffman, and Pike were aware of, possessed, and discussed the OIG guidance stating that an investment may be deemed suspect under the AKS where the amount of capital that participants invest is disproportionately small in comparison to the return-on-investment.

195. On multiple occasions, Reliance, Berry, Hoffman, and Pike were advised by attorneys that their physician-investors should be required to make substantial capital contributions in exchange for their ownership interest in a Reliance POD.

196. By way of example:

- On August 6, 2007, Yee-Yoong Yong, Esq., advised Dr. James Hamada, a Reliance physician-investor, that his capital contribution must “be[] meaningful in terms of an investment risk.” Dr. Hamada circulated this advice to Reliance.
- On April 18, 2008, Catherine M. Greaves, Esq., advised Reliance that “the Company should attempt to structure any investment by physicians to meet the requirements of the safe harbor for investments in small entities.... The features to avoid include ... allowing physicians to invest without true risk.”
- On May 8, 2008, Greaves wrote Reliance again to reiterate that “investors must make a *substantial* capital investment....” (emphasis added)
- On January 23, 2010, business partners of Bret Berry and Adam Pike commissioned a “risk memorandum” seeking to assure potential Reliance physician-investors that their investments would be lawful because, “*Each investor will be required to pay \$45,000, to purchase a block of 10 Units.... This amount is very typical of the amounts commonly required.*” (emphasis added)

1 197. Adam Pike has acknowledged the legal advice referenced above,  
2 stating that, “[i]t’s true that most legal counsel would like to see money invested.”  
3 Further, Pike has been recorded telling a potential physician-investor that attorneys  
4 have told him that, “they [attorneys] want your skin in the game.”  
5

6 198. In spite of this, on July 26, 2011, Adam Pike was recorded stating  
7 Reliance’s investment requirements were “just ... for perception’s sake.” Pike  
8 further stated that each Reliance physician-investor’s initial capital contribution is  
9 “arbitrary to us. We don’t really care ... I mean the money’s going to be good  
10 regardless.”  
11  
12

13 199. Thirteen of Reliance’s thirty-five physician-investors, including Dr.  
14 Mesiwala, paid *nothing* in exchange for their shares in Reliance PODs.  
15

16 200. Ten of Reliance’s physician-investors, including Drs. Sabit and Xie,  
17 made a capital contribution of \$10,000 or less.  
18

19 201. Of the twenty-two Reliance physician-investors that were required to  
20 make a capital contribution, twenty were paid *more* in the first month than what  
21 they had invested.  
22

23 202. On July 26, 2011, Adam Pike was recorded describing Reliance’s  
24 capital contribution requirement as follows: “I mean it’s silly. But ... we did that  
25 to satisfy ... any legal perception so if and when we're ever audited by any ya  
26 know branch of government or any authoritative force, they can see that as a  
27  
28

1 surgeon you didn't just sign up and all the sudden get a fifty or eighty thousand  
2 dollar pay check....”

### 3 **C. Hospital Coercion**

4  
5 203. Reliance expects its physician-investors to help Reliance obtain  
6 approval to sell its implants in the hospitals at which the physicians perform  
7  
8 surgeries.

9 204. In or about May 2010, Reliance, Berry, Hoffman, and Pike shared a  
10 legal opinion memo that counseled a company named Big Mountain Medical LLC  
11 that “Any effort by surgeons to overcome [hospital] reluctance through ‘arm  
12 twisting’ in one form [or] another would increase the legal risk, *and it is critical*  
13 *that surgeons not threaten to take their cases elsewhere* if a hospital will not  
14 contract with their Distributor.” (emphasis added).  
15  
16

17  
18 205. Reliance, however, regularly encouraged its physician-investors to  
19 threaten to take their surgeries elsewhere in situations where the hospital where the  
20 surgery was initially scheduled was initially unwilling to purchase Reliance  
21 implants.  
22

23 206. As explained by Bret Berry, John Hoffman, and Adam Pike, Reliance  
24 expected its physician-investors to act as “champions” on behalf of Reliance within  
25 their hospitals.  
26  
27  
28



1           207. With Bret Berry, Adam Pike, and John Hoffman’s encouragement,  
2 Reliance physician-investors pressured their hospitals to pay above-market prices  
3 for Reliance implants.  
4

5           208. By way of example:

- 6
- 7       • On August 10, 2007, Adam Pike reported approvingly that Reliance’s  
8 “surgeon champions” were “fight[ing] battles on our behalf against Scripps  
9 [Hospitals]”;
- 10      • On October 10, 2007, Dr. Erik Westerlund notified Reliance that he had  
11 threatened to “promptly withdraw [his] support from ... the Scripps system”  
12 unless Scripps discontinued its efforts to obtain “even lower pricing from  
13 [Reliance]”;
- 14      • On April 8, 2010, John Hoffman notified Bret Berry and Adam Pike that an  
15 administrator at Good Samaritan Hospital in Los Angeles, California was  
16 upset that “Dr. [Sean] Xie came into his office mad and upset with the  
17 hospital that they would not negotiate prices (kudos to Sean)”;
- 18      • On August 30, 2010, Larry Sager, a Reliance distributor, noted that  
19 Westlake Medical Center in Austin, Texas was trying to renegotiate payment  
20 terms with Reliance; Adam Pike responded “Time for [Dr. Robert] Josey to  
21 step in.” Later, Pike wrote, “[t]he best message is for Josey to move  
22 [previously scheduled surgeries,] then [Westlake] will likely keep their  
23 promise and pay their bills in the future so long as he remains willing to  
24 move cases.”; and
- 25      • On May 9, 2012, both Bret Berry and Adam Pike encouraged Dr. Raed Ali  
26 to “support” Reliance’s efforts to keep its pricing above the pricing of other  
27 vendor’s at Saint Joseph’s Hospital, in Orange, California.  
28

#### D. Other Instances Where Reliance Ignored Legal Advice

1  
2 209. Reliance, Berry, Hoffman, and Pike disregarded the legal advice they  
3 received concerning the requirements and prohibitions of the AKS in multiple  
4 other ways.  
5

6 210. On October 19, 2010, Reliance circulated within the company a legal  
7 opinion letter that counseled that “physician-owned distributorships ... will face  
8 increased legal scrutiny given that the government believes they create inherent  
9 physician self-referral and conflict of interest issues.... In sum, physician-owned  
10 distributors, while not *per se* illegal, *pose substantial legal risk* for those  
11 participating in such ventures.” (emphasis added).  
12  
13

14  
15 211. On February 11, 2010, Adam Pike wrote Bret Berry to advise him that  
16 Pike had been told that, “[W. Bradley] Tully, the attny that basically wrote  
17 legislation regarding surgeon ownership, is claiming [Reliance’s PODs] to be too  
18 risky for the hospital.” On February 24, 2010, Ramin Raidzdeh, a Reliance  
19 physician-investor, wrote Berry and Pike to remind them that, “Tully is not coming  
20 thru, and is suggesting several road blocks.”  
21  
22

23 212. Bret Berry wrote Adam Pike, stating, “I do want to know what Tully  
24 is saying about our venture ... if he has concern over our model, let’s look into  
25 [this.]” Pike rejected Berry’s request, stating, “I see this as more fees regardless.  
26  
27  
28

1 And we already know the answers. We would be paying 2 attorneys at this point.  
2 I am sick of paying attorneys.”

3  
4 213. On December 11, 2012, David W. Hirshfeld, Esq., warned Reliance  
5 about its plan to buy-out physician-investors and to invite many of the former  
6 investors to become salaried employees of the Reliance distributorship whose  
7 implants they used. Hirshfeld wrote:  
8

9 The proposed compensation arrangements you supplied might not  
10 withstand regulatory scrutiny ... given the totality of the  
11 circumstances, I cannot opine with certainty that the physician  
12 relationship will be respected as a *bona fide* employment  
13 arrangement.... I am concerned that regulators will consider the  
14 employment agreement as an attempt to disguise distributions of  
15 profit ....

16 214. In spite of Hirshfeld’s advice, Reliance hired seventeen of its former  
17 physician-investors, including Dr. Mesiwala, paying them an average of  
18 approximately \$45,000 per month for work that had no real value to Reliance. In  
19 exchange for these payments, Dr. Mesiwala reported an average of approximately  
20 68 hours of work per month for Kronos between January 2014 and October 2014.  
21 Dr. Mesiwala allegedly performed this work in addition to his full-time surgical  
22 practice.  
23

24  
25 **E. Berry, Hoffman, and Pike’s Domination and Control of**  
26 **Reliance, Apex, and Kronos**

27 215. Bret Berry, John Hoffman, and Adam Pike have each benefited  
28 personally from their ownership and operation of Reliance’s distributorships,

1 including Apex and Kronos. Berry and Pike paid themselves approximately \$36  
2 million between June 2007 and December 2012. Hoffman, who had an ownership  
3 interest in several Reliance PODs but not in Reliance itself, was paid  
4 approximately \$7 million during this period.  
5

6 216. At all relevant times, Bret Berry and Adam Pike have exercised total  
7 control over the management of Reliance. At all relevant times, John Hoffman,  
8 along with Berry and Pike, controlled the management of Apex and Kronos.  
9

10 217. Apex and Kronos distribute all of their profits to investors – including  
11 Bret Berry, John Hoffman, and Adam Pike – on a monthly basis.  
12

13 218. On July 26, 2011, Adam Pike was recorded telling a potential investor  
14 that no one can “come after” Reliance because “there’s no money in the account.”  
15

16 219. Bret Berry, John Hoffman, and Adam Pike formed six different  
17 companies through which they own their shares in Apex and Kronos, and other  
18 Reliance PODs. The sole purpose of these companies is to receive profit  
19 distributions from Reliance PODs, and to pass the profits on to Berry, Hoffman,  
20 and Pike.  
21

22 220. Reliance and its distributorships do not maintain corporate records.  
23

24 221. Reliance conducts business from its owners’ personal email accounts,  
25 and Bret Berry and Adam Pike routinely delete emails concerning Reliance and its  
26 PODs from these accounts.  
27  
28

1 222. Adam Pike deleted substantially all emails concerning Reliance and  
2 its distributorships that he sent and received during the period at issue in this  
3 Complaint.  
4

5 **VII. RELIANCE'S PAYMENTS TO PHYSICIANS**

6 **A. Aria Sabit**

7  
8 223. On May 17, 2010, Dr. Sabit made a capital contribution of \$5,000 in  
9 exchange for a 20 percent ownership interest in Apex.  
10

11 224. The payments Reliance, through Apex, made to Dr. Sabit are set forth  
12 below:  
13

14 <b>DATE</b>	<b>PAYMENT TO DR. SABIT</b>
15 5/31/10	\$20,117
16 6/30/10	\$20,755
17 7/31/10	\$54,235
18 8/31/10	\$43,292
19 9/30/10	\$35,896
20 10/31/10	\$25,572
21 11/30/10	\$35,747
22 12/31/10	\$29,343
23 1/31/11	\$12,628
24 2/28/11	\$0
25 3/31/11	\$0
26 4/30/11	\$12,839
27 5/31/11	\$11,620
28 6/30/11	\$15,315
7/31/11	\$21,982
8/31/11	\$12,924
9/30/11	\$2,835
10/31/11	\$10,880

1	11/30/11	\$1,845
2	12/31/11	\$11,716
3	1/31/12	\$0
4	2/29/12	\$14,618
5	3/31/12	\$16,154
6	4/30/12	\$10,156
7	5/31/12	\$5,056
8	6/30/12	\$13,045
9	<b>TOTAL</b>	<b>\$438,570</b>

225. Reliance's payments to Dr. Sabit were based in part on the profits he generated for Apex by using Reliance implants in his surgeries on Medicare patients.

226. The Defendants reasonably could have foreseen that their payments to Dr. Sabit would cause him to perform spinal fusion surgeries using Reliance implants that were not medically necessary, or that were more extensive than what was necessary.

227. As set forth above, Berry and Pike regularly exchanged emails with one another celebrating occasions where Reliance physician-investors scheduled an unusual number of surgeries, or an unusually extensive surgery, using Reliance implants.

**B. Sean Xie**

228. On May 17, 2010, Dr. Xie made a capital contribution of \$5,000 in exchange for a 20 percent ownership interest in Apex.

1 229. The distributions Reliance made to Dr. Xie through Apex are set forth

2 below:

3

4	DATE	PAYMENT TO DR. XIE
5	5/31/10	\$20,117
6	6/30/10	\$20,755
7	7/31/10	\$54,235
8	8/31/10	\$68,864
9	9/30/10	\$35,896
10	10/31/10	\$25,572
11	11/30/10	\$35,747
12	12/31/10	\$29,343
13	1/31/11	\$12,628
14	2/28/11	\$0
15	3/31/11	\$0
16	4/30/11	\$12,839
17	5/31/11	\$11,620
18	6/30/11	\$15,315
19	7/31/11	\$21,982
20	8/31/11	\$12,924
21	9/30/11	\$2,835
22	10/31/11	\$10,880
23	11/30/11	\$1,845
24	12/31/11	\$11,716
25	1/31/12	\$15,279
26	2/29/12	\$14,618
27	3/31/12	\$16,154
28	4/30/12	\$10,156
	5/31/12	\$5,056
	6/30/12	\$13,045
	7/31/12	\$8,475
	8/31/12	\$3,645
	9/30/12	\$2,759
	10/31/12	\$0
	11/30/12	\$11,538

1	12/31/12	\$11,538
2	1/31/13	\$0
3	2/28/13	\$0
4	3/14/13	\$15,279
5	<b>TOTAL</b>	<b>\$507,082</b>

6           230. Reliance paid Dr. Xie an additional \$688,050 through Spine Matrix  
7 Technologies (Spine Matrix), a different Reliance POD in which Dr. Xie was an  
8 investor between August 2007 and March 2010.

9  
10           231. Reliance's payments to Dr. Xie were based in part on the profits he  
11 generated for Apex and Spine Matrix.

12  
13           232. The Defendants reasonably could have foreseen that their payments to  
14 Dr. Xie would cause him to perform spinal fusion surgeries using Reliance  
15 implants that were not medically necessary, or that were more extensive than what  
16 was necessary.

17  
18  
19           **C. Ali Mesiwala**

20           233. Dr. Ali Mesiwala did not make *any* capital contribution in exchange  
21 for his investment interest in Kronos.

22  
23           234. A record of Reliance's payments to Dr. Mesiwala, through Kronos,  
24 from August 2007 until August 2013 is set forth below:

25	8/13/07	\$80,000 <sup>1</sup>
----	---------	-----------------------

26  
27           <sup>1</sup> Reliance's payments to Dr. Mesiwala between August 2007 and  
28 November 2008 were made to SoCal Medical Surgical, a corporation controlled by  
Dr. Mesiwala. A portion of these payments was shared with Dr. David Lundin.



1	9/6/07	\$68,000
2	10/5/07	\$43,200
3	11/1/07	\$60,000
4	11/30/07	\$62,000
5	1/14/08	\$52,400
6	1/31/08	\$39,800
7	2/29/08	\$67,000
8	3/31/08	\$31,000
9	4/30/08	\$57,000
10	5/31/08	\$63,000
11	6/30/08	\$53,200
12	7/31/08	\$31,000
13	8/31/08	\$33,600
14	9/30/08	\$28,600
15	10/31/08	\$43,000
16	11/30/08	\$37,400
17	12/31/08	\$17,800
18	1/31/09	\$35,000
19	2/28/09	\$31,600
20	3/31/09	\$35,500
21	4/30/09	\$41,500
22	5/31/09	\$40,000
23	6/30/09	\$39,200
24	7/31/09	\$66,000
25	8/31/09	\$48,600
26	9/30/09	\$52,700
27	10/31/09	\$56,200
28	11/30/09	\$69,100
	1/15/10	\$79,000
	1/31/10	\$69,400
	2/28/10	\$68,200
	3/31/10	\$54,500
	4/30/10	\$79,700
	5/31/10	\$53,363
	6/30/10	\$58,627

1	7/31/10	\$75,474
	8/31/10	\$38,419
2	9/30/10	\$54,958
3	10/31/10	\$51,113
4	11/30/10	\$69,900
5	12/31/10	\$64,043
	1/31/11	\$21,450
6	2/28/11	\$50,976
7	3/31/11	\$37,852
8	4/30/11	\$39,414
	5/31/11	\$11,093
9	5/31/11	\$20,000
10	6/30/11	\$23,552
11	7/31/11	\$45,344
12	8/31/11	\$36,850
	9/30/11	\$32,466
13	10/31/11	\$57,423
14	11/30/11	\$44,417
15	12/31/11	\$48,709
16	1/31/12	\$66,463
	2/29/12	\$38,089
17	3/31/12	\$24,861
18	4/30/12	\$49,462
19	5/31/12	\$40,636
20	6/30/12	\$37,179
21	7/31/12	\$24,448
	8/31/12	\$47,839
22	9/30/12	\$101,789
23	10/31/12	\$0
	11/30/12	\$0
24	12/31/12	\$0
25	1/31/13	\$0
26	2/1/13	\$51,000
27	3/1/13	\$30,300
28	4/1/13	\$40,350

1	5/1/13	\$47,400
2	6/1/13	\$21,900
3	7/1/13	\$52,050
4	8/1/13	\$30,600
5	<b>TOTAL</b>	<b>\$3,374,009</b>

6           235. Between 2007 and 2012, Reliance paid Dr. Mesiwala an additional  
7 \$323,009 based on profits he generated for Spine Biologics, a different Reliance  
8 POD. Thus, Reliance payments to Dr. Mesiwala through August 2013 totaled  
9 \$3,697,018.  
10

11           236. Reliance's payments to Dr. Mesiwala were based in part on the profits  
12 he generated for Kronos by using Reliance implants in his surgeries on Medicare  
13 patients.  
14

15           237. The Defendants reasonably could have foreseen that their payments to  
16 Dr. Mesiwala would cause him to perform spinal fusion surgeries using Reliance  
17 implants that were not medically necessary, or that were more extensive than what  
18 was necessary.  
19  
20

21                           **D. Gowriharan Thaiyananthan**  
22

23           238. On January 22, 2010, Dr. Thaiyananthan made a capital contribution  
24 of \$100,000 to Kronos.  
25

26           239. By January 31, 2010, Reliance, through Kronos, had repaid the full  
27 amount of Dr. Thaiyananthan's initial investment, plus an additional \$48,400.  
28

1           240. The distributions made by Reliance, through Kronos, to Dr.

2 Thaiyananthan are set forth below:

3

4 <b>DATE</b>	<b>PAYMENT TO DR.</b>
	<b>THAIYANANTHAN</b>
5     1/15/10	\$79,000
6     1/31/10	\$69,400
7     2/28/10	\$68,200
8     3/31/10	\$54,500
9     4/30/10	\$79,700
10    5/31/10	\$53,363
11    6/30/10	\$58,627
12    7/31/10	\$75,474
13    8/31/10	\$38,419
14    9/30/10	\$54,958
15    10/31/10	\$51,113
16    11/30/10	\$69,900
17    12/31/10	\$64,043
18    1/31/11	\$21,450
19    2/28/11	\$50,976
20    3/31/11	\$37,852
21    4/30/11	\$39,414
22    5/31/11	\$11,093
23    5/31/11	\$20,000
24    6/30/11	\$23,552
25    7/31/11	\$45,344
26    8/31/11	\$36,850
27    9/30/11	\$32,466
28    10/31/11	\$57,423
	\$44,417
	\$48,709
	\$66,463
	\$38,089
	\$24,861
	\$49,462

1	5/31/12	\$40,636
2	6/30/12	\$37,179
3	7/31/12	\$24,448
4	<b>TOTAL</b>	<b>\$1,567,381</b>

5           241. Reliance’s payments to Dr. Thaiyananthan were based in part on the  
6 profits he generated for Kronos by using Reliance implants in his surgeries on  
7 Medicare patients.  
8

9           242. The Defendants reasonably could have foreseen that their payments to  
10 Dr. Thaiyananthan would cause him to perform spinal fusion surgeries using  
11 Reliance implants that were not medically necessary, or that were more extensive  
12 than what was necessary.  
13  
14

15                           **E. Bret Berry, John Hoffman, and Adam Pike**  
16

17           243. From June 2007 to the present, Bret Berry, John Hoffman, and Adam  
18 Pike each received and retained a share of the profits that Drs. Sabit, Xie,  
19 Mesiwala, and Thaiyananthan generated for Apex and Kronos.  
20

21           244. Through Apex, Berry, Hoffman, and Pike paid themselves \$525,639  
22 *each* between May 2010 and March 2013. These payments were based on profits  
23 Drs. Sabit and Xie generated for Apex.  
24

25           245. Through Kronos, Berry, Hoffman, and Pike paid themselves  
26 \$2,835,297 *each* between June 2007 and January 2013. These payments were  
27 based on profits Drs. Mesiwala and Thaiyananthan generated for Kronos.  
28

## VIII. MEDICARE CLAIMS

1  
2 246. Between April 1, 2010, and December 31, 2010, Dr. Sabit presented  
3 44 claims for payment to Medicare for the instrumented fusion procedures he  
4 performed using Reliance implants.  
5

6 247. Dr. Sabit was paid \$808,876 by Medicare for his professional services  
7 in connection with the instrumented spinal fusion procedures he performed at  
8 Community Memorial Hospital using Reliance devices while he had a financial  
9 interest in Apex.  
10  
11

12 248. Community Memorial Hospital received at least \$8,408,293.29 from  
13 Medicare for hospital services it provided in connection with the fusion surgeries  
14 that Dr. Sabit performed while Dr. Sabit was a Reliance investor.  
15

16 249. Michigan hospitals – including McLaren Lapeer, Detroit Medical  
17 Group, and Doctor's Hospital of Michigan – also received payments from  
18 Medicare between 2011 and 2012 for spinal fusion surgeries performed by Dr.  
19 Sabit using Reliance implants.  
20  
21

22 250. Los Angeles hospitals also received payments from Medicare  
23 between 2007 and 2012 for spinal fusion surgeries performed by Drs. Xie,  
24 Mesiwala, and Thaiyananthan using Reliance implants.  
25

26 251. By way of example, the Defendants caused to be presented to  
27 Medicare the following false or fraudulent claims for surgical procedures using  
28

1 Reliance implants that were performed by Apex and Kronos physician-investors,  
2 and for the hospital services that were provided in connection with those surgical  
3 procedures:  
4

5 **A. "Patient A"**

6 252. On July 8, 2010, Dr. Sabit performed an instrumented fusion surgery  
7  
8 at Community Memorial Hospital on "Patient A," a Medicare patient.<sup>2</sup>

9 253. At the time he operated on Patient A, Dr. Sabit was an Apex  
10  
11 physician-investor.

12 254. Dr. Sabit ordered Reliance implants for his surgery on Patient A.

13 255. Dr. Sabit performed a T7-L2 (i.e. a seven-level) laminectomy and  
14  
15 fusion on Patient A where only a two-level discectomy was indicated.

16 256. Dr. Sabit submitted claims for payment to Medicare for professional  
17  
18 services in connection with his surgery on Patient A, and Medicare paid him  
19 \$9,765 for this surgery.

20 257. Community Memorial Hospital submitted claims for payment to  
21  
22 Medicare for the hospital services it provided in connection with Dr. Sabit's  
23  
24 surgery on Patient A, and Medicare paid Community Memorial Hospital \$276,228  
25 for those services.

26 <sup>2</sup> The United States will supply detailed information identifying these claims  
27 to defendants –including patient name, HIC number, payer, claim number,  
28 procedure performed, related hospital services provided, diagnosis code, date of  
service, date the claim was submitted, amount claimed, and amount paid – upon  
entry of an appropriate protective order.

1           258. Through Apex, Reliance paid Dr. Sabit \$54,235 on July 31, 2010.  
2 This payment was based in part on profits that Dr. Sabit generated for Apex by  
3 ordering Reliance implants for his surgery on Patient A.  
4

5           259. Dr. Sabit's surgery on Patient A resulted in significant post-operative  
6 complications, including excessive blood loss and severe post-operative pain. A  
7 second surgery was required at a different hospital to remove all the Reliance  
8 hardware that Dr. Sabit implanted.  
9

10                           **B. "Patient B"**  
11

12           260. On November 6, 2010, Dr. Sabit performed a C4-C7 fusion surgery  
13 on "Patient B," a Medicare patient, at Community Memorial Hospital.  
14

15           261. At the time he operated on Patient B, Dr. Sabit was an Apex  
16 physician-investor.  
17

18           262. Dr. Sabit ordered Reliance implants for his surgery on Patient B.  
19

20           263. Dr. Sabit performed a complete corpectomy of C5 even though there  
21 was minimal subluxation of C4 on C5, and at most a discectomy and fusion was  
22 indicated at that level.  
23

24           264. Dr. Sabit submitted claims to Medicare for professional services in  
25 connection with his surgery on Patient B, and Medicare paid him \$4,861 for this  
26 surgery.  
27  
28



1           265. Community Memorial Hospital submitted claims for hospital services  
2 it provided in connection with Dr. Sabit's surgery on Patient B, and Medicare paid  
3 Community Memorial Hospital \$128,022 for those services.  
4

5           266. Through Apex, Reliance paid Dr. Sabit \$35,747 on November 30,  
6 2010. This payment was based in part on profits that Dr. Sabit generated for Apex  
7 by ordering Reliance implants for his surgery on Patient B.  
8

9           267. Dr. Sabit's surgery on Patient B failed, and had to be completely re-  
10 done at a different hospital.  
11

12                   **C. "Patient C"**

13           268. On October 7, 2010, Dr. Sabit performed an instrumented fusion  
14 surgery on "Patient C," a Medicare patient, at Community Memorial Hospital.  
15

16           269. At the time he operated on Patient C, Dr. Sabit was an Apex  
17 physician-investor.  
18

19           270. Patient C suffered from multiple co-morbidities at the time of Dr.  
20 Sabit's surgery, including morbid obesity, diabetes, atrial fibrillation, and anemia.  
21

22           271. Dr. Sabit ordered Reliance implants for his surgery on Patient C.  
23

24           272. Dr. Sabit performed a L3-S1 interbody fusion on Patient C, even  
25 though the indications for fusion were completely absent.  
26  
27  
28

1           273. Dr. Sabit submitted claims to Medicare for professional services in  
2 connection with his surgery on Patient C, and Medicare paid him a total of \$8,209  
3 for these claims.  
4

5           274. Community Memorial Hospital submitted claims for hospital services  
6 it provided in connection with Dr. Sabit's surgery on Patient C, and Medicare paid  
7 Community Memorial Hospital \$347,037 for those services.  
8

9           275. Through Apex, Reliance paid Dr. Sabit \$25,572 on October 31, 2010.  
10 This payment was based in part on profits that Dr. Sabit generated for Apex by  
11 ordering Reliance implants for his surgery on Patient C.  
12

13           276. Patient C had immediate post-operative complications. She was not  
14 discharged from Community Memorial until October 15, 2010 – over one week  
15 after the surgery. Patient C was readmitted for post-operative infections on  
16 October 19, 2010, and died on May 31, 2011.  
17  
18

19           **D. "Patient D"**

20           277. On February 4, 2013, Dr. Ali Mesiwala performed an instrumented  
21 fusion surgery on "Patient D," a Medicare patient, at Pomona Valley Hospital.  
22

23           278. Patient D had multiple comorbidities, including obesity,  
24 hypothyroidism, atrial fibrillation, and hypertension. She had previously had a  
25 coronary artery bypass, and she was a one-pack-per-day smoker. She was 75-years  
26 old at the time Dr. Mesiwala operated on her.  
27  
28

1 279. Dr. Mesiwala was a Kronos physician-investor when he operated on  
2 Patient D.

3 280. Dr. Mesiwala diagnosed Patient D with progressive scoliosis, when in  
4 fact the scoliosis was stable and without progression.  
5

6 281. Patient D was seen by different cardiologists preoperatively, only one  
7 of whom would clear her medically for surgery. The cardiologist who ultimately  
8 cleared her for surgery indicated that "in view of significant cardiac history the  
9 patient is at high risk for perioperative events."  
10  
11

12 282. Dr. Mesiwala performed an anterior lumbar interbody fusion from L5-  
13 S1, and a posterior spinal instrumented fusion from T8 to the ilium on Patient D.  
14

15 283. Dr. Mesiwala ordered Reliance implants for his surgery on Patient D.

16 284. The surgery Dr. Mesiwala performed was more extensive than  
17 necessary given that Patient D's scoliosis was not progressive. At most, a selective  
18 laminectomy or decompression was indicated.  
19

20 285. Patient D suffered life threatening post-operative complications,  
21 including pyelonephritis and Clostridium difficile infection, which required three  
22 additional weeks of hospitalization and eight months of treatment.  
23

24 286. Dr. Mesiwala submitted claims to Medicare for professional services  
25 in connection with his surgery on Patient D, and Medicare paid him a total of  
26 \$7,986.17 for these claims.  
27  
28

1           287. Medicare also paid Pomona Valley Hospital, in Pomona, California,  
2 \$75,502.82 for hospital services in connection with Dr. Mesiwala's surgery on  
3 Patient D.  
4

5           288. Through Kronos, Reliance paid Dr. Mesiwala \$30,300 on March 1,  
6 2013. This payment was based in part on profits that Dr. Mesiwala generated for  
7 Kronos by using Reliance implants in his surgeries.  
8

9           **F. "Patient E"**

10           289. On October 7, 2011 and July 26, 2012, Dr. Gowriharan  
11 Thaiyananthan performed instrumented fusion surgeries on Patient E, a Medicare  
12 Patient, at Pomona Valley Hospital.  
13

14           290. Patient E had multiple comorbidities, including congestive heart  
15 failure, diabetes, mellitus, hepatitis C, hepatitis D, and cirrhosis of the liver. In  
16 addition, Patient E was a chronic smoker, and had a history of IV drug abuse.  
17  
18

19           291. On October 7, 2011 Dr. Thaiyananthan performed an initial L2 to L5  
20 instrumented fusion on Patient E.  
21

22           292. On July 26, 2012, without evidence of nonunion, Dr. Thaiyananthan  
23 performed a second instrumented fusion surgery from L2 to L5, along with a  
24 fusion up to T5.  
25

26           293. Dr. Thaiyananthan was a Kronos physician-investor when he  
27 performed both operations on Patient E.  
28

1           294. Dr. Thaiyananthan ordered Reliance implants for his surgeries on  
2 Patient E.

3           295. Dr. Thaiyananthan's initial surgery on Patient E was more extensive  
4 than necessary, because patient E had only mild degenerative disc disease at L4-5  
5 and a central herniation at L2-3 with no nerve root impingement. The most  
6 extensive treatment indicated would have been a microdiscectomy at L2-3.  
7

8           296. Dr. Thaiyananthan's second surgery on Patient E was also not  
9 indicated and was excessive.  
10

11           297. After Dr. Thaiyananthan's surgery, Patient E developed a kyphotic  
12 deformity that resulted in her being unable to walk or to stand upright.  
13

14           298. Dr. Thaiyananthan submitted claims to Medicare for professional  
15 services in connection with his surgeries on Patient E, and Medicare paid him a  
16 total of \$8,523.97 for these claims.  
17

18           299. Medicare also paid Pomona Valley Hospital, in Pomona, California,  
19 \$108,214.97 for hospital services in connection with Dr. Thaiyananthan's surgery  
20 on Patient E.  
21

22           300. Through Kronos, Reliance paid Dr. Thaiyananthan \$57,423 on  
23 October 31, 2011 and \$24,448 on July 31, 2012. These payments were based in  
24 part on profits that Dr. Thaiyananthan generated for Kronos by using Reliance  
25 implants in his surgeries.  
26  
27  
28

1           301. Reliance, Apex, Berry, Hoffman, and Pike were responsible for  
 2 causing false claims to be submitted in relation to its physician-investors' surgeries  
 3 on Patients A-E for two reasons: first, the Defendants actually knew, deliberately  
 4 ignored, or recklessly disregarded the fact that their payment of kickbacks to the  
 5 physician-investors tainted the surgeries those physicians performed using  
 6 Reliance implants; and second, independent of the fact that these claims were  
 7 tainted by kickbacks, the Defendants knew that their payments to physician-  
 8 investors could cause them to perform surgeries using Reliance implants that were  
 9 more extensive than necessary, as occurred with Patients A-E.  
 10  
 11  
 12

13                                   **COUNT I**  
 14

15                                   **Against Reliance, Apex, Berry, Hoffman, and Pike**  
 16

17                                   **False Claims Act: Presentation of False or Fraudulent Claims**  
 18

19                                   **31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A) (2009)**  
 20

21           302. The United States re-alleges and incorporates herein by reference  
 22 paragraphs 1- 301.  
 23

24           303. Defendants Reliance, Apex, Berry, Hoffman, Pike knowingly caused  
 25 Apex physician-investors and hospitals where those physician-investors performed  
 26 surgeries to present claims for payment to Medicare for surgical procedures and  
 27 related hospital services that were false or fraudulent, and not payable, because  
 28 said Defendants, through Apex, knowingly and willfully paid the physician-

1 investors remuneration in order to induce them to order and use Reliance implants,  
2 in violation of the AKS. Further, said Defendants actually knew, deliberately  
3 ignored, or recklessly disregarded the fact that the physician-investors and  
4 hospitals where the physician-investors performed surgeries were submitting  
5 claims for payment to Medicare that were false or fraudulent, and not payable,  
6 because they were tainted by kickbacks.  
7

9 304. Defendants Reliance, Apex, Berry, Hoffman, and Pike caused the  
10 presentation of the following claims to Medicare that were false or fraudulent, and  
11 not payable:  
12

- 13
- 14 • All of the claims for payment presented to Medicare by Dr. Sabit for  
15 surgical procedures using Reliance implants between April 2010 and July  
16 2012, when Dr. Sabit was receiving illegal remuneration from Reliance,  
17 through Apex, and all of the claims presented to Medicare for the related  
18 hospital services by the hospitals where Dr. Sabit performed those  
19 procedures;
- 20 • All of the claims for payment presented to Medicare by Dr. Xie for surgical  
21 procedures using Reliance implants between April 2010 and March 2013,  
22 when Dr. Xie was receiving illegal remuneration from Reliance, through  
23 Apex, and all of the claims presented to Medicare for the related hospital  
24 services by the hospitals where Dr. Xie performed those procedures;

25 305. In addition to and independent of said Defendants' violations of the  
26 AKS, these Defendants also knowingly caused the above-identified physician  
27 investors and hospitals to present claims for payment to Medicare that were not  
28 payable, and were false and fraudulent because certain of the spinal fusion

1 surgeries performed by Drs. Sabit and Xie using Reliance implants were not  
2 medically necessary or were more extensive than what was necessary. These  
3 Defendants knew that the payments made to these physicians, through Apex,  
4 caused these physicians and hospitals to perform and submit claims to Medicare  
5 for surgeries using Reliance implants and related hospital services that were not  
6 medically necessary and/or more extensive than what was necessary.  
7  
8

9 306. By virtue of these false or fraudulent claims for payment, the United  
10 States suffered damages in an amount to be determined at trial.  
11

## 12 COUNT II

### 13 **Against Reliance, Kronos, Berry, Hoffman, and Pike**

#### 14 **False Claims Act: Presentation of False or Fraudulent Claims**

#### 15 **31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A) (2009)**

16  
17 307. The United States re-alleges and incorporates herein by reference  
18 paragraphs 1-301 .  
19

20 308. Defendants Reliance, Kronos, Berry, Hoffman, Pike knowingly  
21 caused Kronos physician-investors and hospitals where those physician-investors  
22 performed surgeries to present claims for payment to Medicare for surgical  
23 procedures and related hospital services that were false or fraudulent, and not  
24 payable, because said Defendants, through Kronos, knowingly and willfully paid  
25 the physician-investors remuneration in order to induce them to order and use  
26  
27  
28



1 Reliance implants, in violation of the AKS. Further, said Defendants actually  
2 knew, deliberately ignored, or recklessly disregarded the fact that the physician-  
3 investors and hospitals where the physician-investors performed surgeries were  
4 submitting claims for payment to Medicare that were false or fraudulent, and not  
5 payable, because they were tainted by kickbacks.  
6

7  
8 309. Defendants Reliance, Kronos, Berry, Hoffman, and Pike caused the  
9 presentation of the following claims to Medicare that were false or fraudulent, and  
10 not payable:  
11

- 12  
13 • All of the claims for payment presented to Medicare by Dr. Mesiwala for  
14 surgical procedures using Reliance implants between August 2007 and  
15 October 2012, when Dr. Mesiwala was receiving illegal remuneration from  
16 Reliance, through Kronos, and all of the claims presented to Medicare for  
17 the related hospital services by the hospitals where Dr. Mesiwala performed  
18 those procedures; and
- 19 • All of the claims for payment presented to Medicare by Dr. Thaiyananthan  
20 for surgical procedures using Reliance implants between January 2010 and  
21 July 2012, when Dr. Thaiyananthan was receiving illegal remuneration from  
22 Reliance, through Kronos, and all of the claims presented to Medicare for  
23 the related hospital services by the hospitals where Dr. Thaiyananthan  
24 performed those procedures.

25  
26 310. In addition to and independent of said Defendants' violations of the  
27 AKS, these Defendants also knowingly caused the above-identified physician  
28 investors and hospitals to present claims for payment to Medicare that were not  
payable, and were false and fraudulent because certain of the spinal fusion

1 surgeries performed by Drs. Thaiyanantha and Mesiwala using Reliance implants  
2 were not medically necessary or were more extensive than what was necessary.  
3  
4 These Defendants knew that the payments made to these physicians, through  
5 Kronos, caused the physicians and hospitals to perform and submit claims to  
6 Medicare for surgeries using Reliance implants and related hospital services that  
7  
8 were not medically necessary and/or more extensive than what was necessary.

9 **COUNT III**

10 **Against Dr. Sabit**

11  
12 **False Claims Act: Presentation of False or Fraudulent Claims**

13 **31 U.S.C. § 3729(a)(1), 31 U.S.C. § 3729(a)(1)(A) (2009)**

14  
15 311. The United States re-alleges and incorporates herein by reference  
16 paragraphs 1- 301.

17  
18 312. Defendant Dr. Aria Sabit knowingly submitted and caused to be  
19 submitted false or fraudulent claims for payment to the United States in violation  
20 of the FCA. Specifically, Dr. Sabit presented claims and caused hospitals to  
21 present claims for payment to Medicare for services related to spinal fusion  
22 surgeries that Dr. Sabit performed using Reliance implants between April 2010 and  
23 August 2012. These claims were false or fraudulent, and not payable, because Dr.  
24 Sabit knowingly and willfully accepted remuneration from Reliance, through  
25  
26  
27  
28

1 Apex, in exchange for arranging for hospitals to order Reliance implants for use in  
2 those surgeries, in violation of the AKS.

3  
4 **COUNT IV**

5 **Against All Defendants**

6 **False Claims Act: Conspiracy**

7  
8 **31 U.S.C. § 3729(a)(3), 31 U.S.C. § 3729(a)(1)(C) (2009)**

9 313. The United States re-alleges and incorporates herein by reference  
10 paragraphs 1-301.

11  
12 314. The Defendants entered into an unlawful agreement to cause the  
13 presentation of false or fraudulent claims to the United States, and performed acts  
14 in furtherance of this conspiracy. Specifically, Defendants Berry, Hoffman Pike,  
15 and Reliance formed Apex and Kronos as vehicles through which they paid their  
16 physician-investors remuneration in order to induce them to use Reliance implants  
17 in their surgeries. The Defendants performed acts in furtherance of this conspiracy  
18 by actually paying remuneration to the Apex physician-investors, Drs. Sabit and  
19 Xie, and to the Kronos physician-investors, Drs. Mesiwala and Thaiyananthan to  
20 induce them to use Reliance implants.  
21  
22  
23

24  
25 315. Dr. Sabit performed acts in furtherance of this conspiracy by  
26 accepting remuneration from Reliance, through Apex, causing hospitals to order  
27 Reliance implants, using Reliance implants in his surgeries, presenting claims to  
28

1 Medicare for these surgeries, and causing the hospitals where these surgeries were  
2 performed to present false claims to Medicare for hospital services related to these  
3 surgeries.  
4

5 316. By virtue of these false or fraudulent claims, the United States  
6 suffered damages in an amount to be determined at trial.  
7

8 **COUNT V**

9 **Against Bret Berry**

10 **Unjust Enrichment**

11  
12 317. The United States re-alleges and incorporates herein by reference  
13 paragraphs 1 through 301.  
14

15 318. From June 2007 to the present, Reliance, through Apex and Kronos,  
16 paid physicians remuneration to induce them to use Reliance implants in their  
17 surgeries, knowing that those implants would be billed to Medicare in violation of  
18 the AKS. During this period, Apex and Kronos physician-investors generated  
19 approximately \$13 million in illegal profit for Reliance. Berry, Hoffman, and Pike  
20 each received and retained a share of these illegal payments.  
21

22  
23 319. By reason of the payments described above, Bret Berry received  
24 money to which he was not entitled. Thus, Bret Berry has been unjustly enriched.  
25 The United States is entitled to the return of the payments from Apex and Kronos  
26 to Bret Berry.  
27  
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**COUNT VI**

**Against John Hoffman**

**Unjust Enrichment**

320. The United States re-alleges and incorporates herein by reference paragraphs 1 through 301.

321. From June 2007 to the present, Reliance, through Apex and Kronos, paid physicians remuneration to induce them to use Reliance implants in their surgeries, knowing that those implants would be billed to Medicare in violation of the AKS. During this period, Apex and Kronos physician-investors generated approximately \$13 million in illegal profit for Reliance. John Hoffman received and retained a share of these illegal payments.

322. By reason of the payments described above, John Hoffman received money to which he was not entitled. Thus, John Hoffman has been unjustly enriched. The United States is entitled to the return of the payments from Apex and Kronos to John Hoffman.

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**COUNT VII**

**Against Adam Pike**

**Unjust Enrichment**

323. The United States re-alleges and incorporates herein by reference paragraphs 1 through 301.





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**PRAYER FOR RELIEF**

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

- (a) On Counts I, II, III, and IV (False Claims Act), for treble the United States' damages, together with the maximum civil penalties allowed by law;
- (b) On Count V, VI, VII, and VIII (Unjust Enrichment), in the amount by which the Defendants were unjustly enriched;
- (c) On Count IX (Payment by Mistake), in the amount of money illegally obtained and retained by Dr. Sabit;
- (d) Pre- and post-judgment interest, costs, and such other relief as the Court may deem appropriate.



**JURY DEMAND**

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

Respectfully submitted,

DATED: September 5, 2014

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Acting Associate Attorney General

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