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SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES

MARY CAVALIERI, an individual,

Plaintiff,

vs.

HEALTHSMART PACIFIC, INC. d/b/a PACIFIC HOSPITAL OF LONG BEACH;
MICHAEL D. DROBOT;
GARDENS REGIONAL HOSPITAL AND MEDICAL CENTER INC. d/b/a TRI-CITY REGIONAL MEDICAL CENTER;
RIVERSIDE COMMUNITY HOSPITAL;
PARKVIEW COMMUNITY HOSPITAL MEDICAL CENTER, INC.;
ST. BERNARDINE MEDICAL CENTER;
SPINAL SOLUTIONS, LLC;
ORTHOPEDIC ALLIANCE, LLC;
ROGER WILLIAMS;
JEFFREY FIELDS;
MARY SISLER WILLIAMS;

Case No.: **BC 551813**

COMPLAINT FOR:

1. **Battery**
2. **Fraud - Concealment**
3. **Fraud – Intentional Misrepresentation**
4. **Breach of Fiduciary Duty**
5. **Strict Products Liability**
6. **Breach of Express Warranty**
7. **Breach of Implied Warranty**
8. **Medical Monitoring**
9. **Constructive Trust**
10. **Unjust Enrichment**
11. **Intentional Infliction of Emotional Distress**
12. **Negligent Infliction of Emotional Distress**
13. **Negligence**

DEMAND FOR JURY TRIAL

COMPREHENSIVE INTRA-OPERATIVE SYSTEMS, INC.;
MICHAEL "MIC" McGRATH, individually and d/b/a COMPREHENSIVE INTRA-OPERATIVE SYSTEMS, INC.;
DAVID TYSON;
INTERNATIONAL IMPLANTS, LLC;
WILLIAM CROWDER, individually and d/b/a CROWDER MACHINE & TOOL SHOP;
CROWDER MACHINE & TOOL SHOP;
PAUL RANDALL;
JACK AKMAKJIAN, M.D., individually and d/b/a AKMAKJIAN SPINE AND GENERAL ORTHOPEDICS CENTER, INC.;
G. SUNNY UPPAL, M.D.;
KHALID AHMED, M.D.; and
DOES 1 through 200,

Defendants.

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On information and belief, Plaintiff alleges as follows:

I. OVERVIEW

1. On February 21, 2014, the U.S. Department of Justice announced that Defendant MICHAEL D. DROBOT (hereinafter "DROBOT") had entered into a plea agreement in which he admitted running a sophisticated fraud scheme involving the payment of kickbacks to doctors, chiropractors and others who referred patients to Defendant HEALTHSMART PACIFIC, INC. D/B/A PACIFIC HOSPITAL OF LONG BEACH (HEREINAFTER "PACIFIC HOSPITAL") for spinal fusion surgeries and other procedures. The kickbacks added up to tens of millions of dollars and were derived as part of an even larger overarching conspiracy to bilk insurance companies and individuals out of over $500 million, over a five year period, through the submission fraudulent bills for spinal fusion surgeries. This was just the tip of the iceberg – as the conspiratorial plot to secure fraudulent profits involved a much wider network of participants – and included a plan to manufacture, distribute, sell and implant counterfeit medical devices used in spinal fusion surgeries of patients.

2. At all times herein relevant Plaintiff MARY CAVALIERI (hereafter "CAVALIERI") was a patient of Defendant KHALID AHMED, M.D. (hereinafter "AHMED"), an orthopedic surgeon specializing in spinal fusion surgery. Unbeknownst to CALVALIERI, AHMED was a major participant in the conspiracy – a surgeon whose selection of hospitals and implantable spinal fixation devices was influenced by the payment of monetary kickbacks.

3. CAVALIERI underwent two separate lumbar fusion procedures, referred to as "360" or "anterior/posterior lumbar fusion," fusing the back and front of the spine at two levels.

4. On or about June 26, 2010, CAVALIERI underwent the anterior lumbar interbody fusion ("ALIF") procedure at Defendant PACIFIC HOSPITAL, which was owned and operated by DROBOT, with AHMED performing the surgery. On information and belief, AHMED selected PACIFIC HOSPITAL as the location of the surgery to receive a kickback of an undisclosed amount paid by or on behalf of Defendants DROBOT and PACIFIC HOSPITAL. In doing so, AHMED agreed to use certain implantable spinal fixation devices supplied to PACIFIC HOSPITAL through DROBOT's "sham" distributorship of implantable medical devices,

Defendant INTERNATIONAL IMPLANTS, LLC (hereinafter "II"). II and PACIFIC HOSPITAL regularly obtained implantable spinal fixation devices from Defendant SPINAL SOLUTIONS, LLC (hereinafter "SS"), a distributor of medical devices that also manufactured and distributed false, fraudulent, fake, counterfeit, non-FDA approved "knock-off" implantable spinal fixation devices, including screws, rods and interbody cages that were produced in a machine shop in Temecula, California.

5. Three months after the ALIF procedure, on or about September 18, 2010, CAVALIERI underwent the posterior lumbar interbody fusion ("PLIF") procedure at PACIFIC HOSPITAL with AHMED again performing the surgery. AHMED selected PACIFIC HOSPITAL as the location of the second procedure to receive a second kickback of an undisclosed amount paid by or on behalf of Defendants DROBOT and PACIFIC HOSPITAL. In doing so, AHMED again agreed to use implantable spinal fixation devices supplied to PACIFIC HOSPITAL through II.

6. Due to complications associated with the spinal implants from the first two spinal fusion procedures, CAVALIERI had a third procedure to surgically remove her posterior spinal implants. This procedure was performed by Duncan Q. McBride, M.D. at UCLA medical center. CAVALIERI did not have the two cages implanted into her spine removed or "explanted," as it would necessarily reverse the fusion, requiring a refusion procedure, and she was advised that there is substantial risk associated with removing or explanting the interbody cages, including death.

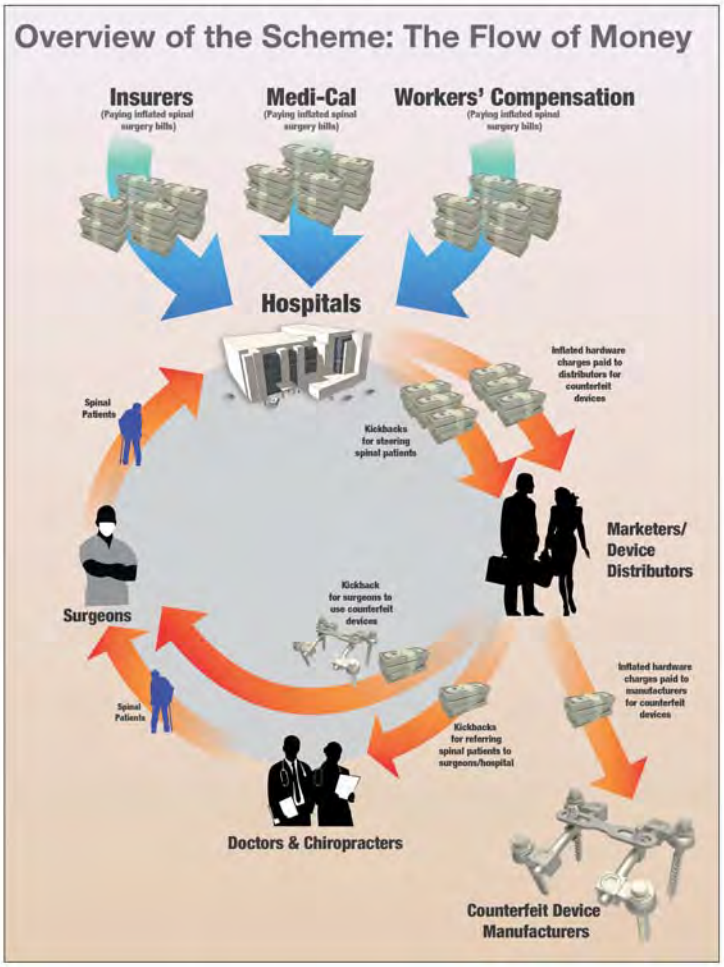
7. CAVALIERI is among thousands of spinal fusion surgery patients in Southern California and elsewhere who had such counterfeit, non-FDA approved medical devices implanted into their bodies as a consequence of the systematic pattern of fraud and deceit carried on by Defendants. With respect to CAVALIERI's surgeries, SS supplied implantable spinal fixation hardware.

8. This lawsuit is brought by CAVALIERI in an effort to stop the prevalent fraud and abuse in our healthcare system by certain doctors, hospitals, marketers, and medical device distributors who willfully engaged in fraudulent activity with a conscious disregard for the health, safety, and well-being of individuals in need of medical care, including Plaintiff, in order to promote their own financial gain. She also brings this lawsuit to seek damages for the implantation

of foreign objects which were surgically implanted into her spine in the course of her spinal fusion surgeries at PACIFIC HOSPITAL.

9. At the center of the scheme was a systematic pattern of fraud and deceit fueled by the payment of illegal kickbacks, which were in turn derived from illegal profits generated by the fraudulent inflation of health care charges billed to insurers and individuals for the cost of implantable spinal fixation devices used in spinal fusion surgeries.

10. In furtherance of the conspiratorial scheme to unlawfully profit from spinal fusion surgeries, Defendants, and each of them, conspired with and/or aided and abetted one another in connection with the manufacture, distribution, sale and use of counterfeit, non-FDA approved spinal fusion hardware that was implanted into the bodies of patients, including Plaintiff, without their knowledge and consent.



11. As a legal result of the concerted wrongful acts of each of the Defendants, CAVALIERI suffered the injuries and damages hereinafter set forth.

II. JURISDICTION AND VENUE

12. This Court has jurisdiction over the entire action because this is a civil action where the matter in controversy, exclusive of interest and costs, exceeds the jurisdictional minimum of the Court. The conspiracy to defraud insurance companies that led to the implantation of foreign objects into the body of Plaintiff occurred in or about the County of Los Angeles, State of California.

13. Venue is proper in the County of Los Angeles because the events giving rise to Plaintiff's claims and/or the injuries sustained by Plaintiff arise from tortious acts and/or omissions, which occurred in the County of Los Angeles, State of California and at least one defendant resides in the County of Los Angeles.

III. PARTIES

A. Plaintiffs

14. CAVALIERI is an individual who, at all times herein relevant, was a resident of Glendora, County of Los Angeles, California.

B. Defendants

1. The Hospital and Hospital Related Defendants

a. Pacific Hospital

15. Defendant PACIFIC HOSPITAL was, at all times herein relevant, a California corporation with its principal place of business in the County of Los Angeles, at 2776 Pacific Avenue, Long Beach, California. PACIFIC HOSPITAL is a for-profit hospital that specialized in surgeries, particularly spinal and orthopedic surgeries, and has been one of the most prolific in performing spinal fusion surgeries during the past decade.

b. Michael D. Drobot

16. DROBOT was a resident of the City of Newport Beach, County of Orange, California and owned, controlled, and managed PACIFIC HOSPITAL. DROBOT purchased the hospital in 1997 and immediately shifted its focus to spinal care for workers' compensation

patients.

c. Tri-City Hospital

17. At all times herein relevant, Defendant GARDENS REGIONAL HOSPITAL AND MEDICAL CENTER INC. d/b/a TRI-CITY REGIONAL MEDICAL CENTER (hereinafter "TRI-CITY") was and is a hospital located in the County of Los Angeles, at 21530 Pioneer Boulevard, Hawaiian Gardens, California.

d. Riverside Hospital

18. Defendant RIVERSIDE COMMUNITY HOSPITAL (hereinafter "RIVERSIDE") is, and at all times relevant was, a hospital located in the County of Riverside, at 4445 Magnolia Avenue, Riverside, California. RIVERSIDE conducts approximately 10,000 inpatient and outpatient surgeries per year, including spinal fusion surgeries.

e. Parkview Hospital

19. Defendant PARKVIEW COMMUNITY HOSPITAL MEDICAL CENTER, INC. (hereinafter "PARKVIEW") is a 193-bed hospital located and doing business in the County of Riverside, at 3865 Jackson Street, Riverside, California.

f. St. Bernardine Hospital

20. Defendant ST. BERNARDINE MEDICAL CENTER (hereinafter "ST. BERNARDINE") is a hospital located and doing business in the County of San Bernardino, at 2101 N. Waterman Avenue, San Bernardino, California. ST. BERNARDINE is part of Dignity Health, one of the largest hospital providers in the country and the largest hospital system in the State of California.

g. Doe Hospital and Hospital-Related Defendants

21. Plaintiff is ignorant of the names and capacities of additional hospital and hospital-related defendants sued herein as DOES 1 through 25, inclusive, and therefore sue such Defendants by fictitious names pursuant to California Code of Civil Procedure section 474. Plaintiff will amend this Complaint to allege the true names and capacities of the fictitiously named Defendants once they are ascertained.

2. The Distributor and Distributor-Related Defendants

a. Spinal Solutions, LLC

22. At all times relevant, SS was a medical-implant distributorship owned and operated by Defendant ROGER WILLIAMS and his then-wife, Defendant MARY SISLER WILLIAMS. Defendant SS was located and doing business in the County of Riverside, at 26157 Jefferson Avenue, Murrieta, California. SS is also a manufacturer defendant.

b. Orthopedic Alliance, LLC

23. Defendant ORTHOPEDIC ALLIANCE, LLC (hereinafter "OA") was, at all times herein relevant, another orthopedic device/implant distributorship owned and operated by Defendant ROGER WILLIAMS and his then-wife, Defendant MARY SISLER WILLIAMS, located at 26157 Jefferson Avenue, Murrieta, California. OA was a subsidiary of SS, operating at the same facility with the same staff, officers, directors, managers, and inventory. OA is also a manufacturer defendant.

c. Roger Williams

24. Defendant ROGER WILLIAMS (hereinafter "WILLIAMS") is an individual who, at all times herein relevant, resided in the County of Riverside, State of California.

d. Jeffrey Fields

25. At all times herein mentioned, Defendant JEFFREY FIELDS (hereinafter "FIELDS") was an individual residing in the County of Riverside, California. At all times herein relevant, FIELDS was the Operations Manager of SS and OA.

e. Mary Sisler Williams

26. Defendant MARY SISLER WILLIAMS (hereinafter "MSW") was an individual who at all times relevant was the wife of Defendant WILLIAMS and resided in the County of Riverside, California.

f. Comprehensive Intra-Operative Services, Inc.

27. Defendant COMPREHENSIVE INTRA-OPERATIVE SYSTEMS, INC. (hereinafter "C.I.O.S.") was at all times relevant a "marketer" and/or distributor of medical services and/or implantable spinal fixation devices doing business as a sole proprietorship, corporation, or

other legal entity in the County of Riverside, California.

g. Michael "Mic" McGrath

28. Defendant MICHAEL "MIC" McGRATH (hereinafter "McGRATH") was at all times relevant an individual residing in the County of Riverside, California. McGrath owned, operated, and/or controlled Defendant C.I.O.S. with respect to the acts and/or omissions hereinafter set forth. McGRATH also acted as a "marketer" for TRI-CITY and PACIFIC HOSPITAL through his "sham" distributorship C.I.O.S. for SS, paying kickbacks to spinal surgeons in exchange for the referral of patients. He is both a distributor and marketer defendant.

h. David Tyson

29. Defendant DAVID TYSON (hereinafter "TYSON") was at all times relevant an individual residing in the City of Riverside, County of Riverside, California. TYSON was a sales representative and technician for Defendants SS and C.I.O.S., and was involved in the sale of the purported implantable hardware.

i. International Implants, LLC

30. Defendant INTERNATIONAL IMPLANTS, LLC (hereinafter "II") was at all times relevant located at 20377 SW Acacia St., Suite 110, Newport Beach California. II was a "sham distributorship" owned and operated by DROBOT to falsely inflate the cost of implantable hardware on bills submitted to insurers.

j. Doe Distributor and Distributor-Related Defendants

31. Plaintiff is ignorant of the names and capacities of additional distributors and distributor-related defendants sued herein as DOES 26 through 50, inclusive, and therefore sue such Defendants by fictitious names pursuant to California Code of Civil Procedure section 474. Plaintiff will amend this Complaint to allege the true names and capacities of the fictitiously named Defendants once they are ascertained.

3. <u>The Manufacturer and Manufacturer-Related Defendants</u>

a. William Crowder

32. At all times herein relevant, Defendant WILLIAM CROWDER (hereinafter "CROWDER") was and is an individual residing in the County of Riverside, California who owns

and operates a machine shop doing business as CROWDER MACHINE & TOOL SHOP (hereinafter "CROWDER MTS") in Temecula, California.

b. Crowder Machine & Tool Shop

33. At all times herein relevant, Defendant CROWDER MTS was at all times relevant located at 43339 Business Park Drive, Temecula, California. The machine shop was owned and operated by CROWDER.

c. Doe Manufacturer and Manufacturer-Related Defendants

34. Plaintiff is ignorant of the names and capacities of additional manufacturers and manufacturer-related defendants sued herein as DOES 51 through 75, inclusive, and therefore sue such Defendants by fictitious names pursuant to California Code of Civil Procedure section 474. Plaintiff will amend this Complaint to allege the true names and capacities of the fictitiously named Defendants once they are ascertained.

4. <u>The Marketer Defendants</u>

a. Paul Randall

35. At all times herein relevant, Defendant PAUL RANDALL (hereinafter "RANDALL") was and is an individual residing in the City and County of Orange, California. Defendant RANDALL recruited a network of loyal doctors and chiropractors who would refer spinal cases to Defendant Hospitals in exchange for illegal kickbacks, paying chiropractors and physicians kickbacks of approximately $15,000 each for a spinal fusion referral. RANDALL also, at various times, acted as a distributor of various medical devices, including, but not limited to, implantable spinal fixation devices.

b. Doe Marketer Defendants

36. Plaintiff is ignorant of the names and capacities of additional marketer defendants sued herein as DOES 76 through 100, inclusive, and therefore sue such Defendants by fictitious names pursuant to California Code of Civil Procedure section 474. Plaintiff will amend this Complaint to allege the true names and capacities of the fictitiously named Defendants once they are ascertained.

5. The Doctor Defendants

a. Jack Akmakjian, M.D.

37. Defendant JACK AKMAKJIAN, M.D. (hereinafter "AKMAKJIAN") is a spinal surgeon performing surgeries in various hospitals throughout Southern California, including PARKVIEW, TRI-CITY, RCH and PACIFIC HOSPITAL. His principal place of business is located in the City of Riverside, County of Riverside, California. AKMAKJIAN owns and operates ASGOC, which has a principal place of business located in the City of Riverside, County of Riverside, California.

b. Gurvinder "Sunny" Uppal, M.D.

38. Defendant GURVINDER "SUNNY" UPPAL, M.D. (hereinafter "UPPAL") is a spinal surgeon performing surgeries in the Southern California region. His principal place of business is located in the City of Riverside, County of Riverside, California.

c. Khalid Ahmed, M.D.

39. Defendant AHMED is a spinal surgeon performing surgeries in the Southern California region and is the owner and operator of Khalid B. Ahmed Medical Corporation. AHMED's principal place of business is located in Pico Rivera, Los Angeles County, California.

d. Doe Doctor Defendants

40. Plaintiff is ignorant of the names and capacities of additional Defendant Doctors sued herein as DOES 101 through 150, inclusive, and therefore sue such Defendants by fictitious names pursuant to California Code of Civil Procedure section 474. Plaintiff will amend this Complaint to allege the true names and capacities of the fictitiously named Defendants once they are ascertained.

C. Doe Defendants

41. The true names and capacities, whether individual, corporate, associate or otherwise, of Defendants DOES 1 through 200, inclusive, and each of them, are currently unknown to Plaintiff who therefore sues such defendants by such fictitious names and capacities. Plaintiff is informed and believes, and thereupon alleges, that each fictitiously named defendant, whether

acting for itself or as an agent, corporation, association, or otherwise, is liable herein. While at this time Plaintiff is unaware of the true names and capacities of the DOE Defendants, Plaintiff will amend this complaint to show the true names of each when then same has been ascertained.

IV. AGENCY AND CONCERT OF ACTION

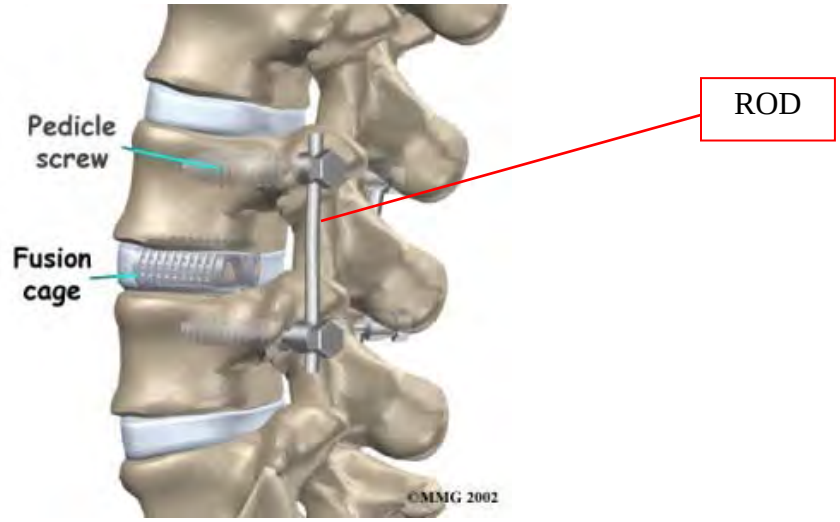
42. At all times herein mentioned, Defendants and/or DOES 1 through 200, and each of them, hereinabove, were the agents, servants, employees, partners, aiders and abettors, co-conspirators, and/or joint venturers of each of the other Defendants named herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, enterprise, conspiracy, and/or joint venture, and each Defendant has ratified and approved the acts of each of the remaining Defendants. Each of the Defendants aided and abetted, encouraged, and rendered substantial assistance to the other Defendants in wrongfully causing injury and damage to Plaintiffs, as alleged herein. In taking action to aid and abet and substantially assist the commission of these wrongful acts and other wrongdoings complained of, as alleged herein, each of the Defendants acted with an awareness of his/her/its primary wrongdoing and realized that his/her/its conduct would substantially assist the accomplishment of the wrongful conduct, wrongful goals, and wrongdoing.

43. Plaintiff is informed and believes, and thereupon alleges, that Defendants and each of the DOE Defendants are in some manner, responsible for the events and happenings herein set forth and proximately caused injury and damages to the Plaintiff as herein alleged.

V. FACTUAL BACKGROUND OF THE FRADULENT SCHEME

A. Spinal Fusion Surgery

44. Spinal fusion is major surgery to join or fuse two or more vertebrae to prevent movement between the vertebrae. The surgery can be performed either through an incision in the back, the abdomen, or a combination of both. In many cases, spinal fusion procedures involve the implantation of a number of different metal spinal fixation devices, including but not limited to plates, screws, rods, screw caps, and interbody cages, used to hold the vertebrae together until new bone grows between them.

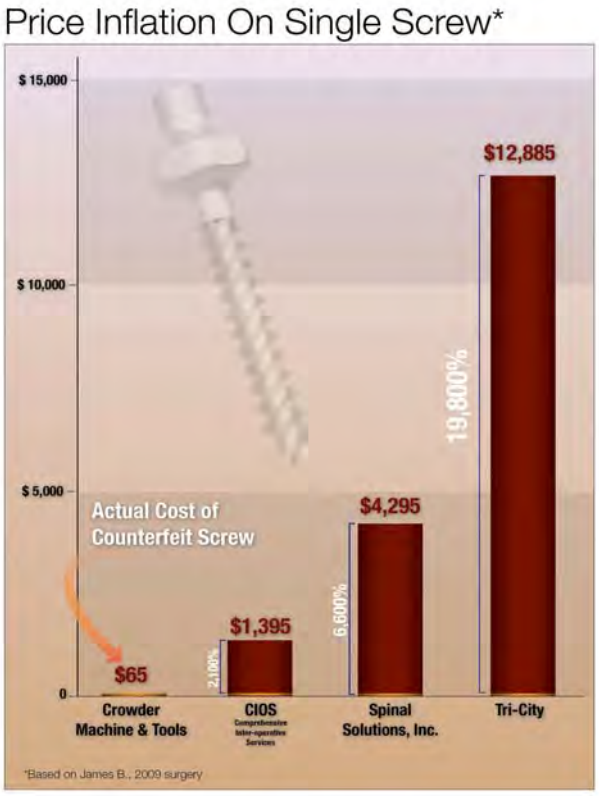


As a result of the intrusive nature of the operation, the surgical hardware cannot be removed without reversing the fusion and without significant risk of death or injury to the patient.

B. <u>Defendants Fraudulently Inflate Medical Bills to Increase Financial Gains</u>

45. Enacted in or around 2002, California Labor Code Section 5318 was intended by the California State Legislature to be a "pass-through" provision requiring workers' compensation carriers in California to pay **100% of a hospital's documented cost of implantable hardware** used in spinal fusion surgeries, plus $250. After the enactment of the legislation, the profits made by manufacturers, distributors and hospitals soared, largely due to the exploitation of the legislation, the creation of "sham" distributorships, and the inflation of the documented cost of hardware through false and fraudulent invoices and bills. The legislation allowed DROBOT and his hospitals and co-conspirators to force the carriers and others to pay whatever artificial, fraudulent sum was listed on the bills. To accomplish this, DROBOT and others bribed and influenced legislators in Sacramento to pass such legislation as fully set forth in Section V.H. of this complaint.

46. At each stage between manufacture and implantation, the single pedicle screw would be astronomically marked up. For example, a legitimate screw would cost $300 to $500 wholesale, or if counterfeit, it would cost roughly $65 but would be listed on a hospital bill submitted to an insurance company at a cost of **over $12,000**.



Attached as **Exhibit 1**, and incorporated herein, are true and correct copies of a series of bills and invoices relating to a single surgery that occurred at TRI-CITY, identified as "James B."

C. The Conspiratorial Scheme is Fueled By the Payment of Kickbacks

47. With the lucrative profits garnered though the conspiracy to defraud carriers, Defendant Hospitals sought to increase their number of spinal fusion surgeries and recruited the assistance of distributors to maximize profit. With the staggering profit made from the illegal scheme, the Hospital Defendants and Distributor Defendants entered into contracts with the Marketer Defendants to pay spinal surgeons and others illegal kickbacks to perform surgeries at Hospital Defendants' facilities through sham consulting agreements. Attached are true and correct copies of a sample marketing agreement and a sample consulting agreement as **Exhibit 2** and **Exhibit 3**, respectively, and incorporated herein. These illegal kickbacks were funneled through the conspiracy and paid for by the inflated hardware bills.

48. As an example of the money paid to the Marketer Defendants to draw spinal fusion surgeries to the hospitals, TRI-CITY paid RANDALL more than $3.2 million to perform "marketing" services involving unlawfully capping, running and steering spinal surgery patients

and doctors to TRI-CITY between 2008 and 2011. As of August 2011, RANDALL entered into a $100,000 per month agreement with DROBOT and PACIFIC HOSPITAL to cap, run and/or steer patients and doctors to PACIFIC HOSPITAL, so that DROBOT, by and through his wholly owned "sham" distributorship, Defendant II, could artificially and falsely increase the cost of the implantable hardware. PACIFIC HOSPITAL would then prepare a false or fraudulent bill, showing the fraudulently increased cost for the spinal hardware, all to defraud insurance companies out of insurance benefits.

49. As a further example, McGRATH owned and operated C.I.O.S. as a "sham" distributorship, which sold and distributed implantable spinal fixation devices for SS and OA, and served as a "marketer" for both TRI-CITY and PACIFIC HOSPITAL. McGRATH profited from this conspiracy to defraud insurance carriers as a distributor of implantable spinal fixation devices, paying kickbacks to surgeons, including, but not limited to, AKMAKJIAN and UPPAL, in exchange for them designating C.I.O.S. supplied implantable hardware for use in spinal fusion surgeries. At the same time, McGRATH profited as a hospital "marketer" where he was highly compensated for engaging in prohibited capping, running, and steering for hospitals and paying spinal surgeons and others kickbacks for the referral of spinal surgeries to the hospital.

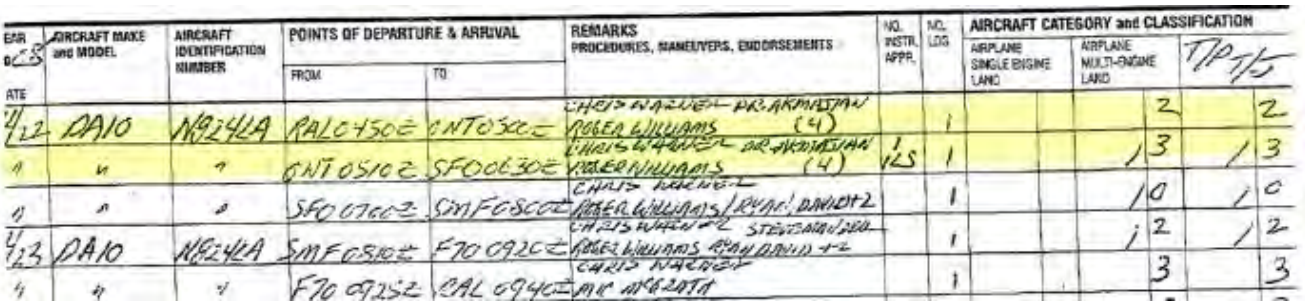
50. The Hospital Defendants also paid kickbacks to health care professionals other than spinal surgeons, including chiropractors and other medical doctors involved in MD/DC or "multidisciplinary" clinics, often operating as "sham" medical corporations, in exchange for the referral of potential surgical candidates in which implantable spinal hardware would be required.

51. The Doctor Defendants were regularly paid kickbacks by the Hospital Defendants through the Marketer Defendants in exchange for the referral of surgeries to the hospitals, with the marketers and hospitals paying the surgeons as much as $15,000 per surgery performed. Such kickback activity was intended to: influence medical decision making; incentivize surgeons to classify patients as surgical candidates; influence the medical decision on the number of vertebral levels to be fused; influence the medical decision to use implantable spinal hardware, as well as the selection of the specific implantable fixation devices; influence the medical decision on the specific type of procedure for stabilization of the spine; and influence the medical decision as to whether

extraction of implanted hardware is required, among other medical decisions. Under this fraudulent scheme and conspiracy, it was axiomatic that the greater the number of procedures performed, the more the Defendant Doctor would be paid in illegal kickbacks, and the more profit all co-conspirators would derive from the illegal billing scheme.

52. The Doctor Defendants were also paid kickbacks by the Distributor Defendants, to ensure the selection of implantable spinal fixation devices distributed by Defendant Distributors, including those implantable spinal fixation devices which were counterfeit, non-FDA approved "knock-offs." The kickbacks were paid by the Distributor Defendants specifically to influence the medical decision making of the spinal surgeons and to induce them to select and use products distributed by the Distributor Defendants.

53. Such kickbacks took different forms, including the payment of cash, the purchase of valuable coins, "sham" consulting agreements, the purchase of sports memorabilia, the "entertainment" by prostitute sand air travel, all of which was and is prohibited by federal and state laws. For example, WILLIAMS leased or owned a number of airplanes which were used to provide travel and entertainment, free of charge, to various spinal surgeons, including, but not limited to the Doctor Defendants. Flight logs from November 2006 to September 2011, prepared and maintained by pilots paid by WILLIAMS and SS/OA, show that flights were provided to a large number of spinal surgeons, including the Defendant Doctors, and transported medical devices and/or instruments, cash, and prostitutes or other "adult entertainers" for the spinal surgeons' enjoyment. Attached as **Exhibit 4** and incorporated herein are true and correct copies of excerpts from flight logs kept by SS pilots.



DATE	AIRCRAFT MAKE and MODEL	AIRCRAFT IDENTIFICATION NUMBER	POINTS OF DEPARTURE & ARRIVAL FROM	TO	REMARKS PROCEDURES, MANEUVERS, ENDORSEMENTS	NO. INSTR. APPR.	NO. LDG	AIRCRAFT CATEGORY and CLASSIFICATION AIRPLANE SINGLE ENGINE LAND	AIRPLANE MULTI-ENGINE LAND	TIME
4/22	DA10	N624A	RAL 0450Z	ONT 0530Z	CHRIS WARNER DR ARMANIAN ROGER WILLIAMS (4)		1		2	2
"	"	"	ONT 0510Z	SFO 0630Z	CHRIS WARNER DR ARMANIAN ROGER WILLIAMS (4)	1 VLS	1		3	3
"	"	"	SFO 0760Z	SMF 0850Z	CHRIS WARNER ROGER WILLIAMS / RYAN / DANIEL +2		1		0	0
4/23	DA10	N624A	SMF 0830Z	F70 0920Z	CHRIS WARNER STEVE ARMANIAN ROGER WILLIAMS RYAN DANIEL +2		1		2	2
"	"	"	F70 0925Z	CAL 0940Z	CHRIS WARNER MR ARMANIAN		1		3	3

54. At all times relevant, the payment of prohibited kickbacks, which were paid as rebates, refunds, commissions, preferences, patronage dividends, discounts, or other consideration, whether in the form of money or otherwise, were paid by the Hospital Defendants, Distributor Defendants, and Marketer Defendants to ensure the flow of spinal fusion surgery patients, all in furtherance of the conspiracy to defraud insurance carriers.

55. At all times relevant, Defendants, and each of them, knew that the payment of kickbacks was, and is, an activity prohibited by state and federal laws to prevent corruption of the medical profession and ensure that medical decisions were in the best interests of patients, unimpaired and free from the influence of the payment of money.

56. Notwithstanding such knowledge, Defendants knowingly and willingly engaged in the payment or acceptance of kickbacks in various forms, or simply turned a "blind-eye" to such activity, knowing that such payment was intended to influence the care and treatment of patients, whose health, safety and well-being were subordinated to the Defendants' interest in financial gain. In addition, each Defendant engaging in the conspiracy alleged herein knew that the payment of prohibited kickbacks cemented the participants to the conspiracy, subjecting them to extortion or blackmail vis-à-vis licensure, professional and community reputation and standing, and professional, personal and family relationships.

57. The Distributor Defendants and Hospital Defendants attempted to disguise or conceal kickback as payments for "consulting services." The Distributor Defendants and Hospital Defendants created false and fraudulent consulting agreements which paid spinal surgeons kickbacks in exchange for using SS or OA distributed product and/or for using specific hospitals without the spinal surgeons performing any of the purported duties of the consulting agreements.

58. To accomplish the goal of the conspiracy, to prepare and present false claims to insurers in connection with the implantable hardware, Defendants, and each of them, made material misrepresentations of fact to insurers, patients, the FDA and others, concealing from them information relating to the conspiracy, including the existence of the kickbacks paid, as herein alleged, and/or that they were participating in a conspiracy to fraudulently inflate the cost of implantable hardware in connection with spinal fusion surgeries.

D. Inflated Billing and Kickbacks Incentivized Defendants to Perform More Surgeries

59. As a result of the payment of kickbacks and financial greed, as well the existence of California Labor Code section 5318 and the scheme to fraudulently inflate the cost of implantable medical devices used in spinal fusion surgeries, the Hospital Defendants experienced a tremendous increase in the number of spinal fusions performed, indicative of money influencing medical decision making.

60. In 1998, spinal fusion surgery was the thirty-seventh most common surgery in the United States. After the enactment of Labor Code section 5318 in California, and by 2008, spinal fusion surgery had become the sixteenth most common surgery, costing $10 billion per year.

61. DROBOT acquired PACIFIC HOSPITAL in 1997 and, by 1998, began entering into agreements with doctors, chiropractors, and marketers to induce them to perform spinal surgeries at hospitals owned and/or controlled by DROBOT in exchange for kickbacks. In the year before DROBOT acquired PACIFIC HOSPITAL, only 162 spinal fusion surgeries were performed at that location. In the year after DROBOT acquired PACIFIC HOSPITAL, that figure increased almost threefold, to 477 spinal fusion surgeries. Between 2001 and 2010, no fewer than 5,138 spinal fusion surgeries were performed on workers' compensation patients at PACIFIC HOSPITAL. For those surgeries, PACIFIC HOSPITAL billed approximately $533 million - three times as much as any other hospital in California for the same period of time, including significantly larger hospitals and major medical centers.

62. TRI-CITY paralleled this growth. In 2007, TRI-CITY had only $3 million in revenue from spinal fusion surgeries performed. As a result of its active participation in the unlawful scheme described herein, however, that figure had risen to $65 million by 2010.

63. By approximately 2005 and largely due to Labor Code section 5318, the Hospital Defendants had increased spinal fusion surgery profits by inflating bills and luring surgeries through kickbacks. In an effort to increase profits and/or financial gains even more, the conspiracy turned to even more illegal and egregious actions – namely counterfeiting medical devices.

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E. Counterfeit Hardware Devices Become A By-Product Of The Kickback And Overbilling Scheme

64. At all times herein relevant, Defendants, and each of them, knew that all implantable spinal fixation devices used in spinal fusion surgeries required the approval of the FDA to assure their safety and effectiveness. Furthermore, they knew that the act of placing an object of unknown origin or provenance in the body of a patient exposed the patient to an unreasonable risk of harm and is inappropriate, unsafe, unethical, illegal, and below standard practice. Each Defendant had an obligation, responsibility, and/or duty to exercise due diligence in determining the origin and provenance of each implantable device which was to be placed into a patient's body and that such device had FDA approval. At all times herein relevant the Defendants, and each of them, knew that the health, safety and well-being of the patient were paramount to any other interest.

65. In furtherance of the conspiracy to defraud insurance carriers and to further increase profits from spinal fusion surgeries requiring implantable spinal fixation devices, Defendants manufactured, distributed, sold, purchased, and/or implanted counterfeit, non-FDA approved, "knock-off" spinal fixation implant devices, including, but not limited to pedicle screws, rods and cages.

66. From approximately 2005 and continuing until at least mid-2011, the Manufacturer Defendants knowingly manufactured and mass-produced for commercial distribution false, fraudulent, fake, counterfeit, and non-FDA approved "knock-off" medical devices at the request, direction, and control of SS, OA, WILLIAMS, MSW, and FIELDS. In manufacturing such devices, no controls were put in place by the Manufacturer Defendants to ensure that such devices were safe and effective for implantation into human patients, such as Plaintiff. The devices and packaging produced by the Manufacturer Defendants were "designed" and intended to give the appearance of being authentic, FDA-approved spinal fixation devices from FDA qualified manufacturers of medical devices.

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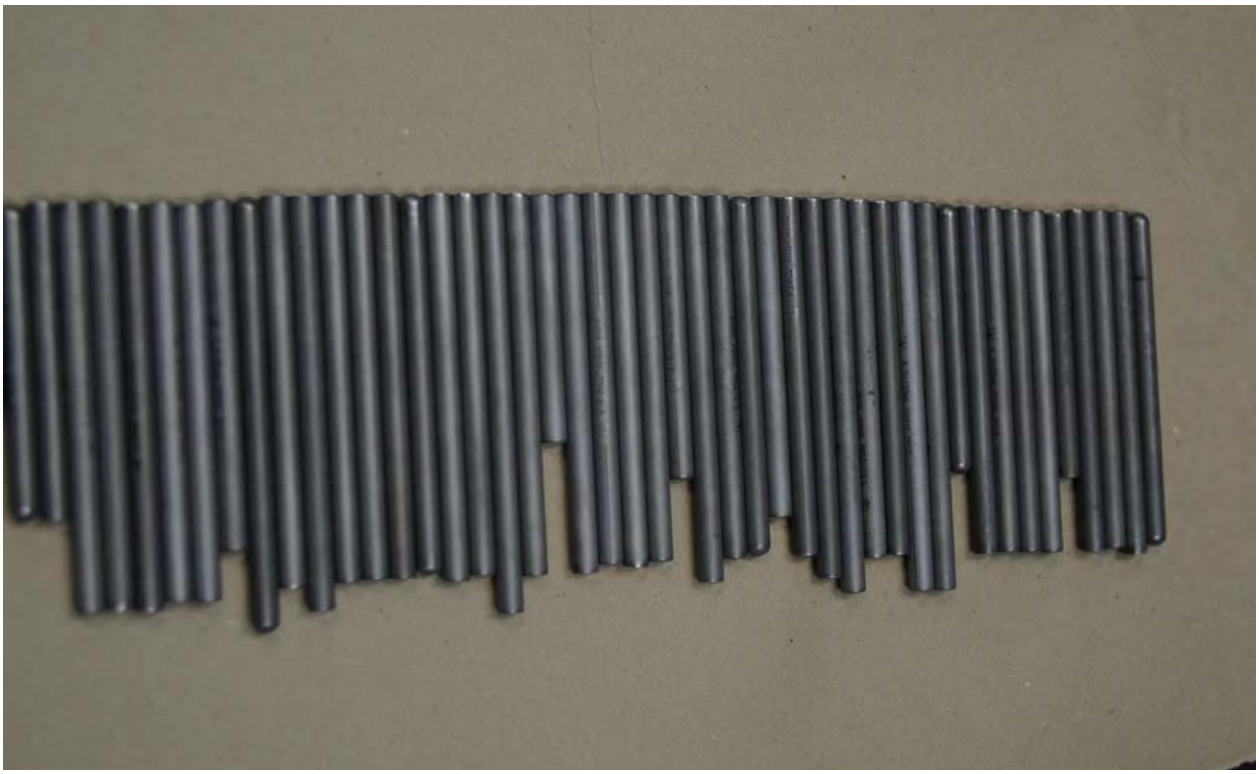
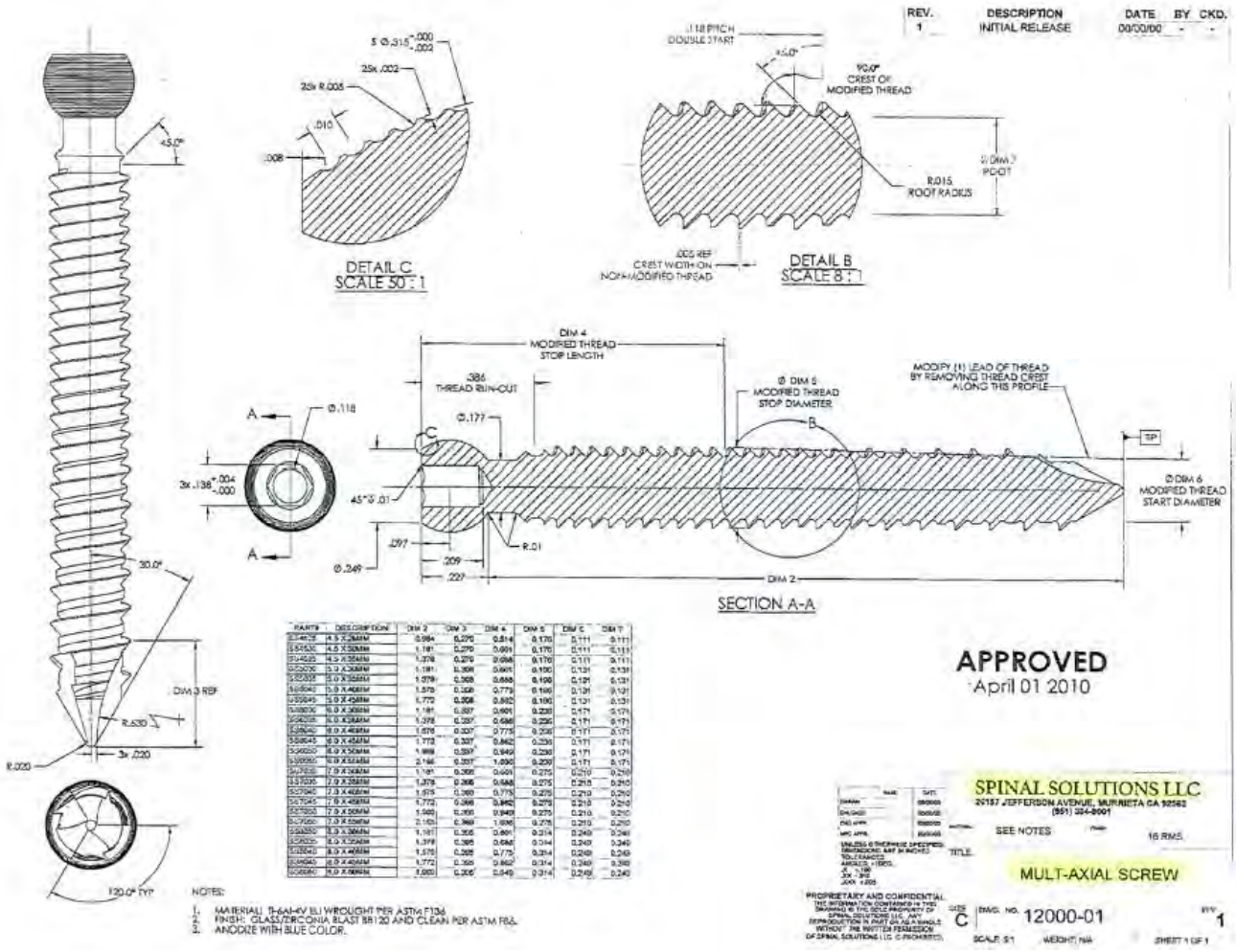


67. CROWDER, at the direction, request, and control of WILLIAMS, MSW, FIELDS, SS, and OA, attempted to copy and/or counterfeit authentic FDA-approved product, including but not limited to those manufactured by U&I Corporation and by Ortho Sol Development (Pty) Ltd. Attached hereto as **Exhibit 5**, and incorporated herein, are true and correct copies of drawings for a "Multi-Axial Screw" and a "Rod Holder, Pedicle Screw System" prepared at the direction of WILLIAMS to imitate Ortho Sol's "Blue & Gold" product line.



68. Representatives from U&I Corporation and Ortho Sol Development (Pty) Ltd. have confirmed that samples of the product and packaging of supposed implantable spinal fixation products bearing their logo and trade name supplied by the Distributor Defendants are not genuine or authentic but are in fact counterfeit "knock-offs." A true and correct copy of an email from

President and CEO Richard Walker of Ortho Sol Development (Pty) Ltd. is attached as **Exhibit 6**, and is incorporated herein.

From: Richard Walker <rwalker@ortho-sol.com>
To: [redacted]
Cc: 'Lyn Millard' <lmillard@ortho-sol.com>
Sent: Thu Mar 29 03:31:56 2012
Subject: RE: Spinal Solutions LLC

With regards to the fraud aspect I am of the opinion that the most effective way to prove this would be to analyse his marketing method, which by all accounts is very simple. In a nutshell what he is doing is firstly introducing the genuine registered article (Our Product) for a period on which he defaults on payment and when this source dries up he substitutes the product with counterfeits and cheap inferior Asian products under the genuine product FDA registration. This is not only fraud but a criminal offence to say the least. This is easy to prove by issuing a subpoena for his shipping receipt documents of other imported products and verifying under what FDA registration the goods were cleared by customs. Should any of those products have been cleared under the Blue and Gold registration other than sourced from our company in South Africa he has committed fraud in the first instance.

In addition to the above I am aware of other products sourced by Roger under false "description declaration" from Europe which require FDA registration, which have been distributed by him in the US and implanted into patients.

You are dealing with an extremely unethical " bad egg" who is in collusion with so called "professionals" of a similar nature that needs to be routed out and exposed for what they are.

We have similar unethical and unprofessional characters of this kind in our country who, over a period of time we have learnt to identify. Nevertheless this a brief overview and any assistance/information that I can provide in detail as evidence to your investigation will be provided on request..

Best Regards

Richard Walker

69. The Manufacturer Defendants sold such devices to the Distributor Defendants at a fraction of the cost of genuine product. Attached hereto as **Exhibit 7** and incorporated herein are two exemplar invoices from CROWDER MTS.

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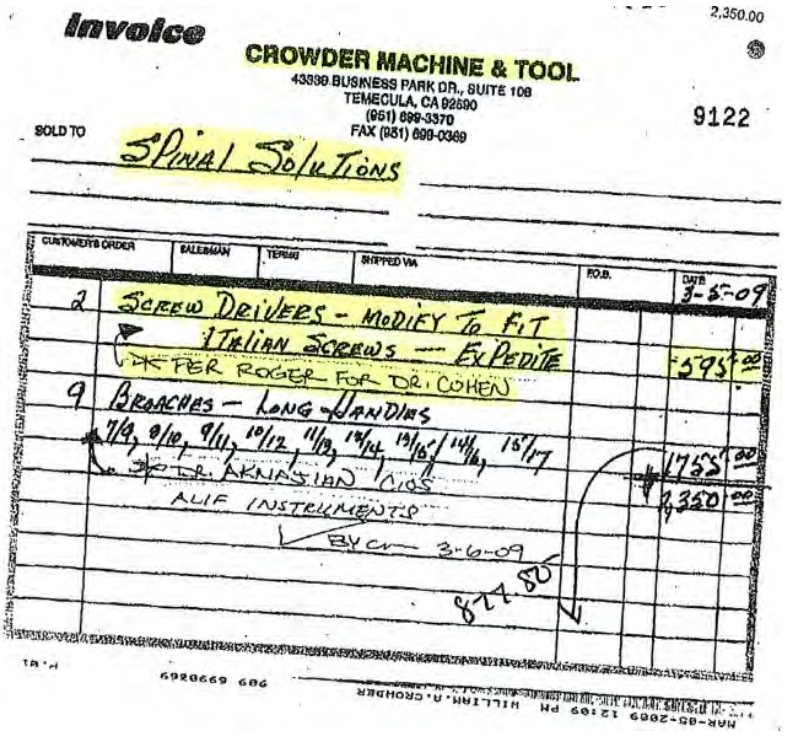

Invoice

CROWDER MACHINE & TOOL
43330 BUSINESS PARK DR., SUITE 108
TEMECULA, CA 92590
(951) 699-3370
FAX (951) 699-0369

2,350.00

9122

SOLD TO SPINAL SOLUTIONS

CUSTOMER'S ORDER	SALESMAN	TERMS	SHIPPED VIA	F.O.B.	DATE
					3-5-09

2 SCREW DRIVERS - MODIFY TO FIT ITALIAN SCREWS — EXPEDITE — 595.00
PK PER ROGER FOR DR. COHEN
9 BROACHES - LONG HANDLES — 1755.00
7/9, 9/10, 9/11, 10/12, 11/13, 13/14, 13/15, 14/16, 15/17
DR. AKNASIAN CIOS — 2,350.00
ALIF INSTRUMENTS
BY CK — 3-6-09
877.50

6926669 686

MAR-05-2009 12:09 PM HILLIAM.A.CROWDER

70. The Distributor Defendants, including SS, OA, WILLIAMS, and MSW, engaged in such counterfeiting activity in furtherance of the conspiracy, including paying the Marketer Defendants to "market" the counterfeit, non-FDA approved implantable hardware to the Doctor Defendants, and to the Hospital Defendants, through the use of financial incentives, such as kickbacks. As the hardware passed from the Manufacturer Defendants to the Distributor Defendants to the Hospital Defendants the cost of the counterfeit hardware rose exponentially.

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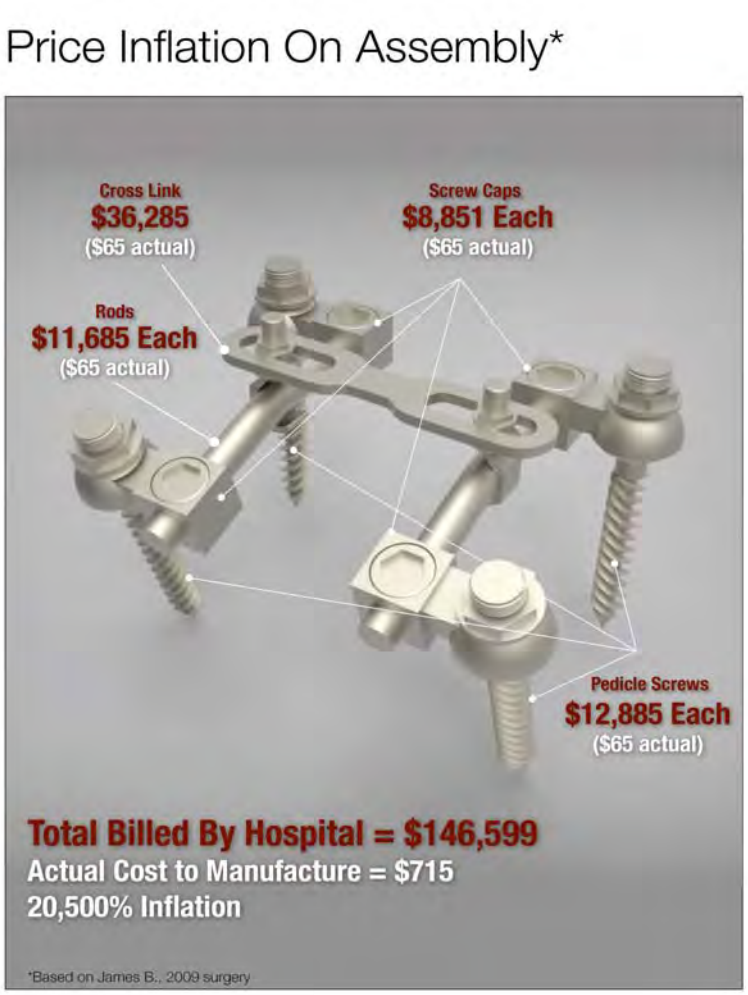


71. The false, fraudulent, fake, counterfeit, and non-FDA approved, "knock-off" medical devices were manufactured, distributed, sold, purchased, and ultimately implanted into thousands of patients, including Plaintiff, by Defendants, and each of them, in furtherance of the conspiracy, and in a conscious disregard for the health, safety and well-being of the patients. At all times relevant, Defendants, and each of them, knowingly participated in the scheme to defraud insurance carriers and engaged in this egregious, oppressive, malicious, and fraudulent conduct for their own financial gain by betraying the inherent trust of an exploitable patient population.

72. At all times herein relevant, the Defendant Hospitals knowingly and willingly entered into agreements with the Distributor Defendants, Marketer Defendants, and/or Doctor Defendants for the purchase of counterfeit, non-FDA approved implantable spinal fixation hardware. The Hospital Defendants readily accepted the surgical hardware, without any due diligence into the origin or provenance of the devices. In light of the conspiracy to defraud

insurers, the Hospital Defendants knowingly and willingly turned a "blind-eye" to any product that was received from the Distributor Defendants. The Hospital Defendants accepted the counterfeit, non-FDA approved "knock-off" spinal implants with the sole intent to fraudulently inflate the cost so that false billing statements could be prepared and submitted to insurers. At all times herein relevant, the safety and effectiveness of the material supplied by the Distributor Defendants was of no concern to the Hospital Defendants. Defendants acted with a conscious disregard for the health, safety and well-being of patients.

73. At all times herein relevant, Doctor Defendants and Hospital Defendants were responsible for the selection of medical devices to be used in connection with spinal fusion surgeries performed by Doctor Defendants at Hospital Defendants, including implantable spinal fixation hardware, such as screws, rods, cages, screw caps and connectors. In selecting implantable hardware or devices to be used in connection with spinal fusion surgeries, Doctor Defendants and Hospital Defendants were required by law to exercise due diligence in determining the origin or provenance of the medical devices to be implanted in patients and were, at all times, fully aware that their decision to use specific implantable hardware was required to be based on the best medical interests of the patient and that the decision was to be made free from the influence of improper inducements, such as rebates, refunds, commissions, preferences, patronage dividends, discounts, or other consideration.

74. At all times herein relevant, the Hospital Defendants knew, or should have known through reasonable inspection and due diligence, that the implantable spinal fixation devices designated by the Doctor Defendants and distributed through the Distributor Defendants were counterfeit, non-FDA approved "knock-offs." Yet the Hospital Defendants allowed the Doctor Defendants to use such implantable hardware in spinal fusion surgeries so that they would be able to submit false and fraudulent billings to insurers and other payers, in accordance with the conspiracy.

75. At all times relevant, Hospital Defendants either willfully ignored their duties and responsibilities, or conducted cursory due diligence in a reckless manner to facilitate the fraudulent overbilling scheme. On information and belief, the counterfeit implantable spinal fixation devices

passed through the materials department of Hospital Defendants with little or no inspection, review, inquiry or investigation into the objects' origin or provenance. In addition, hospital management personnel at PACIFIC HOSPITAL and TRI-CITY, on the recommendation of AKMAKJIAN, specifically advised the materials departments to not conduct due diligence regarding FDA approval of any implantable spinal fixation devices entering the hospital.

76. The Hospital Defendants did not keep records of the implantable spinal fixation products, including the status of 510(k) filings, the manufacturer, and the lot numbers as required by state and federal law. Instead, the obligation of keeping track of the materials was delegated to "technicians" supplied by the Distributor Defendants, such as TYSON, who willfully and fraudulently failed to record any significant information in implant logs during the surgery or willfully created false medical records by recording inaccurate or "made-up" lot numbers.

77. Because the implants were selected by spinal surgeons who could increase revenues to hospitals through the performance of more spinal fusion surgeries, the material that the spinal surgeons specified was accepted without question or inquiry. As a consequence, potentially thousands of spinal fusion patients in Southern California had foreign objects implanted into their spines by spinal surgeons/co-conspirators at the Defendant Hospitals under the guise of such objects being FDA-approved spinal fixation devices.

78. Notwithstanding obligations and duties to conduct due diligence into the origin or provenance of implantable spinal fixation hardware, and to keep records of the same, as well as their knowledge that such duties are required for the health, safety and well-being of patients, Doctor Defendants performed numerous spinal fusion surgeries at Hospital Defendants using spinal fixation devices distributed by SS, OA, and C.I.O.S. that were false, fraudulent, fake, counterfeit, non-FDA approved "knock-offs."

79. At all times herein relevant, the Hospital Defendants knowingly failed to conduct a reasonable inspection and/or their due diligence in connection with the implantable spinal fixation devices supplied by SS, OA, and/or C.I.O.S. The Hospital Defendants acquiesced in the use of the counterfeit, non-FDA approved "knock-off" hardware specified by the Doctor Defendants to keep the lucrative spinal fusion surgeries at the Hospital Defendants' facilities and to facilitate the

submission of grossly inflated bills for the implantable hardware as part of the scheme and in furtherance of the conspiracy.

80. Furthermore, the Hospital Defendants, based on the number of spinal fusion surgeries performed by the Doctor Defendants, knew or should have known that the surgical trays containing implantable spinal fixation devices supplied by SS, C.I.O.S., OA, McGRATH, and WILLIAMS contained bogus, non-FDA approved material, yet willingly accepted the material knowing that it would be implanted into the body of patients, all with a conscious disregard of the rights, health, safety and well-being of patients, including Plaintiff. At all times herein relevant, the Hospital Defendants, and each of them, were reckless in their review and inspection of material provided by the Distributor Defendants and/or turned a blind-eye to their duties and responsibilities of inquiring, knowing that they would make more money by having the Defendant Doctors perform surgeries at their facility. Defendants, and each of them, chose profit over sound medical decision-making.

81. The conspiracy to defraud insurance companies resulted in health insurers, workers' compensation carriers, other payers, including government entities, Medi-Cal and Medicare being bilked out of hundreds of millions of dollars. It directly led to patients being implanted with non-FDA approved medical devices that do not meet performance or safety standards and that can cause harm to patients' health due to implant failure, loosening, lack of sterilization and/or biocompatibility. Caught in the incestuous web of profiteering by these Defendant conspirators, were unsuspecting individuals, including Plaintiff, who, on information and belief, had foreign objects surgically placed in her spine.

F. <u>The FDA's Surprise Inspection of SS and OA in 2011 Caused WILLIAMS, MSW, FIELDS and Others to Engage in Spoliation of Evidence</u>

82. Between July 20, 2011 and September 23, 2011, the FDA inspected both SS and OA as "manufacturers" per FDA regulations for preparing surgery trays which contained components of spinal fixations systems. On information and belief, the FDA was unaware of the counterfeiting or any other manufacturing activities of Defendants when it initiated its inspection of the offices and warehouse of SS and OA.

83. In response to the inspection, SS, OA, WILLIAMS, MSW, FIELDS and others concealed all such activity and all records relating to such activity from the FDA. Subsequent to the commencement of the FDA inspections, SS, OA, WILLIAMS, MSW, FIELDS and others began to destroy and/or hide evidence relating to the origin or provenance of any and all spinal fixation components that were manufactured and/or distributed by SS and OA in an effort to prevent the FDA from learning that such Defendants were manufacturing counterfeit, non-FDA approved "knock-off" medical devices and to prevent the FDA, insurers, patients, and the public from learning that they had manufactured, distributed, sold, and/or implanted counterfeit surgical hardware despite the risk to the health, safety, and well-being of patients.

84. In addition, WILLIAMS and FIELDS lied to and/or intentionally misled the FDA in sworn affidavits, all in furtherance of the conspiracy, by stating that SS and OA did not design or manufacture "Spinal Fixation Systems or components including, screws, rods, caps, or vertebral body replacements." At the time they made such statements, WILLIAMS and FIELDS knew that the statements were untrue, given that WILLIAMS, SS, OA, MSW, FIELDS, CROWDER, CROWDER MTS and others had been involved in the design, manufacture, distribution and sale the false and fraudulent spinal fixation components for approximately four years at that point. Attached hereto as **Exhibit 8**, and incorporated herein, are true and correct copies of the sworn affidavits, executed by WILLIAMS and FIELDS.

85. Upon completion of the investigation, the FDA sent its observations to SS and OA. With respect to SS, the FDA made sixteen observations ranging from failing to prepare or maintain device history records to failing to prepare and maintain distribution records, including identifying the consignee, identification of the quantity of items shipped, the date shipped, and the control numbers for the Spinal Fixation Systems kits and components. True and correct copies of the observations are attached as **Exhibit 9**, and are incorporated herein.

86. In response to the observations of the inspectors, Arnold Neves, Jr., General Counsel for SS and OA, wrote to the FDA agreeing with all of the observations made and deficiencies noted and promised that they would be corrected. A true and correct copy of Mr. Neves' September 29, 2011 correspondence is attached as **Exhibit 10** and incorporated herein.

87. Based on the investigation, the FDA issued two warning letters to SS and OA, indicating that it had determined that SS was a manufacturer because it was a "repacker/kit assembler of spinal implant systems, and an own-label distributor of spinal implant instruments." A true and correct copy of the January 19, 2012 and February 3, 2012 letters are attached as **Exhibit 11** and **Exhibit 12**, respectively, and incorporated herein. In the warning letters, the FDA noted no fewer than fourteen (14) violations of Title 21, Code of Federal Regulations (CFR) Part 820. At the conclusion of the January 19, 2012 letter, the FDA stated, "Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties."

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE

January 19, 2012

W/L 15-12

Roger Williams
President
Spinal Solutions, LLC
26157 Jefferson Ave.
Murrieta, California 92562

Dear Mr. Williams:

During an inspection of your firm located in Murrieta, California, on July 11, 2011, through September 15, 2011, investigators from the United States Food and Drug Administration (FDA) determined that your firm is a manufacturer because you are a repacker/kit assembler of spinal implant systems, and an own-label distributor of spinal implant instruments. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR) Part 820. We received a response from Arnold Neves, Jr., Esq., General Counsel, dated September 29, 2011, concerning our investigators' observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to your firm.

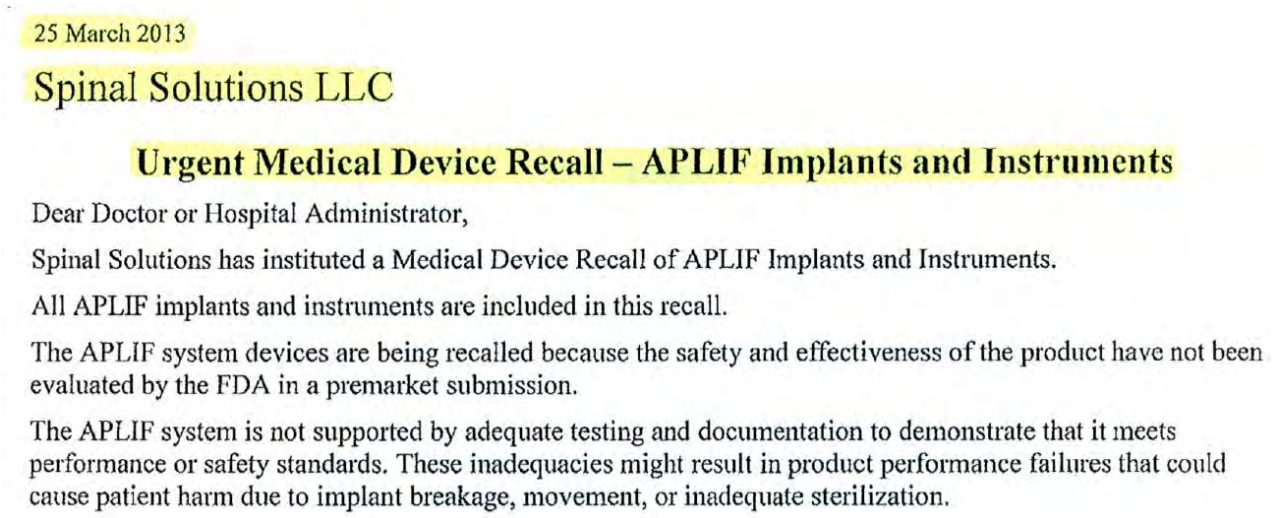
88. On information and belief, WILLIAMS, MSW, and FIELDS did nothing to take corrective action vis-à-vis the observations and continued to manufacture and distribute to hospitals counterfeit, non-FDA approved "knock-off" implantable spinal fixation devices.

89. After receiving the Warning Letter from the FDA, SS, OA and WILLIAMS hired outside medical device and regulatory consultants to respond to the FDA warning letters to SS and OA and to prepare a "Corrective and Prevention Action to Address 483's and Warning Letter." The consultants inspected the facilities maintained by WILLIAMS, MSW and FIELDS and found them to be in disarray, with product unmarked and stored in random locations in the warehouse and in various offices. **The consultants found no records showing product coming into SS from outside suppliers, vendors and manufacturers. They found nothing to suggest that SS was preparing or maintaining records related to manufacturers' lot numbers on spinal fixation products. They observed screws in bulk in plastic bags. They observed "consulting agreements" with medical doctors haphazardly stored in boxes and other random locations.**

90. WILLIAMS and FIELDS intentionally misled and deceived the consultants into believing that implantable spinal fixation devices were being manufactured by CROWDER at CROWDER MTS under an agreement with Ortho Sol Development (Pty) Ltd. Believing in good faith the misrepresentations made by WILLIAMS and FIELDS, the consultants inspected CROWDER MTS with CROWDER present in 2012. At that time CROWDER admitted that he was producing the surgical implant hardware and various tools used in implanting or explanting such product. CROWDER informed the consultants that he did not calibrate his manufacturing equipment to ensure that it met FDA guidelines. The consultants noted that the equipment used to produce the product was antiquated and that the quality of the work was not in conformity with FDA standards, such as screws with varying thread size.

91. Based on the inspection, **the consultants immediately told WILLIAMS that any and all product and tools produced by CROWDER must be quarantined and any product sold or distributed that originated from CROWDER MTS must be recalled, since none of the product met FDA standards and the product represented a safety hazard to patients.** The consultants created recall notices recalling the hardware for failing to meet performance, safety,

testing, and documentation standards. Attached as **Exhibit 13** and incorporated herein are two recall notices prepared by the consultants.



25 March 2013

Spinal Solutions LLC

Urgent Medical Device Recall – APLIF Implants and Instruments

Dear Doctor or Hospital Administrator,

Spinal Solutions has instituted a Medical Device Recall of APLIF Implants and Instruments.

All APLIF implants and instruments are included in this recall.

The APLIF system devices are being recalled because the safety and effectiveness of the product have not been evaluated by the FDA in a premarket submission.

The APLIF system is not supported by adequate testing and documentation to demonstrate that it meets performance or safety standards. These inadequacies might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization.

92. **Despite the consultants' warning that all products emanating from CROWDER and/or CROWDER MTS must be quarantined and recalled based on patient safety, Defendants did nothing, all in furtherance of the conspiracy.**

G. A Cover Up Was Absolutely Necessary to the Continued Success of the Scheme

93. To achieve the goal of the fraudulent scheme it was necessary that the Defendant co-conspirators actively conceal it from patients, insurers, other payers, and the FDA. The fraudulent scheme included agreement by and among the co-Defendants/co-conspirators, and each of them, to disguise the true identity, source, origin, provenance, actual cost and/or manufacturer/producer of implantable hardware used in the spinal fusion surgeries, because Defendants, and each of them, knew there was a lack of documentation or other supporting evidence to establish that the implantable hardware used in thousands of spinal surgeries, including Plaintiff's surgery, was FDA approved or safe for use in spinal fusion surgeries.

94. When the FDA first arrived to inspect SS on the basis that it was the manufacturer of trays for spinal fusion surgeries, **WILLIAMS, in conjunction with MSW and FIELDS, willfully and intentionally destroyed and/or hid records and documents related to the production, manufacture, distribution and sale of the implantable spinal hardware.** WILLIAMS, MSW and FIELDS willfully and intentionally engaged in multiple acts of spoliation

of evidence, acting to conceal the fact that much of the inventory of items used in connection with spinal fusion surgeries was counterfeit, bogus or a non-FDA approved "knock-off." WILLIAMS, MSW and FIELDS engaged in such spoliation to preclude the FDA from learning that CROWDER, at CROWDER MTS was producing the counterfeit product and that thousands of bills had been generated for payment reflecting the cost of original, genuine equipment, not fake product. In doing so, WILLIAMS, MSW and FIELDS acted in their own financial interest with a conscious disregard of the right of patients such as CAVALIERI.

95. Because of the intentional spoliation of evidence and failure to document required information such as product lot numbers, quantity, and destination, the origin and provenance of all products manufactured, distributed and sold by SS and OA cannot be determined. At the time Defendants began to engage in spoliation of evidence in reaction to the FDA inspection, Defendants knew that discovery of the conspiracy, including discovery of the manufacture of counterfeit, non-FDA approved "knock-off" hardware, would cause the immediate cessation of the conspiracy and criminal and civil legal battles. At the time of the destruction of evidence, Defendants were in exclusive control of the documents.

H. Revelations Of The Depth Of The Scheme From The Drobot Indictment

96. The scope and depth of the scheme was publicly exposed on February 21, 2014, when DROBOT, the owner and operator of PACIFIC HOSPITAL, entered into a Plea Agreement regarding his participation and orchestration of a conspiratorial scheme to defraud patients of his or her right to the delivery of honest medical services. A true and correct copy of the Information and Plea Agreement are attached as **Exhibit 14** and **Exhibit 15**, respectively, and incorporated herein.

97. Pursuant to the Plea Agreement, on or about April 24, 2014, DROBOT pled guilty in the United States District Court, Central District of California, before the Hon. Josephine L. Staton, U.S. District Judge, to paying kickbacks to doctors, chiropractors, marketers and others for their referring workers' compensation patients to PACIFIC HOSPITAL for spine surgeries, other types of surgeries, magnetic resonance imaging, toxicology, durable medical equipment and other services. DROBOT presently faces five years in federal prison when he appears for his December 2014 sentencing.

98. In pleading guilty, DROBOT admitted that between 1998 through November 2013, he recruited, as members of a conspiracy, doctors, chiropractors, and marketers, who received kickback payments as a means to induce them to perform surgeries at hospitals owned and/or controlled by DROBOT. DROBOT admitted to paying $15,000 per lumbar fusion surgery and $10,000 per cervical fusion surgery. Additionally, DROBOT utilized medical hardware for surgeries at PACIFIC HOSPITAL supplied by distributors with ties to DROBOT. He also admitted to using II to purchase medical hardware and inflating the price for so that PACIFIC HOSPITAL could submit false claims to payers, including insurance carriers, for payment. DROBOT conceded that the purpose of the conspiracy—utilizing kickbacks—was to artificially increase the cost of the medical hardware as part of the resulting combined charge for spinal surgery and related medical services, delivered by the physician and hospital to the patient.

99. The scheme was so wide in its reach that it included DROBOT paying a stream of financial benefits to a California State Legislator in order to recruit his assistance in defeating legislation that would have eliminated a loophole in the law that threatened the continued existence of the scheme. To grease his way, DROBOT, as well as Defendants, and DOES 1 through 200, donated approximately $1.9 million to political campaigns since 2000 and bribed other politicians to influence legislation that supported their fraudulent scheme.

100. California State Senator Ronald Calderon and his brother, Tom Calderon, accepted kickbacks through phony contracts, extravagant trips, and expensive meals to write, support, and/or reject legislation in furtherance of Defendants' conspiracy. The Calderon brothers also pushed other legislators to introduce and support legislation that was favorable to DROBOT and Defendants' scheme.

101. In 2001, then California State Assembly member Tom Calderon carried a bill that extended a favorable fee schedule for spinal surgeries that was due to expire at the end of 2001. In 2002, Tom Calderon wrote and passed a workers' compensation overhaul bill that, buried within its 39,000 page, made it nearly impossible to cap spinal fusions surgeries prices. When Tom Calderon lost his seat, he continued to influence legislation in favor of Defendants by becoming a consultant to PACIFIC HOSPITAL.

102. As a result of bribes and kickbacks, the Calderon brothers also attempted to block a 2012 bill that would have changed the state workers' compensation and drastically cut Defendants' profits. First introduced as Senate Bill 959, the bill would have eliminated the provisions that allowed hospitals to charge extra for implanting hardware during spinal surgery on workers' compensation patients – undercutting Defendants' tactic of inflating medical bills. The bill was incorporated into Senate Bill 863, which altered the workers' compensation system. Senator Ronald Calderon was one of the nine lawmakers who voted against the bill despite overwhelming support from the other 111 California State Assembly and Senate members.

103. As a result of the donations, bribes, and/or kickbacks, Senator Calderon was indicted on twenty-four criminal charges while Thomas Calderon was charged with eight counts in February 2014. A true and correct copy of Senator Calderon's Indictment is attached as **Exhibit 16** and incorporated herein.

104. The fraudulent scheme to which DROBOT confessed was not limited to the doctors, hospitals and/or suppliers of medical services and medical hardware at PACIFIC HOSPITAL. Nor was the profiteering among the conspirators limited to payments of kickbacks and manipulation of grossly inflated patient billing for surgeries and related hardware. As alleged herein, the scheme at its worst and most despicable extreme involved the counterfeit manufacture and distribution of non-FDA approved medical hardware, including rods, screws and/or cages implanted in patients during spinal surgeries without their knowledge or consent.

I. Defendant Doctors Have Falsified Medical Records as Part of The Conspiracy

105. In addition to making entries in medical records that were and are false and fraudulent, i.e. that FDA-approved implantable spinal hardware was used in connection with spinal fusion surgeries, either expressly or impliedly, Defendant Doctors have made entries into records suggesting that the nature and type of implantable spinal fixation devices was fully discussed with patients prior to surgery. UPPAL clearly knew that the implants that were being placed into the bodies of his patients were not FDA approved. **Shortly after articles appeared in the Wall Street Journal concerning spinal fusion surgeries in Southern California and the payment of kickbacks, UPPAL began to indicate in operative reports and hospital records that he**

advised the patient that the implants that would be used were not FDA approved or "experimental" and may require extraction as a means of trying to insulate himself from liability with respect to the conspiracy and the implantation of counterfeit, non-FDA approved "knock-off" spinal fixation devices. True and correct copies of the February 9, 2012 Wall Street Journal article and the September 21, 2012 operative report prepared by UPPAL are attached as **Exhibit 17** and **Exhibit 18**, respectively, and are incorporated herein.

DATE OF SURGERY 09-21-2012

PREOPERATIVE DIAGNOSIS Stenosis and spondylosis L4-5 and L5-S1.

POSTOPERATIVE DIAGNOSIS Stenosis and spondylosis L4-5 and L5-S1.

NAME OF SURGERY
1. Posterior segment internal fixation L4-5 and L5-S1.
2. Posterior comprehensive decompression L4-5.
3. Posterior comprehensive decompression L5-S1.
4. Posterolateral fusion L4-5.
5. Posterolateral fusion L5-S1.
6. Allograft and autograft use for lumbar spine fusion.
7. Fluoroscopic use.

SURGEON Gurvinder S. Uppal, MD

ASSISTANT SURGEON Todd Peters, MD

ANESTHESIA General.

ANESTHESIOLOGIST

ESTIMATED BLOOD LOSS 200 cc.

FLUIDS Normal saline.

DRAIN Hemovac.

INDICATIONS The patient is a male who is having severe back and leg pain. His radiographs and MRI show stenosis and spondylosis at L4-5 and L5-S1. He has positive straight leg raising. He has psoriatic arthritis. He has weakness in the ankle, dorsi and plantar flexors. He has undergone internal medicine clearance at this point. I have discussed option of no treatment, more nonoperative treatment, and surgery. Surgery is an anterior and posterior decompression and fusion at L4-5 and L5-S1 with instrumentation and bone graft. I have explained the potential risks of the surgery including death, infection, bleeding, paralysis, dural leak, nonunion, malunion, hardware failure, sexual dysfunction, and impotence among others. Risks of the bone graft were also discussed. I have also told him that the hardware to be used is not FDA approved and may need to be removed in the future. The patient understands this and consented for surgery described above.

106. AKMAKJIAN maintains such poor medical records that he is the subject of a pending accusation by the Medical Board of the State of California, a true and correct copy of which is attached as **Exhibit 19** and incorporated herein. **In his operative reports and other**

records prepared in connection with spinal fusion surgeries, he regularly represents that he has discussed the implants to be used in the spinal fusion surgery as well as their FDA status, both of which are untrue.

J. Cavalieri Becomes Collateral Damage to Defendants' Fraudulent Scheme

82. Unbeknownst to CAVALIERI, AHMED was a willing and longstanding participant in the fraudulent scheme carried out by Defendants predicated in the submission of fraudulent bills to payers, including insurance carriers, for the cost of implantable hardware. Similarly, CAVALIERI was unaware that AHMED regularly specified the use of certain specific implantable hardware at PACIFIC HOSPITAL and other hospitals based on the payment of kickbacks to him from the manufacturer, distributor, and/or marketer of such hardware; supplemented by kickbacks paid by or on behalf of hospitals, including, on information and belief, PACIFIC HOSPITAL for AHMED to conduct surgeries at PACIFIC HOSPITAL.

83. On information and belief, PACIFIC HOSPITAL and/or DROBOT, or a person or "marketer" acting on behalf of PACIFIC HOSPITAL, paid AHMED a rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, to perform surgeries at PACIFIC HOSPITAL as part of the larger scheme to defraud insurance companies. AHMED, at all times herein relevant, was knowingly designating and prescribing counterfeit, non-FDA hardware in spinal fusion surgeries through the use of SS, OA and C.I.O.S. DROBOT, II and PACIFIC HOSPITAL were also knowing purchasers and distributors of the counterfeit, non-FDA approved "knock-off" implantable spinal fixation devices supplied by WILLIAMS, SS and OA.

84. AHMED and PACIFIC HOSPITAL were exclusively responsible for the selection of medical devices to be used in connection with CAVALIERI's surgeries, including implantable spinal fixation hardware, such as screws, rods, cages, screw caps and connectors. In selecting the implantable hardware to be used in connection with CAVALIERI's surgeries, AHMED and PACIFIC HOSPITAL were fully aware that their decision to use specific implantable hardware was required to be based on the best medical interests of the patient, and that the decision was to be made free from the influence of improper inducements, such as rebates, refunds, commissions,

preferences, patronage dividends, discounts, or other consideration offered and/or paid by the manufacturer, distributor and/or other vendor of the implantable hardware. In short, Defendants, and each of them, knew that the selection of implantable hardware to be placed into the body of CAVALIERI could not, by law, be influenced, in any respect, by the payment of disguised kickbacks or the prospect of filing a fraudulent insurance claim against CAVALIERI's workers' compensation carrier.

85. As a result of AHMED's unlawful receipt of kickbacks from Defendants, in return for his undivided patronage to his co-Defendants, AHMED knowingly and/or with reckless disregard for the provenance or origin of the implantable spinal fusion hardware, implanted non-FDA approved medical hardware in patients such as CAVALIERI. In short, AHMED used the counterfeit, non-FDA approved spinal fixation hardware that was implanted into CAVALIERI's spine because he was being paid a kickback or kickbacks for doing so.

86. At all times herein relevant, like the other hospitals involved in the conspiracy, DROBOT and PACIFIC HOSPTIAL perceived spinal fusion surgeries as a source of revenue due to the unconscionable, fraudulent and illegal mark-up on spinal implants. As a consequence, DROBOT and PACIFIC HOSPITAL abandoned all responsibility to Plaintiff, to ensure that the material being placed into her body at PACIFIC HOSPITAL was safe, effective, properly manufactured and FDA-approved. On information and belief, in accordance with the conspiracy, it conducted little or no due diligence into the origin or provenance of the objects that were ultimately surgically placed into CAVALIERI's body by AHMED. Instead, in order to continue a revenue stream from spinal fusion surgeries, DROBOT, PACIFIC HOSPITAL, II, and AHMED designated and used undocumented and counterfeit objects for use in surgeries, including Plaintiff's surgeries.

87. As a direct consequence of the conduct of Defendants, and each of them, CAVALIERI sustained injury, including having foreign objects implanted into her spine without her knowledge and consent.

88. In furtherance of the scheme, Defendants, and each of them, have to this day knowingly conspired to conceal from CAVALIERI the true identity, source, origin, provenance and/or manufacturer of the foreign objects that were implanted into her spine during the course of

the ALIF and PLIF procedures performed by AHMED at PACIFIC HOSPITAL. Defendants' concealment continues despite their superior knowledge and/or exclusive control of records and other information concerning the origin or provenance of the foreign objects, despite DROBOT's pledge of cooperation in his plea agreement, and with full knowledge their legal obligation to advise CAVALIERI, as a patient, that there was and is a substantial probability that foreign objects were surgically placed into her body during the course of the surgeries.

89. To Defendants, and each of them, CAVALIERI was simply another patient in whom implantable hardware could be placed, regardless of whether it was authentic, genuine, safe and effective, so that the goal of the conspiracy could be achieved, to defraud insurance companies and ensure a continued stream of unlawful profits for the participant co-conspirator Defendants. At all times herein relevant, Defendants, and each of them, acted with a conscious disregard of the rights, health, safety and well-being of CAVALIERI for the purpose of their own financial gain.

90. At all times herein relevant, CAVALIERI relied on AHMED, that he was placing his obligations as a physician and surgeon to patients, including CAVALIERI, paramount to any consideration of financial gain. CAVALIERI did not know, nor would have reason to know that in exchange for kickbacks, AHMED was a willing participant in the conspiracy described herein. As a consequence, she, like thousands of other patients, now suffers from having foreign objects in her spine, the origin or provenance of which cannot be identified and the safety and efficacy of which cannot be measured due to the extremely egregious conduct of the Defendants, and each of them. Moreover, given the use of the "360" spinal fusion procedures, the cages implanted into CAVALIERI's body cannot be removed without substantial risk of injury or death.

VI. CAUSES OF ACTION

FIRST CAUSE OF ACTION

(Against All Defendants)

(Battery)

91. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

92. Due to the conspiracy to defraud insurance carriers, as alleged herein, and the concerted wrongful acts of Defendants, and each of them, Plaintiff consented to what he believed was a spinal fusion surgery using FDA- approved implantable spinal hardware.

93. On or about June 26, 2010 and September 18, 2010, AHMED performed two spinal fusion surgeries on Plaintiff at PACIFIC HOSPITAL, using false, fraudulent, fake, counterfeit, non-FDA approved "knock-off", and defective spinal hardware, the origin or provenance of which cannot be established save and except that it came from SS, knowing that Plaintiff and any other patient in her position would object and would not consent to surgery using foreign objects under the guise of being non-FDA approved hardware. Plaintiff, at all times herein relevant, believed that AHMED was acting in her best interest, and in the interest of her health, safety and well-being and never consented to the implantation of anything other than FDA approved spinal fixation hardware. As herein alleged, AHMED implanted foreign objects into CAVALIERI's spine on the basis that he was being paid a kickback to use the foreign objects in lieu of FDA-approved spinal hardware.

94. Defendants, and each of them, acting individually and/or in concert as part of a greater conspiracy as hereinabove set forth, knew and/or acted with a wilful and conscious disregard of Plaintiff's rights with regard to the manufacture, supply, distribution, and/or implantation of surgical hardware as part of the surgery performed on Plaintiff.

95. As a means of furthering their own independent economic interest in the continuing flow of profits, kickbacks, and/or other financial rewards, Defendants, and each of them, acted with a conscious disregard for the source of manufacture and/or supply of medical hardware from their co-Defendants, with the knowledge that devices would be used in surgical procedures on patients. Due to conflicts of interest in receiving kickbacks from their co-defendant suppliers of medical hardware, co-defendant hospital and doctors willfully disregarded any inquiry into whether their co-defendant suppliers were approved by the FDA to distribute the medical hardware used in Plaintiff's surgery.

96. Defendants, individually and/or in concert, intentionally, unlawfully, harmfully, unreasonably, and/or offensively performed the spinal fusion surgery without obtaining Plaintiff's

informed consent that non-FDA approved medical devices were used in connection with her surgery and for the purposes of Defendants' financial gain.

97. As a result of the use non-FDA approved spinal implant hardware, Plaintiff was, and continues to be, harmed by the presence of foreign objects in her body, including cages that are now part of a spinal fusion. On information and belief, the counterfeit hardware which has a substantial likelihood of failure, places Plaintiff's life at risk, and may subject Plaintiff to further surgeries to replace the counterfeit hardware.

98. As a direct and legal cause of the acts and omissions of Defendants, and each of them, Plaintiff was hurt in her health, strength, and activity, and sustained bodily injuries, as described herein, which have cause, and continue to cause Plaintiff great physical and severe emotional pain, distress, and suffering, in an amount according to proof.

99. By reason of Defendants' wrongful conduct, Plaintiff was required to and continues to employ physicians and other health care providers to examine, treat and care for her injuries and/or to remove or replace the counterfeit, non-FDA spinal implant hardware. Plaintiff has incurred, and will continue to incur, medical and incidental expenses for such examination, treatment, rehabilitation and care in an amount according to proof.

100. By further reason of the incident, Plaintiff has suffered a loss of income and/or a loss of earning capacity in an amount according to proof.

101. In doing the wrongful and intentional acts as herein alleged, Defendants acted with oppression, fraud and malice and with conscious and willful disregard for the health, safety and general welfare and rights of Plaintiff. Such action was done with malice, oppression and/or fraud and was and is despicable, shocking and offensive and entitles the Plaintiff to an award of punitive damages against Defendants in an amount to be determined at trial.

SECOND CAUSE OF ACTION

(Against All Defendants)

(Fraud – Concealment)

102. Plaintiff incorporates herein by reference and rellages all of the allegations stated in this Complaint.

103. Defendants, and each of them, had fiduciary duties to and/or confidential relationships with Plaintiff in which Defendants had a duty to disclose material facts to Plaintiff relevant to her spinal fusion surgery, including that AHMED implanted foreign objects in her body, that the implanted hardware was counterfeit, non-FDA approved.

104. Only Defendants, and each of them, had knowledge and or access to knowledge of the true source and/or FDA status of the surgical hardware.

105. Blinded by their own independent economic interests, Defendants, and each of them, intentionally and/or in reckless disregard for the truth concealed, suppressed and/or failed to disclose material facts relevant to the spinal hardware with the intent to deceive and influence the actions of Plaintiff.

106. Defendants, and each of them, knew that patients would not and/or could not inspect the hardware to ensure that the hardware was safe and FDA approved. Defendants orally, in writing, and/or by implication led Plaintiff to believe that the medical devices met with FDA approval and/or were safe for spinal fusions.

107. Plaintiff reasonably relied on Defendants' deception in which Defendants concealed the manufacture and supply of counterfeit hardware which Defendants, and each of them, knew would be implanted in patients by co-Defendants. At the time Plaintiff acted in reliance on Defendants' misrepresentations, Plaintiff was unaware of the facts Defendants concealed, suppressed, and/or failed to disclose and would not have consented to surgery if he had known the true facts.

108. Due to Defendants' individual and/or concerted concealment of material information, Plaintiff consented to what she believed was a spinal fusion surgery using FDA approved implantable hardware.

109. As a direct and legal cause of Defendants' concealment, Plaintiff suffered, and continues to suffer, the injuries and damages hereinabove set forth.

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THIRD CAUSE OF ACTION

(Against All Defendants)

(Fraud – Intentional Misrepresentation)

110. Plaintiff incorporates herein by reference and rellages all of the allegations stated in this Complaint.

111. In furtherance of Defendants' individual economic interests, Defendants, and each of them, intentionally and/or in reckless disregard for the truth represented to Plaintiff orally, in writing, and/or by implication that the spinal fusion hardware met with FDA approval and was safe for spinal fusion surgery.

112. In order to maximize their flow of profits, kickbacks, and/or other financial rewards, Defendants, and each of them, represented the true source and/or FDA status of the hardware to Plaintiff with the intent to deceive and induce Plaintiff to consent to surgery.

113. As a direct and legal cause of Defendants' misrepresentations, Plaintiff suffered, and continues to suffer, the injuries and damages hereinabove set forth.

FOURTH CAUSE OF ACTION

(Against All Defendants)

(Breach of Fiduciary Duty)

114. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

115. Defendants, as medical device providers, practitioners, healthcare providers, and surgeons, owed a duty to exercise and possess the degree of skill and care in the prognosis and treatment of Plaintiff, including the performance of surgery and manufacture of medical devices, ordinarily exercised by the average qualified medical device provider, practitioner, healthcare provider, and/or surgeon.

116. In furtherance of Defendants' individual and/or concerted efforts to maximize profits, kickbacks, and/or other financial rewards, Defendants breached and/or encouraged, aided, and/or assisted in breaching the fiduciary duty owed to Plaintiff by failing to advise Plaintiff of the use of counterfeit, non-FDA approved spinal hardware and by failing to act as a reasonably careful

physician, medical provider, supplier, and/or manufacturer of medical hardware.

117. As a direct and legal cause of Defendants' conspiracy to breach the fiduciary duties owed to Plaintiff, Plaintiff suffered, and continues to suffer, the injuries and damages hereinabove set forth.

FIFTH CAUSE OF ACTION

(Against All Defendants)

(Strict Products Liability)

118. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

119. Defendants, and each of them, acted individually and/or in concert to illegally increase profits, kickbacks, and/or financial payments from spinal fusion surgeries by manufacturing, distributing, selling, and/or implanting counterfeit, non-FDA approved spinal hardware.

120. The counterfeit spinal implant hardware, which was not FDA tested, and/or approved, contained a manufacturing defect when it left Defendants' possession, was defectively designed so as not to perform as safely as an ordinary consumer would have expected FDA approved hardware to perform, and had potential risks that were known and/or knowable to Defendants at the time of the manufacture, distribution, sale, and/or use that presented a substantial danger to patients when used in an intended or reasonably foreseeable way.

121. As a direct and legal result of these wrongful acts or omissions of Defendants, Plaintiff suffered, and continues to suffer, the injuries and damages hereinabove set forth.

SIXTH CAUSE OF ACTION

(Against All Defendants)

(Breach of Express Warranty)

122. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

123. In order to maximize Defendants' independent financial rewards from the conspiracy, Defendants, and each of them, represented orally, in writing, and/or by implication to

Plaintiff that the spinal implant hardware used in Plaintiff's spinal fusion surgery would be FDA approved hardware when in fact the surgical implant hardware utilized in Plaintiff's surgery was non-FDA approved surgical hardware and was not of the same quality as FDA approved surgical hardware.

124. As a direct and legal result of these wrongful acts or omissions of Defendants, Plaintiff suffered, and continues to suffer, the injuries and damages hereinabove set forth.

SEVENTH CAUSE OF ACTION

(Against All Defendants)

(Breach of Implied Warranty)

125. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

126. Plaintiff reasonably relied on the skill and judgment of Defendants, and as such their implied warranty, in undergoing spinal fusion surgery with surgical implant hardware manufactured, designed, sold, selected, and/or implanted by Defendants, and each of them.

127. As a direct and legal result of these wrongful acts or omissions of Defendants, Plaintiff suffered, and continues to suffer, the injuries and damages hereinabove set forth.

EIGHTH CAUSE OF ACTION

(Against All Defendants)

(Medical Monitoring)

128. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

129. Defendants, and each of them, manufactured, sold, supplied, and/or implanted counterfeit, non-FDA approved spinal hardware into patients from approximately 2007 through 2013. Such patients are at risk of suffering adverse health effects and/or premature failure of those counterfeit, non-FDA approved medical devices.

130. Plaintiff is similarly situated as a patient of AHMED who received surgery at PACIFIC HOSPITAL and firmly believes that the above described deceitful and fraudulent scheme resulted in a pattern and practice of implanting counterfeit, non-FDA approved surgical hardware.

131. Due to Defendants' fraudulent scheme and concealment of information of which patients received counterfeit devices in their surgeries, Plaintiff will require reasonable future monitoring to determine if Plaintiff has been exposed to health risks and/or premature failure of hardware as a result.

NINTH CAUSE OF ACTION

(Against All Defendants)

(Constructive Trust)

132. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

133. In the name of personal and corporate wealth, Defendants' individual and/or concerted actions resulted in a pattern and practice of promoting, prescribing, and/or performing unnecessary spinal surgeries from 2008 to November 2013 using counterfeit hardware in a conscious and reckless disregard for the health and safety of Plaintiff and other patients.

134. As a result of Defendants' fraudulent conduct and unjust enrichment, Plaintiff requests the imposition of a constructive trust created with the profits, plus interest, earned by Defendants as a result of the conspiracy. The constructive trust will support the medical care and treatment of Plaintiff and similarly situated patients.

TENTH CAUSE OF ACTION

(Against All Defendants)

(Unjust Enrichment)

135. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

136. As a result of their continuous and systematic misrepresentations and failure to disclose the above described conspiracy, Defendants were unjustly enriched.

137. Defendants knew, or should have known, of the benefit they were receiving due to their misrepresentations and failure to disclose, and enjoyed the benefit of increased financial gains, to the detriment of Plaintiff, who paid for a surgery that was prescribed in order to increase Defendants' financial gains and who paid a higher price for a product of lower value. It would be

inequitable and unjust for Defendants to retain these unlawfully obtained profits.

138. Plaintiff seeks an order establishing Defendants as constructive trustees of the profits unjustly obtained, plus interest.

ELEVENTH CAUSE OF ACTION

(Against All Defendants)

(Intentional Infliction of Emotional Distress)

139. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

140. The actions of Defendants, and each of them, as described hereinabove, were outrageous and abused Defendants' positions of authority and/or power over Plaintiff.

141. Defendants, and each of them, intended to cause severe, emotional distress, and/or acted in conscious disregard of the probability that Plaintiff would suffer emotional distress.

142. As a direct and legal result of these wrongful acts or omissions of Defendants, Plaintiff suffered, and continues to suffer, the injuries and damages hereinabove set forth, including but not limited to severe emotional distress.

TWELFTH CAUSE OF ACTION

(Against All Defendants)

(Negligent Infliction of Emotional Distress)

143. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

144. Defendants breached the duties owed to Plaintiff by implanting counterfeit, non-FDA approved spinal hardware in Plaintiff in furtherance of Defendants' personal and/or corporate financial gains.

145. As a direct and legal result of these wrongful acts or omissions of Defendants, Plaintiff suffered, and continues to suffer, the injuries and damages hereinabove set forth.

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THIRTEENTH CAUSE OF ACTION

(Against All Defendants)

(Negligence)

146. Plaintiff incorporates herein by reference and realleges all of the allegations stated in this Complaint.

147. At all times herein mentioned, Defendants, individually and in concert, acted carelessly, negligently, recklessly, and/or unlawfully in respect to the acts hereinabove set forth.

148. As a direct and legal result of these wrongful acts or omissions of Defendants, Plaintiff suffered, and continues to suffer, the injuries and damages hereinabove set forth.

VII. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment against Defendants as follows:

1. For compensatory and general damages according to proof;
2. For past and future medical and incidental expenses according to proof;
3. For past and future loss of earnings and earning capacity according to proof;
4. For an order for restitution and/or restitutionary disgorgement of profits wrongfully obtained by Defendants;
5. For punitive damages to deter and make an example of Defendants;
6. For attorney fees and expert/consultant fees under existing law;
7. For pre-judgment and post-judgment interest as permitted by law;
8. For costs of suit incurred herein; and
9. For such other and further relief as the Court deems just and proper.

Dated: July 15, 2014

COTCHETT, PITRE & McCARTHY, LLP

By: _____
FRANK M. PITRE
Attorneys for Plaintiff

VIII. JURY DEMAND

Plaintiff demands trial by jury on all issues so triable.

Dated: July 15, 2014

COTCHETT, PITRE & McCARTHY, LLP

By: _____
FRANK M. PITRE
Attorneys for ~~Plaintiff~~

EXHIBIT 1

TRI-CITY REGIONAL MEDICAL
21530 S PIONEER BLVD
HAWAIIAN GAR CA 90716
5624215424

11708328
17-55470
0111

33-0738307 123009 010410

[redacted]

IDYLLWILD CA 92549

07081962 M 12300905 3 1 16 62 CA

04 070207

[redacted]

IDYLLWILD CA 92549

IMPLANT INVOICES ATTACHED

Rev. CD.	Description		Serv. Units	Total Charges
121	MED-SUR-GY/2 BED		3	543600
200	INTENSIVE CARE		[illegible]	[illegible]5600
250	PHARMACY		184	665700
258	IV SOLUTIONS		46	38[illegible]
270	MED-SUR SUPPLIES	PAYMENT FOR SERVICES IS DUE W/IN	50	445790
272	STERILE SUPPLY	45 DAYS UPON RECEIPT OF OUR	[illegible]	[illegible]4320
278	SUPPLY/IMPLANTS	CLAIM. IF PAYMENT IS NOT RECEIVED	28	32616630
300	LABORATORY	WITHIN THE 45 DAYS AS NOTED IN	[illegible]	170030
301	LAB/CHEMISTRY	AMENDING LABOR CODE 4603.2 A	8	177510
320	DX X-RAY	15% INTEREST/PENALTIES WILL BE	[illegible]	147800
360	OR SERVICES	ASSESSED.	48	2819480
370	ANESTHESIA		[illegible]	627650
390	BLOOD/STOR-PROC		2	29380
410	RESPIRATORY SVS		[illegible]	590230
420	PHYSICAL THERP		14	126015
460	PULMONARY FUNC		[illegible]	120190
710	RECOVERY ROOM		1	176020
730	EKG/ECG	INVOICE ATTACHED	[illegible]	23825

IMPLANT INVOICES ATTACHED

GENEX
15 MAR 2010

0001 PAGE 1 OF 1 CREATION DATE 011810 TOTALS 41221395

[redacted]

Y Y 41221395 1043373053
050575

03-10-10

[redacted]

18 CLM# 133000560 DOI: 07/02/07 [redacted]

IDYLLWILD ARTS FOUNDATION

7213 Y30401 Y5180 N7828 Y33818 N3051 Y32723 Y2720 Y4019 Y
9496 Y28860 Y53081 Y311 Y30000 Y

72210 72210 454 E9320 E8497

8106 123009 8108 123009 8099 123009

7779 123009 8162 123009 8451 123009

NPI 1285639922
UPPAL G SUNNY
NPI 1285639922
UPPAL G SUNNY

[redacted]
PO BOX 881716
SAN FRANCISCO, CA 94188

33000560

15:14:20 03/09/2010

08/03/2010 01:37 #835 P.008/061 6518658078 MEDICAL CENT

[redacted]

INPATIENT I

TRI-CITY REGIONAL MEDICAL CTR
21530 S PIONEER BLVD
HAWAIIAN GARDENS CA 90716

11708328

699-8393 UPPAL, G SUNNY 17-65-70

[redacted] 12/30/09 1/04/10 5 7/08/1962 33000560

[redacted] 3039 [redacted]

IDYLLWILD, CA 92549

7009459	MAJOR BASIN	12/30/2009	1		755.25
7009541	3/4 SHEET	12/30/2009	6		614.40
7009582	MAYO STAND COVER	12/30/2009	1		64.08
7009616	SURGEON'S GOWN	12/30/2009	4		378.00
7009632	C-ARM DRAPE	12/30/2009	2		140.90
7010168	6-IS SUTURES	12/30/2009	1		367.20
7010283	SKIN STAPLES	12/30/2009	1		161.60
7011224	1500CC N.S. IRRIGATION	12/30/2009	2		171.70
1005081	MASK, OXYGEN	12/30/2009	1		55.45
7010648	AIRWAY ORAL	12/30/2009	1		49.60
7010572	BREATHING CIRCUIT	12/30/2009	1		132.40
7010440	CAUTERY PENCIL	12/30/2009	2		112.10
7010655	DISP. MASK	12/30/2009	1		64.08
7010606	ENDOTRECHEAL TUBE	12/30/2009	1		108.85
7010798	NEURO PATTIES	12/30/2009	1		80.08
7010747	PEANUT SPONGES	12/30/2009	3		115.20
7010861	SPINAL NEEDLE QUICKE TYPE	12/30/2009	1		104.05
7010607	SUCTION TUBING LONG	12/30/2009	2		198.00
7010531	SUCTION YANKAUER	12/30/2009	2		116.30
7010815	WET SKIN PREP TRAY	12/30/2009	2		288.78
7013527	ANDREW FRAME PATIENT KIT	12/30/2009	1		366.56
1002641	SWAB, POVODINE-IODINE	1/01/2010	1		14.60
1002641	SWAB, POVODINE-IODINE	1/01/2010	1		14.60
1002641	SWAB, POVODINE-IODINE	1/01/2010	1		14.60
1001395	SET, CONTINUS-FLO ADMIN	1/01/2010	1		94.60
	** SUBTOTAL **		61		6,443.20

278 Med/Surg Supply Other Implants — SEE ATTACHED INVOICES

7008758	CANCELLOUS CHIPS 30CC	12/30/2009	1 ✓		1,663.00
7008758	10CC ORTHOBLEND	12/30/2009	1 ✓		4,170.00 INV. A
7008758	TISSEEL FIBRIN	12/30/2009	1 ✓		1,500.00
1007764	BONE WAX	12/30/2009	1 ✓		38.80
7008758	SPINAL SOL 6X40MM SCREWS	12/30/2009	4 ✓		31,540.00
7008758	SPINAL SOL 7X35MM SCREWS	12/30/2009	2 ✓		25,770.00
7008758	SPINAL SOL 70MM RODS	12/30/2009	2 ✓		23,370.00 INV. B
7008758	SPINAL SOL SCREW CAPS	12/30/2009	6 ✓		82,110.00
7008758	SPINAL SOL MED CROSS LINK	12/30/2009	1 ✓		36,288.00

[redacted]

INPATIENT I

TRI-CITY REGIONAL MEDICAL CTR
21530 S PIONEER BLVD
HAWAIIAN GARDENS CA 90716

11708328

659-8393 UPPAL, G. SUNNY 17-85-70

[redacted] 12/30/09 1/04/10 5 7/08/1962 33000860

[redacted] 3039 [redacted]

IRVILLWILD, CA 92549

7008758	SPINAL SOL SHIPPING/FREIGHT	12/30/2009	1			
7008758	ORTHO ALL 12MM ALIF CAGES	12/30/2009	2	✓	825.00	
7008758	ORTHO ALL SHIPPING/FREIGHT	12/30/2009	1		96,570.00	INV.C
7008758	GENESIS- NUCEL LARGE 10CC	12/30/2009	1	✓	825.00	
7008758	GENESIS- NUCEL LARGE 10CC	12/30/2009	1	✓	9,900.00	
7008758	GENESIS- NUCEL LARGE 10CC	12/30/2009	1	✓	9,900.00	
7008758	GENESIS- CANCELLOUS CRUSHED 1-4MM	12/30/2009	1	✓	9,900.00	
7008758	GENESIS- SHIPPING/HANDLING	12/30/2009	1	✓	1,500.00	INV.D
	** SUBTOTAL **		28		312.50	
					826,166.30	
	300 Laboratory-Clinical					
1500180	MRSA SCREEN					
1501147	CBC HEMOGRAM & PLATELETS	12/30/2009	1		11.45	
1501196	HEMATOCRIT SPUN	12/30/2009	1		101.15	
1502293	BASIC METABOLIC PANEL	12/30/2009	1		31.10	
1502293	BASIC METABOLIC PANEL	12/31/2009	1		389.90	
1502293	BASIC METABOLIC PANEL	1/01/2010	1		389.90	
1502293	BASIC METABOLIC PANEL	1/02/2010	1		389.90	
	** SUBTOTAL **	1/04/2010	1		389.90	
			7		1,703.30	
	301 Laboratory-Chemistry					
6000017	BLOOD GAS ANALYSIS W/02 S	12/30/2009	1		464.10	
6000020	ARTERIAL PUNCTURE	12/30/2009	1		123.68	
6000018	BLOOD GAS ANALYSIS W/02 S	12/31/2009	1		464.10	
6000020	ARTERIAL PUNCTURE	12/31/2009	1		123.65	
1501162	CBC/W AUTO DIFF WBC	12/31/2009	1		149.90	
1501162	CBC/W AUTO DIFF WBC	1/01/2010	1		149.90	
1501162	CBC/W AUTO DIFF WBC	1/02/2010	1		149.90	
	** SUBTOTAL **	1/04/2010	2		149.90	
			8		1,775.10	
	320 Radiology Diagnostic					
3000585	FLUORO GUIDE EX/ASR/ENT/G					
3000320	CHEST 1 VIEW	12/30/2009	1		829.20	
3000320	CHEST 1 VIEW	12/31/2009	1		324.40	
	** SUBTOTAL **	1/01/2010	1		324.40	
			3		1,478.00	

TRI-CITY REGIONAL MEDICAL CENT
IMPLANT LOG
MARCH 2009

Purchasing/Surgery

Business Office

Cash Poster/Cashier

Date of Service	PO	Account No	Patient Name	Description of Implant	Cost	[illegible]
12/30/09	212	11708328	[redacted]	TISSEEL	$ 2,078.56	STOCK ITEM
12/30/09	TC78376	11708328	[redacted]	SCREWS RODS CAPS	$ 63,300.00	SPINAL SOLUTIONS
12/30/09	TC78378	11708328	[redacted]	CAGE	$ 32,465.00	ORTHOPEDIC ALLIANCE
12/30/09	TC70414	11708328	[redacted]	NUCELS	$ 10,462.50	GENESIS
				TOTALS	$ 108,306.05	

IMPLANT STICKERS

NC-1002
09037085620
12/17/10

NC-1002
09037085631
12/17/10

Bone Bank 7/14/2012
Cancellous Crushed
1-4 cm

NC-1002
090 3708S,820
EXP. 12/17/10

4 - 6 x 40 mm screws T06040
2 - 7 x 35 mm screws TD7035
2 - 70 mm Rods T90070
6 - screw caps T10100
1 - Med. Cross Link T84560
2 - 12 mm ALIF cages 13025-6/2

DESCR: ... SMALL DEFECT
LOT #: DTB ...
PROD CODE: P44150
EXP: ...
Store at ... Do not freeze.

DESCR: CANCELLOUS CHIPS 7.7 - 15mm, ...
SERIAL #: DTB ...
PROD CODE: ...
EXP: 30NOV2014

1071.20

318.40

Before Patient Leaves Operating Room

Nurse verbally confirms with the team:

☑ The name of the procedure recorded	☑ Y ☐ N
☑ That instrument, sponge and needle counts are correct (or not applicable)	☑ Y ☐ N ☐ NA
☑ That specimen is labeled correctly (including patient name)	☐ Y ☐ N ☑ NA

Postoperative Assessment and Condition of Patient

Extubated: ☑ Y ☐ N ☐ NA	Responsive/Commands: ☑ Y ☐ N	Responsive/Pain: ☑ Y ☐ N
Fully Awake: ☐ Y ☑ N	Color: normal	Respirations: regular
Heart Rate/Rhythm: regular		Condition IV site: patent
Condition dressing: dry/intact		Solution: LR TBA:
Foley: patent	Output: 600 cc	☐ Review of Medications/Orders
Notes/Remarks:		
Anesthesiologist: Dr. N......	Transferring RN:	Receiving RN: C. Olalis RN — Time: 1240

Tri-city Regional Medical Center

INVOICE

Stock Item Implant Invoice

21530 S. Pioneer Blvd.
Hawaiian Gardens, CA 90716
Phone (562) 421-6424 Fax (562) 421-7680

DATE: December 30, 2009
INVOICE # 212

TAX ID: 330738307

Ship To: Tri-City Hospital - Surgery Dept.
21530 S. Pioneer Blvd.,
Hawaiian Gardens, CA 90716
Phone (562) 860-0401

Comments or Special Instructions: Patient Name: [redacted](ACCT#11708326)

QUANTITY	DESCRIPTION	UNIT PRICE	AMOUNT
1	CANCELLOUS CHIPS 1.7-10mm 30cc	$ 318.40	318.40
1	10cc ORTHOBLEND SMALL DEFECT	$ 1,071.20	1071.20
1	TISSEEL 10ml	$ 504.30	[illegible]

SUBTOTAL	[illegible]
TAX RATE	8.75%
SALES TAX	[illegible]
SHIPPING & HANDLING	
TOTAL	[illegible] 2078.56

THANK YOU FOR YOUR BUSINESS!

TCRMC Implant InvoiceSales Invoice

INVOICE A

15:14:23 03/09/2010

09:09:33 03/12/2010

Spinal Solutions
P.O. Box 41047
BATON ROUGE LA 70835
Phone(951) 304-9001 Fax(951) 304-9101
Remit Check to Commercial Capital

Invoice

Date	Invoice #
12/30/2009	7563

Bill To
TRI CITY REGIONAL
21530 PIONEER BLVD
HAWAIIAN GARDENS, CA. 90716
ATTN ACCTS PAYABLE

Ship To
Surgeon:Uppal
Patient Name: [redacted]
Surgery Date: 12/30/2009
Procedure: Fusion

P.O. Number	Terms	Rep	Ship	Via	Patient	Project
TC76376	Net 30	DT	12/30/2009			

Quantity	Item Code	Description	Price Each	Amount
4	T05040	6.0 X 40MM POLYAXIAL SCREW	4,295.00	17,180.00
2	T07035	7.0 X 35 POLYAXIAL SCREW	4,295.00	8,590.00
2	T90070	5.5MM X 70 FRS RENT ROD	3,895.00	7,790.00
6	T10100	SET CAPS SCREWS	2,895.00	17,370.00
1	T24560	MEDIUM CROSSLINK	12,095.00	12,095.00
1	S/F	Shipping/Freight	275.00	275.00

RECEIVED
JAN 18 2010
BY:

Tax I.D. #03-0840816

Total $63,300.00

INVOICE B

ORTHOPEDIC ALLIANCE
P.O. Box 41047
Baton Rouge, LA 70835
PH (951)304-9001 FX (951)304-9101
Remit Check To Commercial Capital

Invoice

Date	Invoice #
12/30/2009	9882

Bill To
TRI CITY HOSPITAL
21530 PIONEER BLVD
HAWAIIAN GARDENS CA 90716
ATTN: ACCTS PAYABLE

Ship To
SURGEON: Uppal
PROCEDURE: FUSION
PATIENT: [redacted]
SURGERY DATE: 12/30/09

P.O. Number	Terms	Rep	Ship	Via	Patient	Project
TC16378	Net 30	DT	12/30/2009	Federal Express		

Quantity	Item Code	Description	Price Each	Amount
2	13025-612	12mm ALIF Cage	16,095.00	32,190.00
1	S/F	SHIPPING/FREIGHT	275.00	275.00

RECEIVED
JAN 12 2010
BY: Alena

TAX ID # 35-2187358

Total $32,465.00

INVOICE C

FAXED

Comprehensive Intra-Operative Services, Inc.

CIOS, Inc.
4130 Flat Rock Dr. Suite 150
Riverside, CA 92505

(951)509-0246
angela@cioservices.net

12/31/2009	P18219
Net 30	01/30/2010

Spinal Solutions LLC
41558 Eastman Dr.
Unit A
Murrieta, CA 92562

$11,077.50

Please detach top portion and return with your payment.

12/30/2009	T06040	6x40mm Screws	4	1,395.00	5,580.00
12/30/2009	T07035	7x35mm Screw	2	1,395.00	2,790.00
12/30/2009	T90070	70mm Rod	2	425.00	850.00
12/30/2009	T10100	Screw Caps	6	475.00	2,850.00
12/30/2009	T84560	Med Crosslink	1	1,495.00	1,495.00
12/30/2009	13025-612	30 x 25 x 12mm ALIF Cage	2	4,295.00	8,590.00

Patient: [redacted]
Tri City Hospital
#11708328

SUBTOTAL	$22,155.00
DISCOUNT (50%)	$-11,077.50
TOTAL	$11,077.50

Tri City Hospital - On Spinal Solutions Invoice

Pedicle Screw

Part Number	Dimension	Price
SG5030	5.0 X 30 mm	$1,395.00
SG5035	5.0 x 35 mm	$1,395.00
SG5040	5.0 x 40 mm	$1,395.00
SG6040	6.0 x 40 mm	$1,395.00
SG6045	6.0 x 45 mm	$1,395.00
SG6050	6.0 x 50 mm	$1,395.00
SG6540	6.5 x 40 mm	$1,395.00
SG6545	6.5 x 45 mm	$1,395.00
SG6550	6.5 x 50 mm	$1,395.00
SG6555	6.5 x 55 mm	$1,395.00
SG7035	7.0 x 35 mm	$1,395.00
SG7040	7.0 x 40 mm	
SG7045	7.0 x 45 mm	
SG7050	7.0 x 50 mm	
SG7055	7.0 x 55 mm	
SG7540	7.5 x 40 mm	
SG7545	7.5 x 45 mm	
SG7550	7.5 x 50 mm	
SG7555	7.5 x 55 mm	
SG8040	8.0 x 40 mm	
SG8045	8.0 x 45 mm	
SG8050	8.0 x 50 mm	
SG8055	8.0 x 55 mm	

Transverse Link Assembly

Part Number	Dimension	Price
SGA2103		
SGA2160	Small	$1,495.00
SGA2170	Medium	
SGA2180	Large	

Transverse Link

	Dimension	Price
SG2140	40mm	
SG2150	50mm	$1,495.00
SG2160	60mm	
SG2170	70mm	
SG2180	80mm	

Reduction Screw

Part Number	Dimension	Price
SG6140	6.0 x 40 mm	
SG6145	6.0 X 45 mm	

Eff 2/1/09

Tri City Hospital - On Spinal Solutions.Invoice

Connectors

Part Number	Dimension	Price
SG3601	1.0 mm	$596.00
SG3602	2.0 mm	$596.00
SG3603	3.0 mm	$596.00
SG3604	4.0 mm	$596.00

Screw Cap

Part Number	Dimension	Price
SG3010	0	$475.00

Rod

Part Number	Dimension	Price
SG1604	6.0 x 40 mm	$425.00
SG1605	6.0 x 50 mm	$425.00
SG1606	6.0 x 60 mm	$425.00
SG1607	6.0 x 70 mm	$425.00
SG1608	6.0 x 80 mm	$425.00
SG1609	6.0 x 90 mm	$425.00
SG1610	6.0 x 100 mm	$425.00
SG1612	6.0 x 120 mm	$425.00
SG1615	6.0 x 150 mm	$425.00
SG1620	6.0 x 200 mm	$425.00
SG1630	6.0 x 300 mm	$425.00
SG1640	6.0 x 400 mm	$425.00

ALIF Cages

Part Number	Dimension	Price
13025-612	12mm	$4,295.00
13025-614	14mm	$4,295.00
13025-616	16mm	$4,295.00
13025-618	18mm	$4,295.00

Eff 2/1/09

Tri City Hospital - On Spinal Solutions Invoice

Genex

Part Number	Dimension	Price
920-010	10cc	$1,995.00

Eff 2/1/09

GENESIS

INVOICE

Genesis Biologics, Inc.
8537 Old Conejo Road, Suite 114
Newbury Park, CA 91320
(805) 375-4222 Phone
(805) 376-5955 Fax

INVOICE # 1160

DATE: 01/06/10

BILL TO:
Tri-City Regional Medical Center
Attn: Accounts Payable
21530 S. Pioneer Blvd.
Hawaiian Gardens, CA 90716
(562) 860-0401

SHIP TO:
Tri-City Regional Medical Center
Attn: OR Department
21530 S. Pioneer Blvd.
Hawaiian Gardens, CA 90716

FIELD REP	P.O. NUMBER	ACCOUNT	SHIPPED VIA	TERMS
Mic McGrath	TC78414	Select Surgical Specialists	FedEx - Priority	Net 30

QTY	PRODUCT CODE	DESCRIPTION	UNIT PRICE	TOTAL
1	60003	NuCel Large – 10cc (Graft ID #080370856511)	3,300.00	3,300.00
1	60003	NuCel Large – 10cc (Graft ID #090370856280)	3,300.00	3,300.00
1	60003	NuCel Large – 10cc (Graft ID #090370856320)	3,300.00	3,300.00
1	80130	Cancellous Crushed 1-4mm – 30cc (Graft ID #THB0038692)	500.00	500.00
		DOS: 12/30/09, Dr. Sunny Uppal		
		Patient: [redacted]		

SUBTOTAL	$10,400.00
SALES TAX	0.00
SHIPPING & HANDLING	62.50
TOTAL DUE	$10,462.50

Make all checks payable to Genesis Biologics, Inc.

Thank you for your business!

INVOICE D

15 14:23 03/09/2010

EXHIBIT 2

BUSINESS PROMOTION AND MARKETING AGREEMENT
BETWEEN
TRI-CITY REGIONAL MEDICAL CENTER
AND
COMPREHENSIVE INTRA-OPERATIVE SERVICES, INC.

This **Business Promotion and Marketing Agreement** (*"Agreement"*) is entered into effective this 1st day of December 2010 (*"Effective Date"*) by and between Gardens Regional Hospital and Medical Center, Inc., a California nonprofit corporation, d/b/a Tri-City Regional Medical Center (*"Hospital"*) and Comprehensive Intra-Operative Services, Inc., a California corporation (*"Consultant"*).

RECITALS

A. Hospital owns and operates a general acute care hospital licensed pursuant to California Health and Safety Code Section 1250 and located at 21530 South Pioneer Boulevard, Hawaiian Gardens California 90716. Hospital's clinical programs include spine disorders, sports medicine, general orthopedics, and pain management.

B. Consultant is located at 4130 Flat Rock Drive, Riverside, California and is experienced in designing and implementing, and successfully has designed and implemented, direct promotion services, including business development, promotion and marketing, on behalf of health care providers in Southern California, including those who specialize in spine disorders, sports medicine, general orthopedics, and pain management.

C. Hospital desires to engage Consultant to promote Hospital's facility, medical staff and clinical programs including, without limitation, those pertaining to orthopedics, spinal diseases/injuries, sports medicine, pain management, and workers' compensation services (*"Hospital Services"*), to interested parties in Southern California and to other health care providers including, but not limited to, chiropractors and orthopedic practice professionals; and Consultant desires to perform such services on behalf of Hospital pursuant to the terms and conditions of this Agreement.

NOW THEREFORE, in consideration of the mutual promises herein contained, and for mutual, valuable consideration the value of which is hereby acknowledged, the parties hereto agree as follows:

1. ENGAGEMENT OF CONSULTANT

1.1 **Appointment.** Hospital hereby appoints Consultant to provide the services set forth in the scope of service attached hereto as Exhibit A and incorporated herein by reference (*"Promotion Services"*), which Promotion Services Hospital has determined are necessary in order to effectively inform other health care providers about the nature and availability of

Hospital Services, and Consultant hereby accepts this engagement in accordance with the terms and conditions set forth herein, including in Exhibit A.

1.2 **Control Retained by Hospital.** Notwithstanding anything contained anywhere to the contrary, throughout the term, Hospital, through its Board of Directors (*"Board"*), shall retain all authority and shall exercise control over the business, policies, operation, and assets of Hospital, in accordance with Hospital's governance documents as such documents may be amended from time to time (collectively, *"Governing Documents"*), policies and directives set forth by Hospital's Board (including any written modifications or amendments thereto as may be approved by the Board from time to time), all applicable laws, ordinances, rules and regulations of federal, California state *("State")* and local governments, and the accreditation standards of the DNV and/or other applicable accreditation agency. Consultant shall perform the Promotion Services described in this Agreement in accordance with Hospital's Governing Documents, policies and directives (including any written modifications or amendments thereto as may be approved by the Board from time to time). At all times during the term hereof, Consultant shall be and remain directly responsible and accountable to the chief executive officer of Hospital (*"CEO"*), and any and all Hospital representatives as may be designated by the CEO, for the performance of the Promotion Services and all other duties of Consultant set forth herein. By entering into this Agreement, Hospital does not hereby delegate to Consultant any of the powers, duties, and responsibilities vested in the Board by law or by Hospital's Governing Documents. Nothing in this Agreement authorizes, nor shall be interpreted to authorize, Consultant to exercise control, responsibility or governance of a material amount of the assets or operations of Hospital, nor does this Agreement authorize Consultant to incur any financial obligation on behalf of Hospital without prior approval of the CEO.

1.3 **Independent Contractors.** Hospital and Consultant are and shall be at all times acting hereunder as independent contractors. Nothing contained herein shall be construed as creating a partnership, joint venture, agency or employment relationship between Consultant and Hospital, or any relationship other than that of independent parties contracting with each other solely for the purpose of carrying out the provisions of this Agreement. Consequently, the parties agree that neither party (nor any employee, agent or representative of such party) shall, by virtue of this Agreement, have a claim against the other party for any workers' compensation or any other employment compensation or fringe benefit, and that each party is responsible for all employer withholding, taxes, insurance, workers' compensation contributions, Social Security and Medicare taxes, other payroll taxes and similar mandatory employer withholds and compensation for such party's personnel. Consultant shall supervise the activities of all of its employees, agents and sub-contractors *("Consultant Personnel")* in their performance of Promotion Services on behalf of Consultant. Consultant shall establish and pay all wages, salaries and compensation, and shall establish staffing levels, individual work hours, personnel policies and employee benefit programs for all such Consultant Personnel and Hospital shall have absolutely no responsibility to provide wages, sick leave, vacation, withholding, compensation or benefits of any kind to Consultant Personnel.

2. DUTIES OF CONSULTANT

Hospital _____

Consultant _____

2.1 **Promotion Services.** During the term hereof, Consultant shall provide the Promotion Services pursuant to Section 1.1.

2.2 **Reports.** At a minimum, each month Consultant shall provide Hospital with a Monthly Promotion Services Report (as defined and described more explicitly in Section 7 below), in a form acceptable to the CEO, which describes all Promotion Services performed in the previous calendar month and the time devoted by Consultant in connection with such Promotion Services.

2.3 **Confidentiality.**

2.3.1 **Confidential Information; Trade Secrets.** During the term of this Agreement, Consultant may gain confidential, privileged or proprietary information regarding Hospital's medical, financial or business matters including, but not limited to, fees, schedules, policies, analyses, patient lists, patient information, forms, insurance reimbursements, payor/provider information, business development and marketing strategies, plans, and methods, raw data, costs, rates, contract terms, and any other information or material which derives actual or potential economic or other value from not being generally know to other entities (collectively *"Confidential Information"*). Without limiting the scope of the foregoing, Consultant agrees that the terms and conditions of this Agreement, including, without limitation, the amount of Consultant's compensation, are Confidential Information. Consultant further acknowledges that Hospital, in connection with Hospital's business, has developed and will develop certain operating manuals, websites and content, marketing materials, business plans, symbols, trademarks, trade names, service marks, designs, patients lists, procedures, processes and other copyrighted, patented, trademarked or other legally protectable information that is proprietary and confidential to Hospital (collectively, *"Trade Secrets"*).

2.3.2 **Non-Disclosure; Prohibition Against Use.** Consultant agrees not to use (except in the course of its engagement hereunder), release, disclose or disseminate, to any person or entity any Confidential Information or Trade Secrets except (a) to authorized representatives of Hospital; (b) upon court or governmental agency order; or (c) with the prior written consent of Hospital. Consultant acknowledges that it is prohibited from using any Confidential Information or Trade Secrets of Hospital for the benefit of Consultant, that this prohibition continues after the termination or expiration of this Agreement, and that such unauthorized use may result in the imposition of damages and/or injunctive relief pursuant to Section 2.3.4, below. Upon termination or expiration of this Agreement, Consultant shall immediately return to Hospital any Confidential Information and materials relating to Trade Secrets in its possession pursuant to Section 15.4.3.

2.3.2.1 **Reservation of Rights.** The parties acknowledge and agree that, except for the rights and licenses expressly granted by each party to the other party under this Agreement, each party will retain all right, title and interest in and to its products, services, marks, and all content, information and other materials on its website(s) and in its own marketing and promotion materials, and nothing contained in this Agreement will be construed as

Hospital _____

Consultant _____

conferring upon such party, by implication, operation of law or otherwise, any other license or other right.

2.3.3 **HIPAA Compliance.** Consultant agrees to abide by the terms of the HIPAA Business Associate Addendum attached hereto and incorporated by reference herein as Exhibit B.

2.3.4 **Injunctive Relief.** Consultant recognizes that irreparable injury will result to Hospital's business and property if Consultant breaches any of the provisions in Sections 2.3.2, 2.3.2.1 or 2.3.3, above. Accordingly, Consultant acknowledges and consents to the obtaining by Hospital of whatever injunctive relief may be appropriate to remedy the breach or compel Consultant's performance of Section 2.3.2 and the terms and conditions set forth in the Business Associate Addendum attached as Exhibit B, without the necessity of proving actual damage. Any injunctive relief Hospital obtains shall be in addition to any other remedies and damages available to Hospital.

2.3.5 **Survival.** The provisions set forth in this Section 2.3 shall survive the expiration or other termination of this Agreement.

2.4 **Restrictive Covenant.** Consultant agrees, during the term of this Agreement and any renewal thereof, to abide by the restrictive covenants set forth in Section 2.4.1, below; *further*, in the event Consultant engages in conduct which violates this Section 2.4 or which materially interferes with (or is reasonably anticipated to interfere with) Consultant's performance under this Agreement, Hospital may exercise its rights under Section 15, below.

2.4.1 **Conflict of Interest.** Consultant shall immediately inform the CEO, in writing, of any arrangement that Consultant or any of its officers, members, employees, or affiliates enter into, which present, or are reasonably anticipated to present, a Conflict of Interest (as defined below) or to materially interfere with Consultant's performance of its duties under this Agreement. As used in this Section 2.4.1, the term "***Conflict of Interest***" is defined to include, without limitation, any arrangement or agreement to provide the same or similar services as the Promotion Services to be provided hereunder, to or on behalf of any health care facility or provider that is located within a twenty (20) mile radius of Hospital, and which provides services that are the same or similar to Hospital Services.

3. REPRESENTATIONS AND WARRANTIES

3.1 **Consultant Representations.** Consultant represents and warrants, upon execution and while this Agreement is in effect, as follows:

3.1.1 Consultant is not bound by any contractual arrangement or any other obligation that would preclude Consultant from entering into or fully performing all of Consultant's duties pursuant to this Agreement;

3.1.2 There are no actions, suits, or proceedings pending or threatened, against Consultant or its principals, at law or in equity, before or by any federal, State, municipal, or other governmental department, commission, board, bureau, agency, or instrumentality, that would, if decided adversely, have a materially adverse effect on Consultant or the performance of Consultant's duties pursuant to this Agreement;

3.1.3 Neither Consultant, nor any individual shareholder, officer, director, principal, employee, or subcontractor of Consultant nor Consultant Personnel has ever been: convicted of a criminal offense relating to health care or any crime punishable as a felony; listed by a federal agency as debarred, suspended, excluded or otherwise ineligible for participation in a federal health care program; convicted of any act or acts constituting a felony or misdemeanor involving moral turpitude under the laws of the United States, any state thereof or any foreign jurisdiction, or; is under investigation or involved in any legal proceeding which may lead to such a conviction or exclusion.

3.1.4 No licensed physician or any licensed physician's family member owns an interest in Consultant's businesses.

3.1.5 Neither Consultant, nor any of Consultant's affiliates or subcontractors, nor any of their respective officers, directors, employees, agents, or representatives did in the past, or will in the future, in connection with this Agreement, or otherwise, solicit, receive, pay or give anything of value (including, but not limited to, goods, services, cash, referrals or any other form of remuneration or gift) to or from any physician, administrator, employee, agent or representative of or connected with the Hospital, or to or from any third party who may at this time or in the future be in a position to refer patients to the Hospital.

3.1.6 All of Consultant's activities and Promotion Services are in full and complete compliance with all local, State and federal laws, standards, regulations, and ordinances including, but not limited to, 42 U.S.C. §1320a-7b(b), commonly known as the "Federal Anti-Kickback Statute;" 42 U.S.C. §1395nn, commonly known as the "Stark Act," and; California Business and Professions Code § 650, commonly known as California's "Physician Outpatient Referral Act ('PORA')."

3.1.7 Consultant certifies that it does not engage in the practice of medicine or otherwise provide professional medical or related services to patients, nor does Consultant employ individuals to furnish such services on behalf of Consultant, Hospital, or any other person or entity. Nothing contained herein shall be deemed to authorize or require anyone engaged by Consultant to influence or interfere with any physician's professional judgment.

3.1.8 Consultant acknowledges the prohibition set forth in California Business and Professions Code §2400, within the Medical Practice Act, which provides, "Corporations and other artificial entities shall have no professional rights, privileges, or powers." Neither Consultant nor Consultant Personnel shall offer or conduct patient evaluation, diagnosis, care and/or treatment. Consultant shall not perform or authorize any of Consultant's Personnel to perform any of the following activities, all of which must be conducted by a physician licensed

in the State and would constitute the unlicensed practice of medicine if performed by an unlicensed person:

- Determining what diagnostic tests are appropriate for a particular condition.
- Determining the need for referrals to, or consultation with, another physician/specialist.
- Responsibility for the ultimate overall care of the patient, including treatment options available to the patient.

3.1.9 The person who is executing this Agreement on behalf of Consultant is authorized to enter into this Agreement on its behalf. Consultant represents and warrants, upon execution and while this Agreement is in effect, this Agreement has been duly authorized by Consultant, has been duly executed and delivered by authorized representatives of Consultant, and represents the legal, valid, and binding agreement of Consultant and, to the best of Consultants knowledge and belief, is enforceable against Consultant in accordance with its terms.

3.1.10 Promotion Services to be provided by Consultant and Consultant Personnel and agents, affiliates and subcontractors hereunder in theory and in practice comply with the requirements of all federal, State and local laws, regulations and ordinances and shall in no way (i) jeopardize Hospital's licensure or its participation in any government health care program; or (ii) violate any patient's privacy rights.

3.2 **Hospital Representations.** Hospital represents and warrants, upon execution and while this Agreement is in effect, this Agreement has been duly authorized by Hospital, has been duly executed and delivered by authorized representative of Hospital, and represents the legal, valid, and binding agreement of Hospital and, to the best of Hospital's knowledge and belief, is enforceable against Hospital in accordance with its terms.

3.3 **Joint Representations**. Hospital and Consultant jointly represent and warrant, upon execution and while this Agreement is in effect, that this Agreement sets forth all of the services to be provided by Consultant to Hospital during the term hereof, and that it is intended to satisfy all of the criteria governing satisfaction of the "safe harbor" for "personal services and management contracts" pursuant to Title 42 of C.F.R., Section 1001.952(d).

3.4 **Survival**. The warranties and representations contained in this Section 3 shall survive the expiration or other termination of this Agreement.

4. NO REQUIREMENT TO REFER

Nothing in this Agreement, whether written or oral, nor any consideration in connection herewith contemplates, requires or is intended to induce or pay any person to refer any patient or any other person to Hospital.

5. NON-SOLICITATION

During the term and any renewal of this Agreement, and for a period of one (1) year thereafter, neither party shall, on its own behalf or on behalf of any person or entity, solicit the services of any person currently employed by, or under a service contract with the other party, except insofar as such party seeks such services for purpose of performing such party's duties under this Agreement.

6. USE OF HOSPITAL'S NAME AND FACILITIES

Consultant agrees not to use Hospital's name or any part of Hospital's facilities or premises for any purpose other than the performance of Promotion Services and related duties under this Agreement, subject to Section 2.4.2 above.

7. DOCUMENTATION OF PROMOTION SERVICES

Consultant shall cause Consultant Personnel to prepare on a monthly basis during the term hereof an accurate and complete record documenting the Promotion Services provided by Consultant Personnel during the preceding month (*"Monthly Promotion Services Report"*). No later than ten (10) days after the last day of each month, Consultant shall submit to the CEO, the Monthly Promotion Services Report for the preceding month in a form consistent with the template set forth in Exhibit C attached hereto and incorporated by reference herein or as otherwise may be mutually agreed upon in writing by the parties. The Monthly Promotion Services Report shall include, without limitation, a description of the Promotion Services performed and the number of hours expended by all Consultant Personnel. In the event Consultant fails to produce and timely submit a complete and accurate Monthly Promotion Services Report pursuant to this Section 7, Hospital may exercise its rights under Sections 8.2 and 15 below.

8. COMPENSATION

8.1 **Compensation for Promotion Services.** Consultant shall accrue and accept as its sole and total, all-inclusive flat rate compensation the amount of Twenty Thousand Dollars ($20,000.00) per month (*"Promotion Services Fee"*) for all Promotion Services provided hereunder during the preceding month, subject to the provisions of Section 8.2, below; and *subject, further,* to Consultant's duty to make a timely submission to the CEO of a complete and accurate Monthly Promotion Services Report in accordance with Section 7, above. No other compensation or reimbursements shall be paid by Hospital to Consultant, unless agreed to, in advance, in a writing signed by both parties; Hospital shall not be responsible for payment of any costs and expenses associated with the Promotion Services including, but not limited to, travel, faxes, photocopying, messengers and couriers, postage, telephone, auto, mileage, parking, materials, taxes, secretarial services, insurance, equipment, maintenance, forms, supplies, legal services, clerical services, licenses, certifications and the like.

8.2 **Conditions of Payment.**

Hospital _____

Consultant MG

8.2.1 Within ten (10) days following the last day of each month during the term of this Agreement, Consultant shall furnish the CEO with an invoice and Monthly Promotion Services Report specified in Section 7, above, specifying all Promotion Services provided pursuant to this Agreement.

8.2.2 Anything to the contrary notwithstanding, in the event that Consultant fails to produce a Monthly Promotion Services Report for any month during the term hereof to the satisfaction of the CEO, Hospital shall make no payment of compensation whatsoever to Consultant with respect to the month or months for which Consultant has failed to produce such documentation.

8.2.3 In the event Consultant fails to timely submit an acceptable Monthly Promotion Services Report compliant with the terms stated herein for any month during the term hereof within ninety (90) calendar days following the end of the month during which such Promotion Services were rendered, Hospital, in its sole discretion, shall be fully and forever relieved from any obligation to make payment of any compensation whatsoever with respect to the month(s) for which Consultant has failed to fully and timely produce and submit such Monthly Promotion Services Report.

8.2.4 Subject to Section 8.2.3 above, all payments of compensation by Hospital to Consultant shall be made by Hospital to Consultant on or before the later to occur of (a) the fifteenth (15th) day of the month following the month for which payment is being made, or (b) ten (10) days following the Hospital's receipt of the Monthly Promotion Services Report and an invoice pursuant to Section 8.2.1, above, with respect to such month.

9. INSURANCE

9.1 Comprehensive General Liability Insurance.

9.1.1 Consultant shall procure and maintain during the term hereof, at Consultant's sole and complete expense, comprehensive general liability insurance ("***CGL***") covering Consultant for all activities undertaken by Consultant and all losses that may be incurred by Consultant pursuant to this Agreement. Each policy of CGL insurance shall be provided by a carrier that is licensed to do business in California having at least an "A" Best rating, and, for each policy of coverage, shall provide minimum coverage limits in the amounts of $1,000,000 per claim and $3,000,000 in the aggregate for the policy year. The CGL insurance shall provide coverage for all occurrences or claims during the term of this Agreement and any extension thereof. Hospital shall be named as an additional insured under each policy and proof thereof shall be provided to Hospital promptly upon request. The CGL insurance policy shall not be cancelable or modifiable, except upon thirty (30) days' prior written notice by Consultant to Hospital. In the event of cancellation or modification of the CGL policy, Consultant shall immediately notify Hospital and immediately replace the insurance.

9.2 "Tail" Coverage.

9.2.1 If the insurance obtained and maintained pursuant to Section 9.1.2 hereof is provided on a "claims-made" basis, Consultant agrees that, prior to the effective date of the termination of such coverage, if applicable, Consultant shall purchase, at Consultant's sole and complete expense, "tail" insurance (i.e., an extended reporting endorsement) for an unlimited reporting period with the same coverage limits required pursuant to Section 9.1.1 for all claims arising out of incidents occurring prior to termination of Consultant's current coverage.

9.2.2 No later than ten (10) days prior to the effective date of the expiration or earlier termination of this Agreement, Consultant shall purchase tail coverage with the same coverage limits pursuant to Section 9.1.1 for an unlimited reporting period for all claims arising after the effective date of such expiration or termination and which arise out of incidents occurring during the term hereof. If Consultant fails to do so, Consultant hereby authorizes Hospital to purchase such coverage, and to deduct the cost thereof from any compensation or expense reimbursement otherwise due to Consultant under this Agreement. If Hospital's cost of purchasing such tail coverage pursuant to this Section 9.2.2 exceeds any compensation or expense reimbursement otherwise due to Consultant, Consultant shall pay the difference to Hospital within ten (10) days of Hospital's demand for it. Overdue amounts shall bear interest at ten percent (10%) per annum or, if lower, at the maximum rate allowed by law.

9.3. **Workers' Compensation Insurance; Employer's Liability Coverage.** Consultant shall secure and maintain at all times during the term hereof, at Consultant's sole and complete expense, workers' compensation and employer's liability insurance covering Consultant and all Consultant Personnel and all other employees of Consultant, by a carrier licensed to do business in California and having at least an "A" Best rating, and shall be endorsed to include a (a) waiver of subrogation in favor of Hospital, and (b) thirty (30) days' prior written notice of cancellation. Such coverage shall be primary and non-contributory.

9.4 **Certificates.** Before Consultant provides any Promotion Services under this Agreement, Consultant shall present Hospital with certificates evidencing the insurance coverage required pursuant to this Section 9. In addition, prior to the annual anniversary of the Effective Date of this Agreement, if applicable, Consultant shall present Hospital with a certificate evidencing the continued insurance coverage required pursuant to this Section 9.

10. INDEMNIFICATION

10.1 **Indemnification.** Consultant hereby indemnifies and holds Hospital and Hospital's management company, South Bay Hospital Management, LLC, a California limited liability company, and each of their trustees, officers, directors, employees, representatives and agents harmless from any and all loss, liability, damage, cost and expense (including attorneys' fees) suffered or incurred by Hospital in connection with (a) any claims brought or threatened against Hospital for compensation of Consultant Personnel or any other of Consultant's employees, laborers, workers, staff, agents, subcontractors or independent contractors, (b) claims by any third party against Hospital or Consultant in connection with any act or omission related to the performance of any duty pursuant to this Agreement, (c) any act or omission

(including, without limitation, due to negligence, willful misconduct or otherwise) of Consultant, Consultant Personnel or anyone acting for or on behalf of Consultant in connection with this Agreement, or (d) any act or omission constituting a breach or default in the performance of Consultant's representations, warranties, covenants or obligations under this Agreement.

10.2 **Survival.** The provisions set forth in this Section 10 shall survive the expiration or other termination of this Agreement.

11. ACCESS TO BOOKS AND RECORDS

11.1 **Required Access for "Secretary" and "Comptroller General."** Consultant shall make available, upon written request from the Secretary of the United States Department of Health and Human Services (the *"Secretary"*), or upon the request from the Comptroller General of the United States General Accounting Office (the *"Comptroller General"*), or any of their duly authorized representatives, respectively, a copy of this Agreement and such books, documents, and records as are necessary to verify the nature and extent of the costs of the Promotion Services provided by Consultant under this Agreement. Consultant further agrees that if Consultant carries out any of its duties under this Agreement through a subcontract with a value or cost of Ten Thousand Dollars ($10,000) or more over a twelve (12) month period with an agent or subcontractor, such contract shall contain a clause to the effect that the agent or subcontractor shall make available, upon request from the Secretary, or upon request from the Comptroller General, or any of their duly authorized representatives, respectively, a copy of such contract and such books, documents, and records as are necessary to verify the nature and extent of such costs. The availability of Consultant's books, documents and records shall be subject at all times to all applicable legal requirements, including without limitation, such criteria and procedures for seeking and obtaining access that may be promulgated by the Secretary in federal regulations.

11.2 **Required Access for Hospital.** Consultant shall provide Hospital with all information, records and any other documents related to the performance of Promotion Services hereunder, and shall promptly, at Hospital's request, provide Hospital with copies of any books, documents, and records released to the Secretary or Comptroller General pursuant to Section 11.1, above.

11.3 **Survival.** The provisions set forth in this Section 11 shall survive the expiration or other termination of this Agreement.

12. DISPUTE RESOLUTION

12.1 **Disputes/Arbitration.** The laws of the State of California shall govern this Agreement. Any action or other proceeding under this Agreement shall be commenced and shall take place in Los Angeles County, California.

It is intended that all claims or disputes involving the parties or between the parties to this Agreement between the parties related to any matter, controversy or claim arising out of or relating to this Agreement and/or the breach thereof shall be resolved by binding arbitration.

Hospital _____ *Consultant* _____

Such arbitration shall be held in Los Angeles, California before a retired Judge of the Los Angeles Superior Court, and under the rules of the California Arbitration Act (Cal. Code Civ. Proc. sec 1280 et seq., including section 1283.05 and all of the Act's other mandatory and permissive rights to discovery). The California Code of Evidence shall apply to all testimony and documents submitted to the arbitrator. Consultant and Hospital shall select the arbitrator, and in the event they are not able to agree on the selection of the arbitrator, then, either party may request a list from ADR Services, Inc. (or if ADR is not available, then its successor or a mutually agreeable company of similar reputation and experience) of names of ten (10) Judges retired from the Los Angeles Superior Court who are providing services to ADR. Hospital may first strike the name on the list and, thereafter, the parties shall take turns striking names until one name remains, and that person shall be selected as the arbitrator. If for any reason that person cannot serve, the parties shall repeat the process of selection until a qualified arbitrator is selected. The decision of the arbitrator shall be final and binding on the parties to this Agreement, and judgment upon the award rendered may be entered in any court having jurisdiction thereof. Notwithstanding the foregoing (i) either party shall be entitled to obtain injunctive or seek similar relief, including obtaining a Writ of Attachment, by filing a request for immediate action with the Los Angeles Superior Court; and (ii) in the event of an action by or against any third party, any party to this Agreement may join or otherwise proceed against the other party as part of that action or in an action reasonably related to or arising therefrom.

The parties agree that the arbitrator is authorized to decide all issues of arbitrability, and that with the exception of circumstances that require a request for injunctive relief or Writ of Attachment brought to the Superior Court, the arbitrator shall have exclusive jurisdiction of this matter. The parties will share the cost of arbitration and each will bear its own attorneys' fees and expenses.

THE PARTIES CONFIRM THAT EACH OF THEM HEREBY WAIVES ANY RIGHT TO JURY OR COURT TRIAL AND AGREES TO THE PROVISIONS OF THIS SECTION 12.

Hospital _____ *Consultant* _____

13. CHANGE IN LAW

13.1 **Legal Event; Consequences.** Notwithstanding any other provision of this Agreement, if the governmental agencies that administer Medicare, Medi-Cal, federal workers' compensation or any other federal health care program (or their representatives or agents), or any other federal, State or local governmental or nongovernmental agency, accreditation organization or any court or administrative tribunal passes, issues or promulgates any law, rule, regulation, standard, interpretation, order, decision or judgment including, but not limited, to those relating

Hospital _____

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to any regulations pursuant to State or federal anti-kickback or self-referral statutes (collectively or individually, ***"Legal Event"***), which, in the good faith judgment of one party (the ***"Noticing Party"***), materially and adversely affects either party's licensure, accreditation, certification, or ability to refer, to accept any referral, to bill, to claim, to present a claim, or to receive payment or reimbursement from any federal, State or local governmental or private payor, or which subjects the Noticing Party to a risk of prosecution or civil monetary penalty, or which, in the good faith judgment of the Noticing Party, indicates a rule or regulation with which the Noticing Party desires further compliance, then the Noticing Party may give the other party notice of intent to amend or terminate this Agreement in accordance with Section 13.2, below.

13.2 **Notice Requirements.** The Noticing Party shall give notice to the other party setting forth the following information:

13.2.1 The Legal Event giving rise to the notice;

13.2.2 The consequences of the Legal Event as to the Noticing Party;

13.2.3 The Noticing Party's intention to either:

(a) Terminate this Agreement due to unacceptable risk of prosecution or civil monetary penalty; or

(b) Amend this Agreement, together with a statement that the purpose thereof is one or more of the following:

(1) To further comply with any anti-kickback or Stark (I-III) statutory provisions or rules or regulations created or affected by the Legal Event;

(2) To satisfy any licensure, accreditation or certification requirements created or affected by the Legal Event(s); or

(3) To eliminate or minimize the risk of prosecution or civil monetary penalty;

13.2.4 The Noticing Party's proposed amendment(s); and

13.2.5 The Noticing Party's request for commencement of the Renegotiation Period (as defined below).

13.3 **Renegotiation Period; Termination.** In the event of notice under Sections 13.2.3(a) or 13.2.3(b) above, the parties shall have ten (10) days from the giving of such notice (***"Renegotiation Period"***) within which to attempt to amend this Agreement in accordance with the Noticing Party's proposal (if any) or otherwise as the parties may agree. If this Agreement is not so amended within the Renegotiation Period, this Agreement shall terminate as of midnight on the tenth (10th) day after said notice was given. Except as otherwise required by applicable

to any regulations pursuant to State or federal anti-kickback or self-referral statutes (collectively or individually, ***"Legal Event"***), which, in the good faith judgment of one party (the ***"Noticing Party"***), materially and adversely affects either party's licensure, accreditation, certification, or ability to refer, to accept any referral, to bill, to claim, to present a claim, or to receive payment or reimbursement from any federal, State or local governmental or private payor, or which subjects the Noticing Party to a risk of prosecution or civil monetary penalty, or which, in the good faith judgment of the Noticing Party, indicates a rule or regulation with which the Noticing Party desires further compliance, then the Noticing Party may give the other party notice of intent to amend or terminate this Agreement in accordance with Section 13.2, below.

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13.2.1 The Legal Event giving rise to the notice;

13.2.2 The consequences of the Legal Event as to the Noticing Party;

13.2.3 The Noticing Party's intention to either:

(a) Terminate this Agreement due to unacceptable risk of prosecution or civil monetary penalty; or

(b) Amend this Agreement, together with a statement that the purpose thereof is one or more of the following:

(1) To further comply with any anti-kickback or Stark (I-III) statutory provisions or rules or regulations created or affected by the Legal Event;

(2) To satisfy any licensure, accreditation or certification requirements created or affected by the Legal Event(s); or

(3) To eliminate or minimize the risk of prosecution or civil monetary penalty;

13.2.4 The Noticing Party's proposed amendment(s); and

13.2.5 The Noticing Party's request for commencement of the Renegotiation Period (as defined below).

13.3 **Renegotiation Period; Termination.** In the event of notice under Sections 13.2.3(a) or 13.2.3(b) above, the parties shall have ten (10) days from the giving of such notice (***"Renegotiation Period"***) within which to attempt to amend this Agreement in accordance with the Noticing Party's proposal (if any) or otherwise as the parties may agree. If this Agreement is not so amended within the Renegotiation Period, this Agreement shall terminate as of midnight on the tenth (10th) day after said notice was given. Except as otherwise required by applicable

law, any amounts owing to either party hereunder shall be paid up to the date of such termination, and any obligation hereunder that is to continue beyond expiration or termination shall so continue pursuant to its terms. All opinions of legal counsel presented by the Noticing Party hereunder, and any corresponding opinions given by the other party in response, shall be deemed confidential and given solely for purposes of renegotiation and settlement of a potential dispute, and shall not be deemed disclosed so as to waive any privileges otherwise applicable to said opinions.

14. COMPLIANCE WITH APPLICABLE LAWS

14.1. **Compliance with Law**. In the performance of their respective responsibilities and obligations hereunder, Hospital and Consultant shall comply with the requirements of all federal, State and local laws, regulations and ordinances applicable to their respective organizations and activities.

14.2. **Compliance Program**. Consultant shall implement its own internal compliance activities and report to Hospital the results of any compliance reviews or audits that may affect Consultant's provision of Promotion Services.

14.3 **Hospital Audit**. Consultant shall permit Hospital to audit, as reasonably requested, Consultant's Monthly Promotion Services Reports submitted pursuant to Section 7 of this Agreement, and Consultant's cooperation with any compliance program established by Hospital during the term hereof including, without limitation, access to all claim records, data information, and software required by Hospital or Hospital's authorized agent who performs such audit.

14.4 **Survival**. The rights of Hospital pursuant to Section 14.3, above, shall survive the expiration or other termination of this Agreement.

15. TERM, RENEWAL AND TERMINATION

15.1 **Term; Renewal**. The initial term of this Agreement shall be for a period of one (1) year, commencing on the Effective Date and shall automatically renew for successive one-year terms, unless terminated as set forth below.

15.2 **Immediate Termination by Hospital for Cause**. This Agreement may be terminated by Hospital effective immediately upon written notice to Consultant if any of the following events occurs:

15.2.1 Any conduct by Consultant that jeopardizes or places at risk the health, safety or welfare of a patient of the Hospital or that jeopardizes any licenses, certificates or accreditations of Hospital;

15.2.2 Any failure by Consultant to comply with the protocol set forth in Section 2.1 hereof;

Hospital _____

Consultant MG

15.2.3 Any material breach of the representations and warranties contained in Section 3;

15.2.4 A material breach or default by Consultant of any duty, obligation or covenant made by Consultant contained in this Agreement, and such material breach or default is not cured within ten (10) days after the provision of written notice of such breach or default by Hospital;

15.2.5 The failure of Consultant to obtain, maintain or provide evidence of all of the insurance coverage required pursuant to Section 9 hereof;

15.2.6 Breach by Consultant or any Consultant Personnel of any confidentiality provision set forth in Section 2.3;

15.2.7 The conviction of any manager, administrator, officer, director or executive employee or Consultant Personnel of Consultant for any act or acts constituting a felony or misdemeanor involving moral turpitude under the laws of the United States, any state thereof or any foreign jurisdiction;

15.2.8 Consultant's assignment, or attempted assignment, of this Agreement without Hospital's prior written consent;

15.2.9 The closure of Hospital, the cessation of patient care operations, or the sale or transfer of Hospital or all, or substantially all, of its assets or Hospital's decision to cease bariatric surgery at its facility;

15.2.10 Any Legal Event described in Section 13 that is not resolved by the parties pursuant to Section 13;

15.2.11 Any governmental or regulatory agency undertakes any action or requests that a receiver be appointed with respect to the operation of Hospital; or

15.2.12 In the event either party hereto shall (a) apply for or consent to the appointment of a receiver, trustee, liquidator, or similar official for all or a substantial part of such party's assets; (b) admit in writing such party's inability to pay its debts as they come due; (c) make a general assignment for the benefit of creditors; (d) file a petition to answer seeking an order for relief, a reorganization, or an arrangement with creditors or to take advantage of any insolvency law; or (e) otherwise cease to meet its financial obligations in the ordinary course of business.

15.3 **Termination without Cause.** Either party may, in its sole discretion, terminate this Agreement without cause at any time whatsoever upon providing the non-terminating party ten (10) days' prior written notice.

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15.4 **Effect of Termination.**

15.4.1 Subject to compliance of Consultant with the conditions of compensation set forth in Section 8.2, in the event the effective date of any termination of this Agreement falls prior to the last day of any calendar month, Hospital shall pay the Promotion Services Fee for that final month on a pro-rated basis, in addition to payment owed pursuant to this Agreement, if any, for Promotion Services prior to the final month no later than forty-five (45) days after the effective date of termination.

15.4.2 In the event of termination, Consultant shall provide a final accounting, as of the effective date of termination, to be delivered as soon as reasonably possible, but in no event later than forty-five (45) days after the effective date of termination.

15.4.3 Consultant shall prepare and deliver to Hospital all books, records, computer disks and all other documentation relating to Hospital, and/or Promotion Services, regardless of the form in which such documentation is stored, within forty-five (45) days of the effective date of termination.

16. **MISCELLANEOUS PROVISIONS.**

16.1 **Notice.** Any notice or other communications required or permitted hereunder shall be sufficient if given in writing and delivered either personally or by overnight delivery service *and* also a courtesy copy shall be simultaneously sent by facsimile. All notices or demands must be given at the following addresses and fax numbers or such other addresses and/or fax numbers as may from time to time be designated by notice given as aforesaid and delivered as set forth below:

If to Hospital:
Tri-City Regional Medical Center
21530 South Pioneer Boulevard
Hawaiian Gardens, California 90716
Attention: President/CEO
Facsimile: (562) 860-0401

With a copy to:
Selvin & Weiner, APC
12401 Wilshire Boulevard, Suite 200
Los Angeles, California 90025-1015
Attention: Beryl Weiner, Esq.
Facsimile: (310) 207-3666

If to Consultant:
Comprehensive Intra-Operative Services, Inc.
4130 Flat Rock Dr. #150
Riverside, California 92505
Facsimile: (951) 352-4843
Attn: Michael P. McGrath

16.2. **No Implied Waiver of Breach.** Any waiver of any term and condition hereof must be in writing and signed by the waiving party. A party's neglect or failure in any case or circumstance to require performance of the other party's obligations or to enforce its rights in the event of a breach by the other party shall not affect such party's right to enforce such rights and obligations in any other case or circumstance. A waiver of any individual term or condition shall not be construed as a waiver of any other term or condition nor, unless so provided in such written waiver, of the term or condition thereby waived in the event of a future or continuing breach by the other party, except in the particular circumstance(s) in or for which such waiver was provided.

16.3. **Succession.** This Agreement applies to, inures to the benefit of and binds all parties hereto, their heirs, devisees, legatees, executors, administrators, representatives, successors and assigns. Neither party may assign, delegate or otherwise transfer all or any part of its rights and obligations under this Agreement without the express prior written consent of the other.

16.4 **Severability.** Should any one or more provisions of this Agreement be determined to be invalid or void, the balance of the provisions shall, nevertheless, remain in full force and effect.

16.5 **Time is of the Essence.** Time is strictly of the essence under this Agreement and any amendment, modification or revision hereof.

16.6 **Authorized Signators.** Each individual executing this Agreement on behalf of an entity represents and warrants that he or she is duly authorized by that entity to execute and deliver this Agreement on behalf of each respective entity in accordance with the governing and/or formation documents of said entity, and that all representations and warranties contained in this Agreement, or any documents referenced in this Agreement, are true and correct.

16.7 **Independent Counsel.** Each party who is a signatory to this Agreement hereby acknowledges that he or it has had the opportunity to be represented by independent counsel of its own choice throughout all of the negotiations which preceded the execution of this Agreement, and that it has executed this Agreement freely, voluntarily and without any coercion whatsoever, with the consent and upon the advice of such independent counsel, or having knowingly waived the opportunity to obtain such advice. Each party further acknowledges that it and its counsel, if any, have had adequate opportunity to make whatever investigation or inquiry deemed necessary or desirable in connection with the subject matter of this Agreement prior to the execution hereof and the delivery and acceptance of the considerations specified herein and that each of them has reviewed such documents and information that it deems necessary or appropriate concerning this Agreement. Each party hereto acknowledges that this Agreement has been drafted as a result of negotiations between the parties, and that its terms and provisions should be interpreted in accordance with their fair meaning and not in favor or against any one party.

16.8 **Entire Agreement.** This Agreement, including the recitals, schedules and exhibits attached hereto constitute the entire agreement of the parties with respect to the subject matter

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Consultant MG

hereof, and supersedes all prior understandings or agreements, whether written or oral, with respect to the subject matter hereof. All recitals, exhibits and schedules referred to in this Agreement are an integral part of this Agreement. They are incorporated in this Agreement by this reference as though at this point set forth in full.

16.9 **Third Party Rights.** This Agreement shall not be construed as conferring upon any third party any right or benefit, and any and all claims that may arise hereunder may be enforced solely by Hospital or Consultant.

16.10 **Force Majeure.** Neither party shall be liable nor deemed to be in default for any delay or failure in performance under this Agreement or other interruption of service deemed resulting, directly or indirectly, from acts of God, civil or military authority, acts of public enemy, war, accidents, fires, explosions, earthquakes, floods, failure of transportation, machinery or supplies, vandalism, strikes or other work interruptions beyond the reasonable control of either party. However, both parties shall make good faith efforts to perform under this Agreement in the event of any such circumstances.

16.11 **Further Assurances.** Each party hereto shall furnish such information, execute such documents and take such action as the other party reasonably may request for the purpose of carrying out the intent of this Agreement.

16.12 **Captions and Headings.** The captions and headings throughout this Agreement are for convenience and reference only, and shall in no way be held or deemed to define, limit, describe, explain, modify, amplify or add to the interpretation, construction or meaning of any provision or to the scope or intent of this Agreement or in any other way affect the Agreement.

16.13 **Remedies.** The various rights and remedies provided for herein shall be cumulative and in addition to any other rights and remedies the parties may be entitled to pursue under the law. The exercise of one or more of such rights or remedies will not impair the rights of either party to exercise any other right or remedy at law or in equity.

16.14 **Assignment; Binding Effect.** Hospital may assign this Agreement to any affiliate or subsidiary of Hospital or to any successor of all, or substantially all, of Hospital's operating assets. Consultant shall not assign or transfer, in whole or in part, this Agreement or any of Consultant's rights under this Agreement, without the prior written consent of Hospital, and any assignment or transfer by Consultant without such consent shall be null and void. Further, any assignment or attempted assignment in violation of this Section 16.14 shall give Hospital the right to terminate this Agreement immediately pursuant to Section 15, above.

16.15 **Subcontracting.** If approved by Hospital in advance in writing, Consultant shall be permitted to subcontract for the provision of Promotion Services: *provided, that* Consultant shall (a) cause each such subcontractor to comply with all applicable terms of this Agreement including, without limitation, Sections 2,3,7, and 14; (b) be responsible for the conduct of each such subcontractor and the performance of all of Promotion Services, including Promotion Services performed by such subcontractor; and (c) be responsible for paying all of each such

subcontractors' fees and expenses, without additional charge whatsoever to Hospital beyond the Promotion Services Fee specified in this Agreement.

16.16 **Amendment**. This Agreement shall not be modified or amended except by a written document executed by both parties.

16.17 **Counterparts**. This Agreement may be executed in counterparts, each of which shall be deemed to be an original but which, together, shall constitute but one and the same instrument.

CONSULTANT HAS READ THIS AGREEMENT IN ITS ENTIRETY, HAS HAD THE OPPORTUNITY TO OBTAIN THE ADVICE OF LEGAL COUNSEL AS TO THE MEANING OF ITS CONTENTS, AND FREELY ENTERS INTO AND EXECUTES THIS AGREEMENT, INTENDING TO BE BOUND BY THE PROVISIONS HEREOF.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the Effective Date set forth above.

"HOSPITAL"
Gardens Regional Hospital and Medical Center, Inc.,
a California nonprofit corporation d/b/a Tri-City Regional Medical Center

By: _____
CLIFFORD SHIEPE
SENIOR VICE PRESIDENT

"CONSULTANT"
Comprehensive Intra-Operative Services, Inc.
a California corporation

By: _____
MICHAEL P. MCGRATH
PRESIDENT
E.I.N. 68-0490904

Hospital _____

Consultant MCG

EXHIBIT A

SCOPE OF SERVICE: SUMMARY OF PROMOTION SERVICES

In consultation and collaboration with Hospital, and subject to approval by Hospital, Consultant shall develop, implement and conduct a comprehensive business development and promotion campaign on behalf of Hospital directed at interested parties, including chiropractic and orthopedic medical practice professionals in Southern California, whose patients may benefit from the services and treatments available at Hospital, incorporating the following goals and activities:

1. Enhance the visibility and promote the image, reputation and accessibility, by all proper and appropriate means, of Hospital's facility, medical staff and clinical programs pertaining to orthopedics, spinal diseases/injuries, pain management and workers' compensation (collectively, "***Hospital Services***") with Consultant's network of chiropractors and orthopedic specialists in Los Angeles and Riverside counties.

2. Introduce and promote the availability of Hospital Services for treatment of workers' compensation and personal injuries on a lien basis as well as Hospital's experience with intake, documentation, verification and other issues associated with such treatments.

3. Disseminate marketing materials and other information related to Hospital Services; Hospital shall bear full responsibility and expense to produce and provide such materials to Consultant if Hospital desires for Consultant to disseminate such materials.

4. Establish appropriate links and relationships, on Hospital's behalf, with various groups, institutions and organizations involved in provision of orthopedic or chiropractic services in Los Angeles and Riverside counties.

5. At Consultant's discretion and with Hospital's approval, represent Hospital at health fairs, health screenings, trade shows, educational symposiums, conventions and/or other community outreach forums to enhance Hospital's visibility and develop business opportunities for Hospital's facility, medical staff and Hospital Services.

6. Assist Hospital to secure authorizations for contract patients; assist Hospital with billing and collection services; periodically review billing and collections for workers' compensation and other relevant programs; assist Hospital to optimize reimbursements and collections; verify that reimbursements are in accordance with contract terms.

7. Conduct regular follow up visits and communications, determine level of satisfaction with Hospital Services, perform satisfaction analyses, assist with problem solving and QA review, and the like.

Hospital ~~[illegible]~~

Consultant MCG

8. Consultant shall report directly to the CEO and/or to any other party designated by the CEO in connection with the performance of its duties under this Agreement and shall fulfill all other duties reasonably requested by Hospital and agreed to by Consultant.

Hospital _____

Consultant MCG

EXHIBIT 3

INDEPENDENT CONTRACTOR AGREEMENT

THIS INDEPENDENT CONTRACTOR AGREEMENT ("AGREEMENT") IS MADE AND EFFECTIVE THIS OCTOBER . 1ST 2002, BY AND BETWEEN MANIR UWAYDAH MD.("CONSULTANT") AND SPINELINE USA INC.("COMPANY").

NOW, THEREFORE, CONSULTANT AND COMPANY AGREE AS FOLLOWS:

1. ENGAGEMENT.
COMPANY HEREBY ENGAGES CONSULTANT, AND CONSULTANT ACCEPTS ENGAGEMENT, TO PROVIDE TO COMPANY THE FOLLOWING SERVICES:

USE OF INTRA-OPERATIVE MEDICAL DEVICE REQUIRED FOR ALIF/PLIF, POSTERIOR LUMBAR FUSIONS, (PROCEDURES), DEVELOPMENT OF SUCH DEVICES AND NECESSARY INSTRUMENTATION REQUIRED TO PERFORM SAID PROCEDURES. DEVELOPMENT OF INTRA-OPERATIVE TECHNIQUE AND SUBSEQUENT CLINICAL DATA COLLECTION.

2. TERM.
CONSULTANT SHALL PROVIDE SERVICES TO COMPANY PURSUANT TO THIS AGREEMENT FOR A TERM COMMENCING ON OCTOBER 1ST, 2002 AND ENDING ON SEPTEMBER 30TH, 2003.

3. PLACE OF WORK.
CONSULTANT SHALL RENDER SERVICES PRIMARILY AT PRE-DETERMINED MEDICAL FACILITY, WHEREBY SUCH PROCEDURES ARE COMMONLY PERFORMED, BUT WILL BE WILLING TO UPON REQUEST USE SERVICES AT SUCH OTHER PLACES AS REASONABLY REQUESTED BY COMPANY AS APPROPRIATE FOR THE PERFORMANCE OF PARTICULAR SERVICES.

4. TIME.
CONSULTANT'S DAILY SCHEDULE AND HOURS WORKED UNDER THIS AGREEMENT ON A GIVEN DAY SHALL GENERALLY BE SUBJECT TO CONSULTANT'S DISCRETION, PROVIDED THAT CONSULTANT AND COMPANY ANTICIPATE THAT CONSULTANT SHALL WORK AS REQUIRED PROCEDURES ALLOW IN THE ENGAGEMENT OF TASKS STATED IN SECTION 1. ENGAGEMENT ABOVE. COMPANY RELIES UPON CONSULTANT TO DEVOTE SUFFICIENT TIME AS IS REASONABLY NECESSARY TO FULFILL THE SPIRIT AND PURPOSE OF THIS AGREEMENT.

5. PAYMENT. 120,000.00
COMPANY SHALL PAY CONSULTANT UP TO $~~100,000~~ .00 PER ANNUM FOR SERVICES PERFORMED PURSUANT TO THIS AGREEMENT. PAYMENT SHALL BE MADE QUARTERLY, 30 DAYS PAST EACH CALENDAR MONTH. CONSULTANT SHALL BEAR ALL OF CONSULTANT'S EXPENSES INCURRED IN THE PERFORMANCE OF THIS AGREEMENT.

monthly

6. COVENANT NOT TO COMPETE.
DURING THE TERM OF THIS AGREEMENT ~~AND FOR A PERIOD OF 1 YEAR THEREAFTER~~, CONSULTANT SHALL NOT WITHIN AMERICAN MEDICAL TERRITORY, DIRECTLY OR INDIRECTLY, EITHER FOR HIS OWN ACCOUNT, OR AS A PARTNER, SHAREHOLDER, OFFICER, DIRECTOR, EMPLOYEE, AGENT OR OTHERWISE; OWN, MANAGE, OPERATE, CONTROL, BE EMPLOYED BY, PARTICIPATE IN, CONSULT WITH, PERFORM SERVICES FOR, OR OTHERWISE BE CONNECTED WITH ANY BUSINESS THE SAME AS OR SIMILAR TO THE BUSINESS CONDUCTED BY COMPANY. IN THE EVENT ANY OF THE PROVISIONS OF THIS SECTION 6 ARE DETERMINED TO BE INVALID BY REASON OF THEIR SCOPE OR DURATION, THIS SECTION 6 SHALL BE DEEMED MODIFIED TO THE EXTENT REQUIRED TO CURE THE

INDEPENDENT CONTRACTOR AGREEMENT

THIS INDEPENDENT CONTRACTOR AGREEMENT ("AGREEMENT") IS MADE AND EFFECTIVE THIS OCTOBER, 1ST 2002, BY AND BETWEEN MANIR UWAYDAH MD. ("CONSULTANT") AND SPINE-LINE USA INC, ("COMPANY").

NOW, THEREFORE, CONSULTANT AND COMPANY AGREE AS FOLLOWS:

1. ENGAGEMENT.
COMPANY HEREBY ENGAGES CONSULTANT, AND CONSULTANT ACCEPTS ENGAGEMENT, TO PROVIDE TO COMPANY THE FOLLOWING SERVICES:

USE OF INTRA-OPERATIVE MEDICAL DEVICE REQUIRED FOR ALIF/PLIF, POSTERIOR LUMBAR FUSIONS, (PROCEDURES), DEVELOPMENT OF SUCH DEVICES AND NECESSARY INSTRUMENTATION REQUIRED TO PERFORM SAID PROCEDURES. DEVELOPMENT OF INTRA-OPERATIVE TECHNIQUE AND SUBSEQUENT CLINICAL DATA COLLECTION.

2. TERM.
CONSULTANT SHALL PROVIDE SERVICES TO COMPANY PURSUANT TO THIS AGREEMENT FOR A TERM COMMENCING ON OCTOBER 1ST, 2002 AND ENDING ON SEPTEMBER 30TH, 2003.

3. PLACE OF WORK.
CONSULTANT SHALL RENDER SERVICES PRIMARILY AT PRE-DETERMINED MEDICAL FACILITY, WHEREBY SUCH PROCEDURES ARE COMMONLY PERFORMED, BUT WILL BE WILLING TO UPON REQUEST USE SERVICES AT SUCH OTHER PLACES AS REASONABLY REQUESTED BY COMPANY AS APPROPRIATE FOR THE PERFORMANCE OF PARTICULAR SERVICES.

4. TIME.
CONSULTANT'S DAILY SCHEDULE AND HOURS WORKED UNDER THIS AGREEMENT ON A GIVEN DAY SHALL GENERALLY BE SUBJECT TO CONSULTANT'S DISCRETION, PROVIDED THAT CONSULTANT AND COMPANY ANTICIPATE THAT CONSULTANT SHALL WORK AS REQUIRED PROCEDURES ALLOW IN THE ENGAGEMENT OF TASKS STATED IN SECTION 1. ENGAGEMENT ABOVE. COMPANY RELIES UPON CONSULTANT TO DEVOTE SUFFICIENT TIME AS IS REASONABLY NECESSARY TO FULFILL THE SPIRIT AND PURPOSE OF THIS AGREEMENT.

5. PAYMENT.
COMPANY SHALL PAY CONSULTANT $100,000.00 PER ANNUM FOR SERVICES PERFORMED PURSUANT TO THIS AGREEMENT. PAYMENT SHALL BE MADE MONTHLY. 30 DAYS PAST EACH CALENDAR MONTH. CONSULTANT SHALL BEAR ALL OF CONSULTANT'S EXPENSES INCURRED IN THE PERFORMANCE OF THIS AGREEMENT.

6. COVENANT NOT TO COMPETE.
DURING THE TERM OF THIS AGREEMENT AND FOR A PERIOD OF 1 YEAR THEREAFTER, CONSULTANT SHALL NOT WITHIN SPINE-LINE USA INC, TERRITORY, DIRECTLY OR INDIRECTLY, EITHER FOR HIS OWN ACCOUNT, OR AS A PARTNER, SHAREHOLDER, OFFICER, DIRECTOR, EMPLOYEE, AGENT OR OTHERWISE; OWN, MANAGE, OPERATE, CONTROL, BE EMPLOYED BY, PARTICIPATE IN, CONSULT WITH, PERFORM SERVICES FOR, OR OTHERWISE BE CONNECTED WITH ANY BUSINESS THE SAME AS OR SIMILAR TO THE BUSINESS CONDUCTED BY COMPANY. IN THE EVENT ANY OF THE PROVISIONS OF THIS SECTION 6 ARE DETERMINED TO BE INVALID BY REASON OF THEIR SCOPE OR DURATION, THIS SECTION 6 SHALL BE DEEMED MODIFIED TO THE EXTENT REQUIRED TO CURE THE INVALIDITY. IN THE EVENT OF A BREACH, OR A THREATENED BREACH, OF THIS SECTION 6,

COMPANY SHALL BE ENTITLED TO OBTAIN AN INJUNCTION RESTRAINING THE COMMITMENTS OR CONTINUANCE OF THE BREACH, AS WELL AS ANY OTHER LEGAL OR EQUITABLE REMEDIES PERMITTED BY LAW.

7. CONFIDENTIALITY.

DURING THE TERM OF THIS AGREEMENT,) CONSULTANT SHALL NOT, WITHOUT THE PRIOR WRITTEN CONSENT OF COMPANY, DISCLOSE TO ANYONE ANY CONFIDENTIAL INFORMATION. "CONFIDENTIAL INFORMATION" FOR THE PURPOSES OF THIS AGREEMENT SHALL INCLUDE COMPANY'S PROPRIETARY AND CONFIDENTIAL INFORMATION SUCH AS, BUT NOT LIMITED TO, CUSTOMER LISTS, BUSINESS PLANS, MARKETING PLANS, FINANCIAL INFORMATION, DESIGNS, DRAWING, SPECIFICATIONS, MODELS, SOFTWARE, SOURCE CODES AND OBJECT CODES. CONFIDENTIAL INFORMATION SHALL NOT INCLUDE ANY INFORMATION THAT:

A. IS DISCLOSED BY COMPANY WITHOUT RESTRICTION;

B. BECOMES PUBLICLY AVAILABLE THROUGH NO ACT OF CONSULTANT;

C. IS RIGHTFULLY RECEIVED BY CONSULTANT FROM A THIRD PARTY.

8. TERMINATION.

A. THIS AGREEMENT MAY BE TERMINATED BY COMPANY AS FOLLOWS:

I. IF CONSULTANT IS UNABLE TO PROVIDE THE CONSULTING SERVICES BY REASON OF TEMPORARY OR PERMANENT ILLNESS, DISABILITY, INCAPACITY OR DEATH.

II. BREACH OR DEFAULT OF ANY OBLIGATION OF CONSULTANT PURSUANT TO SECTION 6, COVENANT NOT TO COMPETE, OR SECTION 7, CONFIDENTIALITY, OF THIS AGREEMENT.

III. BREACH OR DEFAULT BY CONSULTANT OF ANY OTHER MATERIAL OBLIGATION IN THIS AGREEMENT, WHICH BREACH OR DEFAULT IS NOT CURED WITHIN FIVE (5) DAYS OF WRITTEN NOTICE FROM COMPANY.

B. CONSULTANT MAY TERMINATE THIS AGREEMENT AS FOLLOWS:

I. BREACH OR DEFAULT OF ANY MATERIAL OBLIGATION OF COMPANY, WHICH BREACH OR DEFAULT IS NOT CURED WITHIN FIVE (5) DAYS OF WRITTEN NOTICE FROM CONSULTANT.

II. IF COMPANY FILES PROTECTION UNDER THE FEDERAL BANKRUPTCY LAWS, OR ANY BANKRUPTCY PETITION OR PETITION FOR RECEIVER IS COMMENCED BY A THIRD PARTY AGAINST COMPANY, ANY OF THE FOREGOING OF WHICH REMAINS UNDISMISSED FOR A PERIOD OF SIXTY (60) DAYS.

9. INDEPENDENT CONTRACTOR.

CONSULTANT IS AND THROUGHOUT THIS AGREEMENT SHALL BE AN INDEPENDENT CONTRACTOR AND NOT AN EMPLOYEE, PARTNER OR AGENT OF COMPANY. CONSULTANT SHALL NOT BE ENTITLED TO NOR RECEIVE ANY BENEFIT NORMALLY PROVIDED TO COMPANY'S EMPLOYEES SUCH AS, BUT NOT LIMITED TO, VACATION PAYMENT, RETIREMENT, HEALTH CARE OR SICK PAY. COMPANY SHALL NOT BE RESPONSIBLE FOR WITHHOLDING INCOME OR OTHER TAXES FROM THE PAYMENTS MADE TO CONSULTANT. CONSULTANT SHALL BE SOLELY RESPONSIBLE FOR FILING ALL RETURNS AND PAYING ANY INCOME, SOCIAL SECURITY OR OTHER TAX LEVIED UPON OR DETERMINED WITH RESPECT TO THE PAYMENTS MADE TO CONSULTANT PURSUANT TO THIS AGREEMENT.

10. TOOLS AND SUPPLIES.
UNLESS OTHERWISE AGREED TO BY COMPANY IN ADVANCE, CONSULTANT SHALL BE SOLELY RESPONSIBLE FOR PROCURING, PAYING FOR AND MAINTAINING ANY COMPUTER EQUIPMENT, SOFTWARE, PAPER, TOOLS OR SUPPLIES NECESSARY OR APPROPRIATE FOR THE PERFORMANCE OF CONSULTANT'S SERVICES HEREUNDER.

11. CONTROLLING LAW.
THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA.

12. HEADINGS.
THE HEADINGS IN THIS AGREEMENT ARE INSERTED FOR CONVENIENCE ONLY AND SHALL NOT BE USED TO DEFINE, LIMIT OR DESCRIBE THE SCOPE OF THIS AGREEMENT OR ANY OF THE OBLIGATIONS HEREIN.

13. FINAL AGREEMENT.
THIS AGREEMENT CONSTITUTES THE FINAL UNDERSTANDING AND AGREEMENT BETWEEN THE PARTIES WITH RESPECT TO THE SUBJECT MATTER HEREOF AND SUPERSEDES ALL PRIOR NEGOTIATIONS, UNDERSTANDINGS AND AGREEMENTS BETWEEN THE PARTIES, WHETHER WRITTEN OR ORAL. THIS AGREEMENT MAY BE AMENDED, SUPPLEMENTED OR CHANGED ONLY BY AN AGREEMENT IN WRITING SIGNED BY BOTH OF THE PARTIES.

14. NOTICES.
ANY NOTICE REQUIRED TO BE GIVEN OR OTHERWISE GIVEN PURSUANT TO THIS AGREEMENT SHALL BE IN WRITING AND SHALL BE HAND DELIVERED, MAILED BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED OR SENT BY RECOGNIZED OVERNIGHT COURIER SERVICE AS FOLLOWS:

IF TO CONSULTANT:

MANIR UWAYDAH MD_____

DATE:_____

IF TO COMPANY:

ROGER WILLIAMS_____ MIC MCGRATH_____

SPINE-LINE USA, INC.

DATE:_____

15. SEVERABILITY.

IF ANY TERM OF THIS AGREEMENT IS HELD BY A COURT OF COMPETENT JURISDICTION TO BE INVALID OR UNENFORCEABLE, THEN THIS AGREEMENT, INCLUDING ALL OF THE REMAINING TERMS, WILL REMAIN IN FULL FORCE AND EFFECT AS IF SUCH INVALID OR UNENFORCEABLE TERM HAD NEVER BEEN INCLUDED.

IN WITNESS WHEREOF, THIS AGREEMENT HAS BEEN EXECUTED BY THE PARTIES AS OF THE DATE FIRST ABOVE WRITTEN.

_____	BY: _____
MANIR UWAYDAH MD	ROGER WILLIAMS MIC MCGRATH SPINE-LINE USA INC,
DATE:_____	DATE:_____

INDEPENDENT CONTRACTOR AGREEMENT

THIS INDEPENDENT CONTRACTOR AGREEMENT ("AGREEMENT") IS MADE AND EFFECTIVE THIS MAY 1ST, 2002, BY AND BETWEEN SUNNY UPPAL MD. ("CONSULTANT") AND CIOSERVICES INC, ("COMPANY").

NOW, THEREFORE, CONSULTANT AND COMPANY AGREE AS FOLLOWS:

1. ENGAGEMENT.
COMPANY HEREBY ENGAGES CONSULTANT, AND CONSULTANT ACCEPTS ENGAGEMENT, TO PROVIDE TO COMPANY THE FOLLOWING SERVICES:

DEVELOPMENT OF PEDICLE SCREW FIXATION SYSTEM ("RELIANCE") PEDICLE SCREW FIXATION SYSTEM FOR USE INTRA-OPERATIVELY ON POSTERIOR LUMBAR FIXATION PROCEDURES.

2. TERM.
CONSULTANT SHALL PROVIDE SERVICES TO COMPANY PURSUANT TO THIS AGREEMENT FOR A TERM COMMENCING ON MAY 1ST, 2002 AND ENDING ON MAY 1ST, 2003.

3. PLACE OF WORK.
CONSULTANT SHALL RENDER SERVICES PRIMARILY AT PRE-DETERMINED MEDICAL FACILITY, WHEREBY SUCH PROCEDURES ARE COMMONLY PERFORMED, BUT WILL BE WILLING TO UPON REQUEST USE SERVICES AT SUCH OTHER PLACES AS REASONABLY REQUESTED BY COMPANY AS APPROPRIATE FOR THE PERFORMANCE OF PARTICULAR SERVICES.

4. TIME.
CONSULTANT'S DAILY SCHEDULE AND HOURS WORKED UNDER THIS AGREEMENT ON A GIVEN DAY SHALL GENERALLY BE SUBJECT TO CONSULTANT'S DISCRETION, PROVIDED THAT CONSULTANT AND COMPANY ANTICIPATE THAT CONSULTANT SHALL WORK AS REQUIRED PROCEDURES ALLOW IN THE ENGAGEMENT OF TASKS STATED IN SECTION 1. ENGAGEMENT ABOVE. COMPANY RELIES UPON CONSULTANT TO DEVOTE SUFFICIENT TIME AS IS REASONABLY NECESSARY TO FULFILL THE SPIRIT AND PURPOSE OF THIS AGREEMENT.

5. PAYMENT.
COMPANY SHALL PAY CONSULTANT $100,000.00 FOR SERVICES PERFORMED PURSUANT TO THIS AGREEMENT. PAYMENT SHALL BE MADE IN FOUR EQUAL PAYMENTS OF $25,000.00, 30 DAYS IN ARREARS PAST EACH CALENDAR QUARTER. CONSULTANT SHALL BEAR ALL OF CONSULTANT'S EXPENSES INCURRED IN THE PERFORMANCE OF THIS AGREEMENT.

6. CONFIDENTIALITY.
DURING THE TERM OF THIS AGREEMENT, AND THEREAFTER FOR A PERIOD OF TWO (2) YEARS, CONSULTANT SHALL NOT, WITHOUT THE PRIOR WRITTEN CONSENT OF COMPANY, DISCLOSE TO ANYONE ANY CONFIDENTIAL INFORMATION. "CONFIDENTIAL INFORMATION" FOR THE PURPOSES OF THIS AGREEMENT SHALL INCLUDE COMPANY'S PROPRIETARY AND CONFIDENTIAL INFORMATION SUCH AS, BUT NOT LIMITED TO, CUSTOMER LISTS, BUSINESS PLANS, MARKETING PLANS, FINANCIAL INFORMATION, DESIGNS, DRAWING, SPECIFICATIONS, MODELS, SOFTWARE, SOURCE CODES AND OBJECT CODES.

CONFIDENTIAL INFORMATION SHALL NOT INCLUDE ANY INFORMATION THAT:

A. IS DISCLOSED BY COMPANY WITHOUT RESTRICTION;

B. BECOMES PUBLICLY AVAILABLE THROUGH NO ACT OF CONSULTANT;

C. IS RIGHTFULLY RECEIVED BY CONSULTANT FROM A THIRD PARTY.

7. TERMINATION.

A. THIS AGREEMENT MAY BE TERMINATED BY COMPANY AS FOLLOWS:

I. IF CONSULTANT IS UNABLE TO PROVIDE THE CONSULTING SERVICES BY REASON OF TEMPORARY OR PERMANENT ILLNESS, DISABILITY, INCAPACITY OR DEATH.

II. BREACH OR DEFAULT OF ANY OBLIGATION OF CONSULTANT PURSUANT TO SECTION 6, COVENANT NOT TO COMPETE, OR SECTION 7, CONFIDENTIALITY, OF THIS AGREEMENT.

III. BREACH OR DEFAULT BY CONSULTANT OF ANY OTHER MATERIAL OBLIGATION IN THIS AGREEMENT, WHICH BREACH OR DEFAULT IS NOT CURED WITHIN FIVE (5) DAYS OF WRITTEN NOTICE FROM COMPANY.

B. CONSULTANT MAY TERMINATE THIS AGREEMENT AS FOLLOWS:

I. BREACH OR DEFAULT OF ANY MATERIAL OBLIGATION OF COMPANY, WHICH BREACH OR DEFAULT IS NOT CURED WITHIN FIVE (5) DAYS OF WRITTEN NOTICE FROM CONSULTANT.

II. IF COMPANY FILES PROTECTION UNDER THE FEDERAL BANKRUPTCY LAWS, OR ANY BANKRUPTCY PETITION OR PETITION FOR RECEIVER IS COMMENCED BY A THIRD PARTY AGAINST COMPANY, ANY OF THE FOREGOING OF WHICH REMAINS UNDISMISSED FOR A PERIOD OF SIXTY (60) DAYS.

8. INDEPENDENT CONTRACTOR.

CONSULTANT IS AND THROUGHOUT THIS AGREEMENT SHALL BE AN INDEPENDENT CONTRACTOR AND NOT AN EMPLOYEE, PARTNER OR AGENT OF COMPANY. CONSULTANT SHALL NOT BE ENTITLED TO NOR RECEIVE ANY BENEFIT NORMALLY PROVIDED TO COMPANY'S EMPLOYEES SUCH AS, BUT NOT LIMITED TO, VACATION PAYMENT, RETIREMENT, HEALTH CARE OR SICK PAY. COMPANY SHALL NOT BE RESPONSIBLE FOR WITHHOLDING INCOME OR OTHER TAXES FROM THE PAYMENTS MADE TO CONSULTANT. CONSULTANT SHALL BE SOLELY RESPONSIBLE FOR FILING ALL RETURNS AND PAYING ANY INCOME, SOCIAL SECURITY OR OTHER TAX LEVIED UPON OR DETERMINED WITH RESPECT TO THE PAYMENTS MADE TO CONSULTANT PURSUANT TO THIS AGREEMENT.

9. TOOLS AND SUPPLIES.

UNLESS OTHERWISE AGREED TO BY COMPANY IN ADVANCE, CONSULTANT SHALL BE SOLELY RESPONSIBLE FOR PROCURING, PAYING FOR AND MAINTAINING ANY COMPUTER EQUIPMENT, SOFTWARE, PAPER, TOOLS OR SUPPLIES NECESSARY OR APPROPRIATE FOR THE PERFORMANCE OF CONSULTANT'S SERVICES HEREUNDER.

10. CONTROLLING LAW.

THIS AGREEMENT SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF CALIFORNIA.

11. HEADINGS.

THE HEADINGS IN THIS AGREEMENT ARE INSERTED FOR CONVENIENCE ONLY AND SHALL

NOT BE USED TO DEFINE, LIMIT OR DESCRIBE THE SCOPE OF THIS AGREEMENT OR ANY OF THE OBLIGATIONS HEREIN.

12. FINAL AGREEMENT.
THIS AGREEMENT CONSTITUTES THE FINAL UNDERSTANDING AND AGREEMENT BETWEEN THE PARTIES WITH RESPECT TO THE SUBJECT MATTER HEREOF AND SUPERSEDES ALL PRIOR NEGOTIATIONS, UNDERSTANDINGS AND AGREEMENTS BETWEEN THE PARTIES, WHETHER WRITTEN OR ORAL. THIS AGREEMENT MAY BE AMENDED, SUPPLEMENTED OR CHANGED ONLY BY AN AGREEMENT IN WRITING SIGNED BY BOTH OF THE PARTIES.

13. NOTICES.
ANY NOTICE REQUIRED TO BE GIVEN OR OTHERWISE GIVEN PURSUANT TO THIS AGREEMENT SHALL BE IN WRITING AND SHALL BE HAND DELIVERED, MAILED BY CERTIFIED MAIL, RETURN RECEIPT REQUESTED OR SENT BY RECOGNIZED OVERNIGHT COURIER SERVICE AS FOLLOWS:

IF TO CONSULTANT:
SUNNY UPPAL MD.
6800 BROCKTON AVE
RIVERSIDE CA 92506

IF TO COMPANY:
CIOSERVICES INC,
2378 KEUSDER WAY
RIVERSIDE, CA 92503

14. SEVERABILITY.
IF ANY TERM OF THIS AGREEMENT IS HELD BY A COURT OF COMPETENT JURISDICTION TO BE INVALID OR UNENFORCEABLE, THEN THIS AGREEMENT, INCLUDING ALL OF THE REMAINING TERMS, WILL REMAIN IN FULL FORCE AND EFFECT AS IF SUCH INVALID OR UNENFORCEABLE TERM HAD NEVER BEEN INCLUDED.

IN WITNESS WHEREOF, THIS AGREEMENT HAS BEEN EXECUTED BY THE PARTIES AS OF THE DATE FIRST ABOVE WRITTEN.

CIOSERVICES INC

_____
SUNNY UPPAL MD.

BY: _____
MIC P MCGRTAH
PRESIDENT

INDEPENDENT CONTRACTOR AGREEMENT

This Independent Contractor Agreement ("Agreement") is made and effective this 1-1-03, by and between [redacted] ("Consultant") and SEE #14 ("Company").

Now, therefore, Consultant and Company agree as follows:

1. **Engagement.**
Company hereby engages Consultant, and Consultant accepts engagement, to provide to Company the following services:
PEDICLE SCREW, GRAFT MATERIAL, ANTERIOR LUMBAR CAGE CERVICAL GRAFT, CERVICAL PLATE, [redacted]. POST-OP DME.

2. **Term.**
Consultant shall provide services to Company pursuant to this Agreement for a term commencing on and ending on

3. **Place of Work.**
Consultant shall render services primarily at Consultant's offices, but will, upon request, provide the services at Company offices or such other places as reasonably requested by Company as appropriate for the performance of particular services.

4. **Time.**
Consultant's daily schedule and hours worked under this Agreement on a given day shall generally be subject to Consultant's discretion, provided that Consultant and Company anticipate that Consultant shall work on average _____ hours per week in the performance of services pursuant to this Agreement. Company relies upon Consultant to devote sufficient time as is reasonably necessary to fulfill the spirit and purpose of this Agreement.

5. **Payment.**
Company shall pay Consultant 130 K for services performed $ 32.5K per QTR pursuant to this Agreement. Payment shall be made QUARTERLY. Consultant shall bear all of Consultant's expenses incurred in the performance of this Agreement.

6. **Covenant Not to Compete.**

During the term of this Agreement and for a period of _____ thereafter, Consultant shall not within _____, directly or indirectly, either for his own account, or as a partner, shareholder, officer, director, employee, agent or otherwise; own, manage, operate, control, be employed by, participate in, consult with, perform services for, or otherwise be connected with any business the same as or similar to the business conducted by Company. In the event any of the provisions of this Section 6 are determined to be invalid by reason of their scope or duration, this Section 6 shall be deemed modified to the extent required to cure the invalidity. In the event of a breach, or a threatened breach, of this Section 6, Company shall be entitled to obtain an injunction restraining the commitments or continuance of the breach, as well as any other legal or equitable remedies permitted by law.

7. **Confidentiality.**
During the term of this Agreement, and thereafter 1 yr., Consultant shall not, without the prior written consent of Company, disclose to anyone any Confidential Information. "Confidential Information" for the purposes of this Agreement shall include Company's proprietary and confidential information such as, but not limited to, customer lists, business plans, marketing plans, financial information, designs, drawing, specifications, models, software, source codes and object codes. Confidential Information shall not include any information that:

A. is disclosed by Company without restriction;

B. becomes publicly available through no act of Consultant;

C. is rightfully received by Consultant from a third party.

8. **Termination.**
A. This Agreement may be terminated by Company as follows:

i. If Consultant is unable to provide the consulting services by reason of temporary or permanent illness, disability, incapacity or death.

ii. Breach or default of any obligation of Consultant pursuant to Section 6, Covenant Not to Compete, or Section 7, Confidentiality, of this Agreement.

iii. Breach or default by Consultant of any other material obligation in this Agreement, which breach or default is not cured within five (5) days of written notice from Company.

B. Consultant may terminate this Agreement as follows:

i. Breach or default of any material obligation of Company, which breach or default is not cured within five (5) days of written notice from Consultant.

ii. If Company files protection under the federal bankruptcy laws, or any bankruptcy petition or petition for receiver is commenced by a third party against Company, any of the foregoing of which remains undismissed for a period of sixty (60) days.

9. **Independent Contractor.**
Consultant is and throughout this Agreement shall be an independent contractor and not an employee, partner or agent of Company. Consultant shall not be entitled to nor receive any benefit normally provided to Company's employees such as, but not limited to, vacation payment, retirement, health care or sick pay. Company shall not be responsible for withholding income or other taxes from the payments made to Consultant. Consultant shall be solely responsible for filing all returns and paying any income, social security or other tax levied upon or determined with respect to the payments made to Consultant pursuant to this Agreement.

10. **Tools and Supplies.**
Unless otherwise agreed to by Company in advance, Consultant shall be solely responsible for procuring, paying for and maintaining any computer equipment, software, paper, tools or supplies necessary or appropriate for the performance of Consultant's services hereunder.

11. **Controlling Law.**
This Agreement shall be governed by and construed in accordance with the laws of the State of CA.

12. **Headings.**
The headings in this Agreement are inserted for convenience only and shall not be used to define, limit or describe the scope of this Agreement or any of the obligations herein.

13. **Final Agreement.**

This Agreement constitutes the final understanding and agreement between the parties with respect to the subject matter hereof and supersedes all prior negotiations, understandings and agreements between the parties, whether written or oral. This Agreement may be amended, supplemented or changed only by an agreement in writing signed by both of the parties.

14. **Notices**.
Any notice required to be given or otherwise given pursuant to this Agreement shall be in writing and shall be hand delivered, mailed by certified mail, return receipt requested or sent by recognized overnight courier service as follows:

If to Consultant:
Des Uppal & Associates

If to Company:
C.I.O Services Inc,

15. **Severability**.
If any term of this Agreement is held by a court of competent jurisdiction to be invalid or unenforceable, then this Agreement, including all of the remaining terms, will remain in full force and effect as if such invalid or unenforceable term had never been included.

IN WITNESS WHEREOF, this Agreement has been executed by the parties as of the date first above written.

[Signature]

EXHIBIT 4

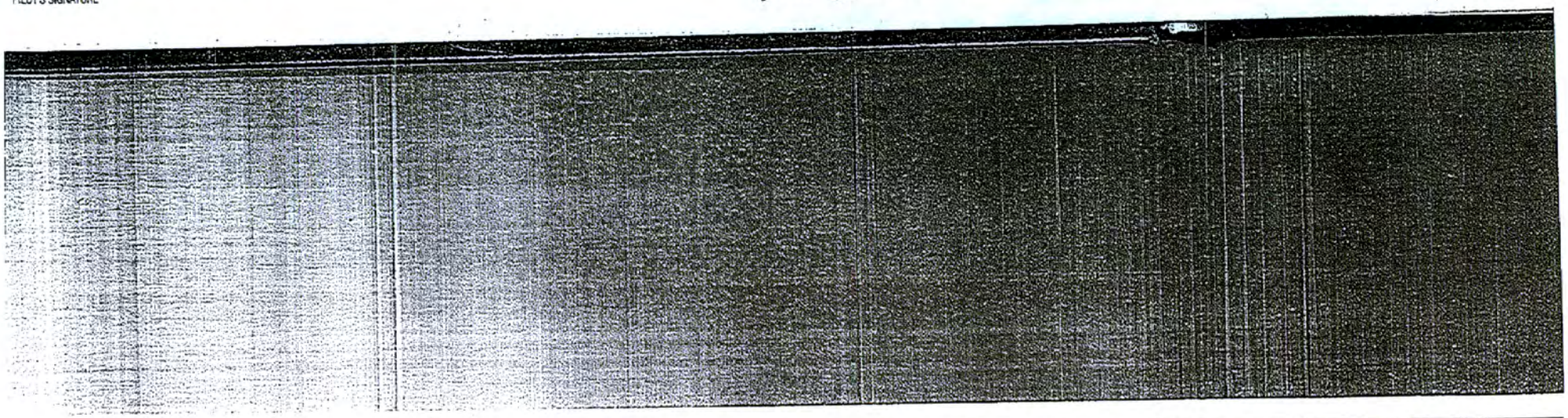

The Standard
PILOT LOG
ASA-SP-57

YEAR DATE	AIRCRAFT MAKE and MODEL	AIRCRAFT IDENTIFICATION NUMBER	POINTS OF DEPARTURE & ARRIVAL FROM	TO	REMARKS PROCEDURES, MANEUVERS, ENDORSEMENTS	NO. INSTR. APPR.	NO. LDG	AIRCRAFT CATEGORY and CLASSIFICATION AIRPLANE SINGLE ENGINE LAND		AIRPLANE MULTI-ENGINE LAND		TP TS		ROTORCRAFT HELICOPTER	AS FLIGHT INSTRUCTOR	CROSS-COUNTRY	CONDITIONS DAY
4/22	DA10	N924LA	RAL 0450	ONT 0530	CHRIS WARNER DR. AKMAJIAN ROGER WILLIAMS (4)		1				2		2				2
"	"	"	ONT 0510	SFO 0630	CHRIS WARNER DR. AKMAJIAN ROGER WILLIAMS (4)	1 VLS	1				1 3		1 3			1	3
"	"	"	SFO 0700	SMF 0850	CHRIS WARNER ROGER WILLIAMS / RYAN DAVIDSON		1				1 0		1 0			1	0
"	"	"	SMF 0810	F70 0920	CHRIS WARNER STEEGMAN JEU ROGER WILLIAMS RYAN DAVIDSON		1				1 2		1 2			1	2
4/23	DA10	N924LA	F70 0925	RAL 0940	CHRIS WARNER MK MCGRATH		1				3		3				3
"	"	"	RAL 0945	F70 1000	CHRIS WARNER AERO		1				3		3				3
"	SR22	N6810D	F70 (1600)	SNA (1620)	CHRIS WARNER		1	3									3
"	"	"	SNA (1620)	LGB (1635)	SIERRA INSTRUMENTS		1	3									5
"	"	"	LGB (1740)	F70 (1810)	AERO		1	5									4
4/24	SR22	N6810D	F70 (1300)	SNA (1350)	ROGER WILLIAMS		1	4									4
"	"	"	SNA (1640)	F70 (1705)	ROGER WILLIAMS		1	4									4
4/26	SR22	N6810D	F70 (1910)	MYF (1000)	AERO		1	4									5
"	"	"	MYF (1030)	RAL (1055)	DR. ROGER SHULTZ		1	5									4
"	"	"	RAL (1650)	LGB (1710)	DR. ROGER SHULTZ		1	4									5
					PAGE TOTAL	1	14	3	2	4	3	4	3			7	5
					AMOUNT FORWARD	30:40	33 80	9344	9	6265	3	2505	2		5936	4 11010	3
					TOTAL TO DATE	30:41	33 94	9348	1	6269	6	2509	5		5936	4 11017	8

I certify that the statements made by me on this form are true.

Robert Garrison

PILOT'S SIGNATURE

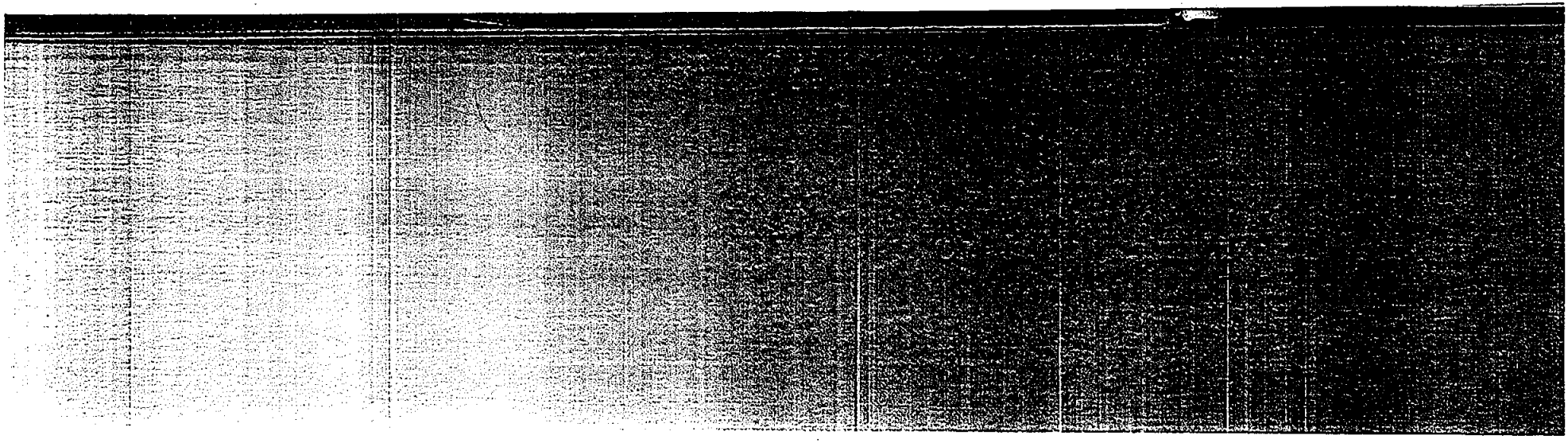


YEAR 20__ DATE	AIRCRAFT MAKE and MODEL	AIRCRAFT IDENTIFICATION NUMBER	POINTS OF DEPARTURE & ARRIVAL FROM	TO	REMARKS PROCEDURES, MANEUVERS, ENDORSEMENTS	NO. INSTR. APPR.	NO. LDG	AIRCRAFT CATEGORY and CLASSIFICATION: AIRPLANE SINGLE ENGINE LAND		AIRPLANE MULTI-ENGINE LAND		ROTORCRAFT HELICOPTER		AS FLIGHT INSTRUCTOR		CROSS-COUNTRY		COND DAY	
											T/P		T/S							
11/26	SR22	N68100	LGB(1715)	MYF(1820)	REPS		1		8									8	
"	"	"	MYF(1815)	LGB(1855)	FOR DR. SHURTZ ANNIE & DAUGHTER		1		7									7	
"	"	"	LGB(1915)	F70(1950)	REPS.		1		6									6	
11/27	SR22	N68100	F70(1035)	MYF(1110)	TRAVIS (CAR Plu)		1		4									4	
"	"	"	MYF(1135)	F70(1200)	REPS		1		5									5	
"	"	"	F70(1335)	SNA(1400)	REPS		1		4									4	
"	"	"	SNA(1405)	F70(1435)	TRAVIS (CAR Plu)		1		5									5	
"	"	"	F70(1440)	SAN(1510)	REPS		1		5									5	
"	"	"	SAN(1550)	F70(1620)	CHRIS WARNER		1		5									5	
"	DA10	N824LA	F70 0045Z	RAL 0102	CHRIS WARNER RYAN; DAVID WILLIAMS		1				3		3					3	
"	"	"	RAL 0115Z	SFO 0235Z	CHRIS WARNER RYAN; DAVID + MICHAEL	ILS	1			1	4		4			1	4		
"	"	"	SFO 0330Z	RAL 0450Z	CHRIS WARNER DR. AKMAJIAN + MIKE MCGRATH		1			1	3		3			1	3		
"	"	"	RAL 0455Z	F70 1510Z	CHRIS WARNER REPS		1				3		3					3	
"	SR22	N68100	F70(2155)	ONT(2215)	CHRIS WARNER		1		4									4	
PAGE TOTAL						1	14		5 3		3		3		3			3	
AMOUNT FORWARD						341	33 014		93 48	1	6269	6	2509	5	5936	4	11017	8	
TOTAL TO DATE						342	33 028		93 53	4	6272	9	2512	8	5936	4	11026	4	

I certify that the statements made by me on this form are true.

Robert Harrison

PILOT'S SIGNATURE



YEAR 2004 DATE	AIRCRAFT MAKE and MODEL	AIRCRAFT IDENTIFICATION NUMBER	POINTS OF DEPARTURE & ARRIVAL FROM	TO	REMARKS PROCEDURES, MANEUVERS, ENDORSEMENTS	NO. INSTR. APPR.	NO. LDG	AIRCRAFT CATEGORY and CLASSIFICATION: AIRPLANE SINGLE ENGINE LAND		AIRPLANE MULTI-ENGINE LAND		T/P	T/J	ROTORCRAFT HELICOPTER		AS FLIGHT INSTRUCTOR		CROSS-COUNTRY
2/26	DA 10	N824LA	ADS 1855Z	CLE 1925Z	CAPT'S WAIVER REPOS FUEL		1				5		5					
"	"	"	CLE 1915Z	SAT 2040Z	CAPT'S WAIVER REPOS		1				9		9					
"	"	"	SAT 2135Z	LAS 0030Z	CAPT'S WAIVER DR ELLIOT CLEARANCE + DUTY		1				2 9		2 9					2
2/27	DA 10	N824LA	LAS 1740Z	GCN 1835Z	CAPT'S WAIVER DR. ELLIOT CLEARANCE + DUTY		1				8		8					
"	"	"	GCN 2016Z	FLG 2035Z	CAPT'S WAIVER REPOS MAINT		1				4		4					
"	"	"	FLG 2340Z	HND 0025Z	CAPT'S WAIVER REPOS		1				7		7					
2/28	DA 10	N824LA	HND 2042Z	SAL 2125Z	CAPT'S WAIVER DR. AKMASIN (JIMAN) 5		1				7		7					
"	"	"	SAL 2130Z	CNT 2245Z	CAPT'S WAIVER REPOS FUEL		1				2		2					
"	"	"	CNT 0350Z	FTC 0415Z	CAPT'S WAIVER REPOS		1				4		4					
					PAGE TOTAL		9			7	5	7	5					7
					AMOUNT FORWARD 30 54		33 938	94	12	8	6324	9	2559	0			5936	7	1113
					TOTAL TO DATE 30 54		33 947	94	12	8	6332	4	2566	5			5936	7	1114

FEB TOTALS

I certify that the statements made by me on this form are true.

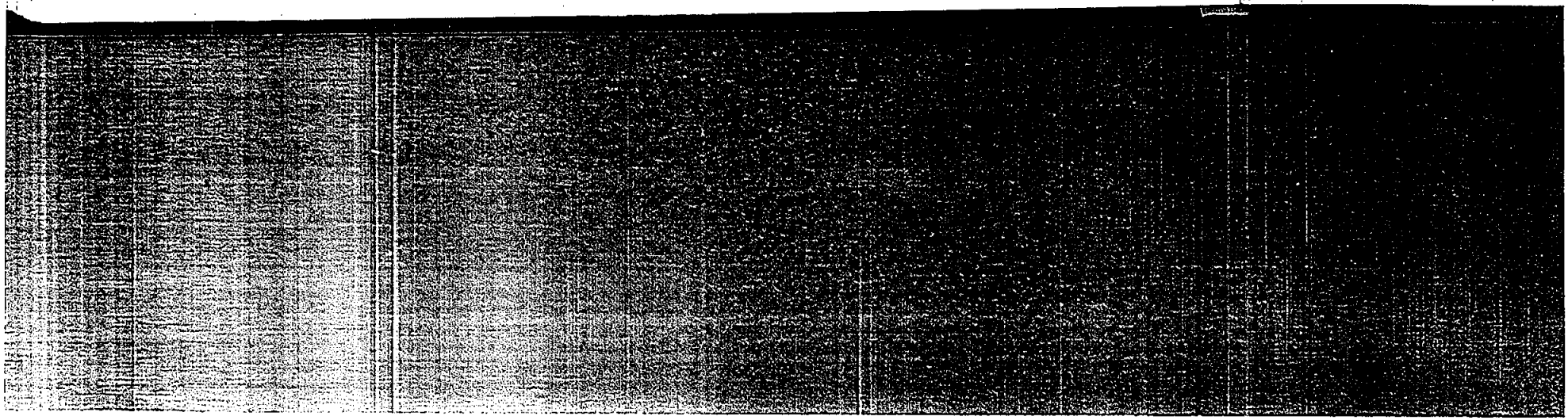
PILOT'S SIGNATURE

YEAR 2009 DATE	AIRCRAFT MAKE and MODEL	AIRCRAFT IDENTIFICATION NUMBER	POINTS OF DEPARTURE & ARRIVAL FROM	TO	REMARKS PROCEDURES, MANEUVERS, ENDORSEMENTS	NO. INSTR. APPR.	NO. LDG	AIRCRAFT CATEGORY and CLASSIFICATION: AIRPLANE SINGLE ENGINE LAND		AIRPLANE MULTI-ENGINE LAND		1/P T/O		ROTORCRAFT HELICOPTER		AS FLIGHT INSTRUCTOR		CROSS-COUNTRY	
5/20	SR22	N681DD	CCR(1925)	SNA(2046)	STEVE MANDELL T.J. MANSER		1	2	3									2	3
"	"	"	SNA(2216)	F70(2230)	T.J. MANSER		1		4										4
5/21	SR22	N681DD	F70(1220)	SNA(1240)	ROGER WILLIAMS		1		3										3
"	"	"	SNA(1245)	VNY(1320)	REPOS		1		6										6
"	"	"	VNY(1655)	F70(1740)	REPOS		1		7										7
5/22	SR22	N681DD	F70(0710)	AJO(0740)	REPOS	LOC	1		5										5
"	"	"	AJO(0740)	SMO(0805)	JOHN GIANNINI	LOC	1		4										4
"	"	"	SMO(0835)	F70(0925)	REPOS		1		8										8
"	DA10	N624LA	F70 0305Z	RAL 0315Z	CHRIS WARNER ROGER & MARY WILLIAMS		1				2		2						2
"	"	"	RAL 0340Z	FNL 0535Z	CHRIS WARNER PAUL RANDALL & CHRISTINE ROGER & MARY WILLIAMS	LOC	1			1	9	1	9					1	9
5/23	DA10	N624LA	FNL 0120Z	APA 0155Z	CHRIS WARNER REPOS		1				6		6						6
"	"	"	APA 0435Z	LAS 0610Z	CHRIS WARNER DR. AKMAJIAN PAUL RANDALL & CHRISTINE ROGER & MARY WILLIAMS		1			1	6	1	6					1	6
"	"	"	LAS 0640Z	RAL 0735Z	CHRIS WARNER DR. AKMAJIAN		1				9		9						9
"	"	"	RAL 0740Z	PSP 0850Z	CHRIS WARNER REPOS		1				3		3						3
					PAGE TOTAL	3	14	6	0	5	5	5	5					11	5
					AMOUNT FORWARD 3068	34 320	9357	5	6428	0	2662	1			5943	2	11353	0
					TOTAL TO DATE 3071	34 334	9363	5	6433	5	2667	6			5943	2	11394	5

I certify that the statements made by me on this form are true.

Robert Samson

PILOT'S SIGNATURE



YEAR 2017 DATE	AIRCRAFT MAKE and MODEL	AIRCRAFT IDENTIFICATION NUMBER	POINTS OF DEPARTURE & ARRIVAL FROM	TO	REMARKS PROCEDURES, MANEUVERS, ENDORSEMENTS	NO. INSTR. APP.	NO. LDG.	AIRCRAFT CATEGORY and CLASSIFICATION AIRPLANE SINGLE ENGINE LAND		AIRPLANE MULTI-ENGINE LAND		9/17/15		ROTORCRAFT HELICOPTER		AS FLIGHT INSTRUCTOR		CROSS-COUNTRY	
11/8	SR22	N681DD	MYF(1945)	RNM(2015)	ROGER WILLIAMS	GPS	1		5										
"	"	"	RNM(2020)	HND(2045)	REPS	[illegible]	1		5										
"	"	"	HND(2215)	RNM(2230)	REPS	WR	1		6										
"	"	"	RNM(2310)	MYF(2320)	ROGER WILLIAMS	ILS	1		2										
"	"	"	MYF(2350)	F70(0010)	REPS	GPS	1		7										
11/10	SR22	N681DD	F70(1100)	RNM(1120)	REPS		1		4										
"	"	"	RNM(1545)	SAN(1605)	NAHM - CX REPS.		1		4										
"	"	"	SAN(1610)	RNM(1635)	ROGER WILLIAMS		1		4										
"	"	"	RNM(1700)	PSP(1730)	DELIVERY - DR. AHMED		1		5										
"	"	"	PSP(1940)	HND(1955)	REPS		1		3										
11/11	SR22	N681DD	HND(2040)	F70(2105)	REPS		1		5										
11/12	SR22	N681DD	F70(1210)	RAL(1230)	REPS		1		4										
"	"	"	RAL(1305)	SMO(1355)	JIM WILLIAMS		1		5										
"	"	"	SMO(1525)	SBP(1635)	JIM WILLIAMS		1	1	2									1	
					PAGE TOTAL	4	14	7	1									7	
					AMOUNT FORWARD	961	639	8559	5	6051	5	2245	4			5893	1	10015	9
					TOTAL TO DATE	965	653	8566	6	6051	5	2245	4			5893	1	10023	[illegible]

I certify that the entries made by me on this form are true.

Robert [illegible]

PILOT'S SIGNATURE

YEAR 2007 DATE	AIRCRAFT MAKE AND MODEL	AIRCRAFT IDENTIFICATION NUMBER	POINTS OF DEPARTURE & ARRIVAL FROM	TO	REMARKS (PROCEDURES, MANEUVERS, EXCURSIONS)	NO. INSTR. APPR.	NO. LDG	AIRCRAFT CATEGORY AND CLASSIFICATION: AIRPLANE (SINGLE-ENGINE LAND)	AIRPLANE (MULTI-ENGINE LAND)	T/P T/J	NIGHT: AIRPLANE	INSTRUMENT: ACTUAL	INSTRUMENT: SIMULATED	CROSS-COUNTRY
12/24	SR22	N681DD	PZ(1710)	TOA(1815)	REPOS		1	1	1					1
"	"	"	TOA(1850)	SAU(1935)	PATRICIA		1		8					8
"	"	"	SAU(1950)	F70(2020)	REPOS		1		6					6
"	"	"	F70(2050)	HDD(2110)	REPOS		1		4					5
12/26	SR22	N681DD	HDD(0735)	SAU(0810)	REPOS		1		6					6
"	"	"	SAU(1145)	TOA(1200)	PATRICIA		1		8					8
"	"	"	TOA(1205)	F70(1240)	REPOS		1		6					6
"	"	"	F70(2005)	HDD(2035)	REPOS		1		4					6
12/27	SR22	N681DD	HDD(0930)	RAL(0955)	REPOS		1		5					5
"	"	"	RAL(1300)	F70(1320)	ANGEL WILLIAMS		1		4					4
"	"	"	F70(1340)	SNA(1500)	REPOS		1		4					4
"	"	"	SNA(1515)	HDD(1600)	TANYA		1		8					8
"	"	"	HDD(1630)	HND(1540)	DR. AHMED TANYA		1	1	2					1
"	"	"	HND(1555)	HDD(1655)	REPOS		1	1	2					1
					PAGE TOTAL:		14	9	9					9
					AMOUNT FORWARD	2795	139	8648	6	6070	1	2314	0	3
					TOTAL TO DATE	2809	153	8658	5	6078	1	2314	0	3

AIRCRAFT: HELICOPTER	AS FLIGHT INSTRUCTOR	CROSS-COUNTRY
		1
		8
		6
		5
		6
		8
		6
		6
		5
		4
		4
		8
		1
		1
		9
	5893 3.	10123
	5893 3.	10133

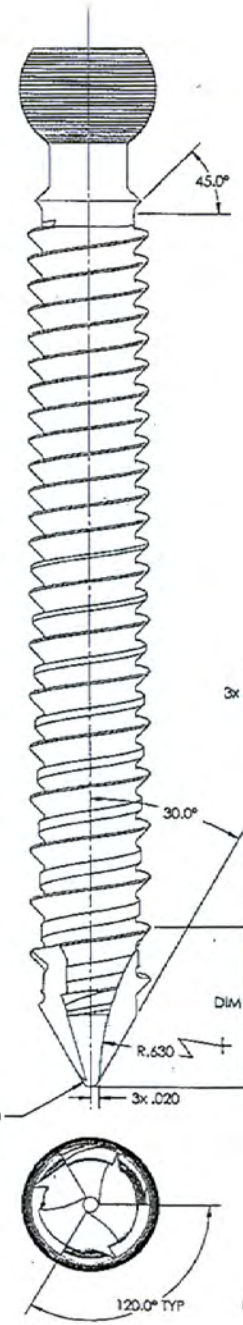
I certify that the entries in this log are true.

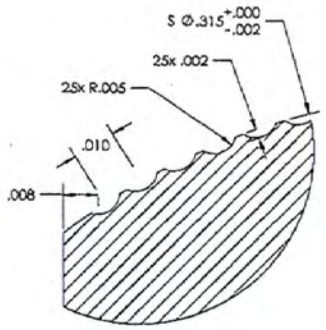
Robert J. Garrison

PILOT'S SIGNATURE

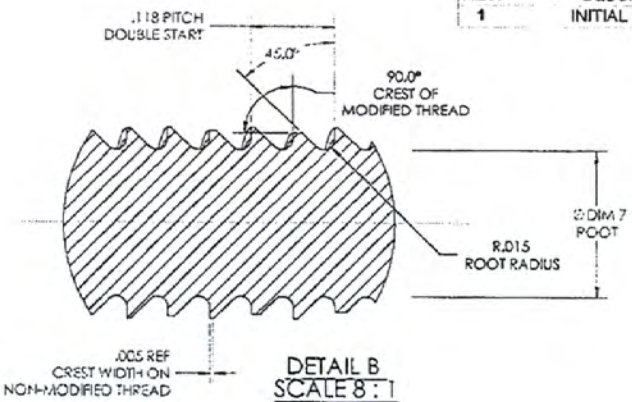
EXHIBIT 5

REV.	DESCRIPTION	DATE	BY	CKD.
1	INITIAL RELEASE	00/00/00	-	-

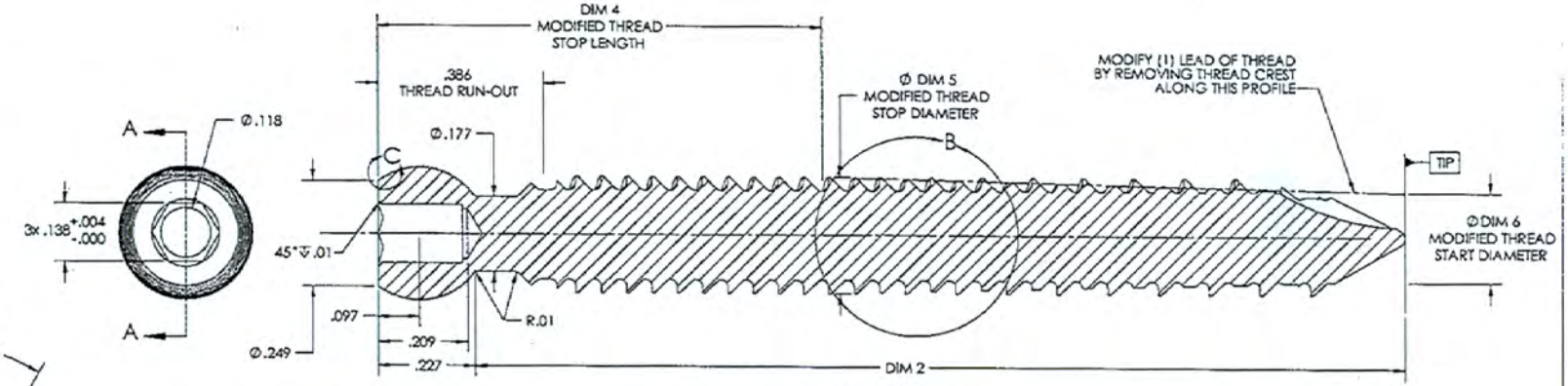




DETAIL C
SCALE 50 : 1



DETAIL B
SCALE 8 : 1



SECTION A-A

PART#	DESCRIPTION	DIM 2	DIM 3	DIM 4	DIM 5	DIM 6	DIM 7
SS4625	4.5 X 25MM	0.984	0.270	0.514	0.176	0.111	0.111
SS4630	4.5 X 30MM	1.181	0.279	0.601	0.176	0.111	0.111
SS4635	4.5 X 35MM	1.378	0.279	0.686	0.176	0.111	0.111
SS5030	5.0 X 30MM	1.181	0.308	0.601	0.196	0.131	0.131
SS5035	5.0 X 35MM	1.378	0.308	0.688	0.196	0.131	0.131
SS5040	5.0 X 40MM	1.575	0.308	0.775	0.196	0.131	0.131
SS5045	5.0 X 45MM	1.772	0.308	0.862	0.196	0.131	0.131
SS6030	6.0 X 30MM	1.181	0.337	0.601	0.236	0.171	0.171
SS6035	6.0 X 35MM	1.378	0.337	0.688	0.236	0.171	0.171
SS6040	6.0 X 40MM	1.575	0.337	0.775	0.236	0.171	0.171
SS6045	6.0 X 45MM	1.772	0.337	0.862	0.236	0.171	0.171
SS6050	6.0 X 50MM	1.969	0.337	0.949	0.236	0.171	0.171
SS6055	6.0 X 55MM	2.165	0.337	1.036	0.236	0.171	0.171
SS7030	7.0 X 30MM	1.181	0.366	0.601	0.275	0.210	0.210
SS7035	7.0 X 35MM	1.378	0.366	0.688	0.275	0.210	0.210
SS7040	7.0 X 40MM	1.575	0.366	0.775	0.275	0.210	0.210
SS7045	7.0 X 45MM	1.772	0.366	0.862	0.275	0.210	0.210
SS7050	7.0 X 50MM	1.969	0.366	0.949	0.275	0.210	0.210
SS7055	7.0 X 55MM	2.165	0.366	1.036	0.275	0.210	0.210
SS8030	8.0 X 30MM	1.181	0.395	0.601	0.314	0.249	0.249
SS8035	8.0 X 35MM	1.378	0.395	0.688	0.314	0.249	0.249
SS8040	8.0 X 40MM	1.575	0.395	0.775	0.314	0.249	0.249
SS8045	8.0 X 45MM	1.772	0.395	0.862	0.314	0.249	0.249
SS8060	8.0 X 60MM	1.969	0.395	0.949	0.314	0.249	0.249

NOTES:

1. MATERIAL: TI-6AL-4V ELI WROUGHT PER ASTM F136
2. FINISH: GLASS/ZIRCONIA BLAST 88120 AND CLEAN PER ASTM F86.
3. ANODIZE WITH BLUE COLOR.

APPROVED
April 01 2010

NAME	DATE
DRAWN	00/00/00
CHECKED	00/00/00
ENG APPR.	00/00/00
MFG APPR.	00/00/00

UNLESS OTHERWISE SPECIFIED: DIMENSIONS ARE IN INCHES. TOLERANCES: ANGULAR: ±1DEG. X ±.100 .XX ±.010 .XXX ±.005

MATERIAL: SEE NOTES FINISH: 16 RMS

TITLE: MULT-AXIAL SCREW

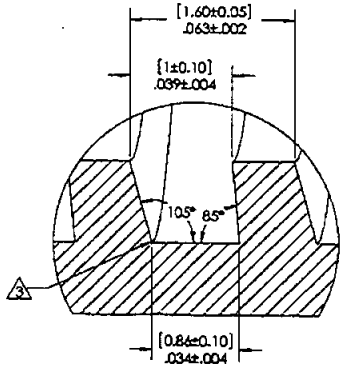
SPINAL SOLUTIONS LLC
29157 JEFFERSON AVENUE, MURRIETA CA 92562
(951) 304-9001

SIZE C | DWG. NO. 12000-01 | REV 1

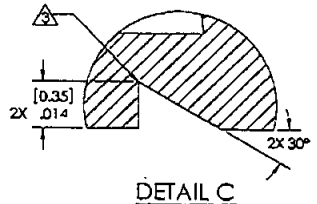
SCALE: 5:1 | WEIGHT: N/A | SHEET 1 OF 1

REV.	DESCRIPTION	DATE	BY	CKD.
1	INITIAL RELEASE	00/00/08	SM	-

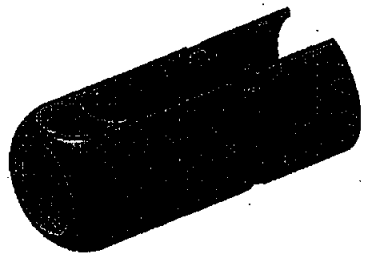
APPROVED
April 01 2010

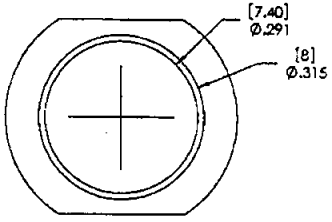


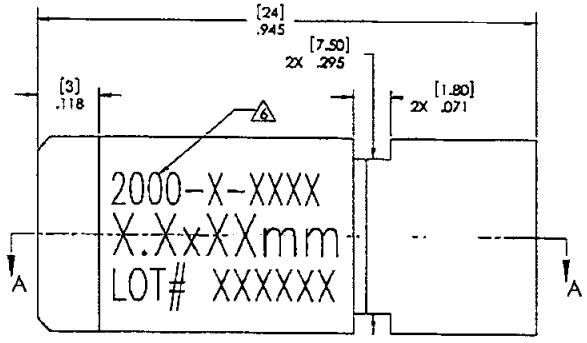
DETAIL B
SCALE 30 : 1

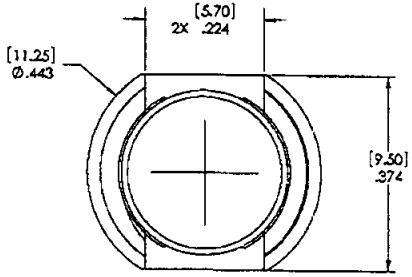


DETAIL C
SCALE 40 : 1

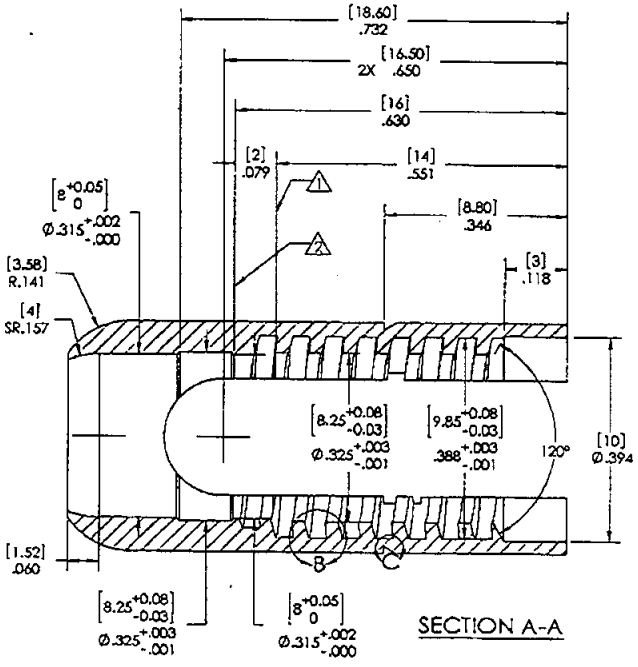








PART #	SIZE	CATALOG#	COLOR
12001-01	4.5mm x 25mm	2000-0-4525	GOLD
12001-02	4.5mm x 30mm	2000-0-4530	
12001-03	4.5mm x 35mm	2000-0-4535	
12001-04	4.5mm x 40mm	2000-0-4540	
12001-05	5.0mm x 30mm	2000-0-5030	SILVER
12001-06	5.0mm x 35mm	2000-0-5035	
12001-07	5.0mm x 40mm	2000-0-5040	
12001-08	5.0mm x 45mm	2000-0-5045	
12001-09	5.0mm x 50mm	2000-0-5050	
12001-10	6.0mm x 30mm	2000-0-6030	PURPLE
12001-11	6.0mm x 35mm	2000-0-6035	
12001-12	6.0mm x 40mm	2000-0-6040	
12001-13	6.0mm x 45mm	2000-0-6045	
12001-14	6.0mm x 50mm	2000-0-6050	
12001-15	6.0mm x 55mm	2000-0-6055	
12001-16	6.0mm x 60mm	2000-0-6060	
12001-17	7.0mm x 30mm	2000-0-7030	BLUE
12001-18	7.0mm x 35mm	2000-0-7035	
12001-19	7.0mm x 40mm	2000-0-7040	
12001-20	7.0mm x 45mm	2000-0-7045	
12001-21	7.0mm x 50mm	2000-0-7050	
12001-22	7.0mm x 55mm	2000-0-7055	
12001-23	7.0mm x 60mm	2000-0-7060	
12001-24	8.0mm x 30mm	2000-0-8030	GREEN
12001-25	8.0mm x 35mm	2000-0-8035	
12001-26	8.0mm x 40mm	2000-0-8040	
12001-27	8.0mm x 45mm	2000-0-8045	
12001-28	8.0mm x 50mm	2000-0-8050	
12001-29	8.0mm x 55mm	2000-0-8055	
12001-30	8.0mm x 60mm	2000-0-8060	



SECTION A-A

1	AT THIS LOCATION, ACME THREADLEAD-OUT BEGINS AND BORE I.D. DECREASES FROM [8.25] TO [8].
2	AT THIS LOCATION, ACME THREADLEAD-OUT ENDS AND BORE I.D. INCREASES FROM [8] TO [8.25].
3	MAINTAIN SHARP (.003 R MAX) INTERNAL CORNERS ON SNAP-TAB AND ACME THREAD.
4.	DIMENSIONS IN BRACKETS AND IN TABLES ARE METRIC.
5.	CATALOG NUMBER, SIZE, AND NITRIDING COLOR ARE SPECIFIED IN TABLE.
6	LASERMARK CATALOG NUMBER IN [1.5] TALL CHARACTERS, SIZE (WHERE "X.X" REPRESENTS THE BONE SCREW MAJOR DIMAMETER AND "XX" REPRESENTS THE BONE SCREW LENGTH) IN [2] TALL CHARACTERS, AND SIX-DIGIT LOT NUMBER IN [1.5] TALL CHARACTERS, IN LOCATION SHOWN. DO NOT LASERMARK PARTS UNTIL FINAL ASSEMBLY HAS BEEN COMPLETED.
7.	PASSIVATE PER SOP-09-009 PRIOR TO NITRIDING.
8.	UNLESS OTHERWISE NOTED: BREAK SHARP EDGES R.010 MAX.

	NAME	DATE
DRAWN	S.AMANDELL	00/00/08
CHECKED		00/00/08
ENG APPR.		00/00/08
MFG APPR.		00/00/08

UNLESS OTHERWISE SPECIFIED:
DIMENSIONS ARE IN INCHES
TOLERANCES:
ANGLES: ±1DEG.
.X ±.100
.XX ±.010
.XXX ±.005

SPINAL SOLUTIONS LLC.
26157 JEFFERSON AVENUE, MURRIETA CA 92562
(951) 304-9001

MATERIAL: TI 6AL-4V ELI
NITRIDED - (SEE TABLE)
FINISH: 16 RMS

TITLE:
ROD HOLDER,
PEDICLE SCREW SYSTEM

SIZE C | DWG. NO. 12001-01 | REV 1

SCALE: 5:1 | WEIGHT: N/A | SHEET 1 OF 1

EXHIBIT 6

From: Richard Walker <rwalker@ortho-sol.com>
To: [redacted]s
Cc: 'Lyn Millard' <lmillard@ortho-sol.com>
Sent: Thu Mar 29 03:31:56 2012
Subject: RE: Spinal Solutions LLC

Hi [redacted]

Thank you for your E Mail.
I guess from your area codes, that you are based in the New York area in which case we have to account for time differences when communicating (6 hours). Hence the delay in response.

Re the contents of your communication, Firstly we have to be very clear of the fact that we have proof that Mr Williams has been involved in counterfeiting surgical hardware and secondly the information that is coming to light that," he may have been manufacturing your hardware" should read , " counterfeiting your hardware" .

To give you a brief background of our companies relationship with Spinal Soloutions(Roger Williams) would be as follows:

1. Appointed as a distributor of our products subject to his obtaining FDA clearance. (We provided the product intellectual data, testing and clinical follow up's to enable him to obtain registration)
2. This was duly attended to and we received confirmation of our registration as the manufacturing facility and a product registration code.
3. Trading commenced on registration and operated smoothly for the first 2 years.
4. Sales growth over the 2 year period was fair and met with our expectations to extend our agreement with his company, which included the allocation of additional states besides California for sole distribution rights (Texas, Nevada and Florida).
5. Spinal Soloutions was supplied on a consignment basis with product, naturally the expansion of territory required a vast increase in consignment inventory as requested by Roger to which we agreed based on his sound performance over the previous 2 years.
6. Alarm bells started to ring approximately 3 months after the provision of the increased inventory levels when payments started drying up and reported sales against consignment inventory dwindled.
7. We let the situation ride for a few months until we became aware of the following:
    A. Reported tampering with product (FDA)
    B. Unethical perverse incentive payments made to surgeons for product use.
    C. Rogers sudden flamboyant increase in lifestyle from mediocre, to a Upper Class Property, flashy vehicles, aircraft and yachts purchases.
8. We then proceeded to suspend the distributorship agreement until reported sales were brought up to date and due payment was received.
9. Roger adopted the" Ostrich" attitude and ignored our further demands to return the consignment inventory and repay the reconciled difference.
10. We were eventually forced to send in an auditor to reconcile and uplift the consignment inventory.
11. The following was established on the return of the inventory to South Africa:
    A. A reconciled difference of missing, sold/stolen inventory in excess of the amount of $ 850 000,00. Additional costs incurred in the recovery and interest amounts to approximately $1 200 000.00. ($ 1.2 million) currently.
    B. Found amongst the returned inventory counterfeits of our product.

I do believe that besides the "fraud" aspect "criminal charges" of theft and the endangering of patients lives, should be laid against Roger as well as the participating surgeons involved.

With regards to the fraud aspect I am of the opinion that the most effective way to prove this would be to analyse his marketing method, which by all accounts is very simple. In a nutshell what he is doing is firstly introducing the genuine registered article (Our Product) for a period on which he defaults on payment and when this source dries up he substitutes the product with counterfeits and cheap inferior Asian products under the genuine product FDA registration. This is not only fraud but a criminal offence to say the least. This is easy to prove by issuing a subpoena for his shipping receipt documents of other imported products and verifying under what FDA registration the goods were cleared by customs. Should any of those products have been cleared under the Blue and Gold registration other than sourced from our company in South Africa he has committed fraud in the first instance.

In addition to the above I am aware of other products sourced by Roger under false "description declaration" from Europe which require FDA registration, which have been distributed by him in the US and implanted into patients.

You are dealing with an extremely unethical " bad egg" who is in collusion with so called "professionals" of a similar nature that needs to be routed out and exposed for what they are.

We have similar unethical and unprofessional characters of this kind in our country who, over a period of time we have learnt to identify. Nevertheless this a brief overview and any assistance/information that I can provide in detail as evidence to your investigation will be provided on request..

Best Regards

Richard Walker

EXHIBIT 7

From:

SPINAL SOLUTIONS LLC

04/01/2009 04:07 #776 P.035/036

Crowder Machine & Tool

Date	Type	Reference
3/5/2009	Bill	9122

Original Amt. 2,350.00 | Balance Due 2,350.00 | 3/9/2009 Discount | Check Amount

08814

Payment 2,350.00
2,350.00

PAYMENT RECORD

Pacific Western Bank

572541 (11/00)

2,350.00

Invoice

CROWDER MACHINE & TOOL
43339 BUSINESS PARK DR., SUITE 108
TEMECULA, CA 92590
(951) 699-3370
FAX (951) 699-0369

9122

SOLD TO SPINAL SOLUTIONS

CUSTOMER'S ORDER	SALESMAN	TERMS	SHIPPED VIA	F.O.B.	DATE
					3-5-09

2 SCREW DRIVERS - MODIFY TO FIT ITALIAN SCREWS — EXPEDITE — 595 00
PER ROGER FOR DR. COHEN

9 BROACHES — LONG HANDLES — 1755 00
7/9, 8/10, 9/11, 10/12, 11/13, 12/14, 13/15, 14/16, 15/17
FOR DR. AKNASIAN C/OS — 2,350 00
ALIF INSTRUMENTS

BY CK — 3-6-09

$17.80

6920669 606

MAR-05-2009 12:09 PM WILLIAM A. CROWDER

From:

Crowder Machine & Tool

Date	Type	Reference	Original Amt.	Balance Due	3/2/2009 Discount	Payment
2/2/2009	Bill	9121	1,750.00	1,750.00		1,750.00

Check Amount 1,750.00

PAYMENT RECORD

Pacific Western Bank

572541 (11/00)

1,750.00

Invoice

CROWDER MACHINE & TOOL

43339 BUSINESS PARK DR., SUITE 108
TEMECULA, CA 92590
(951) 699-3370
FAX (951) 699-0369

INVOICE NO. 9121

SOLD TO SPINAL SOLUTIONS

CUSTOMER'S ORDER	SALESMAN	TERMS	SHIPPED VIA	F.O.B.	DATE 2-24-09
14	TRIALS (2 BROACHES) (6 ALUM) (6 S.S.)				
	FAB. LONG S.S. HANDLES				$1,750.00
	$875
	✓ BY CM				
	TRIALS & BROACHES FOR				
	C105/DR. AKMAJIAN				

EXHIBIT 8

AFFIDAVIT

SAMPLE NO.

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Roger K. Williams in the county and state aforesaid, who, being duly sworn, deposes and says:

I, Roger Williams, am the President for Spinal Solutions, LLC located at 26157 Jefferson Ave. Murrieta, CA 92562. I am also the President for Orthopedic Alliance, LLC, located at the same physical address. Orthopedic Alliance is a wholly-owned subsidiary of Spinal Solutions, LLC; both of which share the same employees. Operations performed at Spinal Solutions, LLC include receiving, storage, assembly, and distribution of surgical trays, which are used during spinal fusion surgery. Spinal Solutions, LLC does not design specifications or manufacture Spinal Fixation Systems or components including, screws, rods, caps, or vertebral body replacements. Spinal Solutions, LLC purchases Spinal Fixation Systems, both kits and individual components used in assembly of kits, from product manufacturers such as Advanced Medical Technology located at Kasteler Str. 11, 66620 Nonnweiler, Germany; and Eminent Spine LLC at 7200 N. I-H 35 Building #1 Georgetown, TX 78626. My company assembles Spinal Fixation System Kits, such as ART (2) Fixation System, Eminent Spine Interbody Fusion System-Copperhead, Crystal Cervical Cage System, and Talon Pedicle Screw System, with components and manual surgical instruments.

I have served as the President at Spinal Solutions, LLC since February 1999, and have worked in the Orthopedic Implant industry since 1980. I am responsible for overseeing the entire company, including, receipt and distribution of products, product sales and marketing, meeting with physicians to generate new business, and hiring of personnel. As such, I have knowledge about the receipt of incoming surgical trays and surgical tray components, such as pedicle screws, vertebral body replacements, and instruments; and outgoing distribution of surgical trays and components at Spinal Solutions, LLC.

On 8/12/2011 I informed Investigator Harris that Spinal Solutions, LLC does not hold any 510(k) Pre-Market Notifications. I explained that 510(k) Pre-Market Notification, K033826, was submitted to FDA under Orthopedic Alliance, LLC for the distribution of a spinal fixation system called the Orthopedic Alliance Spine System. My company referred to the Orthopedic Alliance Spine System as Blue and Gold. I explained to Investigator Harris that Spinal Solutions, LLC has not contracted for the manufacture of this product, nor received, stored, distributed, or sold the Blue and Gold spinal fixation system for 510(k) Pre-Market Notification K033826 since the middle of 2006; and as such, Orthopedic Alliance, LLC will inactivate 510(k) Pre-Market Notification K033826 within six months.

old contract with Rod 8/16/11

AFFIANT'S SIGNATURE AND TITLE

Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Spinal Solutions, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta (City and State)

this 16th day of August, 20 11.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. I of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Roger K. Williams in the county and state aforesaid, who, being duly sworn, deposes and says:

I informed Investigator Harris that Spinal Solutions, LLC has not established a quality policy; appointed a management representative; held management review meetings, conducted quality audits; of established quality system procedures for process control, identification of product, traceability, nonconforming product, acceptance activities, Corrective and Preventive Actions, device labeling, storage, distribution, device history records, document control, quality audits, or training. Investigator Harris asked whether my company analyzes quality data sources and I responded that at this point we do not, but we will.

Investigator Harris asked me if there are Device Master Records and Device History Records for the surgical trays that are assembled at Spinal Solutions, LLC and I informed her that they are not documented.

I explained to Investigator Harris that spinal fixation systems, like the Eminent Spine Interbody Fusion System and Fang Plate System, are received and distributed using either United Parcel Service or FedEx. Additionally, company vans are used to deliver the products to local customers. A company airplane may also be used to deliver products.

ALL (RW) 8/16/11 ALL (RW) 8/16/11

The distribution of products from Spinal Solutions, LLC, are not documented and no shipping records are maintained. Such information as product lot numbers, quantity, and destination, have not been recorded. Both Mr. Jeffrey Fields, Operations Manager, and I informed Investigator Harris that there are no records maintained showing the performance of receiving and final acceptance activities. Investigator Harris asked if the Instructions For Use that accompany the medical devices upon receipt at Spinal Solutions, LLC are maintained with the devices during storage and distribution. I replied that I do not know, however Mr. Arnold Neves, In-house General Counsel, informed me that they are not. The Instructions For Use are also not packaged with the Spinal Fixation System Kits, which are assembled in-house for distribution to customers.

(RW) 8-16-11

In addition to firm employees, my company uses independent contractors to sell products. Spinal Solutions, LLC does not maintain training records or written agreements for contractors which detail how complaints or medical device reports should be handled. Also, my company does not have written

AFFIANT'S SIGNATURE AND TITLE

Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Spinal Solutions, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta (City and State),

this 16th day of August, 20 11.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. I of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Roger K. Williams in the county and state aforesaid, who, being duly sworn, deposes and says:

agreements with suppliers addressing which party is responsible for complaint handling, Medical Device Reporting, recalls, product design changes, label/labeling content, or maintenance of Device History Records.

With respect to all cited issues above it has been our intention to comply with all the regulations of th FDA and we have been in the process of working on these compliance issues. Everything else listed above with the initialed comments/changes are (R) 8-16-11, true and correct.

(RW) 8-16-11

AFFIANT'S SIGNATURE AND TITLE

Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Spinal Solutions, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta (City and State),

this 16th day of August, 20 11.

DeJon N. Harris (Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Roger K. Williams in the county and state aforesaid, who, being duly sworn, deposes and says:

I, Roger Williams, am the President for Orthopedic Alliance, LLC located at 26157 Jefferson Ave. Murrieta, CA 92562. I am also the President for Spinal Solutions, LLC, located at the same physical address. I have served as the President at Orthopedic Alliance, LLC since February 1999, and have worked in the Orthopedic Implant industry since 1980. I am responsible for overseeing the entire company, including, receipt and distribution of products, product sales and marketing, meeting with physicians to generate new business, and hiring of personnel. As such, I have knowledge about the receipt of incoming surgical trays, packaged knee and hip joint prostheses, and instruments; and outgoing distribution of surgical trays, packaged knee and hip joint prostheses, and instruments at Orthopedic Alliance, LLC.

Orthopedic Alliance, LLC is a wholly-owned subsidiary of Spinal Solutions, LLC; both of which share the same employees. Orthopedic Alliance, LLC purchases hip and knee joint prostheses from product manufacturers such as United Orthopedic Corporation located at 57 Park Ave. 2 Science Park Hsinchu 300, Taiwan; and Stem Cup Medical Products AG located at Aargauerstrasse 180 CH-8048, Zurich, Switzerland. Orthopedic Alliance, LLC submitted 510(k) Pre-Market Notifications K031474, K052237, and K033826 for SC Total Hip System, SC Ceramic Ball Heads, and Orthopedic Alliance Spine System, respectively.

I informed Investigator Harris that Orthopedic Alliance, LLC has not developed design specifications, manufactured, or contracted out manufacturing for Hip Joint Prosthesis, Ceramic Ball Heads, Knee joint patellofemorotibial prosthesis, or Spinal Fixation Systems. I explained that I hope to move in the direction of manufacturing for Orthopedic Alliance, LLC and Spinal Solutions, LLC. However, at this time it is still a dream and no steps have been taken to begin the process. Therefore, Orthopedic Alliance, LLC and Spinal Solutions, LLC have not made product prototypes, performed clinical trials, or purchased these services from another entity in relation to the above listed medical devices.

The SC Total Hip System and Ceramic Ball Heads for 510(k) Pre-Market Notifications K031474 and K052237 are designed and manufactured by Stem Cup Medical Products AG in Zurich, Switzerland. Orthopedic Alliance, LLC has not sold the rights of 510(k) Pre-Market Notifications K031474 and K052237; and has not granted the right to manufacture or distribute the product from these 510(k) Pre-

AFFIANT'S SIGNATURE AND TITLE

Manager 8-16-11

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

Orthopedic Alliance, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta, CA *(City and State)*,

this 16th day of August, 20 11.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Roger K. Williams in the county and state aforesaid, who, being duly sworn, deposes and says:

Market Notifications to any other entity. Orthopedic Alliance, LLC and Stem Cup Medical Products AG do not have a written agreement specifying the responsibilities of each company on topics such as design specifications or changes, maintenance of design history files and device master records, manufacturing, product recall, complaint handling, labels/labeling content, and Medical Device Reporting as they relate to the SC Total Hip System and Ceramic Ball Heads.

On 8/12/2011, I informed Investigator Harris that 510(k) Pre-Market Notification, K033826, was submitted to FDA under Orthopedic Alliance, LLC for the distribution of the spinal fixation system called the Orthopedic Alliance Spine System. My company referred to the Orthopedic Alliance Spine System as Blue and Gold. The Orthopedic Alliance Spine System was manufactured and designed by Ortho Sol located at 6 Fearick Street Sidwell Port Elizabeth 6001 South Africa. Orthopedic Alliance, LLC has not sold the rights of 510(k) Pre-Market Notification K033826; and has not granted the right to manufacture the product from this 510(k) Pre-Market Notification to any other entity. I explained that Orthopedic Alliance, LLC and Ortho Sol do not have a written agreement specifying the responsibilities of each company on topics such as design specifications, maintenance of design history file and device master record, manufacturing, product recall, complaint handling, labels/labeling content, and Medical Device Reporting. I explained to Investigator Harris that Orthopedic Alliance, LLC has not received, stored, distributed, or sold the Blue and Gold spinal fixation system for 510(k) Pre-Market Notification K033826 since the middle of 2006; and as such, Orthopedic Alliance, LLC will inactivate 510(k) Pre-Market Notification K033826 within six months.

I explained to Investigator Harris that the U2 Total Knee System and SC Total Hip System are received from United Orthopedic Corporation and Stem Cup Medical Products AG, respectively. The U2 Total Knee System and SC Total Hip System are received and distributed using either United Parcel Service or FedEx. Additionally, my company uses a company car and van to deliver products to local customers such as Arroyo Grande Community Hospital located at 345 South Halcyon Road Arroyo Grande, CA 93420; and private airplane for long distance delivery. The distribution of U2 Total Knee System and SC Total Hip System from Orthopedic Alliance, LLC, with such information as product lot numbers, quantity, destination, and shipping records are not documented.

AFFIANT'S SIGNATURE AND TITLE

Staff Manager 8-16-11

FIRM'S NAME AND ADDRESS *(Include ZIP Code)*

Orthopedic Alliance, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta, CA *(City and State)*

this 16th day of August, 20 11.

Dejon N. Harris *(Employee's Signature)*

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO.

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Roger K. Williams in the county and state aforesaid, who, being duly sworn, deposes and says:

We believe there's a writtn agreement with Orthopedic Alliance LLC and StemCyp Medical Products bA we cannot find it.

RW 8-16-11

The above is true and correct to the best of my knowledge

RW 8-16-11

AFFIANT'S SIGNATURE AND TITLE

Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)

Orthopedic Alliance, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta, CA (City and State)

this 16th day of August, 20 11.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

FORM FDA 463a (5/07)

AFFIDAVIT

SAMPLE NO. 658788

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Jeffrey P. Fields in the county and state aforesaid, who, being duly sworn, deposes and says:

I, Jeffrey P. Fields, am the Operations Manager/System Administrator for Spinal Solutions, LLC located at 26157 Jefferson Ave. Murrieta, CA 92562. I am also the Operations Manager/System Administrator for Orthopedic Alliance, LLC, located at the same physical address. Orthopedic Alliance is a subsidiary of Spinal Solutions, LLC; both of which are owned by Roger Williams, President, and share the same employees. Operations performed at Spinal Solutions, LLC include receiving, storage, assembly, and distribution of surgical trays, which are used during spinal fusion surgery. Spinal Solutions, LLC does not design specifications or manufacture Spinal Fixation Systems or components including, screws, rods, or caps. Spinal Solutions, LLC purchases Spinal Fixation System kits from product manufacturers such as Advanced Medical Technology located at Kasteler Str. 11, 66620 Nonnweiler, Germany; Spinal Element located at 2744 Loker Avenue West, Suite 100, Carlsbad, CA 92010.

I have served as the Operations Manager/System Administrator at Orthopedic Alliance, LLC for approximately five to six years, and have worked for the company for eight years. As such, I am responsible for overseeing daily operations, product price lists, implant and instrument sourcing to customers, hospital agreements, researching 510(k) Notifications to qualify suppliers, and performance of quarterly product inventory. I have knowledge about the receipt of incoming surgical trays and surgical tray components, such as pedicle screws, vertebral body replacements, and instruments; and outgoing distribution of surgical trays and components at Spinal Solutions, LLC.

Spinal Fixation Systems, components, surgical trays, and instruments are received and distributed using either UPS or FedEx. Spinal Solutions, LLC also uses company vans to deliver products to local customers. Chris McWilliams, Surgical Sales Representative for Spinal Solutions, LLC, is responsible for maintaining firm inventory, pick-up or drop-off of shipments at UPS or FedEx, and delivery of products to local customers.

Spinal Solutions, LLC faxes Delivery Slips listing products that were used during surgery to their supplier as a way to place product replacement orders. However, the distribution of products from Orthopedic Alliance, LLC (Murrieta, CA) was not documented, including the use of the ART Posterior Spinal System Implant in Milwaukee, Wisconsin. On 8/3/2011, I identified the following documents

AFFIANT'S SIGNATURE AND TITLE: Operations Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)
Spinal Solutions, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta (City and State)

this 3rd day of August, 20 11.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO. 658788

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Jeffrey P. Fields in the county and state aforesaid, who, being duly sworn, deposes and says:

related to the receipt and use of the ART Posterior Spinal System, distributed by Orthopedic Alliance, LLC (Murrieta, CA), which were provided to FDA Investigator Harris during the inspection.

Receipt of ART Posterior Spinal System from Advanced Medical Technology (Nonnweiler, Germany) to Orthopedic Alliance, LLC (Murrieta, CA):

1. Spinal Solutions LLC Delivery Slip, dated 4-25-11, for order of Catalog No. AP.06.045, AST.06.110, AS.00.011, Am.10.000, AQST.076, OA10822-512, and AQ-06 from Advanced Medical Technology (Nonnweiler, Germany) by Spinal Solutions, LLC (Murrieta, CA). (1 page)

2. FedEx Internationaler Luftfachtbrief air bill 8719 6946 1336, dated 29.04.11, for 0,45kg med. Implants from Advanced Medical Technologies AG (Nonnweiler, Germany) to Spinal Solutions LLC (Murrieta, CA). (1 page)

3. FedEx Detailed Results with Tracking No.: 871969461336, Delivery date May 3, 2011, for shipment of .4kg from KELSTERBACH DE to TEMECULA, CA and signed for pick up by C.MCWILLIAMS. (1 page)

4. amt INVOICE No.: 201101685, referencing Surgery of 4-25-11 and Shipping date: 29.04.2011, dated 29.04.2011, for sale of items AP.06.045, AST.06.110, AS.00.011, Am.10.000, AQST.076, and AQ-06 206 PCS from Advanced Medical Technology (Nonnweiler, Germany) to Spinal Solutions, LLC (Murrieta, CA). (1 page)

I also provided Investigator Harris with the product label, insert and promotional material for the ART Posterior Spinal System by Advanced Medical Technology (Nonnweiler, Germany).

The above statement is true and correct 8/3/2011

AFFIANT'S SIGNATURE AND TITLE: Operations Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)
Spinal Solutions, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta (City and State)

this 3rd day of August, 20 11.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

FORM FDA 463a (6/07)

AFFIDAVIT

SAMPLE NO. 658789

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Jeffrey P. Fields in the county and state aforesaid, who, being duly sworn, deposes and says:

I, Jeffrey P. Fields, am the Operations Manager/System Administrator for Orthopedic Alliance, LLC located at 26157 Jefferson Ave. Murrieta, CA 92562. I am also the Operations Manager/System Administrator for Spinal Solutions, LLC, located at the same physical address. Orthopedic Alliance is a subsidiary of Spinal Solutions, LLC; both of which are owned by Roger Williams, President, and share the same employees. Operations performed under Orthopedic Alliance, LLC include receipt, storage, assembly, and distribution of knee and hip joint prostheses and instruments. Orthopedic Alliance, LLC holds 510(k) Notification K033826 for Orthopedic Alliance Spine System, which was designed and manufactured under the name Blue and Gold by Ortho Sol located at 6 Fearick Street Sidwell Port Elizabeth 6001 South Africa. Orthopedic Alliance, LLC has not developed design specifications, manufactured, or contracted out manufacturing for Hip Joint Prosthesis, Ceramic Ball Heads, Knee joint patellofemorotibial prosthesis, or Spinal Fixation Systems. Orthopedic Alliance, LLC purchases hip and knee joint prostheses from product manufacturers such as United Orthopedic Corporation located at 57 Park Ave. 2 Science Park Hsinchu 300, Taiwan; and Stem Cup Medical Products AG located at Aargauerstrasse 180 CH-8048, Zurich, Switzerland.

I have served as the Operations Manager/System Administrator at Orthopedic Alliance, LLC for approximately five to six years, and have worked for the company for eight years. As such, I am responsible for overseeing daily distribution, product price lists, implant and instrument sourcing, hospital agreements, supplier research, and performance of quarterly product inventory. I have knowledge about the incoming receipt and outgoing distribution of knee and hip joint prostheses, surgical trays, surgical tray components, and instruments at Orthopedic Alliance, LLC.

Knee and hip joint prostheses and surgical trays are received and distributed using either UPS or FedEx. Orthopedic Alliance, LLC uses company vans to deliver products to local customers such as Arroyo Grande Community Hospital located at 345 South Halcyon Road Arroyo Grande, CA 93420. Felipo (Butch) Bonot, Delivery Man for Orthopedic Allianee, LLC, is responsible for picking up shipments from UPS or FedEx; and delivering products to local customers.

On 8/3/2011, I identified the following documents related to the receipt and use of the U2 Total Knee System Implants, distributed by Orthopedic Alliance, LLC (Murrieta, CA), which were provided to

AFFIANT'S SIGNATURE AND TITLE: Operations Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)
Orthopedic Alliance, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta, CA (City and State)

this 3rd day of August, 20 11.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

FORM FDA 463a (5/07)

AFFIDAVIT	SAMPLE NO. 658789
STATE OF California	COUNTY OF Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509, 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Jeffrey P. Fields in the county and state aforesaid, who, being duly sworn, deposes and says:

FDA Investigator Harris during the inspection. The distribution of U2 Total Knee System Implants from Orthopedic Alliance, LLC (Murrieta, CA) to Arroyo Grande Community Hospital was not documented.

Receipt of U2 Total Knee System Implants from United Orthopedic Corporation (Hsinchu, Taiwan) to Orthopedic Alliance, LLC (Murrieta, CA):

1. Purchase Order Number: 06062011UOA, dated 6/6/2011, for 206 units of United Orthopedic Corp U2 Knee Implant including 4 units of Tibial baseplate, cemented, #5 ordered from United Orthopedic Corporation (Hsinchu, Taiwan) by Orthopedic Alliance, LLC (Murrieta, CA). (3 pages)

2. E-mail to Chris McWilliams, an employee of Orthopedic Alliance, LLC, from Hannah Lee, an employee of United Orthopedic Corporation, sent June 13, 2011, referencing Subject: Notification for shipment with attachments including HCM1-110600027 and Fed Ex tracking number 4733 1993 8527. (1 page)

3. FedEx Detailed Results with Tracking No.: 473319938527, referencing HCM1-110600026/27/28/29, Delivery date Jun 15, 2011, for 5 pieces of total shipment weight 123.5lbs, showing shipment from HU KOU HSIANG TW to TEMECULA, CA and signed for pick up by B. Bonot. (1 page)

4. UNITED ORTHOPEDIC CORPORATION Invoice No# HCM1-110600027, dated June 13, 2011, for sale of 206 PCS including 4 pcs of Item No. 2203-3050 Tibial baseplate, cemented, #5 from United Orthopedic Corporation (Hsinchu, Taiwan) to Orthopedic Alliance, LLC (Murrieta, CA). (4 pages)

5. UNITED ORTHOPEDIC CORPORATION Packing List, dated June 13, 2011, for PO.N 04282011U0A, 06062011UOA, and 06032011UOA including 4 units of item 2203-3050 Tibial baseplate, cemented, #5, lots 11C113A and 11C113D, from United Orthopedic Corporation (Hsinchu, Taiwan) to Orthopedic Alliance, LLC (Murrieta, CA). (4 pages)

Use of U2 Total Knee System Implants at Arroyo Grande Community Hospital (Arroyo, CA) from

AFFIANT'S SIGNATURE AND TITLE: Operations Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)
Orthopedic Alliance, LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta, CA (City and State)
this 3rd day of August, 20 11.

DeJon N. Harris (Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

AFFIDAVIT

SAMPLE NO. 658789

STATE OF: California

COUNTY OF: Riverside

Before me, DeJon N. Harris, an employee of the Department of Health and Human Services, Food and Drug Administration, designated by the Secretary, under authority of the Act of January 31, 1925, 43 Statutes at Large 803; Reorganization Plan No. IV, Secs. 12-15, effective June 30, 1940; Reorganization Plan No. 1 of 1953, Secs. 1-9, effective April 11, 1953; and P.L. 96-88, Sec. 509. 93 Statutes at Large 965 (20 U.S.C. 3508) effective May 4, 1980; to administer or take oaths, affirmations, and affidavits, personally appeared Jeffrey P. Fields in the county and state aforesaid, who, being duly sworn, deposes and says:

Orthopedic Alliance, LLC (Murrieta, CA):

6. Orthopedic Alliance LLC DELIVERY SLIP, Surgery Date: 7-19-11, for implant of U2 Total Knee System Tibial Baseplate, Cemented, #5 Lot 11C113A, at ARROYO GRANDE COMM. HOSP. (1 page)

I also provided Investigator Harris with the product label, insert, and promotional material for the U2 Total Knee System Implants made by United Orthopedic Corporation (Hsinchu, Taiwan). The U2 Total Knee System is labeled by United Orthopedic Corporation under the Orthopedic Alliance brand.

The above is True and Correct

8/3/2011

AFFIANT'S SIGNATURE AND TITLE: Operations Manager

FIRM'S NAME AND ADDRESS (Include ZIP Code)
Orthopedic Alliance LLC
26157 Jefferson Ave. Murrieta, CA 92562

Subscribed and sworn to before me at Murrieta, CA (City and State)

this 3rd day of August, 20 11.

(Employee's Signature)

Employee of the Department of Health and Human Services designated under Act of January 31, 1925, Reorganization Plan IV effective June 30, 1940; Reorganization Plan No. 1 of 1953, effective April 11, 1953; and P.L. 96-88, effective May 4, 1980.

EXHIBIT 9

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	07/11/2011 - 09/15/2011* FEI NUMBER 3004884943

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Arnold Neves, General Counsel

FIRM NAME	STREET ADDRESS
Spinal Solutions, LLC	26157 Jefferson Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Murrieta, CA 92562	Medical Device Kit Assembler

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

The device history record does not demonstrate that the device was manufactured in accordance with the device master record.

Specifically, firm management stated they do not prepare or maintain device history records (DHR) for each spinal fixation system kit assembled and distributed for use to hospitals. This includes:

1) dates of manufacture; 2) quantity manufactured; 3) quantity released for distribution; 4) acceptance records demonstrating the device was manufactured in accordance with the Device Master Record; 5) primary identification label and labeling; and 6) any device identification and control number/s used.

Further, your firm has not established a procedure to ensure maintenance of DHR.

OBSERVATION 2

A device master record has not been maintained.

Specifically, Spinal Solutions, LLC assembles and distributes Spinal Fixation Systems kits which generally contain: 150-200 screws of varying size and length; approximately 80 rods, both curved and straight, of varying lengths; about 20 screw caps; and 6-8 crosslinks per set. Your firm has not prepared and does not maintain device master records that identify the components to be included in each kit, process procedures for the kitting operation, applicable quality assurance procedures and acceptance criteria, and the methods and process used to maintain labeling for the Spinal Fixntion System kits that you assemble for any of your nine suppliers. On 7/21/2011, firm personnel that perform kit assembly operations could not demonstrate where to reference instructions on what components and labeling should be included in each kit based on supplier and/or surgeon preference.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	DeJon N. Harris, Investigator Sonya L. Karsik, Investigator	09/15/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
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OBSERVATION 3

Procedures for finished device acceptance have not been established.

Specifically, your firm does not have a procedure to address final device acceptance activities for the Spinal Fixation System trays which you assemble and distribute for use to hospitals. Further, kit assembly operations are not documented; and there is no documentation showing the authorization for release of spinal fixation system trays assembled at Spinal Solutions, LLC.

OBSERVATION 4

Procedures for acceptance of incoming product have not been established.

Specifically,

A.

Procedure Number: 705, Revision: 2/15/10, entitled: "RECEIVING", identifies the Receiving Log & signed Packing Slip as records of the Receiving Inspection Process for purchased finished devices. Per the procedure, upon completion of receiving acceptance activities, the firm employee is to sign and date the packing slip to verify that the information on the slip is complete and accurate.

On 7/21/2011, firm personnel stated that there is no Receiving Log used to document incoming products or inspection. Further, Review of packing slips showed numerous packing slips without signature, date, and indication of acceptance or rejection of incoming material.

B.
Procedure Number: 705, Revision: 2/15/10, entitled: "RECEIVING" has not been approved by a designated individual.

OBSERVATION 5

Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	DeJon N. Harris, Investigator DNH Sonya L. Karsik, Investigator SLK	09/15/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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TO: Arnold Neves, General Counsel

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A.
SOP #: 805, Revision Date: 9/13/10, Procedure entitled: "Customer Complaints":

- does not identify who is responsible for the review and evaluation of complaints; who will determine whether complaint investigations are necessary; and how complaints will be investigated.
- states that a corrective action is to be issued only if the complaint appears to be Spinal Solutions fault, rather than on the basis of investigations of purported nonconformities relating to product, process, or the quality system.
- states that Preventive Actions may be issued if the complaint does not relate to damaged or defective product, but has merit. The procedure does not define the term "merit", and does not refer to potential causes of nonconforming product or quality problems as a basis for issuing a Preventive Action. Further, the procedure references Procedure 804, Corrective and Preventive Action, for guidance, but it has yet to be established.
- was signed by in-house General Counsel, but was not dated; and there are no quality records or documentation identifying the designated individual/s responsible for reviewing and approving the procedure.

B.
On 7/13/2011, In-house General Counsel stated that Spinal Solutions, LLC has never received complaints. However, on 7/14/2011, I observed the following complaints for Company F product in the file for receiving records:

- Company F COMPLAINT REPORT, dated 3/25/08, for stripping of screw caps with event date 1/23/08;
- Company F COMPLAINT REPORT, dated 3/25/08, for caps stripping on 3 of 4 screws with event date 12/12/07

Your firm has no records showing that a designated unit reviewed and evaluated the above complaints to determine if the event was required to be reported as a Medical Device Report; and to determine whether an investigation was necessary.

OBSERVATION 6

Procedures to control labeling activities have not been established.

Specifically, kit assembly operations performed at your firm do not provide for the accompaniment of Instructions for Use (IFU) with spinal fixation system kits throughout distribution. Firm personnel informed me that the IFU received with spinal fixation system components are not included with spinal fixation system kits once they are assembled at the firm and distributed. Further, you do not have a written procedure to address the labeling operations at your firm.

OBSERVATION 7

Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established.

Specifically,
A.
Spinal Solutions, LLC purchases and/or receives Spinal Fixation System kits and components from product manufacturers

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	DeJon N. Harris, Investigator DNH Sonya L. Karsik, Investigator SLK	09/15/2011

for assembly and distribution. Firm personnel identified nine suppliers of Spinal Fixation Systems from which they currently receive kits and components. There are no written quality agreements for 4 out of 9 suppliers of spinal fixation systems. While written agreements were on file for the remaining 5 of 9 suppliers, these agreements were incomplete in that they do not address responsibility for the following quality system requirements:

- Company A- Agreement effective May 4, 2011 does not address complaint handling, medical device reporting, labels/labeling content, product recall, or maintenance of device history records.
- Company B- Agreement dated February 28, 2011 does not address product design changes, complaint handling, medical device reporting, product recall, or maintenance of device history records.
- Company C- Agreement effective 11/6/2007 does not address complaint handling and maintenance of device history records. Further, the term of the agreement expired on the third anniversary of the effective date.
- Company D- Agreement effective January 26, 2010 does not address medical device reporting, product design changes, label content, and device history records. Also, the agreement expired six months after the effective date.
- Company E- Agreement Rev A 2-14-06, does not address product design changes, complaint handling, medical device reporting, recall, label/labeling content, or maintenance of device history records. Additionally, the agreement is not signed and dated.

B.
The document entitled *PROPOSAL for: Spinal Solutions*, dated January 6, 2010, proposing that Consultant A provide services pertaining to the development of quality system documentation, employee training, and implementation assistance, was not signed by both parties although consultant A has written and provided quality system documents to the firm.

C.
SOP #: 704, entitled: "Purchasing":

- does not describe any quality requirements for class I devices, such as manual surgical instruments containing Spinal Solutions' name, purchased by the firm;
- does not define the frequency with which evaluations are to be performed for suppliers, contractors, and consultants.
- is not approved by a designated individual.

Moreover, your firm has not established records of acceptable suppliers, contractors, or consultants. For example, firm personnel were unable to provide an Approved Supplier List, as required by your procedure; and a record demonstrating contractors and consultants were evaluated prior to utilizing their services.

D.
Responsibility for labeling activities has not been defined. On 7/20/2011, I observed metal trays labeled on the outside with Spinal Solutions' name and phone number. These trays contained vertebral body replacements and surgical instruments

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Arnold Neves, General Counsel

FIRM NAME	STREET ADDRESS
Spinal Solutions, LLC	26157 Jefferson Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Murrieta, CA 92562	Medical Device Kit Assembler

labeled with the name and logo of Company C. Firm personnel stated that Company C private labels the metal surgical trays with Spinal Solutions' name and contact information. The most recent Distribution and Marketing Agreement, effective date 11/6/2007, between Company C and Spinal Solutions, LLC does not include provisions for private labeling operations performed on behalf of Spinal Solutions, LLC by Company C.

OBSERVATION 8

Procedures for the control of storage areas and stock rooms have not been established.

Specifically, your firm has not developed methods for prevention of product mixups, damage, or other adverse effects pending use or distribution; and authorized movement to and from storage areas and stock rooms.

For instance:

- I observed rods stored in a room which firm management stated has been designated, but not fully implemented, as a quarantine area. Neither the room, nor products contained in the room were identified as to acceptance status.
- On 7/20/2011, I observed Interbody Fusion Devices (IBFD) in plastic bags stored in the stock room in a set of drawers identified with "Spinal Solutions APLIF 10 DEG". The bag labels read: "RD-0115 14MM APLIF 10 DEG 6 EACH" and "13540", respectively. Neither the product nor the storage location were identified as to acceptance status; and the bags did not contain or reference the location of associated labeling. Firm personnel stated the IBFDS were received from Company D and Company G, but could not locate the affiliated Instructions For Use.

OBSERVATION 9

Distribution records were not maintained and do not include or refer to the location of required information.

Specifically, distribution records which include or refer to the name and address of the initial consignee, identification and quantity of devices shipped, the date shipped, and control numbers for Spinal Fixation System kits and components shipped from Spinal Solutions, LLC, are not always prepared and maintained.

For example:

- The firm uses *Spinal Solutions/Orthopedic Alliance* Form to document drop-off/pick-up of surgical trays containing Spinal Fixation System implants and instruments to local customers. This form does not include fields for documenting consignee address, identification of tray or components within the tray, and affiliated control numbers. Firm management

was unable to provide any controlled procedures or forms for documentation of this information; and In-house General Counsel stated that product delivery personnel only retain completed *Spinal Solutions/Orthopedic Alliance* Forms for approximately one month.

- Firm personnel were unable to show record of product shipments from Spinal Solutions, LLC to non-local customers, in such states as Nevada and Maryland, for Spinal Fixation Systems that were purchased and implanted at user facilities.

OBSERVATION 10

The quality policy, quality objectives, and were not established by management with executive responsibility.

Specifically, Spinal Solutions, LLC Quality Manual, Revision A, DCR #4200, dated 4/8/08, states the Spinal Solutions quality policy and quality objectives are periodically reviewed during management review; and the quality policy is posted throughout the facility. However:

- On 7/28/2011, firm personnel were unable to provide documentation demonstrating a quality policy and objectives have been defined, documented, and implemented.
- The quality policy was not posted in the facility.
- Firm management stated that Management Reviews have not been conducted.

OBSERVATION 11

Quality system procedures and instructions have not been established.

Specifically, Spinal Solutions, LLC Quality Manual, Revision A, DCR #4200, dated 4/8/08, Appendix II Standard Element & SOP Matrix, lists the titles of standard operating procedures pertaining to specific quality manual elements including, but not limited to, quality management system, control of nonconforming product, and corrective and preventive action. Firm Management was unable to provide documentation demonstrating that procedures have been established (defined, documented and implemented) for the following quality system requirements:

- Corrective and Preventive Actions
- identification and traceability of product
- process control (providing written instruction for spinal fixation system kit assembly operations)
- control, review, and disposition of nonconforming product

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TO: Arnold Neves, General Counsel

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Murrieta, CA 92562	Medical Device Kit Assembler

- rework operations
- acceptance activities
- device label and labeling activities
- storage and distribution control
- maintenance of Device History Records
- document control

OBSERVATION 12

The organizational structure has not been adequately established and maintained to ensure that devices are produced in accordance with 21 CFR 820.

Specifically, Spinal Solutions, LLC Quality Manual, Revision A, DCR #4200, dated 4/8/08, references Appendix III, entitled "Process and Responsibility Matrix", which contains the firm's Responsibility and Organizational Chart. During employee interviews, firm personnel were unable to identify who has been assigned responsibility for review and/or approval of quality procedures and records including, inspection/verification operations and nonconforming products.

Additionally, Spinal Solutions, LLC Quality Manual, Revision A, DCR #4200, dated 4/8/08 identifies the QS&RA department Manager as the Managment Representative, however Spinal Solutions, LLC does not have a QS&RA department Manager. On 8/12/2011, firm management with executive responsibility informed me that a Management Representative has not been appointed.

OBSERVATION 13

Procedures for training and identifying training needs have not been established.

Specifically, firm management has not defined, documented, and implemented specific training requirements: 1) for personnel performing each job function; 2) as to possible device defects that may arise from improper performance of specific tasks, including those performed during process and verification activities; and 3) as to applicable current good manufacturing practices.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	DeJon N. Harris, Investigator DNH Sonya L. Karsik, Investigator SLK	09/15/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	07/11/2011 - 09/15/2011* FEI NUMBER 3004884943

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TO: Arnold Neves, General Counsel

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Murrieta, CA 92562	Medical Device Kit Assemblor

OBSERVATION 14

Management with executive responsibility has not reviewed the suitability and effectiveness of the quality system.

Specifically, management with executive responsibility has not conducted management reviews of quality sources including, complaints and acceptance activities to assure that the methods used to process devices are effective in meeting quality system requirements; and to assess the continued effectiveness of the firm's quality system.

OBSERVATION 15

Quality audits and reaudits have not been performed.

Specifically, on 8/12/2011, firm management stated that Spinal Solutions, LLC has had one internal audit conducted by the firm's FDA Compliance Consultant, however the date/s of the audit were not documented. Additionally, your firm has not established a procedure to address the performance of quality audits, re-audits , and corrective actions, for identified deficient matters.

OBSERVATION 16

Documents were not approved by designated individual(s) prior to issuance .

Specifically, Spinal Solutions, LLC Quality Manual, Revision A, DCR #4200, dated 4/8/08, was not approved. Further, there is no procedure establishing responsibility and authority for document approval and distribution.

Annotations to Observations 1-5: Promise to Correct
Annotation to observation 6: Reported Corrected; not verified
Annotations to observations 7-16: Promise to Correct

* DATES OF INSPECTION:
07/11/2011(Mon), 07/13/2011(Wed), 07/14/2011(Thu), 07/20/2011(Wed), 07/21/2011(Thu), 07/28/2011(Thu), 08/03/2011(Wed), 08/12/2011(Fri), 08/16/2011(Tue), 09/02/2011(Fri), 09/15/2011(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	DeJon N. Harris, Investigator Sonya L. Karsik, Investigator	09/15/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	07/20/2011 - 09/23/2011* FEI NUMBER 3004022256

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Arnold Neves, General Counsel

FIRM NAME	STREET ADDRESS
Orthopedic Alliance LLC	26157 Jefferson Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Murrieta, CA 92562	Medical Device Importer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Written MDR procedures have not been developed, maintained, and implemented.

Specifically, your firm does not have a standard review process/procedure which addresses the identification, communication, and evalutation of events subject to medical device reporting; and the documentation and recordkeeping for those events.

OBSERVATION 2

Procedures for recciving, reviewing, and evaluating complaints by a formally designated unit have not been established.

Specifically, as an importer of knee and hip prosthesis, you have not defined, documented, and implemented a procedure which addresses:

- uniform and timely processing of complaints
- documenation of oral complaints;
- evaluation of complaints for events required to be reported to FDA as Medical Device Reports.

OBSERVATION 3

Procedures for corrective and preventive action have not been established.

Specifically, your firm has not defined, documented, and implemented a process for analysis of 1) quality sources, 2)investigation of nonconformities and identificaiton of actions necessary to prevent and correct their occurrence; and 3) any other CAPA requirements as applicable to your operations.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	DeJon N. Harris, Investigator Sonya L. Karsik, Investigator	09/23/2011

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612 (949) 608-2900 Fax:(949) 608-4417 Industry Information: www.fda.gov/oc/industry	07/20/2011 - 09/23/2011* FEI NUMBER 3004022256

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Arnold Neves, General Counsel

FIRM NAME	STREET ADDRESS
Orthopedic Alliance LLC	26157 Jofferson Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Murrieta, CA 92562	Medical Device Importer

OBSERVATION 4

Distribution records were not maintained and do not include or refer to the location of required information.

Specifically,distribution records which include or refer to the name and address of the initial consignee, identification and quantity of devices shipped, the date shipped, and control numbers for hip and knee implants shipped from Orthopedic Alliance, LLC, are not always prepared and maintained.

For example:

- The firm uses *Spinal Solutions/Orthopedic Alliance* Form to document drop-off/pick-up of bins containing Hip and Knee System implants and instruments to local customers. This form does not include fields for documenting consignee address, identification of tray or components within the tray, and affiliated control numbers. firm mgmt was unable to provide any controlled procedures or forms for documetnation of this information; and In-house General Counsel stated that product delivery personnel only retain completed *Spinal Solutions/Orthopedic Alliance* Forms for approximately one month.

- Firm personnel informed me that the *Orthopedic Alliance Packaging Slip* was developed to document products shipped from the firm to Surgical Sales Representatives, but was unable to provide any completed *Orthopedic Alliance Packaging Slip.*

Annotation For observations)-4 ; Promise to Correct

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	DeJon N. Harris, Investigator Sonya L. Karsik, Investigator	09/23/2011

EXHIBIT 10

SPINAL SOLUTIONS, LLC

26157 JEFFERSON AVENUE
MURRIETA, CA 92562
PH :(951) 304-9001 (EXT. 331)
FAX: (951) 304-9101

ARNOLD NEVES, JR., ESQ.
GENERAL COUNSEL
ANEVES@SPINALSOLUTIONSLLC.COM

September 29, 2011

Via FedEx

Alonza E. Cruse
Director, Los Angeles District
Food & Drug Administration
19701 Fairchild
Irvine, CA 92612

Re: Spinal Solutions, LLC; FEI # 3004884943

Dear Mr. Cruse,

The following is the written response of Spinal Solutions, LLC, to the Observations provided to this company on September 15, 2011, by Investigators DeJon N. Harris and Sonya L. Karsik. Let me state at the outset that it is our firm intention to address and rectify each of the problem areas noted in the Observations in the shortest reasonable time possible. Please note that I and a co-worker will be attending an [redacted] workshop and medical device procedure training seminar in [redacted], the week of October 3 following which we will be able to continue focusing on correcting all of the noted deficiencies.

We have been advised that while we sell spinal hardware to hospitals for surgeries, we are considered a "manufacturer" because we "assemble" the surgical implant trays provided by the actual implant manufacturer. In actuality, the trays are initially assembled by the implant manufacturers and either sold or consigned to Spinal Solution. After the tray is returned from the hospital following its first use, the tray is restocked with the same size and type of implants provided by the implant manufacturer. This restocking consists of removing the new implant from either a plastic bag provided by the manufacturer or the bin where the hardware is kept and placing it in its designated slot in the manufacturer's tray for use in the next surgery. This act of restocking we are advised constitutes "repackaging" under 21 CFR 807.3(d)(1) even though we are the "person who makes final delivery or sale [of the device] to the ultimate consumer", namely the hospital. I believe it is important to note that Spinal Solutions does not sell or consign spinal hardware or any other products to other distributors.

As a result of being designated a manufacturer, a number of the provisions of 21 CFR §820 *et.seq.*, are deemed to apply to Spinal Solutions' operations. I now address each Observation set forth in the Inspectional Observations.

OBSERVATION 1

"The device history record does not demonstrate that the device was manufactured in accordance with the device master record.

Specifically, firm management stated they do not prepare or maintain device history records (DHR) for each spinal fixation system kit assembled and distributed for use to hospitals.

This includes:

1) Dates of manufacture; 2) quantity manufactured; 3) quantity released for distribution; 4) acceptance records demonstrating the device was manufactured in accordance with the Device Master Record; 5) primary identification label and labeling; and 6) any device identification and control number/s used.

Further, your firm has not established a procedure to ensure maintenance of DHR."

In speaking with the Investigators concerning this Observation, we are to treat each tray we restock as a manufacturing event. In other words, we need to track the number of spinal hardware trays prepared each day, the quantity released for distribution, etc.

Section 820.3(j) defines the Device Master Record as a compilation of records containing the records and procedures for a finished device. Subpart (i) defines the DHR as the compilation of records containing the production history of a finished product. Section 820.184 sets forth what the contents of the DHR should contain and the Observation mirrors the language of the regulation.

As noted after Observation 16, Spinal Solutions has "Promise[d] to Correct" the above-noted deficiency. I had already begun the procedure to correct many of the issues raised in the Observation before September 15, including making sure that each implant manufacturer's tray is documented on the date it is restocked and that all the contents of the tray by part, lot and quantity numbers are recorded. I will be creating the balance of the documents and procedures shortly and will provide you with a copy for your file.

OBSERVATION 2

"A device master record has not been maintained.

Specifically, Spinal Solutions, LLC assembles and distributes Spinal Fixation Systems kits which generally contain: [redacted] screws of varying size and length; [redacted] rods, both curved and straight, of varying lengths; [redacted] screw caps; and [redacted] crosslinks per set.

Your firm has not prepared and does not maintain device master records that identify the components to be included in each kit, process procedures for the kitting operation, applicable quality assurance procedures and acceptance criteria, and the methods and process used to maintain labeling for the Spinal Fixation System kits that you assemble for any of your [redacted] suppliers. On 7/21/2011, firm personnel that perform kit assembly operations could not demonstrate where to reference instructions on what components and labeling should be included in each kit based on supplier and/or surgeon preference."

This Observation addresses the requirements of §820.181 (Device master record). As noted, we promise to correct this deficiency. We have already begun a documented list of each component part that is to go into each manufacturer's tray and by specific tray. The location of where the implant is placed into the tray is already designated by the manufacturer by label locations within the trays themselves. However, we will document this procedure by reference to the manufacturer's instructions. As to labeling of the implant products, we have already adopted a procedure that ensures that each tray is accompanied by manufacturer's label/instructions for use at the time of delivery to the hospital. I will provide you copies of these procedures in the next 30 to 45 days and the DMR procedure thereafter.

OBSERVATION 3

"Procedures for finished device acceptance have not been established.

Specifically, your firm does not have a procedure to address final device acceptance activities for the Spinal Fixation System trays which you assemble and distribute for use to hospitals. Further, kit assembly operations are not documented; and there is no documentation showing authorization for release of spinal fixation system trays assembled at Spinal Solutions, LLC."

As noted, we have promised to correct this deficiency. In this case, this is simply a matter of documenting the procedures that are already followed each time a tray is restocked in preparation for a surgery. I will have these documented procedures to you as soon as possible, probably in the next 30 days.

OBSERVATION 4

"Procedures for acceptance of incoming product have not been established.

Specifically,

A. Procedure Number: 705, Revision 2/15/10 entitled "RECEIVING", identifies the Receiving Log & signed Packing Slip as records of the Receiving Inspection Process for purchasing finished devices. Per the procedure, upon completion of receiving acceptance activities, the firm employee is to sign and date the packing slip to verify that the information on the slip is complete and accurate.

On 7/21/2011, firm personnel stated that there is no Receiving Log used to document incoming products or inspection. Further, review of packing slips showed numerous packing slips without signature, date, and indication of acceptance or rejection of incoming material.

B. Procedure Number: 705, Revision 2/15/10 entitled "RECEIVING" has not been approved by a designated individual."

We will be correcting this deficiency immediately for not only compliance with FDA regulations and rectify this deficiency but also for our own internal cost controls and tracking. I will send you the adopted procedure and a copy of the Receiving Log as proof that the procedure is being followed in the next few weeks.

OBSERVATION 5

"Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been adequately established.

Specifically,

A. SOP #: 805, Revision Date: 9/13/10, Procedure entitled: Customer Complaints":

- Does not identify who is responsible for the review and evaluation of complaints; who will determine whether complaint investigations are necessary; and how complaints will be investigated.
- States that a corrective action is to be issued only if the complaint appears to be Spinal Solutions fault, rather than on the basis of Investigations of purported nonconformities relating to product, process, or the quality system.
- States that Preventive Actions may be issued if the complaint does not relate to damaged or defective product, but has merit. The procedure does not define the term "merit", and does not refer to potential causes of nonconforming product or quality problems as a basis for issuing a Preventative Action. Further, the procedure references Procedure 804, Corrective and Preventive Action, for guidance, but it has yet to be established.
- Was signed by in-house General Counsel, but was not dated; and there is no quality records or documentation identifying the designated individual/s responsible for reviewing the procedure.

B. On 7/13/2011, In-house General Counsel stated that Spinal Solutions, LLC has never received complaints. However, on 7,14/2011, I observed the following complaints for Company F product in the file for receiving records:

- Company F COMPLAINT REPORT, dated 3/25/08, for stripping of screw caps with event date 1/23/08;
- Company F COMPLAINT REPORT, dated 3/25/08, for caps stripping on 3 of 4 screws with event date 12/12/07

Your firm has no records showing that a designated unit reviewed and evaluated the above complaints to determine if the event was required to be reported as a Medical Device Report; and to determine whether an investigation was necessary."

Since I am mentioned in this Observation, let me first clarify the record. I informed Ms. Harris that I was not aware of any complaints concerning implants since I started with the company, which occurred on June 1, 2009. This is an accurate statement. The manner in which the Observation is written implies that I attempted to mislead her, which is inaccurate. In any event, we are in the process of adopting corrective procedures to address and resolve this deficiency. We will be first incorporating each manufacturer's complaint handling procedures as a part of our procedures and supplement as necessary to ensure that any and all complaints are properly handled. This procedure will be more extensive in preparation and will comply with Part 803 and §820.198. I will forward the new procedure to you upon completion which I hope to have completed in the next 30 to 60 days.

OBSERVATION 6

" Procedure to control labeling activities have not been established.

Specifically, kit assembly operations performed at your firm do not provide for the accompaniment of Instructions for Use (IFU) with spinal fixation system kits throughout distribution. Firm personnel informed me that the IFU received with spinal fixation components are not included with spinal fixation system kits once they are assembled at the firm and distributed. Further, you do not have a written procedure to address the labeling operations at your firm."

As noted, we have corrected this procedure. Attached is a copy of the Tracking Procedure. Paragraph 6 provides that a copy of the IFU is to accompany each spine hardware tray to the hospital. In the past, we had relied on the generally accepted procedure adopted by hospitals purchasing our products which provided for one copy of the IFU to be on file with the hospital for each implant type we were providing. Providing another copy of the IFU each time a spinal hardware tray is delivered is a simple process that has been adopted.

OBSERVATION 7

"Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established.

Specifically,

A. Spinal Solutions, LLC purchases and/or receives Spinal Fixation System kits and components from product manufacturers for assembly and distribution. Firm personnel identified [redacted] suppliers of Spinal Fixation Systems from which they currently receive kits and components. There are no written quality agreements for 4 [redacted] suppliers of spinal fixation systems. While written agreements were on file for [redacted] suppliers, these agreements were incomplete in that they do not address responsibility for the following quality system requirements:

- Company A – Agreement effective May 4, 2011does not address complaint handling, medical device reporting, labels/labeling content, product recall, or maintenance of device history records.
- Company B – Agreement dated February 28, 2011 does not address product design changes, complaint handling, medical device reporting, product recall, or maintenance of device history records.
- Company C – Agreement effective 11/6/2007 does not address complaint handling and maintenance of device history records. Further, the term of the agreement expired on the third anniversary of the effective date.
- Company D – Agreement effective January 26, 2010 does not address medical device reporting, product design changes, label content, and device history records. Also, the agreement expired six months after the effective date.
- Company E – Agreement rev A 2-14-06 does not address product design changes, complaint handling, medical device reporting, recall, label/labeling content, or maintenance of device history records. Additionally, the agreement is not signed and dated.

B. The document entitled *PROPOSAL for: Spinal Solutions*, dated January 6, 2010, proposing that Consultant A provide services pertaining to the development of quality system documentation, employee training, and implantation assistance, was not signed by both parties although consultant A has written and provided quality system documents to the firm.

C. SOP #: 704, entitled "Purchasing":

- does not describe any quality requirements for class I devices, such as manual surgical instruments containing Spinal Solutions' name, purchased by the firm.
- does not identify the frequency with which evaluations are to be performed for suppliers, contractors, and consultants.
- is not approved by the designated individual.

Moreover, your firm has not established records of acceptable suppliers, contractors, or consultants. For example, firm personnel were unable to provide an Approved Supplier List, as required by your procedure; and a record demonstrating contractors and consultants were evaluated prior to utilizing their services.

D. Responsibility for labeling activities has not been defined. On 7/20/2011, I observed metal trays labeled on the outside with Spinal Solutions' name and phone number. These trays contained vertebral body replacements and surgical instruments labeled with the logo of Company C. Firm personnel stated that Company C private labels the metal surgical trays with Spinal Solutions' name and contact information. The most recent Distribution and Marketing Agreement, effective 11/6/2007, between Company C and Spinal Solutions, LLC does not include provisions for private labeling operations performed on behalf of Spinal Solutions, LLC by Company C."

In our response, we promised to correct this deficiency. I will go back to each implant manufacturer to whom we purchase spinal hardware and insist that the provisions dealing with

product design changes, complaint handling, medical device reporting, product recall, maintenance of device history records, and product design changes are all addressed. The contracts will all be updated and maintained current. I estimate that I should have this deficiency completed within the next 30-60 days depending on the response time from the suppliers. As a part of this updating, we will address and resolve the contractual omission relating to "private labeling" of the surgical trays with Spinal Solutions' name and phone number which is done primarily so that our implants trays do not become mislaid or misappropriated at the hospital.

As to Purchasing SOP # 704 (prepared by Consultant A) for Class I devices, I will correct the deficiency in the procedure and verify that it is being followed. This will include preparation of an Approved Supplier List. I estimate to have this completed within the next 30-45 days.

I will forward to you copies of these items as they are developed and implemented.

OBSERVATION 8

"Procedures for the control of storage areas and stock rooms have not been established.

Specifically, your firm has not developed methods for prevention of product mixups, damage, or other adverse effects pending use or distribution; and authorized movement to and from storage areas and stock rooms.

For instance:

- I observed rods stored in a room which firm management stated has been designated, but not fully implemented, as a quarantine area. Neither the room, nor products contained in the room were identified as to acceptance status.
- On 7/20/2011, I observed [redacted] Devices ([redacted]) in plastic bags stored in the stock room in a set of drawers identified with "Spinal Solutions [redacted]". The bag labels red "[redacted]" and "[redacted]", respectively. Neither the product nor the storage location were identified as to acceptance status; and the bags did not contain or reference the location of associated labeling. Firm personnel stated the [redacted] were received from Company D and Company G, but could not locate the affiliated Instructions For Use."

We indicated that Spinal Solutions promised to correct this deficiency. We have already begun to address correcting this deficiency and I will be developing written procedures to ensure compliance such that no product is accepted that does not have the proper labeling from the manufacture together with the appropriate lot numbers. I estimate that complete adoption of the procedure will take approximately 30-45 days. I will forward to you a copy of the adopted procedure upon completion.

OBSERVATION 9

"Distribution records were not maintained and do not include or refer to the location of required information.

Specifically, distribution records which include or refer to the name and address of the initial consignee, identification and quantity of devices shipped, the date shipped, and control numbers for Spinal Fixation System kits and components shipped from Spinal Solutions, LLC, are not always prepared and maintained.

For example:

- The firm uses *Spinal Solutions* [redacted] Form to document drop-off/pick-up of surgical trays containing Spinal Fixation System implants and instruments to local customers. This form does not include fields for documenting consignee address, identification of tray or components within the tray, and affiliated control numbers. Firm management was unable to provide any controlled procedures or forms for documentation of this information; and In-house General Counsel stated that product delivery personnel only retain completed *Spinal Solutions* [redacted] Forms for approximately one month.
- Firm personnel were unable to show record of product shipments from Spinal Solutions, LLC to non-local customers, in such states as [redacted] and [redacted] for Spinal Fixation Systems that were purchased and implanted at user facilities."

We began addressing this deficiency in July and will continue to do so until it is corrected. I have included a copy of the new Tracking Procedure that I prepared in August for your review. Also enclosed are copies of completed shipping reports for some trays awaiting shipments as an example. Tray [redacted]01 is the Spine [redacted] Instrument Tray and [redacted]02 is a corresponding implant tray. I have to make refinements to the form to include the address for the recipient, a signature and date block for the employee authorizing release but otherwise I believe this form and the accompanying procedure addresses the deficiencies noted in Observation 9 along with portions of other Observations. Also, on July 18, 2011, I post for our employees and emailed to our outside sales/surgical agents the enclosed Memorandum regarding the failure to include implant lot numbers on the hospital delivery slips which show which implants were used during a surgery. We now have 100% compliance on this aspect of implant tracking by product lot number. A copy of a surgery delivery slip for a surgery conducted today is enclosed for your review.

Because of the number of trays and implants with their corresponding lot numbers, it will take some time before we achieve full implementation of the tracking procedure. I am planning to have full compliance at our facility in the next 30 days and offsite compliance a month later.

OBSERVATION 10

"The quality policy & quality objectives, and were not established by management with executive responsibility.

Specifically, Spinal Solutions, LLC Quality Manual, Revision A DCR #4200, dated 4/8/08, states the Spinal Solutions quality policy and quality objectives are periodically reviewed during management review; and the quality policy is posted throughout the facility. However:

- On 7/28/2011, firm personnel were unable to provide documentation demonstrating a quality policy and objectives have been defined, documented, and implemented.
- The quality policy was not posted in the facility.
- Firm management stated that Management Reviews have not been conducted."

We will be amending and updating the Quality Manual and quality system requirements consistent with the provisions of §820.20 and other applicable regulations. Thereafter, executive management will ensure implementation and that the procedures are followed. I anticipate that it should not take more than 30-45 days to make the necessary corrections to address the noted deficiencies.

OBSERVATION 11

"Quality system procedures and instructions have not been established.

Specifically, Spinal Solutions, LLC Quality Manual, Revision A, DCR # 4200, dated 4/8/08, Appendix II Standard Element & SOP Matrix, lists the titles of standard operating procedures pertaining to specific quality manual elements including, but not limited to, quality management systems, control of nonconforming product, and corrective and preventative action. Firm Management was unable to provide documentation demonstrating that procedures have been established (defined, documented and implemented) for the following quality system requirements:

- Corrective and Preventative Actions
- Identification and traceability of product
- Process control (providing written instruction for spinal fixation system kit assembly operations)
- Control, review, and disposition of nonconforming product
- Rework operations
- Acceptance activities
- Device label and labeling activities
- Storage and distribution control
- Maintenance of Device History Records
- Document control"

As referenced, Spinal Solutions has promised to correct the deficiencies noted in the Observation. We have already begun addressing certain aspects of the quality system requirements such as labeling activities and device tracking which will flow into the Device History Records. These will continue to be developed until all items are addressed. As mentioned above, I, along with the firm's Operations Manager, are attending a conference [redacted] which focuses on CAPA implementation and related regulatory subjects.

It is my intention that we will have all of the issues addressed and corrected in two to three months, if not sooner, taking into account implementation, follow-up and required procedural modifications.

OBSERVATION 12

"The organizational structure has not been adequately established and maintained to ensure that devices are produced in accordance with 21 CFR 820.

Specifically, Spinal Solutions, LLC Quality Manual, Revision A, DCR # 4200, dated 4/8/08, references Appendix III, entitled "Process and Responsibility Matrix", which contains the firm's Responsibility and Organizational Chart. During employee interviews, firm personnel were unable to identify who has been assigned responsibility for review and/or approval of quality procedures and records including, inspection/verification operations and nonconforming products.

Additionally, Spinal Solutions, LLC Quality Manual, Revision A, DCR # 4200, dated 4/8/08 identifies the QS&RA department Manager as the Management Representative, however Spinal Solutions, LLC does not have a QS&RA department Manager. On 8/12/2011, firm management with executive responsibility informed me that a Management Representative has not been appointed."

As indicated, Spinal Solutions has promised to correct the deficiencies noted in the Observation. As stated, the Quality Manual will be amended and updated to correctly reflect the operations of the company. Since September 15, the company has retained the services of a full time manager whose job duties include the operational aspects noted in the Observation. I, along with executive management, will be preparing and implementing the required procedures to address each deficiency noted in the Observations. The time required for establishing the corrected procedures should be approximately 30 days, training and implementation of the new procedures should be completed 30 days thereafter.

OBSERVATION 13

"Procedures for training and identifying training needs have not been established.

Specifically, firm management has not defined, documented, and implemented specific training requirements: 1) for personnel performing each job function; 2) as to possible device defects that may arise from improper performance of specific tasks, including those performed during process and verification activities; and 3) as to applicable current good manufacturing practices."

We have promised to correct this deficiency. This procedure is one of documentation. We are in the process of preparing a training manual that addresses each job function. Because of the scope involved and the participants whose input is required, this project may take approximately 2 months to complete. In the interim, we have coordinated additional training programs with

some of our suppliers that will cover subjects such as tray assembly, restock and verification, device use training, and claim handling. These events will be documented by the trainers and the records retained as part of the quality procedure.

OBSERVATION 14
"Management with executive responsibility has not reviewed the suitability and effectiveness of the quality system.

Specifically, management with executive responsibility has not conducted management reviews of quality sources including, complaints and acceptance activities to assure that the methods used to process devices are effective in meeting quality system requirements; and to assess the continued effectiveness of the firm's quality system."

As indicated, Spinal Solutions has promises to correct this deficiency. Following development of the procedures outlined above for quality sources, including complaint handling and quality systems, management will conduct its review following documented procedures to assess the effectiveness of the quality system and make necessary changes as appropriate. This review will be conducted immediately following implementation of each procedure and will be documented. I will forward to you the results of the review(s) as they are conducted.

OBSERVATION 15
"Quality audits and reaudits have not been performed.

Specifically, on 8/12/2011, firm management stated that Spinal Solutions, LLC has had one internal audit conducted by the firm's FDA Compliance Consultant, however the date/s of the audit were not documented. Additionally, your firm has not established a procedure to address the performance of quality audits, re-audits, and corrective actions, for identified deficient matters."

Likewise, executive management will perform required quality audits following established written procedures. I anticipate the first audit to be conducted in the next 90 days to determine what corrective actions need to be implemented, with a follow-up audit conducted a few months later to verify that the procedures are being followed.

OBSERVATION 16
"Documents were not approved by designated individual(s) prior to issuance.

Specifically, Spinal Solutions, LLC Quality Manual, Revision A, DRC # 4200, dated 4/8/08, was not approved. Further, there is no established responsibility and authority for document approval and distribution."

We will correct this deficiency as a part of the overall process of addressing each respective Observation. As stated, the Quality Manual will be revised and in this regard,

responsibility and authority for approval and distribution of documented procedures will be clearly established and followed.

It is our serious intention to provide full cooperation with the FDA and to undertake all necessary and immediate steps to implement required procedures which address each Observation completely to obtain full compliance. Likewise, we intend to follow-up to make sure these procedures are being followed after implementation. [redacted]. It would be helpful if I could obtain feedback following your receipt of the written documentation confirming our efforts that I will be subsequently sending to you.

If you have any questions or comments with respect to any of the foregoing, please do not hesitate to contact me.

Sincerely,

Arnold Neves, Jr., Esq.

Cc: DeJon N. Harris, Investigator

EXHIBIT 11

Inspections, Compliance, Enforcement, and Criminal Investigations

Spinal Solutions, LLC 1/19/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE

January 19, 2012

W/L 15-12

Roger Williams
President
Spinal Solutions, LLC
26157 Jefferson Ave.
Murrieta, California 92562

Dear Mr. Williams:

During an inspection of your firm located in Murrieta, California, on July 11, 2011, through September 15, 2011, investigators from the United States Food and Drug Administration (FDA) determined that your firm is a manufacturer because you are a repacker/kit assembler of spinal implant systems, and an own-label distributor of spinal implant instruments. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR) Part 820. We received a response from Arnold Neves, Jr., Esq., General Counsel, dated September 29, 2011, concerning our investigators' observations noted on the Form FDA 483 (FDA 483), List of Inspectional Observations, that was issued to your firm.

We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).

For example: Your firm does not have any procedures for corrective and preventive actions (CAPA).

We reviewed your firm's response and conclude that it is not adequate. Your firm promised to correct the observation, but has not provided us with a CAPA procedure, evidence of its implementation, and evaluation of previous CAPA sources to determine if a CAPA should have been initiated.

2. Failure to establish and maintain procedures to control product that does not conform to specified requirements, as required by 21 CFR 820.90(a).

For example: Your firm does not have any procedures for control of nonconforming product or facilities for segregation of nonconforming product.

We reviewed your firm' s response and conclude that it is not adequate. Your firm promised to correct the observation, but has not provided us with a nonconforming product procedure, evidence of its implementation, and evaluation of previously-processed product to ensure that nonconforming product was not distributed without documentation of justification.

3. Failure to establish and maintain adequate procedures for receiving, reviewing, and evaluating complaints, as required by 21 CFR 820.198(a).

For example: Procedure 805, "Customer Complaints," does not identify who is responsible for the review and evaluation of complaints; who will determine whether complaint investigations are necessary and the methods used for that determination; and how complaints will be investigated.

We reviewed your firm's response and conclude that it is not adequate. The response indicates that Spinal Solutions will incorporate the individual manufacturers' complaint handling and MDR procedures into its own procedures and supplementing those procedures with additional requirements, but the response does not include any revised procedures, evidence of implementation, or evaluation of previous complaints to determine if an investigation is necessary.

4. Failure to establish and maintain adequate procedures to ensure that all purchased or otherwise received product and services conform to specified requirements, as required by 21 CFR 820.50.

For example:

a. Procedure 704, "Purchasing," indicates that all finished device manufacturers supplying product to your firm require a Supplier Agreement that defines product and quality system requirements. Your firm identified **(b)(4)** from which it currently receives kits and components, but your firm does not have quality agreements with 4

of the **(b)(4)** In addition:

i. The agreement with **(b)(4)** does not address complaint handling, medical device reporting, labels/labeling content, product recall, or maintenance of device history records.

ii. The agreement with **(b)(4)** does not address product design changes, complaint handling, medical device reporting, product recall, or maintenance of device history records.

iii. The agreement with **(b)(4)** does not address complaint handling and maintenance of device history records. Further, the term of the agreement expired on the third anniversary of the effective date.

iv. The agreement with **(b)(4)** does not address medical device reporting, product design changes, label content, and device history records. Also, the agreement expired six months after the effective date.

v. The agreement with **(b)(4)** does not address product design changes, complaint handling, medical device reporting, recalls, label/labeling content, or maintenance of device history records. Additionally, the agreement is not signed and dated.

We reviewed your firm's response and conclude that it is not adequate. Your firm indicated that it will revise its purchasing agreements with its suppliers to include provisions dealing with product design changes, complaint handling, medical device reporting, product recall, and maintenance of device history records. However, Spinal Solutions has not provided any new or revised purchasing agreements, reviews of any other suppliers to ensure that adequate supplier agreements exist, or investigations to ensure that there have not been any previous design changes of which your firm is unaware.

b. Procedure 704, "Purchasing," does not describe any quality requirements for Class I devices, such as manual surgical instruments, nor does it define the frequency with which evaluations are to be performed for suppliers, contractors, and consultants. In addition, the procedure requires your firm to maintain an Approved Suppliers List and evaluate suppliers prior to utilization of services, but the firm does not have an Approved Supplier List or records of evaluation of suppliers.

We reviewed your firm's response and conclude that it is not adequate. Your firm indicated that Procedure 704 will be revised to include requirements for Class I devices, but the response does not include any new or revised purchasing control procedures, including evidence of implementation, or evaluation of previously received Class I devices to ensure that the supplier was in compliance. In addition, the response does not address the observation as it pertains to the lack of an Approved Supplier List and records of evaluation of suppliers.

5. Failure to establish and maintain procedures for finished device acceptance to ensure that each production run, lot, or batch of finished devices meets acceptance criteria, as required by 21 CFR 820.80(d).

For example: Your firm has not developed any final acceptance specifications or release criteria for any of its products, does not document any final acceptance activities, and has no

procedures for final acceptance activities.

We reviewed your firm's response and conclude that it is not adequate. Your firm indicates that final device acceptance procedures will be developed, but Spinal Solutions has not provided any such procedures, and it has not provided any evaluation of previously distributed product to ensure that it was adequately evaluated and approved.

6. Failure to establish and maintain adequate procedures for acceptance of incoming product, as required by 21 CFR 820.80(b).

For example: According to Procedure 705, "Receiving," **(b)(4)** receiving acceptance activities are to be documented on a receiving log and approval documented on the packing slip. However, your firm has not developed or maintained a receiving log, and **(b)(4)** Packing Slips **(b)(4)** and **(b)(4)**) and **(b)(4)** Packing Lists **(b)(4)**, and **(b)(4)** do not contain a signature and date for acceptance.

We reviewed your firm's response and conclude that it is not adequate. Your firm promised to revise procedure 705 and develop a receiving log, but the response does not include that a new procedure, receiving log, or an evaluation of previously-received products to determine whether proper receiving acceptance activities were performed and that the received product was approved.

7. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22.

For example: Your firm has not established a procedure for the performance of quality audits. In addition, your firm stated that it has had one internal audit conducted by your firm's FDA Compliance Consultant; however, the date of the audit was not documented.

We reviewed your firm's response and conclude that it is not adequate. Your firm promised to perform quality audits, but the response does not include any quality audit procedures or evidence of the performance of any quality audits.

8. Failure of management with executive responsibility to review the suitability and effectiveness of the quality system at defined intervals and with sufficient frequency according to established procedures to ensure that the quality system satisfies the requirements of 21 CFR Part 820 and the manufacturer's established quality policy and objectives, as required by 21 CFR 820.20(c).

For example: Though your firm's Quality Manual, Revision A, **(b)(4)** states that management review is conducted twice each year, no management reviews have been documented.

We reviewed your firm's response and conclude that it is not adequate. In the response, Spinal Solutions promised to document management reviews, but the response does not include any evidence of the performance of any management reviews.

9. Failure to establish procedures for identifying training needs and ensure that all personnel are trained to adequately perform their assigned responsibilities, as required by 21 CFR 820.25(b).

For example: Your firm has not defined or documented procedures for identifying training

needs.

We reviewed your firm's response and conclude that it is not adequate. Spinal Solutions indicated that training manuals are in development, but the response does not include any training manuals, any procedures for identifying training needs, or evidence of the implementation of new training requirements.

10. Failure of management with executive responsibility to establish its policy and objectives for, and commitment to, quality, as required by 21 CFR 820.20(a).

For example: Though Quality Manual, Revision A, **(b)(4)** states the Spinal Solutions quality policy and quality objectives are to be periodically reviewed during management review and that the quality policy is to be posted throughout the facility, a quality policy and objectives have not been defined, documented, and implemented.

We reviewed your firm's response and conclude that it is not adequate. Your firm indicated that executive management will ensure implementation of quality requirements and will ensure that quality systems procedures are followed, but the response does not indicate that executive management will develop a quality policy and objectives and establish such a policy and objectives, or include evidence of the distribution of the firm's quality policy and objectives.

11. Failure of management with executive responsibility to appoint, and document the appointment of, a member of management who, irrespective of other responsibilities, shall have established authority over and responsibility for: (i) ensuring that quality system requirements are effectively established and effectively maintained in accordance with 21 CFR Part 820; and (ii) reporting on the performance of the quality system to management with executive responsibility for review, as required by 21 CFR 820.20(b)(3).

For example: Though Quality Manual, Revision A, **(b)(4)** identifies the QS&RA Department Manager as the Management Representative, Spinal Solutions does not have a QS&RA Department Manager and has not designated any other individual as a management representative.

The adequacy of your firm's response cannot be determined at this time. Your firm indicated that Spinal Solutions has appointed a management representative, but no evidence has been provided of such an appointment.

12. Failure to establish and maintain adequate procedures to control all documents that are required by 21 CFR Part 820, as required by 21 CFR 820.40.

For example: Your firm does not have a procedure designating an individual to review for adequacy and approve prior to issuance all documents established to meet the requirements of 21 CFR Part 820. In addition, Quality Manual, Revision A, **(b)(4)** was not approved.

We reviewed your firm's response and conclude that it is not adequate. The response indicates that Spinal Solutions will revise the Quality Manual to include document control requirements, but the response does not include a revised Quality Manual or evidence of implementation of document control requirements. In addition, your firm has not reviewed all other documentation to ensure that it is properly approved.

13. Failure to maintain device history records (DHRs), as required by 21 CFR 820.184. For

example: Your firm does not document any information required in a DHR, nor does it have procedures to ensure that DHRs are maintained.

The adequacy of your firm's response cannot be determined at this time. The response indicates that Spinal Solutions has begun developing a procedure for maintaining DHRs and will begin creating DHRs for all new trays, but your firm has not provided any DHR procedures, including evidence of their implementation, or any method for determining any of the information that would have been documented in the DHRs of products that have already been distributed.

14. Failure to maintain device master records (DMRs), as required by 21 CFR 820.181.

For example: Your firm does not document any information required in a DMR.

We reviewed your firm's response and conclude that it is not adequate. The response indicates that Spinal Solutions has begun developing a procedure for maintaining DMRs and has created procedures for assembling trays and labeling, but your firm has not provided any DMR procedures, including evidence of their implementation, any documentation of specifications and quality assurance procedures, or any evaluation of previously-distributed kits to determine if they were produced using adequate processes.

Our inspection also revealed that your firm's devices are misbranded under Section 502(f)(1) of the Act, 21 U.S.C. § 352(f)(1), in that the labeling for the devices fails to bear adequate directions for use for the purposes for which they are intended.

For example: Your firm did not provide package inserts for the spinal systems in its kits. Those package inserts are required in order to provide adequate directions for use.

The adequacy of your firm's response cannot be determined at this time. Your firm indicated that a copy of the label/Instructions For Use will be provided to the hospital with a set each time, but it has not provided any evidence of implementation of this corrective action. In addition, your firm has not provided any evidence of actions taken to ensure that devices that have already been distributed bare adequate instructions for use.

Our inspection also revealed that your firm's devices are misbranded under Section 502(f)(2) of the Act, 21 U.S.C. 352(t)(2), in that the labeling for the device fails to bear adequate warnings.

For example: Your firm did not provide package inserts for the spinal systems in its kits. Those package inserts include all of the warnings and contraindications associated with the spinal systems. Therefore, the device labeling does not bear adequate warnings without the package inserts.

The adequacy of your Firm's response cannot be determined at this time. Your firm indicated that a copy of the label/Instructions For Use will be provided to the hospital with a set each time, but it has not provided any evidence of implementation of this corrective action. In addition, your firm has not provided any evidence of actions taken to ensure that devices that have already been distributed bare adequate warnings.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices

so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

Blake Bevill
Director, Compliance Branch
U.S. Food and Drug Administration
19701 Fairchild
Irvine, CA 92612-2506

Refer to the Unique Identification Number 235836 when replying. If you have any questions about the contents of this letter, please contact Jessica Mu, Compliance Officer, at 949-608-4477.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Alonza E. Cruse
District Director

Page Last Updated: 03/26/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)

Links on this page:

EXHIBIT 12

Inspections, Compliance, Enforcement, and Criminal Investigations

Orthopedic Alliance 2/3/12

Department of Health and Human Services

Public Health Service
Food and Drug Administration
Los Angeles District
Pacific Region
19701 Fairchild
Irvine, CA 92612-2506
Telephone: 949-608-2900
FAX: 949-608-4415

WARNING LETTER

VIA UNITED PARCEL SERVICE
SIGNATURE SERVICE REQUIRED

February 3, 2012

W/L 17-12

Mr. Roger Williams, President
Orthopedic Alliance
26157 Jefferson Avenue
Murrieta, California 92562

Dear Mr. Williams:

During an inspection of your firm located in Murrieta, California, on July 20, 2011, through September 23, 2011, investigators from the United States Food and Drug Administration (FDA) determined that your firm manufactures various orthopedic implant devices, including the SC Total Hip System and the SC Ceramic Ball Heads. Under Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), these products are devices because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or they are intended to affect the structure or function of the body.

This inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act (21 U.S.C. § 351(h)), in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the current good manufacturing practice requirements of the Quality System regulation found at Title 21, Code of Federal Regulations (CFR), Part 820. We received a response from Mr. Arnold Neves, Jr., dated September 30, 2011, concerning our investigator's observations noted on the Form FDA 483, List of Inspectional Observations, that was issued to your firm. We address this response below, in relation to each of the noted violations. These violations include, but are not limited to, the

following:

1. Failure to establish and maintain procedures for implementing corrective and preventive action (CAPA), as required by 21 CFR 820.100(a).

For example, your firm's General Counsel Representative stated that there was no corrective and preventive action procedure.

We reviewed your firm's response and conclude that it is not adequate. Your firm stated that two of its employees will be attending a CAPA workshop in early October, 2011, and that the CAPA procedure will be implemented in sixty days. However, neither procedures nor additional procedural details have been submitted for our review. In addition, your firm did not provide a rationale for requiring up to sixty days to complete this corrective action.

2. Failure to establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally-designated unit, as required by 21 CFR 820.198(a).

For example, your firm's General Counsel Representative stated that there was no complaint procedure.

We reviewed your firm's response and conclude that it is not adequate. Your firm stated that its complaint handling program is being developed in conjunction with the Medical Device Reporting program and that these programs should be implemented "within the next thirty to sixty days." However, neither procedures nor additional procedural details have been submitted for our review. In addition, your firm did not provide a rationale for requiring the timeframe of up to sixty days to complete this corrective action.

3. Failure to establish and maintain adequate procedures for control and distribution of finished devices to ensure that only those devices approved for release are distributed and that purchase orders are reviewed to ensure that ambiguities and errors are resolved before distribution, as required by 21 CFR 820.160(a).

For example, the distribution records that include or refer to the name and address of the initial consignee, identification and quantity of devices shipped, the date shipped, and control numbers for hip and knee implants shipped from Orthopedic Alliance, LLC, are not always prepared and maintained.

We reviewed your firm's response and conclude that it is not adequate. Your firm stated that it has begun to implement a new tracking procedure which should be completed in the next month, and that it will send copies of process shipping records upon completion for spinal and orthopedic implants to the district office. However, no tracking procedure was provided, nor was there evidence that the new procedure had been implemented.

Our inspection also revealed that your firm's U2 Total Knee System and SC Total Hip System and SC Ceramic Ball Heads are misbranded under Section 502(t)(2) of the Act, 21 U.S.C. § 352(t)(2), in that your firm failed or refused to furnish material or information respecting the device that is required by or under Section 519 of the Act, 21 U.S.C. § 360i, and 21 CFR Part 803 - Medical Device Reporting. Significant violations include, but are not limited to, the following:

Failure to develop, maintain and implement a Medical Device Reporting (MDR) procedure, as required by 21 CFR 803.17.

We reviewed your firm's response and conclude that it is not adequate. Your firm stated that its MDR program is being developed in conjunction with the complaint handling program and that the programs should be implemented "within the next thirty to sixty days." However, no additional detailed procedures have been submitted for our review. In addition, your firm did not provide a rationale for requiring the timeframe of up to sixty days to complete this corrective action.

Your firm should take prompt action to correct the violations addressed in this letter. Failure to promptly correct these violations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties. Also, federal agencies may be advised of the issuance of Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, premarket approval applications for Class III devices to which the Quality System regulation violations are reasonably related will not be approved until the violations have been corrected. Requests for Certificates to Foreign Governments will not be granted until the violations related to the subject devices have been corrected.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to correct the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (including any systemic corrective actions) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address all violations included in this Warning Letter.

Your firm's response should be sent to:

Blake Bevill
Director, Compliance Branch
U.S. Food & Drug Administration
19701 Fairchild
Irvine, California 92612-2446

Refer to the Unique Identification Number 235834 when replying. If you have any questions about the contents of this letter, please contact: Jessica Mu, Compliance Officer, at 949-608-4477.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of the violations, and take prompt actions to correct the violations and bring the products into compliance.

Sincerely,
/S/
Alonza E. Cruse, Director
Los Angeles District

Cc: Ingeborg Small, Branch Chief

California Department of Public Health
Food and Drug Branch
1500 Capitol Avenue, MS-7602
P.O. Box 997413
Sacramento, CA 95899-7413

Page Last Updated: 03/26/2012
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

Links on this page:

EXHIBIT 13

25 March 2013

Spinal Solutions LLC

Urgent Medical Device Recall – APLIF Implants and Instruments

Dear Doctor or Hospital Administrator,

Spinal Solutions has instituted a Medical Device Recall of APLIF Implants and Instruments.

All APLIF implants and instruments are included in this recall.

The APLIF system devices are being recalled because the safety and effectiveness of the product have not been evaluated by the FDA in a premarket submission.

The APLIF system is not supported by adequate testing and documentation to demonstrate that it meets performance or safety standards. These inadequacies might result in product performance failures that could cause patient harm due to implant breakage, movement, or inadequate sterilization.

Urgent Medical Device Recall – Actions

- There are no other specific actions requested of you with regards to this recall other than acknowledgement of the receipt of this letter.
- We are not recommending that these devices be explanted from patients.
- Our records indicate that you do not have any Blue & Gold implants or instruments in your possession, however if you do, please do not use them and contact me to arrange for their return to Orthopedic Alliance.
- If you have any questions with regards to this recall, please contact me at the number listed below.
- Please complete the bottom of this form and return it by FAX to (858) 764-9739

Thank you for your assistance in this matter.

Natalie J. Kennel
RA/QA Consultant
(858) 705-0350

I have examined my implant and instrument inventory and certify that:

Check all that apply

◯ I do not have any APLIF implants or instruments in my possession.

◯ I have shipped all APLIF implants and instruments to Spinal Solutions.

Contact Name:_____ Phone Number: (_____) _____
Print

Signature:_____ Date:_____

Spinal Solutions, LLC

25 March 2013

Orthopedic Alliance, LLC

Urgent Medical Device Recall
Blue & Gold Implants and Instruments

Dear Doctor or Hospital Administrator,

Orthopedic Alliance has instituted a Medical Device Recall of Blue & Gold Implants and Instruments.

All Blue & Gold implants and instruments are included in this recall.

The Blue & Gold system is not supported by adequate testing and documentation to demonstrate that it meets performance or safety standards. These inadequacies might result in product performance failures that could cause patient harm due to implant breakage, loosening, or inadequate sterilization.

Urgent Medical Device Recall –Actions

- There are no other specific actions requested of you with regards to this recall other than acknowledgement of the receipt of this letter.
- We are not recommending that these devices be explanted from patients.
- Our records indicate that you do not have any Blue & Gold implants or instruments in your possession, however if you do, please do not use them and contact me to arrange for their return to Orthopedic Alliance.
- If you have any questions with regards to this recall, please contact me at the number listed below.
- Please complete the bottom of this form and return it by FAX to (858) 764-9739

Thank you for your assistance in this matter.

Natalie J. Kennel
RA/QA Consultant
(858) 705-0350

I have examined my implant and instrument inventory and certify that:

Check all that apply

◯ I do not have any Blue & Gold implants or instruments in my possession.

◯ I have shipped all Blue & Gold implants and instruments to Orthopedic Alliance.

Contact Name:_____ Phone Number: (____) _____
Print

Signature:_____ Date:_____

Orthopedic Alliance, LLC

26157 Jefferson Avenue
Murrieta, CA 92562

Phone (951) 304-9001
Fax (951) 304-9101

Orthopedicalliance.com

EXHIBIT 14

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. MICHAEL D. DROBOT, Defendant.	SA CR No. SACR14-00034 I N F O R M A T I O N [18 U.S.C. § 371: Conspiracy; 42 U.S.C. § 1320a-7b(b)(2)(A): Payment of Kickbacks in Connection with a Federal Health Care Program]

The United States Attorney alleges:

COUNT ONE

[18 U.S.C. § 371]

A. RELEVANT PERSONS AND ENTITIES

At all times relevant to this Information:

1. Pacific Hospital of Long Beach ("Pacific Hospital") was a hospital located in Long Beach, California, specializing in surgeries, particularly spinal and orthopedic surgeries. From at least in or around 1997 to in or around November 2013, Pacific Hospital was owned and/or operated by defendant MICHAEL D. DROBOT ("defendant DROBOT").

2. International Implants LLC ("I2") was a limited liability company owned and operated by defendant DROBOT that was located in Newport Beach, California. I2 purchased implantable medical devices ("hardware") for use in spinal surgeries from original manufacturers and sold them to hospitals, particularly Pacific Hospital. I2 was registered with the United States Food and Drug Administration as a repackager/relabeler, but was not registered as a manufacturer, and, in fact, did not manufacture medical devices.

3. Ronald S. Calderon was an elected California State Senator ("Senator Calderon") who owed a fiduciary duty and a duty of honest services to the citizens of California, including his constituents in the 30th Senate District, which included, among others, the cities of Bell, Bell Gardens, Commerce, Cudahy, Montebello, Norwalk, Pico Rivera, Santa Fe Springs, and Whittier.

B. RELEVANT LEGISLATION

4. The California Workers' Compensation System ("CWCS") was a system created by California law to provide insurance covering treatment of injury or illness suffered by individuals in the course of their employment. Under the CWCS, employers were required to purchase workers' compensation insurance policies from insurance carriers to cover their employees. When an employee suffered a covered injury or illness and received medical services, the medical service provider submitted a claim for payment to the relevant insurance carrier, which then paid the claim. Claims were submitted to and paid by the insurance carriers either by mail or electronically. The CWCS was governed by various California laws and regulations.

5. The California State Compensation Insurance Fund ("SCIF") was a non-profit insurance carrier, created by the California Legislature, which provided workers' compensation insurance to employees in California, including serving as the "insurer of last resort" under the CWCS system for employees without any other coverage.

6. California law, including but not limited to the California Business and Professions Code, the California Insurance Code, and the California Labor Code, prohibited the offering, delivering, soliciting, or receiving of anything of value in return for referring a patient for medical services.

7. Before January 2013, California law allowed a hospital to bill the cost of medical hardware separately from the other costs of a spinal surgery, such as the hospital's and surgeon's services, the reimbursement rates of which were set by a fee schedule. The hardware was considered a "pass-through" cost and billing was limited to $250 over what the hospital paid for the hardware.

8. Between in or around January 2010 and in or around August 2012, the California Senate and the Division of Workers' Compensation, an agency within the CWCS system, took several steps designed to modify or eliminate this pass-through. This was due, in part, to studies that showed eliminating this pass-through could result in savings of as much as $60 million.

9. By January 2013, California law was changed to eliminate the separate billing of medical hardware used in spinal surgeries; subsequently, reimbursement for all costs of such a surgery was limited to a fee schedule.

10. The Federal Employees' Compensation Act ("FECA") provided benefits to civilian employees of the United States, including United States Postal Service employees, for medical expenses and wage-loss disability due to a traumatic injury or occupational disease sustained while working as a federal employee. Benefits available to injured employees included rehabilitation, medical, surgical, hospital, pharmaceutical, and supplies for treatment of an injury. The Department of Labor ("DOL") - Office of Workers' Compensation Programs ("OWCP") was the governmental body responsible for administering the FECA. When a federal employee suffered a covered injury or illness and received medical services, the medical service provider submitted a claim for payment by mail or electronically to Affiliated Computer Services ("ACS"), located in London, Kentucky, which was contracted with the DOL to handle such claims. Upon approval of the claim, ACS sent payment by mail or electronic funds transfer from the U.S. Treasury in Philadelphia, Pennsylvania, to the medical service provider.

11. Federal law prohibited the offering, delivering, soliciting, or receiving of anything of value in return for referring a patient for medical services paid for by a federal health care benefit program.

C. OBJECTS OF THE CONSPIRACY

12. Beginning in or around 1998 and continuing to in or around November 2013, in Orange and Los Angeles Counties, within the Central District of California, and elsewhere, defendant DROBOT, together with other co-conspirators known and unknown to the United States Attorney, knowingly combined, conspired, and agreed to commit the following offenses against the United States: 18 U.S.C. §§ 1341 and

1346 (Mail Fraud and Honest Services Mail Fraud); 18 U.S.C. § 1952(a)(3) (Interstate Travel in Aid of a Racketeering Enterprise); 18 U.S.C. § 1957 (Monetary Transactions in Property Derived from Specified Unlawful Activity); and 42 U.S.C. § 1320a-7b(b)(2)(A) (Payment or Receipt of Kickbacks in Connection with a Federal Health Care Program).

D. MANNER AND MEANS TO ACCOMPLISH THE CONSPIRACY

13. The objects of the conspiracy were to be carried out, and were carried out, in the following ways, among others:

a. Defendant DROBOT and other co-conspirators offered to pay kickbacks to dozens of doctors, chiropractors, marketers, and others for their referring workers' compensation patients to Pacific Hospital for spinal surgeries, other types of surgeries, magnetic resonance imaging, toxicology, durable medical equipment, and other services, to be paid primarily through the CWCS and the FECA. For spinal surgeries, typically, defendant DROBOT offered to pay a kickback of $15,000 per lumbar fusion surgery and $10,000 per cervical fusion surgery.

b. Influenced by the promise of kickbacks, doctors, chiropractors, marketers, and others referred patients insured through the CWCS and the FECA to Pacific Hospital for spinal surgeries, other types of surgeries, and other medical services. The workers' compensation patients were not informed that the medical professionals had been offered kickbacks to induce them to refer the surgeries and other medical services to Pacific Hospital.

c. The surgeries and other medical services were performed on the referred workers' compensation patients at Pacific Hospital.

d. I2, or, at times, another distributor who was a co-conspirator, purchased medical hardware from a manufacturer and sold it to Pacific Hospital for use in spinal surgeries. Typically, the price I2 or the co-conspirator distributor charged for the hardware was inflated by a multiple of the price at which I2 or the other distributor had purchased the device from the manufacturer. At some point, I2 included a stamp on its invoices falsely stating that I2 was an "FDA Registered Manufacturer."

e. Pacific Hospital submitted claims, by mail and electronically, to SCIF and other workers' compensation insurance carriers for payment of the costs of the surgeries and other medical services. Included with the claims for spinal surgeries were the inflated hardware invoices from I2 or the co-conspirator distributor.

f. As defendant DROBOT and the other co-conspirators knew and intended, and as was reasonably foreseeable to them, in submitting claims for payment, Pacific Hospital made materially false and misleading statements to, and concealed material information from, SCIF and other workers' compensation insurance carriers, including that a) Pacific Hospital did not disclose to the insurance carriers that it had offered or paid kickbacks for the referral of the surgeries and other medical services for which it was submitting claims, and b) the hardware invoices were fraudulently inflated.

g. The insurance carriers paid Pacific Hospital's claims, by mail or electronically.

h. Defendant DROBOT and other co-conspirators paid and caused others to pay kickbacks to the doctors, chiropractors, marketers, and others who had referred patients to Pacific Hospital for surgeries and other medical services.

i. To conceal the nature of the kickback payments from both workers' compensation insurance carriers and patients, defendant DROBOT, through one of the companies he owned and/or operated, entered into bogus contracts with the doctors, chiropractors, marketers, and others. The services discussed in those contracts were, in fact, generally not provided or were provided at highly inflated prices; rather, the compensation paid was based on the number and type of surgeries and other medical services referred to Pacific Hospital. Defendant DROBOT and his co-conspirators entered into the following bogus contracts, among others, in order to hide kickback payments: collection agreements, option agreements, research and development agreements, lease and rental agreements, consulting agreements, marketing agreements, and management agreements.

j. Defendant DROBOT and other co-conspirators kept records of the number of surgeries and other medical services performed at Pacific Hospital due to referrals from the kickback recipients, as well amounts paid to the kickback recipients for those referrals. Periodically, defendant DROBOT and other co-conspirators amended the bogus contracts with the kickback recipients to increase or decrease the amount of agreed compensation described in the contracts, in order to match the amount of kickbacks paid or promised in return for referrals.

k. The spinal pass-through, the provision of California law that allowed Pacific Hospital to fraudulently inflate the cost of the medical hardware used during spinal surgeries, was a vital component of defendant DROBOT's ability to pay kickbacks to the doctors, chiropractors, marketers, and others who had referred

patients to Pacific Hospital for surgeries and other medical services.

l. To prevent and delay steps being taken in the California Senate and the Division of Workers' Compensation to limit or eliminate the pass-through, as well as to promote legislative efforts that would protect and expand his health care fraud scheme, defendant DROBOT would pay bribes to Senator Calderon to influence, and in exchange for, Senator Calderon's official acts relating to the pass-through and other areas of workers' compensation and regulation.

m. The bribe payments were primarily in the form of hiring Senator Calderon's son to perform clerical duties at one or more of defendant DROBOT's companies during the summers of 2010, 2011, and 2012, and paying Senator Calderon's son approximately $10,000 per summer for approximately 15 days of work per summer. Defendant DROBOT would also provide Senator Calderon a stream of other financial benefits, such as trips on privately chartered airplanes, golf at exclusive, high-end golf resorts, and meals at expensive restaurants.

n. In exchange for these financial benefits, defendant DROBOT would have Senator Calderon perform official acts favorable to defendant DROBOT in connection with the spinal pass-through and other areas of worker's compensation legislation and regulation. For example, defendant DROBOT would have Senator Calderon arrange and participate in meetings with other public officials and their staff, where defendant DROBOT and Senator Calderon would attempt to convince the other public officials and their staff to take action favorable to defendant DROBOT in connection with the spinal pass-through and other areas of worker's compensation legislation and regulation.

More specifically, this favorable action by Senator Calderon and other public officials would support defendant DROBOT's ability to commit and expand his health care fraud scheme.

E. EFFECTS OF THE CONSPIRACY

14. Had SCIF and the other workers' compensation insurance carriers known the true facts regarding a) the payment of kickbacks for the referral of workers' compensation patients for surgeries and other medical services performed at Pacific Hospital, and b) the fraudulent inflation of the cost of medical hardware used in spinal surgeries, they would not have paid the claims or would have paid a lesser amount.

15. From in or around 2008 to in or around April 2013, Pacific Hospital billed workers' compensation insurance carriers approximately $500 million in claims for spinal surgeries that were the result of the payment of a kickback; and defendant DROBOT or other co-conspirators paid kickback recipients between approximately $20 million and $50 million in kickbacks relating to those claims.

F. OVERT ACTS IN FURTHERANCE OF THE CONSPIRACY

16. In furtherance of the conspiracy and to accomplish the objects of the conspiracy, defendant DROBOT and other co-conspirators known and unknown to the United States Attorney, committed various overt acts within the Central District of California, including but not limited to the following:

Overt Act No. 1

On or about November 10, 2009, defendant DROBOT caused a check in the amount of $43,650.00 from SCIF to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient

J.M. performed by doctor C.D., which claim was induced by the payment of a kickback to J.C.

Overt Act No. 2

In or around February 2010, defendant DROBOT met with Senator Calderon in Sacramento, California, and agreed to hire Senator Calderon's son each summer for the next several summers and to pay him $10,000 per summer, so that Senator Calderon would have enough money to pay for his son's college tuition.

Overt Act No. 3

On or about April 14, 2010, defendant DROBOT caused a check in the amount of $90,467.80 from SCIF to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient L.T. performed by doctor M.C., which claim was induced by the payment of a kickback to P.S.

Overt Act No. 4

In or around April 2010, defendant DROBOT had Senator Calderon meet with a Director at the Division of Workers' Compensation and discuss the negative impact that proposed regulations would have on Pacific Hospital and other hospitals.

Overt Act No. 5

On or about July 13, 2010, defendant DROBOT caused Senator Calderon's son to be paid $10,000 in advance of clerical work Senator Calderon's son was to perform at one of defendant DROBOT's companies.

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Overt Act No. 6

In or around February 2011, defendant DROBOT had Senator Calderon meet with Senator A and request that Senator A introduce legislation in the California Senate that would be favorable to defendant DROBOT.

Overt Act No. 7

On or about March 31, 2011, defendant DROBOT caused a check in the amount of $23,531.23 from Vanliner to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient R.S. performed by doctor S.O., which claim was induced by the payment of a kickback to S.O.

Overt Act No. 8

On or about July 11, 2011, defendant DROBOT caused Senator Calderon's son to be paid $5,000 for clerical work Senator Calderon's son had performed at one of defendant DROBOT's companies.

Overt Act No. 9

On or about August 16, 2011, defendant DROBOT caused Senator Calderon's son to be paid $5,000 for clerical work Senator Calderon's son had performed at one of defendant DROBOT's companies.

Overt Act No. 10

On or about June 12, 2012, defendant DROBOT had Senator Calderon arrange and participate in a meeting with Senator B, where Senator Calderon and defendant DROBOT discussed the negative impact Senator B's proposed legislation would have on Pacific Hospital and other hospitals.

Overt Act No. 11

On or about June 29, 2012, defendant DROBOT caused a kickback in the amount of $100,000 to be paid to S.O. for the referral of lumbar

and cervical spinal surgeries performed at Pacific Hospital, including on patients covered by the FECA.

Overt Act No. 12

On or about August 1, 2012, defendant DROBOT authorized Senator Calderon's son to be paid a gross salary of $18,510.90 for clerical work Senator Calderon's son was performing at one of defendant DROBOT's companies in order to guarantee that Senator Calderon's son's take-home (or net) salary totaled approximately $10,000 for the summer of 2012.

Overt Act No. 13

On or about January 18, 2013, defendant DROBOT caused a check in the amount of $51,115.44 from Traveler's Insurance to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient F.C. performed by doctor T.R., which claim was induced by the payment of a kickback to T.R.

Overt Act No. 14

On or about January 24, 2013, defendant DROBOT caused a check in the amount of $117,142.36 from Vanliner to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient S.F. performed by doctor G.A., which claim was induced by the payment of a kickback to G.A.

Overt Act No. 15

On or about April 24, 2013, defendant DROBOT caused a check in the amount of $24,209.90 from ICW to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient F.A. performed by doctor L.T., which claim was induced by the payment of a kickback to L.T.

Overt Act No. 16

On or about November 27, 2013, defendant DROBOT caused a check in the amount of $50,903.76 from Traveler's Insurance to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient T.V. performed by doctor L.T., which claim resulted from the payment of a kickback to A.I.

COUNT TWO

[42 U.S.C. § 1320a-7b(b)(2)(A)]

17. Paragraphs one through eleven of this Information are re-alleged and incorporated as if fully set forth herein.

18. Beginning in or around 1998 and continuing to in or around November 2013, in Orange and Los Angeles Counties, within the Central District of California, and elsewhere, defendant DROBOT, together with other co-conspirators known and unknown to the United States Attorney, knowingly and willfully offered and paid remuneration, that is, cash and checks, directly and indirectly, to persons to induce those persons to refer individuals to Pacific Hospital for spinal surgery and other medical services for which payment could be made in whole and in part under a Federal health care program, namely, the FECA.

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EXHIBIT 15

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Attorneys for Plaintiff
UNITED STATES OF AMERICA

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. MICHAEL D. DROBOT, Defendant.	No. SA CR 14- SACR14-00034 PLEA AGREEMENT FOR DEFENDANT MICHAEL D. DROBOT

1. This constitutes the plea agreement between MICHAEL D. DROBOT ("defendant") and the United States Attorney's Office for the Central District of California ("the USAO") in the above-captioned case. This agreement is limited to the USAO and cannot bind any other federal, state, local, or foreign prosecuting, enforcement, administrative, or regulatory authorities.

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DEFENDANT'S OBLIGATIONS

2. Defendant agrees to:

a) Give up the right to indictment by a grand jury and, at the earliest opportunity requested by the USAO and provided by the Court, appear and plead guilty to a two-count criminal Information in the form attached to this agreement as Exhibit A or a substantially similar form, which charges defendant with Conspiracy in violation of 18 U.S.C. § 371, and Payment of Kickbacks in Connection with a Federal Health Care Program in violation of 42 U.S.C. § 1320a-7b(b)(2)(A).

b) Not contest facts agreed to in this agreement.

c) Abide by all agreements regarding sentencing contained in this agreement.

d) Appear for all court appearances, surrender as ordered for service of sentence, obey all conditions of any bond, and obey any other ongoing court order in this matter.

e) Not commit any crime; however, offenses that would be excluded for sentencing purposes under United States Sentencing Guidelines ("U.S.S.G." or "Sentencing Guidelines") § 4A1.2(c) are not within the scope of this agreement.

f) Be truthful at all times with Pretrial Services, the United States Probation Office, and the Court.

g) Pay the applicable special assessments at or before the time of sentencing unless defendant lacks the ability to pay and prior to sentencing submits a completed financial statement on a form to be provided by the USAO.

3. Defendant further agrees:

a) Truthfully to disclose to law enforcement officials, at a date and time to be set by the USAO, the location of, defendant's ownership interest in, and all other information known to defendant about, all monies, properties, and/or assets of any kind, derived from or acquired as a result of, or used to facilitate the commission of, defendant's illegal activities, and to forfeit all right, title, and interest in and to such items.

b) To the Court's entry of an order of forfeiture at or before sentencing with respect to these assets and to the forfeiture of the assets.

c) To take whatever steps are necessary to pass to the United States clear title to the assets described above, including, without limitation, the execution of a consent decree of forfeiture and the completing of any other legal documents required for the transfer of title to the United States.

d) Not to contest any administrative forfeiture proceedings or civil judicial proceedings commenced by the United States of America against these properties.

e) Not to assist any other individual in any effort falsely to contest the forfeiture of the assets described above.

f) Not to claim that reasonable cause to seize the assets was lacking.

g) To prevent the transfer, sale, destruction, or loss of any and all assets described above to the extent defendant has the ability to do so.

h) To fill out and deliver to the USAO a completed financial statement listing defendant's assets on a form provided by the USAO.

4. Defendant further agrees to cooperate fully with the USAO, the Federal Bureau of Investigation, the United States Postal Service - Office of Inspector General, the Internal Revenue Service, and, as directed by the USAO, any other federal, state, local, or foreign prosecuting, enforcement, administrative, or regulatory authority. This cooperation requires defendant to:

a) Respond truthfully and completely to all questions that may be put to defendant, whether in interviews, before a grand jury, or at any trial or other court proceeding.

b) Attend all meetings, grand jury sessions, trials or other proceedings at which defendant's presence is requested by the USAO or compelled by subpoena or court order.

c) Produce voluntarily all documents, records, or other tangible evidence relating to matters about which the USAO, or its designee, inquires.

5. For purposes of this agreement: (1) "Cooperation Information" shall mean any statements made, or documents, records, tangible evidence, or other information provided, by defendant pursuant to defendant's cooperation under this agreement; and (2) "Plea Information" shall mean any statements made by defendant, under oath, at the guilty plea hearing and the agreed to factual basis statement in this agreement.

THE USAO'S OBLIGATIONS

6. The USAO agrees to:

a) Not contest facts agreed to in this agreement.

b) Abide by all agreements regarding sentencing contained in this agreement.

c) At the time of sentencing, provided that defendant demonstrates an acceptance of responsibility for the offense up to and including the time of sentencing, recommend a two-level reduction in the applicable Sentencing Guidelines offense level, pursuant to U.S.S.G. § 3E1.1, and recommend and, if necessary, move for an additional one-level reduction if available under that section.

d) Recommend that defendant be sentenced to a term of imprisonment no higher than the low end of the applicable Sentencing Guidelines range, provided that the offense level used by the Court to determine that range is 35 and provided that the Court does not depart downward in criminal history category. For purposes of this agreement, the low end of the Sentencing Guidelines range is that defined by the Sentencing Table in U.S.S.G. Chapter 5, Part A , without regard to reductions in the term of imprisonment that may be permissible through the substitution of community confinement or home detention as a result of the offense level falling within Zone B or Zone C of the Sentencing Table.

e) Except for criminal tax violations (including conspiracy to commit such violations chargeable under 18 U.S.C. § 371), not further criminally prosecute defendant for violations arising out of defendant's conduct described in the agreed-to factual basis set forth in paragraph 21 below. Defendant understands that the USAO is free to criminally prosecute defendant for any other unlawful past conduct or any unlawful conduct that occurs after the date of this agreement. Defendant agrees that at the time of sentencing the Court may consider the uncharged conduct in determining the applicable Sentencing Guidelines range, the

propriety and extent of any departure from that range, and the sentence to be imposed after consideration of the Sentencing Guidelines and all other relevant factors under 18 U.S.C. § 3553(a).

7. The USAO further agrees:

a) Not to offer as evidence in its case-in-chief in the above-captioned case or any other criminal prosecution that may be brought against defendant by the USAO, or in connection with any sentencing proceeding in any criminal case that may be brought against defendant by the USAO, any Cooperation Information. Defendant agrees, however, that the USAO may use both Cooperation Information and Plea Information: (1) to obtain and pursue leads to other evidence, which evidence may be used for any purpose, including any criminal prosecution of defendant; (2) to cross-examine defendant should defendant testify, or to rebut any evidence offered, or argument or representation made, by defendant, defendant's counsel, or a witness called by defendant in any trial, sentencing hearing, or other court proceeding; and (3) in any criminal prosecution of defendant for false statement, obstruction of justice, or perjury.

b) Not to use Cooperation Information against defendant at sentencing for the purpose of determining the applicable guideline range, including the appropriateness of an upward departure, or the sentence to be imposed, and to recommend to the Court that Cooperation Information not be used in determining the applicable guideline range or the sentence to be imposed. Defendant understands, however, that Cooperation Information will be disclosed to the probation office and the Court, and that the Court may use

Cooperation Information for the purposes set forth in U.S.S.G § 1B1.8(b) and for determining the sentence to be imposed.

c) In connection with defendant's sentencing, to bring to the Court's attention the nature and extent of defendant's cooperation.

d) If the USAO determines, in its exclusive judgment, that defendant has both complied with defendant's obligations under paragraphs 2 through 4 above and provided substantial assistance to law enforcement in the prosecution or investigation of another ("substantial assistance"), to move the Court pursuant to U.S.S.G. § 5K1.1, to fix an offense level and corresponding guideline range below that otherwise dictated by the sentencing guidelines, and to recommend a term of imprisonment within this reduced range.

DEFENDANT'S UNDERSTANDINGS REGARDING COOPERATION

8. Defendant understands the following:

a) Any knowingly false or misleading statement by defendant will subject defendant to prosecution for false statement, obstruction of justice, and perjury and will constitute a breach by defendant of this agreement.

b) Nothing in this agreement requires the USAO or any other prosecuting, enforcement, administrative, or regulatory authority to accept any cooperation or assistance that defendant may offer, or to use it in any particular way.

c) Defendant cannot withdraw defendant's guilty plea if the USAO does not make a motion pursuant to U.S.S.G. § 5K1.1 for a reduced guideline range or if the USAO makes such a motion and the Court does not grant it or if the Court grants such a USAO motion but elects to sentence above the reduced range.

d) At this time the USAO makes no agreement or representation as to whether any cooperation that defendant has provided or intends to provide constitutes or will constitute substantial assistance. The decision whether defendant has provided substantial assistance will rest solely within the exclusive judgment of the USAO.

e) The USAO's determination whether defendant has provided substantial assistance will not depend in any way on whether the government prevails at any trial or court hearing in which defendant testifies or in which the government otherwise presents information resulting from defendant's cooperation.

NATURE OF THE OFFENSE

9. Defendant understands that for defendant to be guilty of the crime charged in count one of the Information, that is, Conspiracy, in violation of Title 18, United States Code, Section 371, the following must be true: (1) Beginning in or around 1998 and continuing through in or around November 2013, there was an agreement between two or more persons to commit a violation of Title 18, United States Code, Sections 1341 and 1346 (Mail Fraud and Honest Services Mail Fraud); Title 18, United States Code, Section 1952(a)(3) (Interstate Travel in Aid of a Racketeering Enterprise); Title 18, United States Code, Section 1957 (Monetary Transactions in Property Derived from Specified Unlawful Activity); and Title 42, United States Code, Section 1320a-7b(b)(2)(A) (Payment or Receipt of Kickbacks in Connection with a Federal Health Care Program); (2) defendant became a member of the conspiracy knowing of at least one of its objects and intending to help accomplish it; and (3) one of

the members of the conspiracy performed at least one overt act for the purpose of carrying out the conspiracy.

10. Defendant understands that Mail Fraud, in violation of Title 18, United States Code, Section 1341, has the following elements: (1) the defendant knowingly devised or participated in a scheme or plan to defraud, or a scheme or plan for obtaining money or property by means of false or fraudulent pretenses, representations or promises; (2) the statements made or facts omitted as part of the scheme were material, that is, they had a natural tendency to influence, or were capable of influencing, a person to part with money or property; (3) the defendant acted with the intent to defraud; and (4) the defendant used, or caused to be used, the mails to carry out or attempt to carry out an essential part of the scheme. Defendant further understands that Honest Services Mail Fraud, in violation of Title 18, United States Code, Section 1346, has the following elements: (1) the defendant devised or participated in a scheme or plan to deprive a patient of his or her right to honest services; (2) the scheme or plan consisted of a bribe or kickback in exchange for medical services; (3) a medical professional person owed a fiduciary duty to the patient; (4) the defendant acted with the intent to defraud by depriving the patient of his or her right of honest services; (5) the defendant's act was material, that is, it had a natural tendency to influence, or was capable of influencing, a person's acts; and (6) the defendant used, or caused someone to use, the mails to carry out or attempt to carry out the scheme or plan.

11. Defendant understands that Interstate Travel in Aid of a Racketeering Enterprise, in violation of Title 18, United States

Code, Section 1952(a)(3), has the following elements: (1) defendant used the mail or a facility of interstate commerce with the intent to promote, manage, establish, or carry on, or facilitate the promotion, management, establishment, or carrying on, of unlawful activity, specifically payment and receipt of kickbacks in violation of California Business & Professions Code § 650, California Insurance Code § 750, and California Labor Code § 3215; and (2) after doing so, defendant performed or attempted to perform an act to promote, manage, establish, or carry on, or facilitate the promotion, management, establishment, or carrying on, of such unlawful activity.

12. Defendant understands that Money Laundering, in violation of Title 18, United States Code, Section 1957, has the following elements: (1) the defendant knowingly engaged or attempted to engage in a monetary transaction; (2) the defendant knew the transaction involved criminally derived property; (3) the property had a value greater than $10,000; (4) the property was, in fact, derived from mail fraud; and (5) the transaction occurred in the United States.

13. Defendant further understands that for defendant to be guilty of the crime charged in count two of the information, that is, Payment of Kickbacks in Connection with a Federal Health Care Program, in violation of 42 U.S.C. § 1320a-7b(b)(2)(A), the following must be true: (1) defendant knowingly and wilfully paid remuneration, directly or indirectly, in cash or in kind, to another person; (2) the remuneration was given to induce that person to refer an individual for the furnishing or arranging for the furnishing of any item or service for which payment may be made in

whole or in part under a Federal health care program; and (3) defendant knew that such payment of remuneration was illegal.

PENALTIES AND RESTITUTION

14. Defendant understands that the statutory maximum sentence that the Court can impose for a violation of Title 18, United States Code, Section 371, is: 5 years imprisonment; a 3-year period of supervised release; a fine of $250,000 or twice the gross gain or gross loss resulting from the offense, whichever is greatest; and a mandatory special assessment of $100.

15. Defendant understands that the statutory maximum sentence that the Court can impose for a violation of Title 42, United States Code, Section 1320a-7b(b)(2)(A), is: 5 years imprisonment; a 3-year period of supervised release; a fine of $250,000 or twice the gross gain or gross loss resulting from the offense, whichever is greatest; and a mandatory special assessment of $100.

16. Defendant therefore understands that the total maximum sentence for all offenses to which defendant is pleading guilty is: 10 years imprisonment; a three-year period of supervised release; a fine of $500,000 or twice the gross gain or gross loss resulting from the offense, whichever is greatest; and a mandatory special assessment of $200.

17. Defendant understands that supervised release is a period of time following imprisonment during which defendant will be subject to various restrictions and requirements. Defendant understands that if defendant violates one or more of the conditions of any supervised release imposed, defendant may be returned to prison for all or part of the term of supervised release authorized by statute for the offenses that resulted in the term of supervised

release, which could result in defendant serving a total term of imprisonment greater than the statutory maximum stated above.

18. Defendant understands that, by pleading guilty, defendant may be giving up valuable government benefits and valuable civic rights, such as the right to vote, the right to possess a firearm, the right to hold office, and the right to serve on a jury. Defendant understands that once the court accepts defendant's guilty pleas, it will be a federal felony for defendant to possess a firearm or ammunition. Defendant understands that the convictions in this case may also subject defendant to various other collateral consequences, including but not limited to revocation of probation, parole, or supervised release in another case and suspension or revocation of a professional license. Defendant understands that unanticipated collateral consequences will not serve as grounds to withdraw defendant's guilty pleas.

19. Defendant understands that, if defendant is not a United States citizen, the felony convictions in this case may subject defendant to: removal, also known as deportation, which may, under some circumstances, be mandatory; denial of citizenship; and denial of admission to the United States in the future. The court cannot, and defendant's attorney also may not be able to, advise defendant fully regarding the immigration consequences of the felony convictions in this case. Defendant understands that unexpected immigration consequences will not serve as grounds to withdraw defendant's guilty pleas.

20. Defendant understands that defendant will be required to pay full restitution to the victims of the offenses to which defendant is pleading guilty. Defendant agrees that, in return for

"sentencing order"

the USAO's compliance with its obligations under this agreement, the Court may order restitution to persons other than the victims of the offenses to which defendant is pleading guilty and in amounts greater than those alleged in the counts to which defendant is pleading guilty. In particular, defendant agrees that the Court may order restitution to any victim of any of the following for any losses suffered by that victim as a result: (a) any relevant conduct, as defined in U.S.S.G. § 1B1.3, in connection with the offenses to which defendant is pleading guilty; and (b) any charges not prosecuted pursuant to this agreement as well as all relevant conduct, as defined in U.S.S.G. § 1B1.3, in connection with those counts and charges. The parties have not come to an agreement on the amount of restitution.

FACTUAL BASIS

21. Defendant admits that defendant is, in fact, guilty of the offenses to which defendant is agreeing to plead guilty. Defendant and the USAO agree to the statement of facts provided below and agree that this statement of facts is sufficient to support pleas of guilty to the charges described in this agreement and to establish the Sentencing Guidelines factors set forth in paragraph 23 below but is not meant to be a complete recitation of all facts relevant to the underlying criminal conduct or all facts known to either party that relate to that conduct.

Pacific Hospital of Long Beach ("Pacific Hospital") was a hospital located in Long Beach, California, specializing in surgeries, particularly spinal and orthopedic surgeries. From at least in or around 1997 to October 2013, Pacific Hospital was owned and/or operated by defendant.

Beginning in or around 1998 and continuing through in or around November 2013, defendant conspired with dozens of doctors, chiropractors, marketers, and others to pay kickbacks in return for those persons to refer thousands of patients to Pacific Hospital for spinal surgeries and other medical services paid for primarily through the Federal Employees' Compensation Act ("FECA") and the California Workers' Compensation System ("CWCS"). To help generate the monies for the kickback payments, defendant used a co-schemers company or his own company International Implants ("I2"), located in Newport Beach, California, to fraudulently inflate the price of medical hardware purchased by Pacific Hospital to be used in the spinal surgeries; defendant knew that, under California law, medical hardware was considered a "pass-through" cost that could be billed at no more than $250 over what Pacific Hospital paid for the hardware. In paying the kickbacks, inflating the medical hardware costs, and submitting the resulting claims for spinal surgeries and medical services, defendant and his co-conspirators acted with the intent to defraud workers' compensation insurance carriers and to deprive the patients of their right of honest services.

Defendant also provided a stream of financial benefits to California State Senator Ronald S. Calderon ("Senator Calderon") in order to influence him to support, and in exchange for supporting, defendant's positions on legislation and regulations that would enhance defendant's ability to commit and expand his health care fraud scheme -- in particular, legislation concerning hospitals' ability to "pass through" to workers' compensation insurance carriers the cost of medical hardware used in spinal surgeries.

The hospital kickback scheme operated as follows: defendant and other co-conspirators offered to pay kickbacks to doctors, chiropractors, marketers, and others (the "kickback recipients") in return for their referring workers' compensation patients to Pacific Hospital for spinal surgeries, other types of surgeries, magnetic resonance imaging, toxicology, durable medical equipment, and other services, to be paid through FECA and the CWCS. For spinal surgeries, typically, defendant offered to pay a kickback of $15,000 per lumbar fusion surgery and $10,000 per cervical fusion surgery provided that the surgeon used in the surgery hardware supplied by a specified distributor. Beginning in approximately 2008, defendant's company I2 typically was the specified distributor; if the surgeon did not use I2's hardware in the surgery, the kickbacks offered were smaller.

Influenced by the promise of kickbacks, the kickback recipients referred patients insured through the CWCS and the FECA to Pacific Hospital for spinal surgeries, other types of surgeries, and other medical services. In some cases, the patients lived dozens or hundreds of miles from Pacific Hospital, and closer to other qualified medical facilities. The workers' compensation patients were not informed that the medical professionals had been offered kickbacks to induce them to refer the surgeries to Pacific Hospital.

Pursuant to the kickback agreements, the kickback recipients referred patients to Pacific Hospital. In the case of spinal surgeries, as part of the kickback agreements, surgeons often used the specified distributor, including I2. Typically, for surgeries covered by the CWCS, the price I2 or the co-conspirator distributor charged for the hardware was inflated by a multiple of the price at

which I2 or the other distributor had purchased the device from the manufacturer.

Pacific Hospital submitted claims, by mail and electronically, to workers' compensation insurance carriers for payment of the costs of the surgeries and other medical services. For a spinal surgery, Pacific Hospital typically submitted a claim for the hospital's services and the medical hardware used in the surgery. For surgeries covered by the CWCS, Pacific Hospital submitted the inflated invoice for the hardware from I2 or other specified distributors who were co-conspirators, plus an additional $250. Thus, the purported "pass-through" cost submitted in the claims for medical hardware was thousands of dollars -- and sometimes tens of thousands of dollars -- higher than what the manufacturer actually charged and what I2 or the co-conspirator distributor actually paid for the hardware.

As defendant and his co-conspirators knew, federal and California law prohibited paying or receiving the aforementioned kickbacks for the referral of patients for medical services. Defendant and his co-conspirators also knew that the insurance carriers would be unwilling to pay claims for medical services that were obtained through such illegal kickbacks. Moreover, defendant and his co-conspirators knew that the insurance carriers would be unwilling to pay claims for spinal surgery hardware that were artificially inflated and substantially above the manufacturer's price. However, defendant and his co-conspirators deliberately did not disclose to the insurance carriers the kickbacks, the inflation of the medical hardware, or the fact that I2 was owned and controlled by defendant and was not a manufacturer of such hardware.

Rather, at some point, defendant and his co-conspirators included on I2's invoices stamps falsely stating that I2 was an "FDA Registered Manufacturer."

Further, to conceal the illegal kickback payments from the workers' compensation insurance carriers and patients, defendant and his co-conspirators entered into bogus contracts under which the kickback recipients purported to provide services to defendant's companies to justify the kickback payments. The services and other items of value discussed in those contracts were, in fact, generally not provided to Pacific Hospital or were provided at highly inflated prices. The compensation to the kickback recipients was actually based on the number and type of surgeries they referred to the hospital. These contracts included, among others, the following: collection agreements, option agreements, research and development agreements, lease and rental agreements, consulting agreements, marketing agreements, and management agreements.

Defendant and his co-conspirators kept records of the number of surgeries and other medical services performed at Pacific Hospital due to referrals from the kickback recipients, as well as amounts paid to the kickback recipients for those referrals. Periodically, defendant and others amended the bogus contracts with the kickback recipients to increase or decrease the amount of agreed compensation described in the contracts, in order to match the amount of kickbacks paid or promised in return for referrals.

From in or around 2008 to in or around April 2013, Pacific Hospital billed workers' compensation insurance carriers approximately $500 million in claims for several thousand spinal surgeries that were the result of the payment of kickbacks; and

defendant and other co-conspirators paid kickback recipients between approximately $20 million and $50 million in kickbacks relating to those claims.

To preserve his ability to pass on the inflated spinal surgery hardware costs to the insurance carriers, and thus to help to pay the kickbacks, defendant provided a stream of financial benefits to Senator Calderon in order to induce the senator to oppose legislation and regulation that would have eliminated the "pass-through" rule, as well as to support legislation that would have supported defendant's health care fraud scheme. For example, at Senator Calderon's request, defendant agreed to pay Senator Calderon's son $10,000 per summer (take-home or net) to work as a summer file clerk for defendant's company in 2010, 2011, and 2012. Defendant would not have ordinarily done this, but did so here in order to ensure that Senator Calderon would take positions on spinal surgery and pass-through legislation favorable to defendant. In 2010, at Senator Calderon's request, defendant caused his company to pay Senator Calderon's son $10,000 upfront to be a summer file clerk. In 2011, again at Senator Calderon's request, defendant caused his company to pay Senator Calderon's son $10,000 to be a summer file clerk. In 2012, defendant made Senator Calderon's son a W-2 employee, which caused taxes to be withheld from his paycheck. When Senator Calderon informed defendant that his son needed to net $10,000 in the summer, defendant caused his company, despite that it was in financial difficulty and laying off workers, to pay Senator Calderon's son an increased amount of up to near $18,000 so that Senator Calderon's son would net $10,000 for the summer of 2012. Defendant ensured that his company made these payments to Senator

Calderon's son each summer regardless of how few days Senator Calderon's son actually worked.

In addition, on several occasions and while Senator Calderon was supporting legislative positions favorable to defendant, defendant took Senator Calderon to exclusive, high-end golf resorts. Defendant paid for these golf outings in order to ensure Senator Calderon's continued legislative support. Additionally, defendant took Senator Calderon out to expensive dinners and provided him with free flights on a private plane. All of these financial benefits were intended to ensure that Senator Calderon would take legislative positions favorable to defendant and Pacific Hospital, which would allow defendant to continue to commit and expand his health care fraud scheme. In response to these financial benefits from defendant, Senator Calderon, among other things, arranged meetings for defendant with other senators to discuss defendant's legislative agenda and advocated positions on legislation that would financially benefit defendant and Pacific Hospital.

In furtherance of the conspiracy and to accomplish the objects of the conspiracy, defendant and other co-conspirators committed various overt acts within the Central District of California, including but not limited to the following:

Overt Act No. 1

On or about November 10, 2009, defendant caused a check in the amount of $43,650.00 from SCIF to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient J.M. performed by doctor C.D., which claim was induced by the payment of a kickback to J.C.

/ / /

Overt Act No. 2

In or around February 2010, defendant met with Senator Calderon in Sacramento, California and agreed to hire Senator Calderon's son each summer for the next several summers and to pay him $10,000 per summer, so that Senator Calderon would have enough money to pay for his son's college tuition.

Overt Act No. 3

On or about April 14, 2010, defendant caused a check in the amount of $90,467.80 from SCIF to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient L.T. performed by doctor M.C., which claim was induced by the payment of a kickback to P.S.

Overt Act No. 4

In or around April 2010, defendant had Senator Calderon meet with a Director at the Division of Workers' Compensation and discuss the negative impact that proposed regulations would have on Pacific Hospital and other hospitals.

Overt Act No. 5

On or about July 13, 2010, defendant caused Senator Calderon's son to be paid $10,000 in advance of clerical work Senator Calderon's son was to perform at one of defendant's companies.

Overt Act No. 6

In or around February 2011, defendant had Senator Calderon meet with Senator A and request that Senator A introduce legislation in the California Senate that would be favorable to defendant.

Overt Act No. 7

On or about March 31, 2011, defendant caused a check in the amount of $23,531.23 from Vanliner to be sent by mail to Pacific

Hospital in reimbursement for a claim for spine surgery on patient R.S. performed by doctor S.O., which claim was induced by the payment of a kickback to S.O.

Overt Act No. 8

On or about July 11, 2011, defendant caused Senator Calderon's son to be paid $5,000 for clerical work Senator Calderon's son had performed at one of defendant's companies.

Overt Act No. 9

On or about August 16, 2011, defendant caused Senator Calderon's son to be paid $5,000 for clerical work Senator Calderon's son had performed at one of defendant's companies.

Overt Act No. 10

On or about June 12, 2012, defendant had Senator Calderon arrange and participate in a meeting with Senator B, where Senator Calderon and defendant discussed the negative impact Senator B's proposed legislation would have on Pacific Hospital and other hospitals.

Overt Act No. 11

On or about June 29, 2012, defendant caused a kickback in the amount of $100,000 to be paid to S.O. for the referral of lumbar and cervical spinal surgeries performed at Pacific Hospital, including on patients covered by the FECA.

Overt Act No. 12

On or about August 1, 2012, defendant authorized Senator Calderon's son to a gross salary of $18,510.90 for clerical work Senator Calderon's son was performing at one of defendant's companies in order to guarantee that Senator Calderon's son's take-

home (or net) salary totaled approximately $10,000 for the summer of 2012.

Overt Act No. 13

On or about January 18, 2013, defendant caused a check in the amount of $51,115.44 from Traveler's Insurance to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient F.C. performed by doctor T.R., which claim was induced by the payment of a kickback to T.R.

Overt Act No. 14

On or about January 24, 2013, defendant caused a check in the amount of $117,142.36 from Vanliner to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient S.F. performed by doctor G.A., which claim was induced by the payment of a kickback to G.A.

Overt Act No. 15

On or about April 24, 2013, defendant caused a check in the amount of $24,209.90 from ICW to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient F.A. performed by doctor L.T., which claim was induced by the payment of a kickback to L.T.

Overt Act No. 16

On or about November 27, 2013, defendant caused a check in the amount of $50,903.76 from Traveler's Insurance to be sent by mail to Pacific Hospital in reimbursement for a claim for spine surgery on patient T.V. performed by doctor L.T., which claim resulted from the payment of a kickback to A.I.

SENTENCING FACTORS

22. Defendant understands that in determining defendant's sentence the Court is required to calculate the applicable Sentencing Guidelines range and to consider that range, possible departures under the Sentencing Guidelines, and the other sentencing factors set forth in 18 U.S.C. § 3553(a). Defendant understands that the Sentencing Guidelines are advisory only, that defendant cannot have any expectation of receiving a sentence within the calculated Sentencing Guidelines range, and that after considering the Sentencing Guidelines and the other § 3553(a) factors, the Court will be free to exercise its discretion to impose any sentence it finds appropriate up to the maximum set by statute for the crimes of conviction.

23. Defendant and the USAO agree to the following applicable Sentencing Guidelines factors:

Base Offense Level:	6	[U.S.S.G. § 2B1.1(a)(2)]
Specific Offense Characteristics		
Loss between $20M to $50M:	+22	[U.S.S.G. § 2B1.1(b)(1)(L)]
More than 50 victims:	+4	[U.S.S.G. § 2B1.1(b)(2)(B)]
Federal health care offense with gov't program loss of between $1M-$7M:	+2	[U.S.S.G. § 2B1.1(b)(7)]
Adjustments		
Aggravating Role:	+4	[U.S.S.G. § 3B1.1(a)]
Acceptance of Responsibility:	-3	[U.S.S.G. § 3E1.1]
Total:	35	

The USAO will agree to a two-level downward adjustment for acceptance of responsibility (and, if applicable, move for an additional one-level downward adjustment under U.S.S.G. § 3E1.1(b)) only if the conditions set forth in paragraph 6(c)) are met. Subject to paragraph 7 above and paragraph 35 below, defendant and the USAO agree not to seek, argue, or suggest in any way, either orally or in writing, that any other specific offense characteristics, adjustments, or departures relating to the offense level be imposed. Defendant agrees, however, that if, after signing this agreement but prior to sentencing, defendant were to commit an act, or the USAO were to discover a previously undiscovered act committed by defendant prior to signing this agreement, which act, in the judgment of the USAO, constituted obstruction of justice within the meaning of U.S.S.G. § 3C1.1, the USAO would be free to seek the enhancement set forth in that section.

24. Defendant understands that there is no agreement as to defendant's criminal history or criminal history category.

25. Defendant and the USAO reserve the right to argue for a sentence outside the sentencing range established by the Sentencing Guidelines based on the factors set forth in 18 U.S.C. § 3553(a)(1), (a)(2), (a)(3), (a)(6), and (a)(7).

WAIVER OF CONSTITUTIONAL RIGHTS

26. Defendant understands that by pleading guilty, defendant gives up the following rights:

a) The right to persist in a plea of not guilty.

b) The right to a speedy and public trial by jury.

c) The right to be represented by counsel - and if necessary have the court appoint counsel - at trial. Defendant

understands, however, that, defendant retains the right to be represented by counsel - and if necessary have the court appoint counsel - at every other stage of the proceeding.

d) The right to be presumed innocent and to have the burden of proof placed on the government to prove defendant guilty beyond a reasonable doubt.

e) The right to confront and cross-examine witnesses against defendant.

f) The right to testify and to present evidence in opposition to the charges, including the right to compel the attendance of witnesses to testify.

g) The right not to be compelled to testify, and, if defendant chose not to testify or present evidence, to have that choice not be used against defendant.

h) Any and all rights to pursue any affirmative defenses, Fourth Amendment or Fifth Amendment claims, and other pretrial motions that have been filed or could be filed.

WAIVER OF APPEAL OF CONVICTION

27. Defendant understands that, with the exception of an appeal based on a claim that defendant's guilty pleas were involuntary, by pleading guilty defendant is waiving and giving up any right to appeal defendant's convictions on the offenses to which defendant is pleading guilty.

LIMITED MUTUAL WAIVER OF APPEAL OF SENTENCE

28. Defendant agrees that, provided the Court imposes a total term of imprisonment on all counts of conviction of no more than the low end of the Guidelines range corresponding to a total offense level of 35 and defendant's criminal history category, defendant

gives up the right to appeal all of the following: (a) the procedures and calculations used to determine and impose any portion of the sentence; (b) the term of imprisonment imposed by the Court, provided it is within the statutory maximum; (c) the fine imposed by the court, provided it is within the statutory maximum; (d) the amount and terms of any restitution order, provided it requires payment of no more than $20,000,000; (e) the term of probation or supervised release imposed by the Court, provided it is within the statutory maximum; and (f) any of the following conditions of probation or supervised release imposed by the Court: the conditions set forth in General Orders 318, 01-05, and/or 05-02 of this Court; the drug testing conditions mandated by 18 U.S.C. §§ 3563(a)(5) and 3583(d); and the alcohol and drug use conditions authorized by 18 U.S.C. § 3563(b)(7).

29. The USAO agrees that, provided (a) all portions of the sentence are at or below the statutory maximum specified above and (b) the Court imposes a term of imprisonment of no less than the low end of the Guidelines range corresponding to a total offense level of 35 and defendant's criminal history category, the USAO gives up its right to appeal any portion of the sentence, with the exception that the USAO reserves the right to appeal the following: the amount of restitution ordered, if that amount is less than $50,000,000.

RESULT OF WITHDRAWAL OF GUILTY PLEA

30. Defendant agrees that if, after entering guilty pleas pursuant to this agreement, defendant seeks to withdraw and succeeds in withdrawing defendant's guilty pleas on any basis other than a claim and finding that entry into this plea agreement was involuntary, then (a) the USAO will be relieved of all of its

obligations under this agreement, including in particular its obligations regarding the use of Cooperation Information; (b) in any investigation, criminal prosecution, or civil, administrative, or regulatory action, defendant agrees that any Cooperation Information and any evidence derived from any Cooperation Information shall be admissible against defendant, and defendant will not assert, and hereby waives and gives up, any claim under the United States Constitution, any statute, or any federal rule, that any Cooperation Information or any evidence derived from any Cooperation Information should be suppressed or is inadmissible; and (c) should the USAO choose to pursue any charge that was not filed as a result of this agreement, then (i) any applicable statute of limitations will be tolled between the date of defendant's signing of this agreement and the filing commencing any such action; and (ii) defendant waives and gives up all defenses based on the statute of limitations, any claim of pre-indictment delay, or any speedy trial claim with respect to any such action, except to the extent that such defenses existed as of the date of defendant's signing this agreement.

EFFECTIVE DATE OF AGREEMENT

31. This agreement is effective upon signature and execution of all required certifications by defendant, defendant's counsel, and an Assistant United States Attorney.

BREACH OF AGREEMENT

32. Defendant agrees that if defendant, at any time after the signature of this agreement and execution of all required certifications by defendant, defendant's counsel, and an Assistant United States Attorney, knowingly violates or fails to perform any of defendant's obligations under this agreement ("a breach"), the

USAO may declare this agreement breached. For example, if defendant knowingly, in an interview, before a grand jury, or at trial, falsely accuses another person of criminal conduct or falsely minimizes defendant's own role, or the role of another, in criminal conduct, defendant will have breached this agreement. All of defendant's obligations are material, a single breach of this agreement is sufficient for the USAO to declare a breach, and defendant shall not be deemed to have cured a breach without the express agreement of the USAO in writing. If the USAO declares this agreement breached, and the Court finds such a breach to have occurred, then:

a) If defendant has previously entered guilty pleas pursuant to this agreement, defendant will not be able to withdraw the guilty pleas.

b) The USAO will be relieved of all its obligations under this agreement; in particular, the USAO: (i) will no longer be bound by any agreements concerning sentencing and will be free to seek any sentence up to the statutory maximum for the crime to which defendant has pleaded guilty; (ii) will no longer be bound by any agreements regarding criminal prosecution, and will be free to criminally prosecute defendant for any crime, including charges that the USAO would otherwise have been obligated not to criminally prosecute pursuant to this agreement; and (iii) will no longer be bound by any agreement regarding the use of Cooperation Information and will be free to use any Cooperation Information in any way in any investigation, criminal prosecution, or civil, administrative, or regulatory action by the United States.

c) The USAO will be free to criminally prosecute defendant for false statement, obstruction of justice, and perjury based on any knowingly false or misleading statement by defendant.

d) In any investigation, criminal prosecution, or civil, administrative, or regulatory action by the United States: (i) defendant will not assert, and hereby waives and gives up, any claim that any Cooperation Information was obtained in violation of the Fifth Amendment privilege against compelled self-incrimination; and (ii) defendant agrees that any Cooperation Information and any Plea Information, as well as any evidence derived from any Cooperation Information or any Plea Information, shall be admissible against defendant, and defendant will not assert, and hereby waives and gives up, any claim under the United States Constitution, any statute, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, or any other federal rule, that any Cooperation Information, any Plea Information, or any evidence derived from any Cooperation Information or any Plea Information should be suppressed or is inadmissible.

33. Following the Court's finding of a knowing breach of this agreement by defendant, should the USAO choose to pursue any charge that was not filed as a result of this agreement, then:

a) Defendant agrees that any applicable statute of limitations is tolled between the date of defendant's signing of this agreement and the filing commencing any such action.

b) Defendant waives and gives up all defenses based on the statute of limitations, any claim of pre-indictment delay, or any speedy trial claim with respect to any such action, except to

the extent that such defenses existed as of the date of defendant's signing this agreement.

COURT AND PROBATION OFFICE NOT PARTIES

34. Defendant understands that the Court and the United States Probation Office are not parties to this agreement and need not accept any of the USAO's sentencing recommendations or the parties' agreements to facts or sentencing factors.

35. Defendant understands that both defendant and the USAO are free to: (a) supplement the facts by supplying relevant information to the United States Probation Office and the Court, (b) correct any and all factual misstatements relating to the Court's Sentencing Guidelines calculations and determination of sentence, and (c) argue on appeal and collateral review that the Court's Sentencing Guidelines calculations and the sentence it chooses to impose are not error, although each party agrees to maintain its view that the calculations in paragraph 23 are consistent with the facts of this case. While this paragraph permits both the USAO and defendant to submit full and complete factual information to the United States Probation Office and the Court, even if that factual information may be viewed as inconsistent with the facts agreed to in this agreement, this paragraph does not affect defendant's and the USAO's obligations not to contest the facts agreed to in this agreement.

36. Defendant understands that even if the Court ignores any sentencing recommendation, finds facts or reaches conclusions different from those agreed to, and/or imposes any sentence up to the maximum established by statute, defendant cannot, for that reason, withdraw defendant's guilty pleas, and defendant will remain bound to fulfill all defendant's obligations under this agreement.

Defendant understands that no one -- not the prosecutor, defendant's attorney, or the Court -- can make a binding prediction or promise regarding the sentence defendant will receive, except that it will be within the statutory maximum.

NO ADDITIONAL AGREEMENTS

37. Defendant understands that, except as set forth herein, there are no promises, understandings, or agreements between the USAO and defendant or defendant's attorney, and that no additional promise, understanding, or agreement may be entered into unless in a writing signed by all parties or on the record in court.

PLEA AGREEMENT PART OF THE GUILTY PLEA HEARING

38. The parties agree that this agreement will be considered part of the record of defendant's guilty plea hearing as if the entire agreement had been read into the record of the proceeding.

AGREED AND ACCEPTED

UNITED STATES ATTORNEY'S OFFICE
FOR THE CENTRAL DISTRICT OF CALIFORNIA

ANDRÉ BIROTTE JR.
United States Attorney

JEANNIE M. JOSEPH
Assistant United States Attorney — Date: 2/20/14

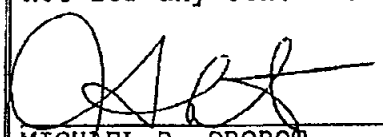
MICHAEL D. DROBOT
Defendant — Date: FEB 20, 2014

JEFFREY N. RUTHERFORD/JANET LEVINE
Attorneys for Defendant
Michael D. Drobot — Date: Feb. 20, 2014

TERREE A. BOWERS
Attorney for Defendant
Michael D. Drobot — Date:

CERTIFICATION OF DEFENDANT

I have read this agreement in its entirety. I have had enough time to review and consider this agreement, and I have carefully and thoroughly discussed every part of it with my attorneys. I understand the terms of this agreement, and I voluntarily agree to those terms. I have discussed the evidence with my attorneys, and my attorneys have advised me of my rights, of possible pretrial motions that might be filed, of possible defenses that might be asserted either prior to or at trial, of the sentencing factors set forth in 18 U.S.C. § 3553(a), of relevant Sentencing Guidelines provisions, and of the consequences of entering into this agreement. No promises, inducements, or representations of any kind have been made to me other than those contained in this agreement. No one has threatened or forced me in any way to enter into this agreement. I am satisfied with the representation of my attorneys in this matter, and I am pleading guilty because I am guilty of the charges and wish to take advantage of the promises set forth in this agreement, and not for any other reason.



MICHAEL D. DROBOT
Defendant

FEB 20, 2014
Date

CERTIFICATION OF DEFENDANT'S ATTORNEY

I am Michael D. Drobot's attorney. I have carefully and thoroughly discussed every part of this agreement with my client. Further, I have fully advised my client of his rights, of possible pretrial motions that might be filed, of possible defenses that might be asserted either prior to or at trial, of the sentencing factors set forth in 18 U.S.C. § 3553(a), of relevant Sentencing Guidelines provisions, and of the consequences of entering into this agreement. To my knowledge: no promises, inducements, or representations of any kind have been made to my client other than those contained in this agreement; no one has threatened or forced my client in any way to enter into this agreement; my client's decision to enter into this agreement is an informed and voluntary one; and the factual basis set forth in this agreement is sufficient to support my client's entry of guilty pleas pursuant to this agreement.

JEFFREY H. RUTHERFORD/JANET LEVINE
Attorneys for Defendant
Michael D. Drobot

Feb. 20, 2014
Date

CERTIFICATION OF DEFENDANT'S ATTORNEY

I am Michael D. Drobot's attorney. I have carefully and thoroughly discussed every part of this agreement with my client. Further, I have fully advised my client of his rights, of possible pretrial motions that might be filed, of possible defenses that might be asserted either prior to or at trial, of the sentencing factors set forth in 18 U.S.C. § 3553(a), of relevant Sentencing Guidelines provisions, and of the consequences of entering into this agreement. To my knowledge: no promises, inducements, or representations of any kind have been made to my client other than those contained in this agreement; no one has threatened or forced my client in any way to enter into this agreement; my client's decision to enter into this agreement is an informed and voluntary one; and the factual basis set forth in this agreement is sufficient to support my client's entry of guilty pleas pursuant to this agreement.

TERREE A. BOWERS
Attorney for Defendant
Michael D. Drobot

2/22/14
Date

CERTIFICATE OF SERVICE

I am a citizen of the United States and a resident of Orange County, California. I am over 18 years of age, and I am not a party to the above-entitled action. My business address is the United States Attorney's Office, Ronald Reagan Federal Building and United States Courthouse, 411 West Fourth Street, Suite 8000, Santa Ana, California 92701.

That I am employed by the United States Attorney for the Central District of California, who is a member of the Bar of the United States District Court for the Central District of California, at whose direction the service was made. On this date, February 21, 2014, I served a copy of the foregoing documents, described as follows: **PLEA AGREEMENT FOR DEFENDANT MICHAEL D. DROBOT** in the following manner:

☒ by placing a true copy in a sealed envelope, addressed to the person specified below, and placing it for interoffice delivery within the courthouse:

☐ by placing the document in a sealed envelope, bearing the requisite postage thereon, and placing it for mailing via the U.S. Postal Service addressed as follows:

☐ by fax to the person and fax number specified below:

☐ by e-mailing a pdf. version of the document to the e-mail address specified below:

Jeffrey H. Rutherford/Janet Levine
Crowell & Moring LLP
515 South Flower Street, 40th Floor
Los Angeles, California 90017

Terree A. Bowers
Arent Fox
555 West Fifth Street, 48th Floor
Los Angeles, California 90013

I declare under penalty of perjury that the foregoing is true and correct, executed on February 21, 2014, at Santa Ana, California.

GINA HERNANDEZ

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CRIMINAL MINUTES - GENERAL

Case No. SACR 14-00034-JLS Date April 24, 2014

Present: The Honorable **JOSEPHINE L. STATON, U.S. DISTRICT JUDGE**

Interpreter None

Ellen Matheson	Miriam Baird	Jeannie Joseph
Deputy Clerk	*Court Reporter/Recorder*	*Assistant U.S. Attorney*

U.S.A. v. Defendant(s):	Present Cust.	Bond	Attorneys for Defendants:	Present App.	Ret.
(1) Michael D. Drobot	X	X	(1) Derek Hahn, Terree Bowers, and Jeffrey Rutherford	X	X

Also present in court,.

Proceedings: **CHANGE OF PLEA**

X Defendant moves to change plea to Counts 1 and 2 of the 2-Count Information. Waiver of Indictment previously filed; Court enters findings and accepts the Waiver as filed.

X Defendant sworn, and states true name as Michael Dennis Drobot.

X Defendant enters new and different plea of GUILTY to Counts 1 and 2 of the Information.

X The Court questions the defendant regarding plea of GUILTY and FINDS that a factual basis has been laid, and further FINDS the plea is knowledgeable and voluntarily made. The Court ORDERS the plea accepted and entered.

X The Court further ORDERS the Plea Agreement incorporated into this proceeding.

X The Court refers the defendant to the Probation Office for investigation and pre-sentencing report, and the matter is continued to **December 12, 2014, at 10:30 a.m.** for sentencing. Further, sentencing position papers are to be filed with the Court no later than two (2) weeks before the date of sentencing, including service on the assigned U.S. Probation Officer.

X The Court further ORDERS the Scheduling Conference set for May 16, 2014, and the Jury Trial scheduled for May 27, 2014, VACATED.

X The Court further ORDERS the defendant released on the same terms and conditions as previously set, pending sentencing. Defendant and counsel are ordered to appear on December 12, 2014, at 10:30 a.m. for sentencing.

00 : 50

Initials of Deputy Clerk enm

cc: **USPO; PSA**

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA, Plaintiff, v. Michael D. Drobot Defendant/Material Witness.	CASE NUMBER: SACR14-34	
	COMPLAINT:	INDICTMENT / INFORMATION:
	VIOLATION OF TITLE: 18 USC; 42 USC	SECTION: 371; 1320a-7b(2)(A)

☐ PERSONAL RECOGNIZANCE (Signature only - no dollar amount)
☒ UNSECURED APPEARANCE BOND IN THE AMOUNT OF $ 5,000.00 RELEASE No. SUMMONS
☒ APPEARANCE BOND IN THE AMOUNT OF $ _____
☐ WITH CASH DEPOSIT (AMOUNT OR %) _____
☐ WITH AFFIDAVIT OF SURETY NO JUSTIFICATION (Form CR-4)
_____
_____
☐ WITH AFFIDAVIT WITH JUSTIFICATION OF SURETY (Form CR-3)
_____
_____
☐ WITH DEEDING OF PROPERTY
☐ COLLATERAL BOND IN AMOUNT OF (Cash or Negotiable Securities) $ _____
☐ CORPORATE SURETY BOND IN AMOUNT OF (Separate Form Required) $ _____
☐ ADDITIONAL REQUIREMENTS: _____
☒ BAIL FIXED BY COURT _____ Deputy Clerk ☒ ALL REQUIREMENTS HAVE BEEN MET: _____ 3/31/14 Deputy Clerk

☐ RELEASE TO PRETRIAL ONLY
☐ FORTHWITH RELEASE
☐ ALL CONDITIONS OF BOND SHALL BE MET AND BOND POSTED BY: _____ Date

PRE-CONDITIONS TO RELEASE

☐ Bail is subject to Nebbia hearing which is a hearing to inquire about the source of the collateral.
☐ The Nebbia hearing can be waived by the government.

ADDITIONAL CONDITIONS OF RELEASE

In addition to the GENERAL CONDITIONS of RELEASE, as specified on other side, the following conditions of release are imposed upon you:

☒ Defendant shall submit to: ☒ Pretrial Supervision. [ ] Intensive Pretrial Supervision.
☒ Surrender all passports to the ~~Clerk of Court~~ PSA, or sign a declaration no later than, _____ and not apply for the issuance of a passport during the pendency of this case.
☒ Travel is restricted to: ~~CD/CA~~ CD CA, OC, Texas, Michigan + Colorado
☐ Do not enter premises of any airport, seaport, railroad, or bus terminal which permits exit from the Continental U.S. or area of restricted travel without Court permission.
☒ Reside as approved by PSA and do not relocate without prior permission from PSA. _____
☐ Maintain or actively seek employment and provide proof to PSA.
☐ Maintain or commence an educational program and provide proof to PSA.
☐ Avoid all contact, directly or indirectly, with any person who is or who may become a victim or potential witness in the subject investigation or prosecution, including but not limited to: _____
☐ Not possess any firearms, ammunition, destructive devices, or other dangerous weapons. [ ] In order to determine compliance, you will agree to submit to a search of your person and/or property by Pretrial Services in conjunction with the US Marshal.
☐ Not use/possess any identification other than in your own legal name or true name. [ ] In order to determine compliance, you will agree to submit to a search of your person and/or property by Pretrial Services in conjunction with the U.S. Marshal.
☐ Not use alcohol.
☐ Not use or possess illegal drugs. [ ] In order to determine compliance, you will agree to submit to a search of your person and/or property by Pretrial Services in conjunction with the US Marshal.
☐ Submit to drug [and/or] alcohol testing and outpatient treatment as directed by PSA. You shall pay all or part of the cost for testing and treatment based upon your ability to pay as determined by PSA.
☐ Participate in residential drug [and/or] alcohol treatment as deemed necessary by PSA. You shall pay all or part of the cost for treatment based upon your ability to pay as determined by PSA. [ ] Release to PSA only.
☐ Participate in mental health evaluation, and/or counseling and/or treatment as directed by PSA. You shall pay all or part of the costs based upon your ability to pay as determined by PSA.

☒ Defendant Initials _____ Date 3/31/14 ☒

ORIGINAL - YELLOW COPY PINK- PRETRIAL SERVICES WHITE - DEFENDANT COPY

UNITED STATES DISTRICT COURT FOR THE CENTRAL DISTRICT OF CALIFORNIA

Michael D. Drobot Defendant/~~Material-Witness~~.	CASE NUMBER: SACR 14-34

☐ Participate in one of the following home confinement program components and abide by all requirements of the program which [ ] will or [ ] will not include electronic monitoring or other location verification system. You shall pay all or part of the cost of the program based upon your ability to pay as determined by PSA.

[ ] Curfew. You are restricted to your residence every day: [ ] from _____ to _____. [ ] as directed by PSA. [ ] **Release to PSA only.**

[ ] **Home Detention.** You are restricted to your residence at all times except for employment; education; religious services; medical, substance abuse, or mental health treatment; attorney visits; court-ordered obligations; or other activities as pre-approved by PSA. [ ] **Release to PSA only.**

[ ] **Home Incarceration.** You are restricted to your residence at all times except for medical needs or treatment; religious services; and court appearances as pre-approved by PSA. [ ] **Release to PSA only.**

☐ Not possess or have access to, either in the home, the workplace, or any other location, any device which offers Internet access, except as approved by PSA. [ ] In order to determine compliance, you will agree to submit to a search of your person and/or property by Pretrial Services in conjunction with the US Marshal.

☐ Not associate or have verbal, written, telephonic, or electronic communication with any person who is less than the age of 18 except in the presence of another adult who is the parent or legal guardian of the minor.

☐ Not loiter/be found within 100 feet of any school yard, park, playground, arcade, or other place primarily used by children under the age of 18.

☐ Not be employed by, affiliate with, own, control, or otherwise participate directly or indirectly in conducting the affairs of any daycare facility, school, or other organization dealing with the care, custody, or control of children under the age of 18.

☐ Not view or possess child pornography or child erotica. [ ] In order to determine compliance, you will agree to submit to a search of your person and/or property, including computer hardware and software, by Pretrial Services in conjunction with the US Marshal.

☐ Other conditions: _____

_____

X 3/31/14 X _____ X 562/299-7099

Date *Defendant/~~Material-Witness~~ Signature* *Telephone Number*

X Corona Del Mar, CA. 92625

City, State And Zip Code

☐ **Check if interpreter is used:** I have interpreted into the _____ language all of the above conditions of release and have been told by the defendant that he or she understands all of the conditions of release.

_____ _____

Interpreter's signature *Date*

Approved: /s/ DOUGLAS F. McCORMICK 4/1/14

United States District Judge / Magistrate Judge *Date*

If Cash Deposited: Receipt # _____ For $_____

(This bond may require surety agreements and affidavits pursuant to Local Criminal Rules 46-3.2 and 46-6)

ORIGINAL - YELLOW COPY PINK- PRETRIAL SERVICES WHITE - DEFENDANT COPY

GPO U.S. GOVERNMENT PRINTING OFFICE: 2010 672-039

GENERAL CONDITIONS OF RELEASE

I will appear in person in accordance with any and all directions and orders relating to my appearance in the above entitled matter as may be given or issued by the Court or any judicial officer thereof, in that Court or before any Magistrate Judge thereof, or in any other United States District Court to which I may be removed or to which the case may be transferred.

I will abide by any judgment entered in this matter by surrendering myself to serve any sentence imposed and will obey any order or direction in connection with such judgment as the Court may prescribe.

I will not leave the State of California except upon order of this Court, and I will immediately inform my counsel of any change in my residence address or telephone number so that I may be reached at all times.

I will not commit a Federal, State, or local crime during the period of release.

I will not intimidate any witness, juror or officer of the court or obstruct the criminal investigation in this case in violation of Title 18 U.S.C. Section 1503 and 1510. Additionally, I will not tamper with, harass or retaliate against any alleged witness, victim or informant in this case in violation of Title 18 U.S.C. Section 1512 and 1513.

ACKNOWLEDGMENT OF DEFENDANT/MATERIAL WITNESS

AS A CONDITION OF MY RELEASE ON THIS BOND, PURSUANT TO TITLE 18 OF THE UNITED STATES CODE, I HAVE READ OR HAVE HAD INTERPRETED TO ME AND UNDERSTAND THE GENERAL CONDITIONS OF RELEASE, THE PRE-CONDITION AND ADDITIONAL CONDITIONS OF RELEASE AND AGREE TO COMPLY WITH ALL CONDITIONS OF RELEASE IMPOSED ON ME AND TO BE BOUND BY THE PROVISIONS OF LOCAL CRIMINAL RULE 46-6.

FURTHERMORE, IT IS AGREED & UNDERSTOOD THAT THIS IS A CONTINUING BOND (INCLUDING ANY PROCEEDING ON APPEAL OR REVIEW) WHICH SHALL CONTINUE IN FULL FORCE & EFFECT UNTIL SUCH TIME AS DULY EXONERATED.

I UNDERSTAND THAT VIOLATION OF ANY OF THE GENERAL AND/OR ADDITIONAL CONDITIONS OF RELEASE AS GIVEN ON THE FACE OF THIS BOND MAY RESULT IN A REVOCATION OF RELEASE, AN ORDER OF DETENTION AND A NEW PROSECUTION FOR AN ADDITIONAL OFFENSE WHICH COULD RESULT IN A TERM OF IMPRISONMENT AND/OR FINE.

I FURTHER UNDERSTAND THAT IF I FAIL TO OBEY AND PERFORM ANY OF THE GENERAL AND/OR ADDITIONAL CONDITIONS OF RELEASE AS GIVEN ON THE FACE OF THIS BOND, THIS BOND MAY BE FORFEITED TO THE UNITED STATES OF AMERICA. IF SAID **FORFEITURE IS NOT SET ASIDE, JUDGMENT MAY BE SUMMARILY ENTERED IN THIS COURT AGAINST MYSELF AND EACH SURETY, JOINTLY AND SEVERALLY, FOR THE BOND AMOUNT, TOGETHER WITH INTEREST AND COSTS, AND EXECUTION OF THE JUDGMENT MAY BE ISSUED OR PAYMENT SECURED AS PROVIDED BY THE FEDERAL RULES OF CRIMINAL PROCEDURE AND OTHER LAWS OF THE UNITED STATES AND ANY CASH, REAL OR PERSONAL PROPERTY OR THE COLLATERAL PREVIOUSLY POSTED IN CONNECTION WITH THIS BOND MAY BE FORFEITED.**

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

USA, PLAINTIFF(S) v. Michael D Drobot, DEFENDANT(S).	CASE NUMBER SACR14-00034 DOC **ORDER RE TRANSFER PURSUANT TO GENERAL ORDER 08-05 (Related Criminal Case)**

CONSENT

I hereby consent to the transfer of the above-entitled case to my calendar, pursuant to General Order 08-05.

4.01.14
Date

Josephine L. Staton
United States District Judge

DECLINATION

I hereby decline to transfer the above-entitled case to my calendar for the reasons set forth below:

Date

United States District Judge

REASON FOR TRANSFER AS INDICATED BY COUNSEL

Case SACR12-00023 JLS and the present case:

☑ A. Arise out of the same conspiracy, common scheme, transaction, series of transactions or events; or
☐ B. Involve one or more defendants in common, and would entail substantial duplication of labor in pretrial, trial or sentencing proceedings if heard by different judges.

Notice to Counsel from Clerk

On all documents subsequently filed in this case, please substitute the initials JLS after the case number in place of the initials of the prior judge, so that the case number will read SACR14-00034 JLS. This is very important because traditionally filed documents are routed to the assigned judge by means of these initials.

Traditionally filed subsequent documents must be filed at the: ☐ Western ☑ Southern ☐ Eastern Division. Failure to file at the proper location will result in your documents being returned to you.

cc: ☐ *PSALA* ☐ *PSASA* ☐ *PSAED* ☐ *USMLA* ☐ *USMSA* ☐ *USMED* ☑ *Previous Judge* ☑ *Statistics Clerk*

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

CRIMINAL MINUTES - GENERAL

Case No. **SACR 14-00034-JLS** Date **April 2, 2014**

Present: The Honorable JOSEPHINE L. STATON, U.S. DISTRICT JUDGE

Interpreter NONE

Terry Guerrero	NONE	NOT PRESENT
Deputy Clerk	*Court Reporter/Recorder*	*Assistant U.S. Attorney*

U.S.A. v. Defendant(s):	Present	Cust.	Bond	Attorneys for Defendants:	Present	App.	Ret.
MICHAEL D. DROBOT	NOT		X	Derek A. Hahn	NOT		X
				Jeffrey H. Rutherford	NOT		X
				Terree A. Bowers	NOT		X

Proceedings: (IN CHAMBERS) **ORDER ON REASSIGNMENT OF CASE**

This case having been transferred to this Court pursuant to General Order 08-05, the following matters are scheduled. A Status Conference is scheduled for May 16, 2014, at 11:30 a.m., and Jury Trial is scheduled for May 27, 2014, at 9:00 a.m. Defendant and counsel are ordered to appear at those times.

All hearing dates previously scheduled before Judge Carter are ordered VACATED.

Counsel are referred to the Court's Order re Criminal Pre-trial Motions, Trials, and Sentencing, located on the Court's website, Judges' Procedures and Schedules.

_____ : _____

Initials of Deputy Clerk tg

cc: PSA

Terree A. Bowers
Arent Fox LLP
555 West 5th St.
Los Angeles, CA 90013

UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

United States of America PLAINTIFF v. Michael D. Drobot DEFENDANT(S).	CASE NUMBER SACR 14-00034 DESIGNATION AND APPEARANCE OF COUNSEL

DESIGNATION OF COUNSEL

I, the undersigned defendant in the above-numbered case, hereby designate and appoint Terree A. Bowers, Esquire, as my attorney to appear for me throughout all proceedings in this case.

3/31/2014
Date

Defendant's Signature

Santa Ana, CA
City and State

APPEARANCE OF COUNSEL

I, Terree A. Bowers Attorney at law duly admitted to practice before the United States District Court for the Central District of California, hereby consent to my designation and appointment as counsel for the above-named defendant. The Clerk is therefore requested to enter my appearance as defendant's counsel.

Receipt is hereby acknowledged of a copy of the Indictment or Information in this case.

3/31/2014
Date

Attorney's Signature

89334
California State Bar Number

555 West 5th St.
Street Address

Los Angeles, CA 90013
City, State, Zip Code

213-443-7573 213-629-7401
Telephone Number *Fax Number*

BOWERS.TERREE@ARENTFOX.COM
E-mail Address

EXHIBIT 16

UNITED STATES DISTRICT COURT

FOR THE CENTRAL DISTRICT OF CALIFORNIA

October 2012 Grand Jury

UNITED STATES OF AMERICA, Plaintiff, v. RONALD S. CALDERON and THOMAS M. CALDERON, Defendants.	CR No. 14-CR14-0103 I N D I C T M E N T [18 U.S.C. § 1341: Mail Fraud; 18 U.S.C. § 1343: Wire Fraud; 18 U.S.C. § 1346: Honest Services Fraud; 18 U.S.C. § 666: Bribery Concerning Programs Receiving Federal Funds; 18 U.S.C. § 1956(h): Conspiracy to Commit Money Laundering; 18 U.S.C. § 1956(a)(1)(B)(i): Money Laundering; 26 U.S.C. § 7206(2): Aiding in the Filing of False Tax Return]

The Grand Jury charges:

INTRODUCTORY ALLEGATIONS

At all times relevant to this Indictment:

A. RELEVANT PERSONS AND ENTITIES

1. Defendant RONALD S. CALDERON was an elected California State Senator who owed a fiduciary duty and a duty of honest services to the citizens of California, including his

DMM:dmm
MEJ:mej

constituents in the 30th Senate District, which included, among others, the cities of Bell, Bell Gardens, Commerce, Cudahy, Montebello, Norwalk, Pico Rivera, Santa Fe Springs, and Whittier.

2. Defendant THOMAS M. CALDERON was defendant RONALD S. CALDERON's brother and a former California State Assemblymen for the 58th Assembly District, which included, among others, the cities of Montebello, Norwalk, and Whittier.

3. The Calderon Group Incorporated ("the Calderon Group") was a privately-owned consulting company founded by defendant THOMAS M. CALDERON after he left the California State Assembly in 2002.

4. Californians for Diversity was a tax-exempt public benefit corporation under Title 26, United States Code, Section 501(c)(4), for which defendant THOMAS M. CALDERON served as Chief Executive Officer and President.

5. Michael D. Drobot ("Drobot") owned and/or operated Pacific Hospital of Long Beach ("Pacific Hospital") from in or around 1997 to in or around October 2013. Pacific Hospital was a hospital located in Long Beach, California, specializing in surgeries, particularly spinal and orthopedic surgeries.

6. UC-1 was an undercover agent for the Federal Bureau of Investigation ("FBI") who held himself out to defendant RONALD S. CALDERON, defendant THOMAS M. CALDERON, and others as the owner of an independent film studio in Los Angeles, California.

7. UC-2 was an undercover agent for the FBI who held herself out to defendant RONALD S. CALDERON, defendant THOMAS M. CALDERON, and others as UC-1's girlfriend.

8. UC-3 was an undercover agent for the FBI who held himself out to defendant RONALD S. CALDERON, defendant THOMAS M. CALDERON, and others as the owner of an entertainment company in Florida and an investor in UC-1's independent film studio.

B. THE CALIFORNIA LEGISLATURE

9. The California State Senate (the "Senate") was one of two legislative bodies in the California State Legislature. The Senate was comprised of approximately 40 elected representatives ("Senators").

10. Senators were agents of California, a government that received more than $10,000 per fiscal year in funds from the United States in the form of grants, contracts, subsidies, loans, guarantees, insurance, and other forms of federal assistance.

11. Senators, in their official capacity, would customarily: (1) draft and vote on legislation; (2) meet with other public officials and their staff to discuss legislation; (3) issue press releases, letters of support, and other public statements indicating their position on legislation; and (4) hire staff members whose salaries were paid for by the State of California to assist them in their responsibilities as Senators.

C. RELEVANT LEGISLATION

12. Pursuant to California law, California's Workers' Compensation System ("CWCS") required California employers to provide workers' compensation benefits to employees who were injured in the course of their employment.

13. Before January 2013, California law, in a provision referred to herein as the "spinal pass-through," allowed a

hospital to bill the cost of medical hardware separately from the other costs of a surgery, such as the hospital's and surgeon's services, the reimbursement rates of which were set by a fee schedule. The hardware was considered a pass-through cost and billing was limited to $250 over what the hospital paid for the hardware.

14. Between January 2010 and August 2012, the California Senate and the Division of Workers' Compensation, an agency within the CWCS system, took several steps designed to modify or eliminate the spinal pass-through. This was due, in part, to studies that showed eliminating the spinal pass-through could result in savings of as much as $60 million to California taxpayers.

15. By January 2013, California law was changed to eliminate the spinal pass-through; subsequently, reimbursement for all costs of a surgery was limited to a fee schedule.

16. Pursuant to California law, in a provision referred to herein as the "film tax credit," producers of certain independent films and qualified motion pictures in California were entitled to receive a state tax credit for certain expenditures. The film tax credit defined independent films as motion pictures with a minimum budget of $1,000,000 and a maximum budget of $10,000,000 that were produced by certain individuals and companies.

17. Pursuant to California law, Senators were required to file Statements of Economic Interests and similar forms with the California Fair Political Practices Commission, wherein they disclosed, among other things, certain income, gifts, loans, and

travel they had received, as well as certain payments they had requested, solicited, or suggested be made to third parties.

18. These Introductory Allegations are hereby incorporated by reference into each count of this Indictment as though set forth fully therein.

COUNTS ONE THROUGH TEN

[18 U.S.C. §§ 1341, 1343, 1346]

A. THE SCHEME TO DEFRAUD

Beginning on a date unknown to the Grand Jury and continuing through on or about May 4, 2013, in Los Angeles County, within the Central District of California, and elsewhere, defendant RONALD S. CALDERON, together with others known and unknown to the Grand Jury, knowingly and with intent to defraud, devised, participated in, and executed a scheme to defraud the citizens of the State of California of their right to the honest services of their elected officials through bribery and kickbacks, and the concealment of material information, which scheme is described further below.

B. MEANS AND METHODS OF THE SCHEME TO DEFRAUD

Defendant RONALD S. CALDERON, together with others known and unknown to the Grand Jury, defrauded the citizens of the State of California by the following means and methods:

1. Defendant RONALD S. CALDERON would seek and accept bribes and kickbacks in the form of financial benefits and payments to himself, his children, and to Californians for Diversity and the Calderon Group.

2. Defendant RONALD S. CALDERON would perform official acts favorable to the individuals paying him bribes and kickbacks, including introducing and supporting legislation on their behalf, and seeking the support of other public officials and their staff for such legislation.

3. Defendant RONALD S. CALDERON would disclose some of the official acts he had performed on behalf of co-schemers

paying him bribes to induce others to continue paying him bribes.

4. Defendant RONALD S. CALDERON would take steps to disguise, conceal, and cover up the bribe payments he was receiving and, in several instances, the official acts he had performed in exchange for the bribe payments.

Bribes Involving the Spinal Pass-Through

5. Defendant RONALD S. CALDERON would solicit and accept benefits, such as employment for his son, trips on privately-chartered airplanes, golf at exclusive, high-end golf resorts, and meals at expensive restaurants, from Drobot with the understanding that such benefits were to influence, and in exchange for, defendant RONALD S. CALDERON's official acts in connection with the spinal pass-through and worker's compensation legislation and regulation.

6. Defendant RONALD S. CALDERON would solicit Drobot to hire defendant RONALD S. CALDERON's son at one or more of Drobot's companies during the summers of 2010, 2011, and 2012, and to pay defendant RONALD S. CALDERON's son approximately $10,000 per summer.

7. Drobot would agree to hire defendant RONALD S. CALDERON's son to perform clerical duties at one or more of Drobot's companies during the summers of 2010, 2011, and 2012, and cause defendant RONALD S. CALDERON's son to be paid approximately $10,000 per summer, or approximately $30,000 total, for approximately 15 days of work per summer, which payments were disbursed on or about the following dates:

DATE	AMOUNT
7/13/2010	$10,000
7/11/2011	$5,000
8/16/2011	$5,000
7/13/2012	$1,490.95
7/27/2012	$1,490.95
8/02/2012	$7,018.10

8. Defendant RONALD S. CALDERON would perform official acts favorable to Drobot in connection with the spinal pass-through and worker's compensation legislation and regulation.

9. Defendant RONALD S. CALDERON would communicate with other public officials and their staff and attempt to convince them to take action favorable to Drobot in connection with the spinal pass-through and worker's compensation legislation and regulation. For example:

a. In or about February 2010, defendant RONALD S. CALDERON met with Drobot in or around Sacramento, California and solicited Drobot to hire defendant RONALD S. CALDERON's son for the next several summers and to pay him $10,000 per summer, so that defendant RONALD S. CALDERON's son would have enough money to pay his college tuition.

b. In or about April 2010, defendant RONALD S. CALDERON met with a Director at the Division of Workers' Compensation and discussed the negative impact that proposed regulations would have on Pacific Hospital and other hospitals.

c. On or about February 18, 2011, defendant RONALD S. CALDERON met with Senator A and requested that Senator A

introduce legislation in the Senate favorable to Drobot and Pacific Hospital ("Bill #1").

d. On or about March 5, 2011, defendant RONALD S. CALDERON wrote an email to Senator B, discussing the importance of the spinal pass-through and worker's compensation legislation and regulation.

e. On or about June 12, 2012, defendant RONALD S. CALDERON and Drobot met with Senator C and discussed the negative impact Senator C's proposed legislation would have on Pacific Hospital and other hospitals ("Bill #2").

Bribes Involving the Film Tax Credit

10. Defendant RONALD S. CALDERON would solicit and accept financial benefits, such as trips to Las Vegas, meals, and employment for his daughter, from UC-1 and UC-3 with the understanding that such benefits were to influence, and in exchange for, defendant RONALD S. CALDERON's official acts in connection with the film tax credit.

11. Defendant RONALD S. CALDERON would negotiate the terms of his daughter's employment with UC-1 and UC-3, including that they were under no obligation to continue paying his daughter if defendant RONALD S. CALDERON did not "deliver" on his support for the film tax credit.

12. Defendant RONALD S. CALDERON would cause UC-1 and UC-3 to pay his daughter multiple payments of $3,000 or more under what purported to be a "Studio Services Agreement," even though defendant RONALD S. CALDERON knew his daughter was not expected to perform any work under the purported agreement and that the payments of $3,000 or more were to influence, and in exchange

for, defendant RONALD S. CALDERON's official acts in connection with the film tax credit.

13. Defendant RONALD S. CALDERON would cause UC-1 and UC-3 to make the payments of $3,000 or more, which totaled approximately $39,000, on or about the following dates, in the following approximate disbursements:

DATE	AMOUNT
7/19/2012	$3,000
8/01/2012	$3,000
9/08/2012	$3,000
9/28/2012	$3,000
11/01/2012	$3,000
12/01/2012	$3,000
1/01/2013	$3,000
2/02/2013	$3,000
3/02/2013	$3,000
3/27/2013	$3,000
4/18/2013	$9,000

14. Defendant RONALD S. CALDERON would inform UC-1 of the official acts he had performed on behalf of Drobot in connection with the spinal pass-through and worker's compensation legislation and regulation to induce UC-1 to continue making bribe payments in connection with the film tax credit.

15. Defendant RONALD S. CALDERON would perform official acts favorable to UC-1 and UC-3 in connection with the film tax credit. For example:

a. On or about September 12, 2012, defendant RONALD S. CALDERON signed a letter in his capacity as a Senator expressing his support for amending the film tax credit to lower the threshold for independent films from $1 million to $750,000.

b. On or about October 25, 2012, defendant RONALD S. CALDERON met with Senator B to discuss the benefits of lowering the film tax credit threshold for independent films below $1 million.

c. On or about February 19, 2013, defendant RONALD S. CALDERON caused legislation to be introduced in the Senate, which he intended to use as a vehicle to create a separate tax credit for independent filmmakers with budgets below $1 million.

d. On or about April 24, 2013, defendant RONALD S. CALDERON met with Senator C to discuss legislation that would create a separate tax credit for independent filmmakers and producers of commercials with budgets below $1 million.

Bribes Involving the Hiring of UC-2

16. Defendant RONALD S. CALDERON would solicit and accept benefits, including money towards his son's college tuition and a large financial contribution to Californians for Diversity, from UC-1 with the understanding that such benefits were to influence, and in exchange for, defendant RONALD S. CALDERON's official acts in connection with hiring UC-2 to defendant RONALD S. CALDERON's Senate staff.

17. Defendant RONALD S. CALDERON would solicit and accept a $5,000 payment towards his son's college tuition from UC-1.

18. Defendant RONALD S. CALDERON would direct UC-1 to make a $25,000 payment to Californians for Diversity after explaining to UC-1 that defendant RONALD S. CALDERON and Thomas M. Calderon intended to use that money to pay themselves.

19. Defendant RONALD S. CALDERON would perform official

acts favorable to UC-1 and UC-2 in connection with the hiring of UC-2 to defendant RONALD S. CALDERON's Senate staff. For example:

a. On or about January 11, 2013, defendant RONALD S. CALDERON sought Senator A's approval to hire UC-2 as a member of defendant RONALD S. CALDERON's Senate staff.

b. On or about January 16, 2013, defendant RONALD S. CALDERON requested the Secretary of the Senate to hire UC-2 as a member of defendant RONALD S. CALDERON's Senate staff.

The Concealment of Material Information

20. Defendant RONALD S. CALDERON would take steps to conceal and disguise the bribe payments he received and, in several instances, the official acts he performed in exchange for the bribe payments. For example:

a. In or about February 2011, defendant RONALD S. CALDERON had Senator A introduce Bill #1 in the Senate to conceal from the citizens of California that defendant RONALD S. CALDERON was a main proponent of legislation favorable to Drobot.

b. On or about September 12, 2012, defendant RONALD S. CALDERON signed an official letter indicating his support for lowering the threshold for independent films from $1 million to $750,000, knowing the letter was addressed to a fictitious organization, to conceal from the citizens of California that the letter was written at the request, and for the benefit, of UC-1.

c. On or about January 16, 2013, defendant RONALD S. CALDERON falsely claimed that he was hiring UC-2 to service the

new communities in his Senate district to conceal from the citizens of California that UC-2 was actually being hired at the request, and for the benefit, of UC-1.

d. On or about February 14, 2013, defendant RONALD S. CALDERON failed to disclose to the California Fair Political Practices Commission that he had directed UC-1 to make a $25,000 contribution to Californians for Diversity to conceal from the citizens of California the fact that the payment was made at his behest.

e. On or about March 1, 2013, defendant RONALD S. CALDERON caused a false Statement of Economic Interest, California Form 700, to be submitted to the California Fair Political Practices Commission, which failed to disclose certain gifts, travel, and money defendant RONALD S. CALDERON had received from Drobot and UC-1 during 2012.

C. THE USE OF WIRES

On or about the dates set forth below, within the Central District of California and elsewhere, defendant RONALD S. CALDERON, for the purpose of executing the above-described scheme to defraud, caused the transmission of the following items by means of wire and radio communication in interstate and foreign commerce:

//

//

COUNT	DATE	ITEM WIRED
ONE	6/18/2012	An email from defendant RONALD S. CALDERON's America Online email account to Drobot's email account at Pacific Hospital regarding when and how much money defendant RONALD S. CALDERON's son should be paid by Drobot
TWO	6/28/2012	An email from defendant RONALD S. CALDERON's America Online email account to Drobot's email account at Pacific Hospital regarding when and how much money defendant RONALD S. CALDERON's son should be paid by Drobot

D. THE USE OF THE MAIL

On or about the dates set forth below, within the Central District of California and elsewhere, defendant RONALD S. CALDERON, for the purpose of executing the above-described scheme to defraud, caused the following items to be placed in an authorized depository for mail matter to be sent and delivered by the United States Postal Service according to the directions thereon:

COUNT	DATE	ITEM MAILED
THREE	7/20/2012	Envelope addressed to what was represented to be UC-1's independent film studio in Los Angeles, California, containing a "Studio Services Agreement" signed by defendant RONALD S. CALDERON's daughter and UC-1
FOUR	8/12/2012	Envelope addressed to defendant RONALD S. CALDERON at his home address containing a $3,000 check payable to defendant RONALD S. CALDERON's daughter
FIVE	9/28/2012	Envelope addressed to defendant RONALD S. CALDERON at his home address containing a $3,000 check payable to defendant RONALD S. CALDERON's daughter

COUNT	DATE	ITEM MAILED
SIX	1/03/2013	Envelope addressed to defendant RONALD S. CALDERON at his home address containing a $3,000 check payable to defendant RONALD S. CALDERON's daughter
SEVEN	1/15/2013	Envelope addressed to Californians for Diversity in Covina, California, containing a $25,000 check payable to Californians for Diversity
EIGHT	2/05/2013	Envelope addressed to defendant RONALD S. CALDERON at his home address containing a $3,000 check payable to defendant RONALD S. CALDERON's daughter
NINE	2/27/2013	Envelope addressed to UC-2's mailing address in Los Angeles, California, containing a Senate Benefits Package
TEN	3/01/2013	Envelope addressed to defendant RONALD S. CALDERON at his home address containing a $3,000 check payable to defendant RONALD S. CALDERON's daughter

COUNT ELEVEN

[18 U.S.C. § 666(a)(1)(B)]

On or about July 13, 2010, in Los Angeles County, within the Central District of California, and elsewhere, defendant RONALD S. CALDERON, an agent of the State of California, a state government that received in any one-year period benefits in excess of $10,000 under a Federal program, corruptly solicited and demanded for the benefit of a person, and accepted and agreed to accept, something of value from a person, intending to be influenced and rewarded in connection with a business, transaction, and series of transactions of the State of California having a value of $5,000 or more. Specifically, defendant RONALD S. CALDERON solicited, demanded, accepted, and agreed to accept from Michael D. Drobot employment for defendant RONALD S. CALDERON's son, intending to be influenced and rewarded in connection with supporting the spinal pass-through and worker's compensation legislation and regulation.

COUNT TWELVE

[18 U.S.C. § 666(a)(1)(B)]

Between on or about July 20, 2011 and on or about August 16, 2011, in Los Angeles County, within the Central District of California, and elsewhere, defendant RONALD S. CALDERON, an agent of the State of California, a state government that received in any one-year period benefits in excess of $10,000 under a Federal program, corruptly solicited and demanded for the benefit of a person, and accepted and agreed to accept, something of value from a person, intending to be influenced and rewarded in connection with a business, transaction, and series of transactions of the State of California having a value of $5,000 or more. Specifically, defendant RONALD S. CALDERON solicited, demanded, accepted, and agreed to accept from Michael D. Drobot employment for defendant RONALD S. CALDERON's son, intending to be influenced and rewarded in connection with supporting the spinal pass-through and worker's compensation legislation and regulation.

COUNT THIRTEEN

[18 U.S.C. § 666(a)(1)(B)]

Between on or about June 18, 2012 and on or about August 14, 2012, in Los Angeles County, within the Central District of California, and elsewhere, defendant RONALD S. CALDERON, an agent of the State of California, a state government that received in any one-year period benefits in excess of $10,000 under a Federal program, corruptly solicited and demanded for the benefit of a person, and accepted and agreed to accept, something of value from a person, intending to be influenced and rewarded in connection with a business, transaction, and series of transactions of the State of California having a value of $5,000 or more. Specifically, defendant RONALD S. CALDERON solicited, demanded, accepted, and agreed to accept from Michael D. Drobot employment for defendant RONALD S. CALDERON's son, intending to be influenced and rewarded in connection with supporting the spinal pass-through and worker's compensation legislation and regulation.

COUNT FOURTEEN

[18 U.S.C. § 666(a)(1)(B)]

Between on or about February 24, 2012 and on or about May 4, 2013, in Los Angeles County, within the Central District of California, and elsewhere, defendant RONALD S. CALDERON, an agent of the State of California, a state government that received in any one-year period benefits in excess of $10,000 under a Federal program, corruptly solicited and demanded for the benefit of a person, and accepted and agreed to accept, something of value from a person, intending to be influenced and rewarded in connection with a business, transaction, and series of transactions of the State of California having a value of $5,000 or more. Specifically, defendant RONALD S. CALDERON solicited, demanded, accepted, and agreed to accept from UC-1 and UC-3, money, employment for defendant RONALD S. CALDERON's daughter, and other financial benefits, intending to be influenced and rewarded in connection with the Film tax credit legislation and the hiring of UC-2 to a Senate staff position.

COUNT FIFTEEN

[18 U.S.C. § 1956(h)]

A. THE OBJECT OF THE CONSPIRACY

Between in or about January 2013 and on or about May 4, 2013, in Los Angeles County, within the Central District of California, and elsewhere, defendants RONALD S. CALDERON, THOMAS M. CALDERON, unindicted coconspirator #1, and others known and unknown to the Grand Jury, knowingly conspired and agreed with each other to conduct financial transactions affecting interstate commerce involving the proceeds of specified unlawful activity, namely, bribery, knowing that the property involved in the transactions represented the proceeds of some form of unlawful activity, and knowing that the transactions were designed, in whole and in part, to conceal and disguise the nature, the location, the source, the ownership, and the control of said proceeds, in violation of Title 18, United States Code, Section 1956(a)(1)(B)(i).

B. THE MANNER AND MEANS OF THE CONSPIRACY

The object of the conspiracy was carried out, and to be carried out, in substance, as follows:

1. Defendant RONALD S. CALDERON would solicit and accept bribes and kickbacks from UC-1 and UC-3.

2. Defendant RONALD S. CALDERON would direct UC-1 and UC-3 to make bribe payments to Californians for Diversity and the Calderon Group, two entities over which defendant THOMAS M. CALDERON had financial control.

3. Defendant THOMAS M. CALDERON would use the bribe payments made by UC-1 and UC-3 to engage in monetary

transactions at financial institutions, including California Bank and Trust and Camino Federal Credit Union, designed to conceal and disguise the nature, location, source, ownership, and control of the bribe payments.

C. OVERT ACTS

In furtherance of the conspiracy, and to accomplish its object, defendants RONALD S. CALDERON, THOMAS M. CALDERON, unindicted coconspirator #1, and others known and unknown to the Grand Jury, committed and willfully caused others to commit the following overt acts, among others, in the Central District of California and elsewhere:

Overt Act No. 1: On or about January 11, 2013, defendant RONALD S. CALDERON directed UC-1 to make a contribution of approximately $25,000 to Californians for Diversity, an entity over which defendant THOMAS M. CALDERON had financial control.

Overt Act No. 2: On or about January 22, 2013, defendant THOMAS M. CALDERON caused Californians for Diversity to issue a payment of $6,500 to the Calderon Group.

Overt Act No. 3: On or about January 23, 2013, defendant THOMAS M. CALDERON caused a $6,500 check from Californians for Diversity to be deposited into the Calderon Group credit union account at Camino Federal Credit Union (XXX53-9).

Overt Act No. 4: On or about February 28, 2013, defendant THOMAS M. CALDERON caused a $6,500 check from Californians for Diversity to be deposited into the Calderon Group credit union account at Camino Federal Credit Union (XXX53-9).

Overt Act No. 5: On or about March 14, 2013, defendant THOMAS M. CALDERON caused a transfer of approximately $700 from

his personal credit union account to defendant RONALD S. CALDERON's credit union account at Camino Federal Credit Union (XXX56-9).

Overt Act No. 6: On or about March 29, 2013, defendant RONALD S. CALDERON spoke with defendant THOMAS M. CALDERON over the telephone and asked defendant THOMAS M. CALDERON how much more money defendant THOMAS M. CALDERON could draw from Californians for Diversity "without drawing too much attention."

Overt Act No. 7: On or about April 4, 2013, defendant RONALD S. CALDERON spoke with unindicted coconspirator #1 over the telephone and discussed ways of getting money from UC-3 to defendant RONALD S. CALDERON, including using defendant THOMAS M. CALDERON to "funnel" the money.

Overt Act No. 8: On or about April 11, 2013, defendant THOMAS M. CALDERON caused a $6,500 check from Californians for Diversity to be deposited into the Calderon Group credit union account at Camino Federal Credit Union (XXX53-9).

Overt Act No. 9: On or about April 12, 2013, defendant THOMAS M. CALDERON caused a transfer of approximately $7,000 from the Calderon Group credit union account at Camino Federal Credit Union (XXX53-9) to defendant THOMAS M. CALDERON's personal credit union account at Camino Federal Credit Union (XXX91-9).

Overt Act No. 10: On or about April 12, 2013, defendant THOMAS M. CALDERON caused a withdrawal of approximately $9,900 in cash from his personal credit union account at Camino Federal Credit Union (XXX91-9).

Overt Act No. 11: On or about April 12, 2013, defendant RONALD S. CALDERON spoke with defendant THOMAS M. CALDERON over the telephone and told defendant THOMAS M. CALDERON that he had "closed the deal" with UC-3 and that UC-3 had agreed to send future bribe payments through defendant THOMAS M. CALDERON's company, the Calderon Group.

Overt Act No. 12: On or about April 12, 2013, defendant RONALD S. CALDERON spoke with defendant THOMAS M. CALDERON over the telephone and discussed meeting later that day so defendant THOMAS M. CALDERON could give defendant RONALD S. CALDERON "half" of the money defendant RONALD S. CALDERON was to receive from defendant THOMAS M. CALDERON.

Overt Act No. 13: On or about April 16, 2013, defendant THOMAS M. CALDERON instructed UC-3 to send a check for $30,000 to the Calderon Group via United States mail, which defendant THOMAS M. CALDERON knew included $9,000 in bribe payments to defendant RONALD S. CALDERON's daughter.

Overt Act No. 14: On or about April 29, 2013, defendant THOMAS M. CALDERON caused the $30,000 check from UC-3 to be deposited into the Calderon Group's credit union account at Camino Federal Credit Union (XXX53-9).

Overt Act No. 15: On or about April 29, 2013, defendant THOMAS M. CALDERON caused a $9,000 check from the Calderon Group credit union account at Camino Federal Credit Union (XXX53-9) to be issued to defendant RONALD S. CALDERON's daughter.

COUNTS SIXTEEN THROUGH TWENTY-TWO

[18 U.S.C. § 1956(a)(1)(B)(i)]

On or about the following dates, in Los Angeles County, within the Central District of California, and elsewhere, defendants RONALD S. CALDERON, THOMAS M. CALDERON, and others known and unknown to the Grand Jury, knowing that the property involved in each of the financial transactions described below represented the proceeds of some form of unlawful activity, knowingly conducted and attempted to conduct, the following financial transactions affecting interstate commerce, which transactions, in fact, involved the proceeds of specified unlawful activity, namely, bribery, knowing that each of the transactions was designed in whole and in part to conceal and disguise the nature, location, source, ownership, and control of the proceeds of such specified unlawful activity:

COUNT	DATE	FINANCIAL TRANSACTION
SIXTEEN	1/23/2013	The deposit of a check issued from Californians for Diversity's bank account for approximately $6,500 into the Calderon Group credit union account at Camino Federal Credit Union (XXX53-9)
SEVENTEEN	2/28/2013	The deposit of a check issued from Californians for Diversity's bank at California Bank and Trust for approximately $6,500 into the Calderon Group credit union account at Camino Federal Credit Union (XXX53-9)
EIGHTEEN	3/14/2013	The transfer of approximately $700 from defendant THOMAS M. CALDERON's personal credit union account at Camino Federal Credit Union (XXX91-9) to defendant RONALD S. CALDERON's personal credit union account at Camino Federal Credit Union (XXX56-9)

COUNT	DATE	FINANCIAL TRANSACTION
NINETEEN	4/11/2013	The deposit of a check issued from Californians for Diversity's bank account at California Bank and Trust for approximately $6,500 into the Calderon Group credit union account at Camino Federal Credit Union (XXX53-9)
TWENTY	4/12/2013	The transfer of approximately $7,000 from the Calderon Group bank account at Camino Federal Credit Union (XXX53-9) to defendant THOMAS M. CALDERON's personal credit union account at Camino Federal Credit Union (XXX91-9)
TWENTY-ONE	4/12/2013	The withdrawal of approximately $9,900 in cash from defendant THOMAS M. CALDERON's personal credit union account at Camino Federal Credit Union (XXX91-9).
TWENTY-TWO	4/29/2013	The issuance of a check for approximately $9,000 from the Calderon Group bank account at Camino Federal Credit Union (XXX53-9) made payable to defendant RONALD S. CALDERON's daughter.

COUNT TWENTY-THREE

[26 U.S.C. § 7206(2)]

On or about March 28, 2011, in Los Angeles County, within the Central District of California, and elsewhere, defendant RONALD S. CALDERON willfully aided and assisted in, and procured, counseled, and advised the preparation and presentation of a United States Individual Income Tax Return, Form 1040, to the Internal Revenue Service, for defendant RONALD S. CALDERON's son as to the 2010 tax year, which was false and fraudulent as to material matters, in that it falsely claimed approximately $6,826 in business expense deductions from the $10,000 defendant RONALD S. CALDERON's son received through his summer employment with International Implants Incorporated, one of Michael D. Drobot's companies, when, in fact, as defendant RONALD S. CALDERON well knew, his son had not incurred said amount of business expenses.

COUNT TWENTY-FOUR

[26 U.S.C. § 7206(2)]

On or about April 4, 2012, in Los Angeles County, within the Central District of California, and elsewhere, defendant RONALD S. CALDERON willfully aided and assisted in, and procured, counseled, and advised the preparation and presentation of a United States Individual Income Tax Return, Form 1040, to the Internal Revenue Service, for defendant RONALD S. CALDERON's son as to the 2011 tax year, which was false and fraudulent as to material matters, in that it falsely claimed approximately $6,805 in business expense deductions from the $10,000 defendant RONALD S. CALDERON's son received through his

//

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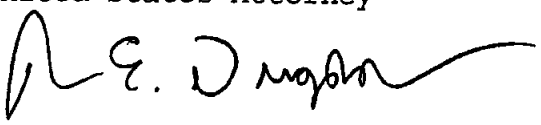
summer employment with International Implants Incorporated, on of Michael D. Drobot's companies, when, in fact, as defendant RONALD S. CALDERON well knew, his son had not incurred said amount of business expenses.

A TRUE BILL

Foreperson

ANDRÉ BIROTTE JR.
United States Attorney



ROBERT E. DUGDALE
Assistant United States Attorney
Chief, Criminal Division

LAWRENCE S. MIDDLETON
Assistant United States Attorney
Chief, Public Corruption & Civil Rights Section

DOUGLAS M. MILLER
MACK E. JENKINS
Assistant United States Attorneys
Public Corruption & Civil Rights Section

EXHIBIT 17

TOP STORIES IN BUSINESS 1 of 12

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HEALTH

In Small California Hospitals, the Marketing of Back Surgery

Email Print Save Comments

By JOHN CARREYROU, TOM MCGINTY and JOEL MILLMAN
February 9,2012

HAWAIIAN GARDENS, Calif.—Consuelo Solorio, a middle-aged tomato-cannery employee, traveled three hours from her home in the San Joaquin Valley to have spine surgery here for an injury from tumbling off a ladder.

Paul Richard Randall *Darin Rogers*

Her destination was Tri-City Regional Medical Center, a hospital that has developed a thriving business doing back surgery on workers' compensation patients.

It built up this business rapidly. For an operation known as spinal fusion, which joins two or more vertebrae, the small hospital billed workers' compensation insurers $65 million in 2010, up from less than $3 million three years earlier, state hospital discharge data show.

Helping spur the business was Paul Richard Randall, a consultant to whom Tri-City has paid millions of dollars in marketing fees. According to people familiar with his role, it was twofold: bringing surgery cases to the hospital by recruiting surgeons to operate there, and supplying metal implants for the surgeries through distributorships he owned.

The U.S. attorney in Los Angeles has investigated Mr. Randall's practices. By last August, federal prosecutors had prepared a charge that, if filed in court, would accuse him of conspiring to inflate the cost of spinal-surgery hardware and use part of the proceeds to pay kickbacks to doctors to refer workers' compensation patients for surgeries at Tri-City, according to a copy of the charge reviewed by The Wall Street Journal.

Spinal Fusions

See statistics for the top 20 California hospitals ranked by the number of spinal fusions performed on injured workers from 2008 through 2010.

Mr. Randall said he is just one of a dozen spinal-implant distributors in the Los Angeles area who mark up the price of the surgical hardware they provide to hospitals, and "there's nothing illegal about what I'm doing, my lawyer tells me." As for the kickback allegation, "that's not true," Mr. Randall said.

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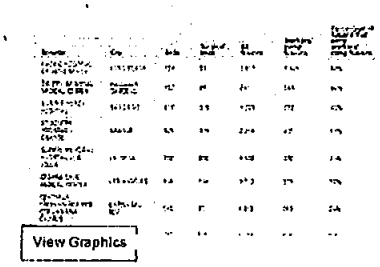

The U.S. attorney's office declined to comment. The status of its investigation is unclear. A lawyer for Mr. Randall said no charges have been filed against his client.

An official of Tri-City said the hospital ended its relationship with Mr. Randall in the middle of last year, a few months after it ousted the executive who had hired him. An internal investigation involving various issues at the hospital is under way, a review that a hospital tax filing said has found numerous "improprieties."

A lawyer who is conducting the internal inquiry said the hospital didn't know that Mr. Randall was inflating the cost of spinal-surgery hardware he sold to the hospital until late in 2010, and it never has been aware of any possible kickbacks to doctors. Hospital officials also said they weren't aware of any federal investigation of the hospital or Mr. Randall.

Related Reading

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Top Spine Surgeons Reap Royalties, Medicare Bounty
12/20/10

Tri-City, a 107-bed facility just south of Los Angeles near Long Beach, illustrates a U.S. health-care trend, the increasing total bill for back surgery, that the Journal has traced in articles over the past 15 months.

In California, this trend shows up in the workers' compensation system. California employers paid $7.1 billion in insurance premiums to cover their workers' compensation liability in 2010. Spinal-fusion surgery is a growing part of the care these premiums pay for. It accounted for 40% of inpatient hospital charges to the state workers' compensation system in 2010, up from 30% in 2001, a Journal analysis of hospital discharge data shows.

Mr. Randall, 52 years old, an entrepreneur with a collection of sports memorabilia and a yen for gambling, began his career as a hospital marketer in the mid-1990s after serving a stint in federal prison for racketeering. He was convicted of the felony in 1993 for deals that involved buying wooden shipping pallets on credit and reselling them without paying the original vendors, and was sentenced to a 21-month term.

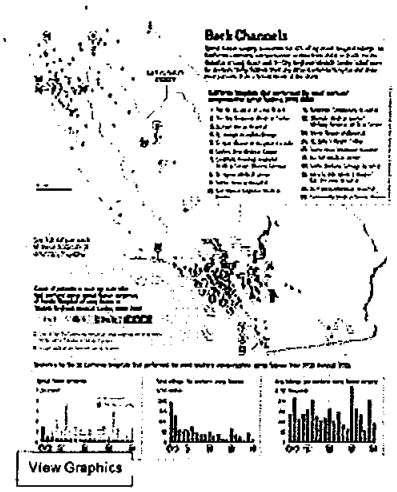
After serving time in the Terminal Island federal correctional facility in Long Beach harbor, Mr. Randall went into business with Michael D. Drobot, the owner of another small hospital near Tri-City called Pacific Hospital of Long Beach.

A Naval officer in the Vietnam era, Mr. Drobot bought Pacific in 1997 and shifted its focus to spine care for workers' compensation patients, a clientele other hospitals weren't keen to treat because of bureaucratic and legal headaches of dealing with insurers and uncertainties about payment.

For a decade, Messrs. Randall and Drobot operated a business that arranged for magnetic resonance imaging, or MRI, services. Mr. Randall also introduced Mr. Drobot to doctors to increase spine-surgery business at Pacific Hospital, according to a person with knowledge of the arrangement. Asked about that, Mr. Drobot said through a spokesman that Mr. Randall introduced "a few" doctors.

He said Mr. Randall was paid $25,000 a month to run the MRI business plus a share of profits. For a time, the two men also co-owned a weekend retreat in Bullhead City, Ariz., along with a doctor.

Mr. Drobot created several businesses focused on workers' compensation patients: a van service to shuttle patients, a provider of Spanish interpretation and a distributorship of metal implants used in back surgery. His hospital became one of the most prolific spine-surgery facilities in California. Between 2001 and 2010, Pacific performed 5,138 spinal-fusion surgeries on workers' compensation patients, according to state hospital



discharge data, and billed $533 million for them—three times as much as any other hospital in the state, including much larger ones.

Through his spokesman, Mr. Drobot said the number of surgeries was even higher than that tally but the money received for them was lower, just $231 million. Insurers often fight hospitals over billings and end up paying less.

After a business dispute between the two men, Mr. Randall in 2008 moved to Tri-City, a hospital eight miles away that then focused on bariatric surgery.

Tri-City, which is a nonprofit institution, paid Mr. Randall more than $3.2 million between 2008 and July 2011 as a business-development consultant, according to its filings to the Internal Revenue Service and a hospital lawyer. Mr. Randall recruited some of the same spine surgeons to Tri-City that he earlier introduced to Mr. Drobot at Pacific, according to a person familiar with the matter.

Like Pacific before it, Tri-City soon was doing many more back operations; within three years, Tri-City's billings for spine surgery on workers' compensation patients soared twentyfold to $65 million. A lawyer for the hospital says amounts actually collected totaled just $22.5 million.

As Mr. Drobot had done at Pacific, Mr. Randall formed spinal-implant distributorships, which purchased hardware and resold it to Tri-City hospital.

California's Workers' Compensation Division permits hospitals to bill separately for spinal implants, rather than include their cost in an overall charge for surgery, as is the case in the Medicare and Medicaid systems.

The California Workers' Compensation Institute, an insurers' group, has estimated that separate billing for implants added $55 million in costs to the program in 2008. The workers' compensation division says it is considering modifying the system in a way that would eliminate the extra costs.

The workers' compensation division doesn't put a limit on how much a distributor may mark up the cost of implants when it sells them to a hospital, although it does restrict how much a hospital may mark up its own implant cost when it bills an insurance company.

Mr. Randall's distributorships imposed some steep markups, invoices reveal. Invoices for 16 spine surgeries at Tri-City between July 2010 and March 2011 show items for which suppliers charged Mr. Randall's distributors $326,000, while his distributors charged the hospital $1.1 million.

The draft charge the U.S. attorney's office prepared last year, but hasn't filed, stated that in 2010 Mr. Randall submitted to Tri-City an invoice for spinal-surgery hardware that listed the cost as $42,467, when the actual cost of the hardware bought by the Randall distributorship was $3,600.

The draft charge further alleged that Mr. Randall conspired to pay chiropractors and physicians kickbacks of approximately $15,000 to $20,000 per spinal surgery to refer workers' compensation patients for operations at Tri-City. It alleged that he "paid the kickbacks...from his profits on inflating the cost of the spinal surgery hardware" by "2-10 times the actual purchase price."

By August of last year, the federal prosecutors had prepared a proposed plea agreement for Mr. Randall. He said he hasn't signed it.

Kenneth Yood, a lawyer hired by Tri-City's board in late 2010 to do an internal

investigation of various matters at the hospital, said that Tri-City isn't aware of any possible kickbacks to doctors.

He said Tri-City's board didn't become aware until the fall of 2010 that charges for spinal implants by Mr. Randall's distributor "were arguably excessive." Mr. Yood said the hospital has since made changes "to address several mattars related to vendor-supplied implants," including raquiring vendors to attest that they comply with all applicable laws and regulations.

Mr. Yood said his review is examining what he called "highly questionable transactions" a former chief executive "caused the hospital to enter into with third-party vendors, including Paul Randall." The former CEO, Arthur Gerrick, was removed for misconduct in April, according to the hospital's general counsel, Beryl Weiner.

Mr. Gerrick "categorically denies" all Tri-City allegations against him, his lawyer said.

Messrs. Gerrick and Weiner were partners in a company that managed Tri-City for several years through the end of last year. The nonprofit hospital paid this management company about $3.4 million a year.

Mr. Weiner said Tri-City ended its relationship with Mr. Randall last summer, after receiving an anonymous letter that described his criminal past.

The chairman of Tri-City's board, Brian Walton, said that "over the past three years, the hospital went through some traumas. As best we can, we've been trying to clean up the mess.... Obviously, we could concede that there are things that went on in the past that could be upsetting."

Ms. Solorio, the tomato-cannery employee, is one of hundreds of injured workers treated at Tri-City during those three years.

She worked as a cleaner in a Rio Bravo Tomato Co. cannery in the San Joaquin Valley, an area home to many Hispanic field workers. Over the past decade, at least 550 workers from the region had spinal fusions at the two Long Beach-area hospitals Mr. Randall was connected with, chiefly at Pacific, according to state discharge data.

Ms. Solorio lived with her husband, Rafael, and a son in a brown bungalow around the corner from a trailer park in Shafter, an impoverished town along a stretch of rural highway. She injured her neck falling off a ladder at work, according to Mr. Solorio, a Mexican-born ranch hand who speaks little English.

An attorney who handled her workers' compensation claim, William Berry, said he first referred her to a local chiropractor and then to a spine surgeon, who, Mr. Berry said, didn't recommend surgery.

At some point, according to several people familiar with the matter, Ms. Solorio became a patient of Edward C. Kolpin, a surgeon who operated at both Pacific Hospital and Tri-City. Dr. Kolpin scheduled surgery for the 52-year-old worker at Tri-City, which is 150 miles from her home.

The surgery on Oct. 6, 2010, joined four neck vertebrae, in what is known as a three-level cervical fusion.

State hospital discharge records show Dr. Kolpin used a bone-growth product that accelerates fusion, called bone morphogenetic protein. The Food and Drug Administration approves this substance only for a particular type of surgery of the lower spine; the FDA warned in 2008 against using it on the neck area because of reports of life-threatening tissue swelling that compressed patients' airways.

The day after the surgery, Ms. Solorio experienced difficulty breathing and died. The surgeon, Dr. Kolpin, didn't return calls and text messages seeking comment.

A surgeon who assisted in the surgery, Khalid Ahmed, who also operates at Pacific, said the outcome had nothing to do with the surgery, which he described as "well performed."

State hospital discharge data show Tri-City billed $177,138 for Ms. Solorio's surgery. Tri-City, citing patient privacy, declined to comment other than to say it regrets any instances

"in which patients expire while in the hospital or thereafter."

By August 2011, Mr. Randall said, he was back to doing spine-surgery marketing work for Mr. Drobot at Pacific Hospital of Long Beach.

Mr. Randall said he signed a $100,000-a-month marketing agreement with Mr. Drobot—technically between Mr. Drobot's spinal-implant distributorship and a Randall marketing firm—under which Mr. Randall is to provide services such as "recruiting surgeons to the medical staff of hospitals that use" implants Mr. Drobot distributes. The Journal reviewed a copy of the purported contract.

Mr. Drobot said through a spokesman that he didn't recall entering into any such contract and that he didn't believe the signature on the document was his.

Tom McGinty at tom.mcginty@wsj.com and Joel Millman at joel.millman@wsj.com

EXHIBIT 18

00046

todd194

DATE OF SURGERY 09-21-2012

PREOPERATIVE DIAGNOSIS Stenosis and spondylosis L4-5 and L5-S1.

POSTOPERATIVE DIAGNOSIS Stenosis and spondylosis L4-5 and L5-S1.

NAME OF SURGERY
1. Posterior segment internal fixation L4-5 and L5-S1.
2. Posterior comprehensive decompression L4-5.
3. Posterior comprehensive decompression L5-S1.
4. Posterolateral fusion L4-5.
5. Posterolateral fusion L5-S1.
6. Allograft and autograft use for lumbar spine fusion.
7. Fluoroscopic use.

SURGEON Gurvinder S. Uppal, MD

ASSISTANT SURGEON Todd Peters, MD

ANESTHESIA General.

ANESTHESIOLOGIST

ESTIMATED BLOOD LOSS 200 cc.

FLUIDS Normal saline.

DRAIN Hemovac.

INDICATIONS The patient is a male who is having severe back and leg pain. His radiographs and MRI show stenosis and spondylosis at L4-5 and L5-S1. He has positive straight leg raising. He has psoriatic arthritis. He has weakness in the ankle, dorsi and plantar flexors. He has undergone internal medicine clearance at this point. I have discussed option of no treatment, more nonoperative treatment, and surgery. Surgery is an anterior and posterior decompression and fusion at L4-5 and L5-S1 with instrumentation and bone graft. I have explained the potential risks of the surgery including death, infection, bleeding, paralysis, dural leak, nonunion, malunion, hardware failure, sexual dysfunction, and impotence among others. Risks of the bone graft were also discussed. I have also told him that the hardware to be used is not FDA approved and may need to be removed in the future. The patient understands this and consented for surgery described above.

PROCEDURE IN DETAIL The patient was brought to the operating room and identified, general tracheal anesthesia administered. He was positioned in the operating room table in the prone position and positioned properly. He was padded appropriately. Because of his large body habitus, spinal cord monitoring was initiated. Back was washed in betadine and prepped with betadine solution and draped in

the usual sterile fashion. Midline skin incision was made. Subcutaneous tissue was dissected sharply. Electrocautery was used for hemocoagulation. Bilateral fascial openings were done. Soft tissue was retracted off the spinous process over the lamina and over the facet joint to the tip of the transverse process bilaterally. We placed a probe into the L4 pedicle. Fluoroscope visualization confirmed this level. Next the L4-5 and L5-S1 facet joints were identified. There was marked cystic degenerative changes. The facet joint capsule was removed with electrocautery. Spinous process of L4 and L5 were removed. A curette was used to identify the intervertebral lamina underlying soft tissue. Laminectomy was done at L4-5 and L5-S1. There was marked stenosis much worse than visualized on MRI. Lateral recesses was very stenotic. Cottonoids were placed over the exposed dural elements. Medial facetectomies were done with osteotome. Nerve roots were still tight in the neural foramen. Foraminotomies were done bilaterally at L4-5 and L5-S1 by using Kerrison to remove bone and soft tissue, dural elements. Now the gallbladder dilator _____ neural foramen. This documented a complete decompression with gently retracting nerve roots. There was significant disk fragments both at L4-5 and L5-S1. This was entered with #15-blade, diskectomies were done. This rendered the spine even further unstable requiring fusion. Next landmarks for pedicle fixation were mid transverse process from medial to lateral facet joint _____ was used to complete this. We diligently probed this. Once confirmed there was no perforation, 6-mm tap was used to tap the hole. After we confirmed that there was perforation once again by sounding the hole, 6.5 x 40 mm screws were placed in the L4-L5 and 7.5 x 35 mm at S1. From the inside of the canal, cephalomedial and inferior walls of pedicles were probed. There was no abnormal placement of the screws. Muscle relaxer was reversed. Intraoperative EMG on screws failed to reveal any abnormalities. Back wound was irrigated with antibiotic irrigation. Transverse process of L4-L5 and sacral ala were decortioated. The remainder of the facet joint was tangentially osteotomized. This laminectomy bone was morselized combined with BioD stem cell bone graft material and packed over decortioated regions at L4-5 and L5-S1. Rods were measured from L4-S1 contouring the lumbar lordosis, placing center screws. Set screws were used to lock it in place using a torque wrench and a counter-torque device. Top set screws were removed. Cross linking was done. This was a very stable construct. Spinal canal was then explored to ensure there was no inadvertently placed bone graft in the canal, there was none. Tisseel was placed over the exposed dural elements. There was no evidence of any dural leak. Needle, sponge, and instrument counts were correct. Next over the Hemovac drain, the deep fascia was closed with #1 PDS, subcutaneous with 2-0 Vicryl, and skin was closed with staples. Sterile dressing was applied. The patient was awakened and brought to the recovery room. Needle, sponge, and instrument count was reported to be correct.

PACIFIC HOSPITAL OF LONG BEACH

OPERATIVE 2-3	PT NAME	[redacted]	
	MR NUMBER	509865	
	ADMIT DATE	09-21-2012	
	ATTENDING		
	SERVICE	SUR	LOCATION Unit B8-A
	DISCHARGE		

00046

Gurvinder S. Uppal, MD

BC/57968268/18258276 D 09-22-2012 0800 T 09-23-2012 0535 R
09-23-2012 1241

Pacific Hospital of Long Beach
2776 Pacific Ave., Long Beach, CA 90806

PACIFIC HOSPITAL OF LONG BEACH

OPERATIVE 3-3

PT NAME [redacted]
MR NUMBER 509865
ADMIT DATE 09-21-2012
ATTENDING
SERVICE SUR LOCATION Unit BB-A
DISCHARGE

EXHIBIT 19

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BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **JACK H. AKMAKJIAN, M.D.** 7300 Magnolia Avenue Riverside, California 92504 **Physician's and Surgeon's Certificate Number G 62470** Respondent.	Case No. 18-2011-214764 **ACCUSATION**

Complainant alleges:

PARTIES

1. Kimberly Kirchmeyer (complainant) brings this Accusation solely in her official capacity as the Executive Director of the Medical Board of California, Department of Consumer Affairs (Board).

2. On or about March 21, 1988, the Board issued Physician's and Surgeon's Certificate Number G 62470 to Jack H. Akmakjian, M.D. (respondent). The Physician's and Surgeon's Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on October 15, 2015, unless renewed.

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JURISDICTION

3. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

4. Section 2004 of the Code states in part:

"The board shall have the responsibility for the following:

"(a) The enforcement of the disciplinary and criminal provisions of the Medical Practice Act.

"(b) The administration and hearing of disciplinary actions.

"(c) Carrying out disciplinary actions appropriate to findings made by a panel or an administrative law judge.

"(d) Suspending, revoking, or otherwise limiting certificates after the conclusion of disciplinary actions.

"(e) Reviewing the quality of medical practice carried out by physician and surgeon certificate holders under the jurisdiction of the board.

". . ."

5. Section 2234 of the Code states:

"The board shall take action against any licensee who is charged with unprofessional conduct. In addition to other provisions of this article, unprofessional conduct includes, but is not limited to, the following:

"(a) Violating or attempting to violate, directly or indirectly, assisting in or abetting the violation of, or conspiring to violate any provision of this chapter.

"(b) Gross negligence.

"(c) Repeated negligent acts. To be repeated, there must be two or more negligent acts or omissions. An initial negligent act or omission followed by a separate and distinct departure from the applicable standard of care shall constitute repeated negligent acts.

"(1) An initial negligent diagnosis followed by an act or omission medically appropriate for that negligent diagnosis of the patient shall constitute a single negligent act.

"(2) When the standard of care requires a change in the diagnosis, act, or omission that

constitutes the negligent act described in paragraph (1), including, but not limited to, a reevaluation of the diagnosis or a change in treatment, and the licensee's conduct departs from the applicable standard of care, each departure constitutes a separate and distinct breach of the standard of care.

". . ."

6. Section 2227 of the Code states:

"(a) A licensee whose matter has been heard by an administrative law judge of the Medical Quality Hearing Panel as designated in Section 11371 of the Government Code, or whose default has been entered, and who is found guilty, or who has entered into a stipulation for disciplinary action with the division,[1] may, in accordance with the provisions of this chapter:

"(1) Have his or her license revoked upon order of the division.

"(2) Have his or her right to practice suspended for a period not to exceed one year upon order of the division.

"(3) Be placed on probation and be required to pay the costs of probation monitoring upon order of the division.

"(4) Be publicly reprimanded by the division.

"(5) Have any other action taken in relation to discipline as part of an order of probation, as the division or an administrative law judge may deem proper.

"(b) Any matter heard pursuant to subdivision (a), except for warning letters, medical review or advisory conferences, professional competency examinations, continuing education activities, and cost reimbursement associated therewith that are agreed to with the division and successfully completed by the licensee, or other matters made confidential or privileged by existing law, is deemed public, and shall be made available to the public by the board pursuant to Section 803.1."

7. Section 2266 of the Code states: "The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes

[1] Pursuant to Business and Professions Code section 2002, "Division of Medical Quality" or "Division" shall be deemed to refer to the Medical Board of California.

unprofessional conduct."

8. Section 2242 of the Code states:

"(a) Prescribing, dispensing, or furnishing dangerous drugs as defined in Section 4022 without an appropriate prior examination and a medical indication, constitutes unprofessional conduct.

". . ."

9. Section 725 of the Code states:

"(a) Repeated acts of clearly excessive prescribing, furnishing, dispensing, or administering of drugs or treatment, repeated acts of clearly excessive use of diagnostic procedures, or repeated acts of clearly excessive use of diagnostic or treatment facilities as determined by the standard of the community of licensees is unprofessional conduct for a physician and surgeon, dentist, podiatrist, psychologist, physical therapist, chiropractor, optometrist, speech-language pathologist, or audiologist.

"(b) Any person who engages in repeated acts of clearly excessive prescribing or administering of drugs or treatment is guilty of a misdemeanor and shall be punished by a fine of not less than one hundred dollars ($100) nor more than six hundred dollars ($600), or by imprisonment for a term of not less than 60 days nor more than 180 days, or by both that fine and imprisonment.

"(c) A practitioner who has a medical basis for prescribing, furnishing, dispensing, or administering dangerous drugs or prescription controlled substances shall not be subject to disciplinary action or prosecution under this section.

"(d) No physician and surgeon shall be subject to disciplinary action pursuant to this section for treating intractable pain in compliance with Section 2241.5."

10. Section 3501, subdivision (b) of the Code states: "A physician assistant acts as an agent of the supervising physician when performing any activity authorized by this chapter or regulations adopted under this chapter."

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THE PATIENTS[2]

11. A.L.

Respondent treated A.L. from 2008 to the end of 2012. A.L. suffered disc disease and received a combination of treatments including lumbar epidural steroid injections, lumbar fusion from L4- S1, and removal of hardware. Respondent prescribed a treatment plan which included a multitude of pain medications, including Lunesta, hydrocodone, Ambien, clonazepam, and temazepam. The patient was often seen with the help of respondent's physician assistants.

12. J.M.

Respondent treated J.M. from 2008 to 2013. J.M. suffered disc disease and received a combination of treatments including epidural injections, lumbar fusion from L4- S1, and removal of hardware. The patient received a multitude of pain medications, including Lunesta, Nucynta, hydrocodone, Oxycontin, Ambien, clonazepam, and temazepam. The patient was often seen with the help of respondent's physician assistants.

13. "S.F."

"S.F.," a Board investigator posing as a patient, was seen one time on February 26, 2013 by a physician assistant under respondent's supervision. During the examination, "S.F." stated that she fell off a motorcycle in 2005 and had pain that measured 2 on a scale of 10. She requested Oxycontin and stated she had received that medication previously. The physician assistant prescribed 180 tablets of Norco, a one- or two-month supply, scheduled "S.F." to return in six to eight weeks and noted "will need copies of previous medical records." "S.F." was given a narcotic contract to sign.

14. M.H.

Respondent treated M.H. who presented with low back pain, neck pain, and shoulder pain, from 2010-2013. Respondent supervised a treatment plan which included a combination of Oxycontin, hydrocodone, and alprazolam. There were repeated incidences of urine tests that

[2] Complainant will refer to the patients by their initials in order to protect their privacy. Respondent may obtain their names and other information about them by requesting discovery pursuant to Government Code section 11507.6.

were not consistent with the medications he was on. There are no notes that a discussion occurred to have the patient explain why there was a discrepancy and no change occurred in his dosing. The physician assistants provided prescriptions.

15. J.S.

J.S. presented with a failed back syndrome and was treated by respondent from 2008 to 2013. He was prescribed a combination of hydrocodone, clonazepam, zolpidem, and lorazepam. The patient was often seen with the help of respondent's physician assistants.

16. R.E.

R.E. was seen from 2008- 2012 by respondent for chronic low back pain and treated with a combination of medications and lumbar epidural steroid injections. She was given clonazepam and hydrocodone. There were repeated incidences of urine tests that were not consistent with the medications she was on. There are no notes that a discussion occurred to have the patient explain why there was a discrepancy and no change occurred in his dosing. In fact, she was prescribed a higher dose of clonazepam after not having this drug in her system.

17. V.G.

V.G. was seen by respondent from 2008 to 2013 with cervical and lumbar disc disease that was treated with a combination of spinal fusion, removal of hardware, trigger point injections, and medications. Medications that were prescribed included Oxycontin, methadone, alprazolam, clonazepam, oxycodone, and hydrocodone. The patient was often seen with the help of respondent's physician assistants.

18. K.B.

Respondent treated K.B. from 2008 to 2012 for a failed back syndrome after fusion. She was treated with a combination of trigger point injections, medications, and spinal fusion. Her medications included hydrocodone, clonazepam, and Soma. The patient was often seen with the help of respondent's physician assistants.

19. T.P.

Respondent treated T.P., who suffered from low back pain and neck pain, from 2009 to 2012. She was treated with a combination of two-level cervical fusion, trigger point injections,

and medications. The medications prescribed include zolpidem, hydrocodone, alprazolam, lorezapam, and clonazepam. The patient was often seen with the help of respondent's physician assistants.

20. S.G.

Respondent treated S.G. from 2009 to 2013 for chronic neck pain with a combination of neck fusion, cervical facet injections, and medications. Medications she received included hydrocodone and Soma. The patient was often seen with the help of respondent's physician assistants.

21. S.B.

Respondent treated S.B., who suffered from chronic knee pain and chronic back pain, from 2009 to 2013. She was treated with knee replacement, lumbar epidural steroid injections, and medications. The medications she received included hydrocodone, Flexeril, Soma, and Nucynta. The patient was often seen with the help of respondent's physician assistants.

22. L.B.

Respondent treated L.B. from 2008 to 2012 for low back pain and neck pain. She underwent two-level cervical fusion, lumbar facet injections, and medication management. Medications she took included Ambien, lorazepam, clonazepam, zolpidem, Percocet, and Soma. The patient was often seen with the help of respondent's physician assistants.

23. D.O.

Respondent treated D.O. from 2009 to 2012 for low back pain and chronic disc disease that was treated with medications, failed spinal fusion, removal of hardware, trigger point injections, and facet injections. Medications that were prescribed include Oxycontin, alprazolam, zolpidem, clonazepam, and hydrocodone. The patient was often seen with the help of respondent's physician assistants.

24. E.G.

Respondent treated E.G., who presented with chronic low back pain, neck pain, and hip pain, from 2008 to 2012. She was treated with a combination of medications, lumbar fusion, epidural steroid injections, and trigger point injections. She was prescribed a combination of

clonazepam, temazepam, lorazepam, and hydrocodone. The patient was often seen with the help of respondent's physician assistants.

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

25. Respondent is subject to disciplinary action under Section 2234, subdivision (b), of the Code in that he was grossly negligent in his treatment of M.H., R.E., V.G., D.O. and E.G. The circumstances are as follows:

26. Complainant repeats the allegations of paragraphs 14, 16, 17, 23 and 24 as if set forth in full.

27. When there is a discrepancy between a drug screening test and what the physician has prescribed, a discussion must occur with the patient to clarify the reason for this. It is possible that the patient is not taking his medications. Worse, the patient could be diverting his or her medications. M.H., R.E., V.G., D.O. and E.G. each had at least one test that was positive for medications not prescribed and/or were missing medications that should have been in the test results.[3] Respondent's records do not document that a discussion about the discrepancy occurred. The patients continued to receive prescriptions. Respondent's failures to respond appropriately to the test results were extreme departures from the standard of care.

28. There is a maximum dose of steroids that is safe to inject into patients. It is unclear what the exact maximum dose is. However, most pain physicians give a maximum of three to four doses over a one-year period. Over-administration can lead to a multitude of medical problems, including hyperglycemia, hypertension, weakening of the connective tissue, weight gain and avascular necrosis of the femoral head

29. Respondent conducted a physical examination of D.O. on or about November 21, 2012, that showed 2-3+ pitting edema, a possible sign of excess steroid injections. Respondent continued to inject steroids into D.O., thus committing an extreme departure from the standard of care.

[3] The pain management expert review dated November 9, 2013, specifies whether each patient had a positive test for a drug not prescribed or a negative test for a prescribed drug.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

30. Respondent is subject to disciplinary action under Section 2234, subdivision (c), of the Code in that he negligently treated all of the patients listed in "The Patients" above. The circumstances are as follows:

31. Complainant repeats the allegations of paragraphs 11 through 24 and 27 through 29 as if set forth in full.

32. The standard of care requires the medical records document that the physician discuss the risks and benefits of the use of controlled substances along with other treatment modalities. An actual written consent, the terms of which are often in a narcotic contract, is not required but is recommended.

33. Respondent's record of the care of each patient listed in "The Patients" section above except that of S.F. contains no documentation that the respondent had a discussion with the patient about the risks and benefits of controlled substances. Each such failure to obtain informed consent for treatment with controlled substances was a simple departure from the standard of care.

34. There is a maximum dose of steroids that is safe to inject into patients. It is unclear what the exact maximum dose is. However, most pain physicians give a maximum of three to four doses over a one- year period. Over-administration can lead to a multitude of medical problems, including hyperglycemia, hypertension, weakening of the connective tissue, weight gain and avascular necrosis of the femoral head.

35. Respondent administered steroids more often than was safe to J.M., T.P. and D.O.[4] Each instance of excessive administration of steroids was a simple departure from the standard of care.

36. The standard of care for the prescription of controlled substances for chronic pain follows the guidelines set forth by the Medical Board of California. The guidelines have six

[4] The pain management expert review dated November 9, 2013, describes the unsafe administration of steroids as to each of these patients.

components that the physician should meet before prescribing or when continuing to prescribe: (a) a medical history and physical examination, (b) a treatment plan and objectives, (c) informed consent, (d) periodic review, (e) consultation, and (f) adequate records. The history and physical examination should reveal a recognized indication for the use of the controlled substance prescribed.

37. Respondent prescribed a benzodiazepine medication to A.L., J.M., V.G., T.P., L.B., D.O. and E.G. He thereafter prescribed a second benzodiazepine medication to each of these patients to be used simultaneously with the benzodiazepine medication previously prescribed.[5] The prescription of the second benzodiazepine did not add any additional benefit to the management of any of these patients' pain. Each prescription of a second benzodiazepine constituted a simple departure from the standard of care.

38. Respondent did not obtain previous medical records or other verification that another physician had prescribed narcotic pain medication to "S.F." before giving "S.F." a prescription for 180 tablets of Norco. Prescribing only a few days' supply would have complied with the standard of care; prescribing 180 tablets was excessive under the circumstances and constituted a simple departure from the standard of care.

THIRD CAUSE FOR DISCIPLINE

(Prescribing Drugs Without an Appropriate Prior Examination or Medical Indication)

39. Respondent is subject to discipline in that he prescribed dangerous drugs without an appropriate prior examination or medical indication in violation of section 2242, subdivision (a) of the Code. The circumstances are as follows:

40. Complainant repeats the allegations of paragraphs 11, 12, 17, 19, 22, 23, 24, and 37 as if set forth in full.

41. There was no medical indication for prescribing the second benzodiazepine medication to each of the listed patients.

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[5] The pain management expert review dated November 9, 2013, describes both the first and second benzodiazepine medication prescribed to each patient.

FOURTH CAUSE FOR DISCIPLINE

(Excessive Prescribing)

42. Respondent is subject to disciplinary action under Section 725 of the Code in that respondent repeatedly and clearly prescribed drugs excessively. The circumstances are as follows:

43. Complainant repeats the allegations of paragraphs 13, 14, 16, 17, 23, 24, 37 and 38 as if set forth in full.

44. Respondent prescribed drugs to M.H., R.E., V.G., D.O. and E.G. in a clearly excessive manner in that he continued to prescribe to them after inconsistent drug screening test results and before discussing the inconsistent results with the patient. He also prescribed a 30 to 60-day supply of Norco to "S.F." instead of a supply sufficient for a few days.

FIFTH CAUSE FOR DISCIPLINE

(Failure to Maintain Adequate and Accurate Medical Records)

45. Respondent is subject to disciplinary action under Section 2266 of the Code in that he failed to maintain adequate and accurate records relating to this care and treatment of all of the patients listed herein. The circumstances are as follows:

46. Complainant repeats the allegations of the First through Fourth Causes for Discipline as if set forth in full.

PRAYER

WHEREFORE, complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Medical Board of California issue a decision:

1. Revoking or suspending Physician and Surgeon's Certificate Number G 62470, issued to Jack H. Akmakjian, M.D.;

2. Revoking, suspending or denying approval of Jack H. Akmakjian, M.D.'s authority to supervise physician assistants, pursuant to Section 3527 of the Code;

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3. Ordering Jack H. Akmakjian, M.D., if placed on probation, to pay the Medical Board of California the costs of probation monitoring; and,

4. Taking such other and further action as deemed necessary and proper.

DATED: _____

KIMBERLY KIRCHMEYER
Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

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