UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

UNITED STATES OF AMERICA, Petitioner, v. ARIA O. SABIT, Respondent.	)	MISC NO. _____

APPLICATION FOR ORDER TO SHOW CAUSE AND FOR SUMMARY ENFORCEMENT OF CIVIL INVESTIGATIVE DEMAND 13-338

This is an action for summary enforcement of a Civil Investigative Demand ("CID") 13-338 issued by the United States Department of Justice in connection with an investigation into, *inter alia*, kickbacks to physicians.

This Application is supported by the attached Memorandum and by the Declaration of Special Agent Keith Kuntz, the latter of which is identified as Exhibit 1.

The United States respectfully requests an Order enforcing the CID. A proposed Order is attached.

Respectfully submitted,

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DATED: February 7, 2014

MEMORANDUM IN SUPPORT OF THE UNITED STATES' PETITION FOR ORDER TO SHOW CAUSE AND FOR SUMMARY ENFORCEMENT OF CIVIL INVESTIGATIVE DEMAND 13-338

This is a summary proceeding filed by the United States as petitioner to obtain judicial enforcement of a Civil Investigative Demand (CID) issued by the United States Department of Justice to Dr. Aria O. Sabit pursuant to the False Claims Act, 31 U.S.C. § 3731(a)(1).

CID 13-338, which was personally served on Dr. Sabit on August 16, 2013, seeks information relevant to the Government's investigation into whether "Reliance Medical Systems, LLC, and its investors violated federal law by offering and/or paying kickbacks to physicians in order to induce them to use Reliance-branded medical devices, and that Reliance physician-investors performed medically unnecessary spinal fusion procedures." *See* Kuntz Decl., Ex. A (CID 13-338).

Dr. Sabit has invoked the Fifth Amendment and refused to produce any documents responsive to CID 13-338, with the exception of his *curriculum vitae* (CV). Neither the documents responsive to CID 13-338 themselves, nor the act of producing these documents are "testimonial" in nature. Thus, Dr. Sabit's reliance on the Fifth Amendment to shield himself

from the Government's civil document requests is without basis, and these demands should be summarily enforced.[1]

BACKGROUND

A physician-owned distributorship (POD) is a company that derives revenue from selling implantable medical devices to hospitals for use on their physician investors' patients. Until late 2012, Reliance Medical Systems (Reliance) operated several PODs. From May 2010 until December 2010, Reliance conducted business in Ventura, California through one such POD, a company called Apex Medical Technologies, LLC (Apex). Aria Sabit was one of Apex's two founding physician investors. In May 2010, Dr. Sabit made a $5,000 initial "investment" and started using Reliance implants on his patients. *See* Kuntz Decl., ¶10.

On average, Reliance paid Dr. Sabit over $30,000 each month he practiced in California. *Id.* The rates at which Dr. Sabit performed surgeries that involve implanted spinal devices, such as cages and screws, increased dramatically during this period. For instance, Dr. Sabit's use of PEEK cages

[1] The Government does not contest Dr. Sabit's invocation of the Fifth Amendment as a basis for refusing to give testimony or answer interrogatories. This action concerns only his refusal to produce documents.

on Medicare patients increased over 400% during the period he was an Apex "investor."[2] *Id.* at Ex. D (Sabit Medicare Claims Data Summary).

In the Fall of 2010, hospital staff became alarmed that Dr. Sabit's infection and return-to-surgery rates were substantially higher than those of the other members of the surgical staff. In December 2010, the hospital suspended Dr. Sabit, and hired an outside expert to conduct an independent review of some of Dr. Sabit's surgeries. Days after the conclusion of this review, Sabit resigned. The hospital subsequently referred its concerns to the California Board of Medicine, which, in September 2013, filed a public accusation seeking the revocation of Sabit's medical license based on gross negligence and dishonest and corrupt acts. Kuntz Decl. at Ex. E (California Bd. of Med. Public Accusation). The proceeding to revoke Dr. Sabit's medical license is ongoing.

After he "resigned" from the hospital in California where he had been practicing, Sabit relocated to Michigan, where he currently resides and where he resumed his surgical practice. Although Sabit has repeatedly denied under oath having a financial relationship with Reliance or Apex, in fact Sabit remained an Apex "investor" until July 2012. Reliance paid Sabit

[2] Polyetheretherketone (or PEEK) cages are small plastic cylindrical devices that are placed in the disc space. Cages are often used in connection with other spinal implants to promote the fusion of spinal vertebrae.

over $400,000 during the two years he was an "investor." *See* Kuntz Decl., ¶10.

Statutory Framework: the Anti-Kickback Statute and the False Claims Act

The Anti-Kickback Statute (AKS) prohibits both the payment and receipt of any remuneration to induce a person to order goods for which payment may be made under a federal health program, including Medicare and Medicaid. *See* 42 U.S.C. § 1320a-7b(b).[3] On March 26, 2013, the Department of Health and Human Services Office of the Inspector General (OIG) issued a Special Fraud Alert in which it expressed its conclusion that physician-owned distributorships such as Reliance, "are inherently suspect under the anti- kickback statute." Kuntz Decl., Ex. M (Special Fraud Alert).

[3] Specifically, the AKS provides that "(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind — (A) in return for referring an individual to a person 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, or (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony …

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person — (A) to refer an individual to a person 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, or (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony … [unless one of ten enumerated exceptions apply]" 42 U.S.C. § 1320a-7b(b).

The False Claims Act (FCA) imposes civil liability when a person commits any of seven specified deceptive practices involving government funds or property. *See* 31 U.S.C. § 3729(a)(1)(A)-(G). In particular, Section 3729(a)(1)(A) imposes civil liability for "knowingly presenting or causing to be presented a false or fraudulent claim for payment." A claim for payment that is tainted by a violation of the AKS "constitutes a false or fraudulent claim for purposes of" the False Claims Act. 42 U.S.C. § 1320a–7b(g); *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112, 127 & n.25 (D. Mass. 2011) (citing cases, and noting that, even prior to the most recent amendment of the AKS, "the majority of trial courts … have also held that violations of the AKS cause any resulting claim to be false.").

Section 3733 of the FCA empowers the Attorney General or his designee to issue a CID to "any person" who has information "relevant to a false claims law investigation." 31 U.S.C. § 3733(a)(1). "Congress intended the false claims CID to provide the Department of Justice with a means to assess quickly, and at the least cost to the taxpayers or to the party from whom information is requested, whether grounds exist for initiating a false claim suit under 31 U.S.C. §§ 3729-32 …" *United States v. Markwood*, 48 F.3d 969, 979 (6th Cir. 1995). The Attorney General may file a petition for

an enforcement of a CID in any judicial district in which the CID recipient resides. 31 U.S.C. § 3733(j)(1).

CID 13-338, and the Government's Efforts to Confer with Dr. Sabit

CID 13-338 seeks documents, testimony, and interrogatory responses from Dr. Sabit concerning his relationship with Reliance. Specifically, the CID seeks documents reflecting communications between Dr. Sabit and Reliance. CID 13-338, Attach. C, #3. The CID also requires copies of medical records for the patients on whom Dr. Sabit used Reliance implants, and documents in Dr. Sabit's possession concerning the Medical Board of California's investigation. *Id*.

CID 13-338 was personally served on Dr. Sabit on August 16, 2013. Kuntz Decl., Ex. F (Certificate of Service). On September 9, 2013, Dr. Sabit's counsel, Jonathan Frank, wrote an email to the undersigned stating that that "Dr. Sabit does intend to comply with the subpoena." *Id.*, Ex. G (Frank email). Mr. Frank further stated that, "we would like to set the response date at October 18 if possible." *Id.* At no time following that email did the undersigned relieve Dr. Sabit of any of his obligations under the CID, except to agree to Mr. Frank's proposed October 18 date of production.

In an in-person meeting with Mr. Frank on November 4, 2013, and again in writing on November 5, the undersigned repeated the Government's position that "[w]e expect Dr. Sabit to fully comply with the CID …. We need to know now where you object, the basis for your objection(s), and – where you do not object – when you expect to produce." *Id.* at Ex. H (Finkelstein Email). On Monday November 18 – one month after the agreed-upon production date – Mr. Frank responded, objecting to the production of any documents responsive to the CID with the exception of Dr. Sabit's CV. Kuntz Decl., Ex. I (Sabit Response to CID 13-338). Mr. Frank set forth the basis for Dr. Sabit's objection as follows:

> you have indicated that the Department of Justice is investigating potential civil and criminal violations of the False Claims Act by Reliance and/or Dr. Sabit … Given this, Dr. Sabit invokes his right under the Fifth Amendment not to produce documents or to provide testimony in response to this document request on the grounds that, rightly or wrongly, Dr. Sabit's act of producing such documents … in these subject areas may be used by the DOJ, correctly or incorrectly, in an effort to incriminate him.[4]

[4] Mr. Frank's assertion that the DOJ "indicated that the Department of Justice is investigating potential civil and criminal violations of the False Claims Act by Reliance and/or Dr. Sabit" is incorrect. The undersigned confirmed the civil investigation, but informed Mr. Frank that he was not authorized to speak about the status of any criminal investigation. The undersigned provided the names and phone numbers of attorneys within the Criminal Division to whom Mr. Frank could address questions concerning any criminal investigation.

Id. Mr. Frank did not explain how the act of producing responsive documents could be deemed "testimonial" in nature.[5]

DISCUSSION

A CID may be issued to "any person" who has information "relevant to a false claims law investigation." 31 U.S.C. § 3733(a)(1). That person may be required to give oral testimony, answer written interrogatories, produce documents, or all of the above. *Id.* CIDs are a type of administrative subpoena. *United States v. Markwood*, 48 F.3d 969, 976 (6th Cir. 1995); *FTC v. Invention Submission Corp.*, 965 F.2d 1086, 1087 (D.C. Cir. 1992), and may be enforced in any judicial district in which the CID recipient resides. 31 U.S.C. § 3733(j)(1).

The role of the district court in evaluating a petition for enforcement of an administrative subpoena "is a strictly limited one." *FTC v. Texaco*, 555 F.2d 862, 873 (D.C. Cir. 1976) (*en banc*). The sole issue in an enforcement proceeding is whether "the court's process would or would not be abused by enforcement." *SEC v. Wheeling-Pittsburgh Steel Corp.*, 648 F.2d 118, 125 (3d Cir. 1981). No abuse is present where the enforcing court determines that "the inquiry is within the authority of the agency, the

[5] In a final effort to avoid unnecessary litigation, the undersigned contacted Mr. Frank on February 3, 2014, to inform him that the Government would commence a proceeding to enforce the CID unless Dr. Sabit withdrew his objections to the Government's document requests. Although Mr. Frank agreed to respond by February 4, he failed to meet this deadline.

demand is not too indefinite and the information sought is reasonably relevant" to the agency's inquiry. *United States v. Morton Salt Co*., 338 U.S. 632, 652 (1950); *United States v. Aero Mayflower Transit Co*., 831 F.2d 1142 (D.C. Cir. 1987); *United States v. Westinghouse Electric Corp*., 788 F.2d 164, 166 (3d Cir. 1986).

In order to set forth a *prima facie* case for enforcement of an administrative subpoena, it is sufficient for the issuing authority to submit an affidavit to the enforcing court that demonstrates the basis for its conclusion that the investigation is within the scope of the agency's authority and that the requested documents are relevant to the inquiry. *In re EEOC*, 709 F.2d 392, 400 (5th Cir. 1983); *United States v. Blue Cross & Blue Shield of Michigan*, 726 F. Supp. 1523, at 1524-25 (E.D. Mich. 1989). The attached sworn declaration of OIG Special Agent Keith Kuntz satisfies this requirement.

1. The Documents the Government Seeks Are Within the Scope of Its Authority to Investigate Violations of the False Claims Act.

The Government's investigation of Dr. Sabit and Reliance is well within the scope of its authority to investigate violations of the FCA, and the information the Government seeks is relevant to its investigation. The Government is investigating whether Reliance's financial relationship with

Dr. Sabit violated the AKS, and whether Reliance and Dr. Sabit caused hospitals to submit tainted claims for reimbursement for spinal fusion surgeries in violation of the FCA. The evidence shows that Apex paid Dr. Sabit more than four hundred thousand dollars between May 2010 and June 2012, during which time Dr. Sabit performed surgeries using Reliance implants that were billed to and paid for by federal health care programs. Further, there is evidence that Dr. Sabit's surgeries using Reliance implants have resulted in significant complications and at least one death. The Government may "investigate merely on suspicion that the law is being violated, or even because it wants assurance that it is not." *Morton Salt*, 338 U.S. at 642-43. Here, the Government's suspicion that Reliance's payments to Sabit were kickbacks, and that those kickbacks caused hospitals to submit false claims to federal health care programs, authorizes it to issue CIDs.

Further, the evidence shows that both Dr. Sabit and Reliance have attempted to obscure the true nature of their relationship. In particular, Sabit, while testifying under oath, has repeatedly mischaracterized the nature of his relationship with Reliance. During a series of depositions, Dr. Sabit repeatedly denied having had a financial relationship with Apex or Reliance. For instance, Sabit denied "ever [having] been compensated by a medical instrument manufacturer for use of their devices," denied "personally

mak[ing] any money depending on what instrumentation was being used," and denied "know[ing] anybody running a device company out of Bountiful, Utah," where Reliance is based. *See* Kuntz Decl., Ex. J (Sabit Deposition Testimony).[6]

Reliance principals have also mischaracterized their company's relationship with Dr. Sabit. For instance, on March 7, 2013, Brett Berry testified that "Dr. Sabit was only with us for a year or so," and that Reliance continued its relationship with Dr. Sabit "[m]aybe a handful of months" following his move to Michigan. Berry also testified that Reliance "pulled our product" from Dr. Sabit's hospitals shortly after he moved his practice to Michigan. *See* Kuntz Decl., Ex. K (Berry Deposition Testimony). None of these claims is true. In fact, Reliance continued its financial relationship with Dr. Sabit until late 2012 – more than a year and a half after he "resigned" from the hospital in California where he had been practicing – and Reliance continued to supply implants to hospitals in Michigan where Dr. Sabit performed surgery until as recently as April 2013. In view of

[6] After years of denying any financial relationship with Reliance, in a deposition on September 9, 2013 Sabit admitted to "own[ing] stocks in various companies," including presumably Apex. However, Sabit went on to insist that "[d]oing a spinal surgery on [a particular patient] did not dictate that I would make or lose money." This last statement is misleading, as even Reliance principal Brett Berry admits that "in general if you did more cases, if there was – if the company did more cases, then there would be a larger profit."

Reliance's and Sabit's efforts to obscure the nature of their relationship, the Government's efforts to conduct further inquiry are manifestly legitimate.

2. Sabit's Production of Responsive Documents Is Not "Testimonial" in Nature.

The Fifth Amendment of the Constitution provides that no person "shall be compelled in any criminal case to be a witness against himself." U.S. Const. Amend. V; *see also Chavez v. Martinez*, 538 U.S. 760, 769 (2003); *United States v. Washington*, 431 U.S. 181, 188 (1977); *United States v. Monica*, 317 U.S. 424, 427 (1943). The burden is on the person seeking to avoid production to explain why a response would pose a real danger of incrimination. *United States v. Baker*, 721 F.2d 647, 650 (8th Cir.1983); *Bear Sterns & Co., Inc. v. Wyler*, 182 F. Supp. 2d 679, 684 (N.D. Ill. 2002). A witness cannot "draw a conjurer's circle around the whole matter by his own declaration that to write any word upon the government blank would bring him into danger of the law." *United States v. Sullivan*, 274 U.S. 259, 264 (1927).

"[A] person may be required to produce specific documents even though they contain incriminating assertions of fact or belief because the creation of those documents was not 'compelled' within the meaning of the privilege." *United States v. Hubbell*, 530 U.S. 27, 35-36 (2000). CID 13-338 seeks documents that already exist and are in Dr. Sabit's possession.

This action seeks the enforcement of three categories of document requests to which Dr. Sabit has objected:

- Communications – including emails – between Reliance and Dr. Sabit;
- medical records of patients on whom Reliance devices have been used; and
- records – including audio recordings of interviews – provided to Dr. Sabit by the Medical Board of California.

CID 13-338, Attachment C, #3. In each case, Dr. Sabit objects in general terms, asserting: "rightly or wrongly, Dr. Sabit's act of producing such documents … in these subject areas may be used by DOJ, correctly or incorrectly, in an effort to incriminate him." Sabit Response to CID 13-338. However, the mere suggestion that the requested documents "may be used" in a criminal case falls short of Dr. Sabit's burden of showing that the underlying information would incriminate him. *Baker*, 721 F.2d at 650; *Bear Sterns*, 182 F. Supp. 2d at 684.

More significantly, despite several conversations with the undersigned, Dr. Sabit has not explained how the act of producing responsive documents that are already in existence would be "testimonial" in nature. The act of producing documents in response to a subpoena may be deemed testimonial in certain limited circumstances. *See Hubbell*, 530 U.S. at 36; *see also United States v. Grable*, 98 F.3d 251, 253 (6th Cir.1996).

However, an act of production will be deemed testimonial only where it would be tantamount to answering a series of interrogatories asking a witness to disclose the existence and location of documents fitting certain broad descriptions. *Hubbell*, 530 U.S. at 41. Thus, the courts of appeals that have considered the scope of the "act of production" doctrine after *Hubbell* have held it to apply only where the government is unable to describe the documents to be produced with "reasonable particularity." *See United States v. Ponds*, 454 F.3d 313, 320 (D.C. Cir. 2006); *In re Grand Jury Subpoena Dated April 18, 2003*, 383 F.3d 905, 910 (9th Cir. 2004); *United States v. Teeple*, 286 F.3d 1047, 1051 (8th Cir. 2002). Put otherwise, where the Government does not need the subpoena recipient's assistance to identify potential sources of information – where the recipient is not required "to make extensive use of the contents of his own mind" in order to respond to the subpoena – then the act of production doctrine does not apply. *See Ponds*, 454 F.3d at 320.

The "act of production" doctrine does not apply in this case because the Government seeks to enforce CID 13-338 only with respect to documents that it independently knows to exist and can describe with reasonable particularity. First, and most obviously, the "act of production" doctrine does not justify Dr. Sabit's efforts to withhold production of the

medical records of patients on whom he has used Reliance implants. Dr. Sabit argues both that he doesn't have any such records – that documents related to his practice in Michigan are in the possession and control of the hospitals in Michigan – and that the act of producing such documents is protected by the Fifth Amendment. Both arguments are unavailing. The CID seeks only records from Dr. Sabit's own practice, not from the hospitals where he has performed surgeries. Records in Dr. Sabit's possession likely include reports memorializing his evaluation and physician examination of patients on whom Reliance implants were subsequently used.

The act of producing the medical records at issue is not protected by the Fifth Amendment. The Government is aware of over seventy cases in which Dr. Sabit used Reliance implants on patients after he relocated to Michigan. The Government, as payor in many of Dr. Sabit's surgeries, has the right to examine the records that furnish the basis for Dr. Sabit's claims. And Dr. Sabit is required by his Medicare provider agreement to maintain such records. *See* Kuntz Decl., ¶6. Because these records already exist, and the Government can describe the records it seeks with reasonable particularity, Dr. Sabit's act of producing these records would not be "testimonial."

The "act of production" doctrine also does not justify Dr. Sabit's efforts to withhold production of his communications with Reliance. The Government is aware of emails between Dr. Sabit and Reliance's non-physician owners. By way of example, on July 9, 2010, Dr. Sabit sent an email from his personal Yahoo account to Brett Berry's personal Yahoo account requesting that Reliance purchase certain instruments from other vendors rather than modify Reliance's own instruments. *See* Kuntz Decl., Ex. L ("Sabit email"). CID 13-338 seeks *all* such communications in Dr. Sabit's possession or control. Again, because the Government has described the documents it seeks in the CID with reasonable particularity, the "act of production" doctrine does not apply. *See Teeple*, 286 F.3d at 1051.

Finally, the "act of production" doctrine does not justify Dr. Sabit's refusal to produce records provided to him by the Medical Board of California. The Government is aware that Dr. Sabit participated in a lengthy interview with representatives of the Medical Board, that this interview was tape-recorded, and that Dr. Sabit was given a copy of this recording. In this interview, Dr. Sabit speaks at length about some of the surgeries he performed at Community Memorial Hospital in California. The Government is entitled to discover evidence that is already in existence of statements that Dr. Sabit made to the Medical Board. Again, because the

Government has independent knowledge of the existence of this evidence, that "act of production" doctrine does not apply.

CONCLUSION

The Government investigation under which the contested CID was issued is fully authorized under the False Claims Act; the materials requested by subpoena are reasonably relevant to the inquiry; and the act of producing these materials would not be testimonial in nature. Accordingly, the United States respectfully requests this Court to summarily enforce the CID.

Respectfully submitted,

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Dated: February 7, 2014

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN

UNITED STATES, Petitioner, v. ARIA O. SABIT, Respondent.	)	MISC NO. _____

DECLARATION OF SPECIAL AGENT KEITH KUNTZ IN SUPPORT OF THE UNITED STATES' PETITION FOR SUMMARY ENFORCEMENT OF CIVIL INVESTIGATIVE DEMAND 13-338

Keith Kuntz, on the date below and pursuant to Section 1746 of Title 28 of the United States Code, declares the following to be true and correct under penalty of perjury:

1. I am a Special Agent with the U.S. Department of Health and Human Services ("HHS") Office of Inspector General ("OIG"). I have been a Special Agent with the HHS OIG for over 20 years. My duties include investigating fraud and abuse perpetrated upon the Medicare program. During the tenure of my career, I have participated in hundreds of health care fraud investigations. I have personal knowledge of the matters set forth herein and could competently testify if called as a witness.

2. I am assigned to investigate allegations of fraud by Reliance Medical Systems, LLC, Brett Berry, Adam Pike, John Hoffman, and Aria O. Sabit – among others – upon the Medicare program. This investigation arises out of allegations that Reliance

Medical Systems paid kickbacks to at least thirty-five physicians, including Aria O. Sabit.

3. I make this declaration in support of the United States' petition for enforcement of Civil Investigative Demand ("CID") 13-338, which was issued to Aria O. Sabit pursuant to 31 U.S.C. § 3733, and which is attached to this declaration as Exhibit A. CID 13-338 was signed by the Assistant Attorney General for the Civil Division of the Department of Justice on August 8, 2013. The CID principally seeks documents in Sabit's possession about Reliance, documents provided by Reliance, and documents sent to Reliance. The CID also seeks patient medical records in Sabit's possession. The requests in these CIDs are narrowly tailored to the needs of the OIG and DOJ investigation.

4. Reliance Medical Systems sells spinal implants to hospitals. For some implants it sells, Reliance has obtained Food and Drug Administration ("FDA") 510k clearances based on the Reliance devices' "substantial equivalence" to devices already on the market. In other cases, Reliance simply licenses other companies' implants.

5. The Medicare program compensates hospitals for spine surgeries based on the diagnoses and procedures performed on insured patients. Medicare payments are intended to compensate hospitals for the total expected cost of surgery, including the hospital's implant costs.

6. As a condition of payment by the Medicare program, providers must sign a certification in their provider agreement that, *inter alia*, they will not violate the Anti-Kickback Statute. Further, when they submit claims, they must certify that they "agree to keep such records as are necessary to disclose fully the extent of services provided …"

7. On January 13, 2013, in connection with the above-referenced investigation, the United States Department of Justice ("DOJ") issued CID 13-36 to Reliance. This CID seeks documents pertaining to Reliance's interactions with its physician-investors. At the same time, CIDs for documents and testimony were issued to Reliance's owners Brett Berry (CID 13-37) and Adam Pike (CID 13-38).

9. Included in the records Reliance produced in response to CID 13-36, and attached as Exhibit B, is a subscription agreement between Apex Medical Technologies and Aria Sabit.

10. Also included in Reliance's response to CID 13-36 were accounting statements. I have reviewed these accounting statements, which show more than $400,000 of payments from Reliance to Sabit between May 2010 and June 2012.

11. As part of my investigation into the impact of Reliance's payments to Sabit, I reviewed a summary of Sabit's Medicare claims data between 2009 and 2012. Attached as Exhibit D is a chart showing by year the number of times Sabit billed certain Current Procedure Terminology (or "CPT") codes by means of which physicians seek reimbursement for implanting spinal devices. This chart shows that the rate at which Sabit billed for implanting spinal devices increased dramatically in 2010, the year he became a Reliance investor.

12. Of particular note is CPT code 22851, which is the code by which physicians seek reimbursement for implanting PEEK cages, a type of implant that Reliance sells to hospitals. Exhibit D shows that Sabit billed 22851 seven times in 2009, but that he billed this code fifty-four times in 2010, they year that he became an Apex investor.

13. Attached as Exhibit E is a true copy of the Accusation the California Board of Medicine files against Dr. Sabit, accusing him of gross negligence, and dishonest and corrupt acts.

14. Attached as Exhibit F is a declaration of service for CID 13-338, indicating that Sabit was served personally on August 16, 2013.

15. Attached as Exhibit G is an email dated September 9, 2013 from Sabit's attorney, pledging that "Dr. Sabit does intend to comply with the subpoena." Sabit's attorney proposed to "set the response date at October 18."

16. Attached as Exhibit H is an email chain containing an email from David Finkelstein, a Trial Attorney in the DOJ Civil Fraud Section, dated November 8, 2013. Finkelstein states to Sabit's attorney: "We write in a final effort to resolve whatever disagreements we may have – which you still have not identified – concerning Dr. Sabit's obligations under the CID. Please produce all responsive documents in Dr. Sabit's possession no later than Friday November 15, or unambiguously state your basis for objecting to production."

17. Attached as Exhibit I is Sabit's response to CID 13-338, which objects to providing any documents with the exception of his CV on Fifth Amendment grounds. Sabit also objects to providing interrogatory responses identifying the location and value of his assets, also on Fifth Amendment grounds.

18. Attached as Exhibit J are excerpts from Sabit's deposition testimony in medical malpractices cases that have been filed against him in California state court.

19. Attached as Exhibit K are excerpts from Brett Berry's deposition testimony in response to CID 13-37.

20. Attached as Exhibit L is a redacted copy of an email exchange between Brett Berry and Aria Sabit. This email was produced by Reliance in response to CID 13-36.

21. Attached as Exhibit M is a true copy of the OIG's March 26, 2013 Special Fraud Alert concerning physician-owned entities.

22. The investigation that I am conducting is within the authority of the Inspector General, and the information required by the CID is relevant to that investigation.

KEITH KUNTZ

Dated: 12/6/2013

Kuntz Declaration, Exhibit A

Civil Investigative Demand - Documentary Material, Interrogatories, and Oral Testimony

UNITED STATES DEPARTMENT OF JUSTICE
Washington, D.C. 20530

TO: Dr. Aria Sabit
1254 North Main Street
Lapeer, Michigan 48446

Civil Investigative
Demand No. 13-338

This Civil Investigative Demand is issued pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733, in the course of a False Claims Act investigation to determine whether there is or has been a violation of 31 U.S.C. § 3729. The False Claims Act investigation concerns allegations that Reliance Medical Systems, LLC (Reliance) and its investors violated federal law by offering and/or paying kickbacks to physicians in order to induce them to use Reliance-branded medical devices, and that Reliance physician-investors performed medically unnecessary spinal fusion procedures.

This Demand requires you to provide documents, answers to interrogatories, and testimony to the Federal Government. This is the original of the Demand; no copies have been served on other parties. The information and documents provided in response to this Demand may be shared, used, and disclosed as provided by 31 U.S.C. § 3733.

Documentary Material

In conjunction with the Instructions set forth in **Attachment A** and **Attachment B**, you are required by this Demand to produce any and all documents specified in **Attachment C**.

You must make this material available to David Finkelstein, who has been designated as a False Claims Act custodian in this case. Mr. Finkelstein may be contacted at (202) 616-2971, if you have any questions.

These documents shall be produced no later than thirty (30) days from the receipt of this Demand, at the United States Department of Justice, 601 D Street N.W., Suite 9605, Washington, DC 20004, or at another location to be mutually agreed upon by yourself and the False Claims Act custodian. The production of documentary material in response to this Demand must be made under a sworn certificate in the form printed in this Demand.

Interrogatories

You are required by this Demand to answer the interrogatories included as **Attachment D**. The answers to interrogatories shall be submitted no later than twenty (20) days from the receipt of this Demand, at the United States Department of Justice, 601 D

Street N.W., Suite 9605, Washington, DC 20004. The interrogatories shall be answered separately and fully in writing under oath and also shall be submitted under a sworn certificate in the form printed in this Demand. If you object to any interrogatory, the reasons for the objection shall be stated with specificity.

Oral Testimony

You are further required by this Demand to give oral testimony under oath, commencing thirty (30) days from the date of receipt of this Demand, at 9:30am, at the United States Attorney's Office for the Eastern District of Michigan, 211 W. Fort Street, Detroit, MI 48226, or at such time and in such other place as may be agreed upon by David Finkelstein and you. The general nature of the testimony will be whether Reliance offered or paid kickbacks to physicians in order to induce them to use Reliance-branded medical devices, and whether Reliance physician-investors performed medically unnecessary spinal procedures. The primary areas of inquiry for the testimony are specified in **Attachment E.**

David Finkelstein will be the False Claims Act investigator who will conduct the examination. The custodian to whom the transcript of the deposition will be delivered is Mr. Finkelstein.

Your attendance and testimony at the oral examination are necessary to the conduct of the False Claims Act investigation described above. You have the right to be accompanied by an attorney and any other personal representative at the oral examination.

Issued at Washington, D.C., this 8th day of August, 2013.

Stuart F. Delery
Assistant Attorney General
Civil Division

CERTIFICATE OF COMPLIANCE

I have responsibility for answering the interrogatories and producing the documents requested in Civil Investigative Demand No. 13-338. I hereby certify that all the information and materials required by that Civil Investigative Demand which are in the possession, custody or control of the person to whom the Demand is directed have been submitted to a custodian named therein.

If any information or material has not been produced because of a lawful objection, the objection to the document request and the reasons for the objection have been stated.

Signature _____

Title _____

SWORN TO before me this _____ day of

_____, 2013

_____

NOTARY PUBLIC

VERIFIED RETURN OF SERVICE

I, _____, an employee of the United States working under the direction and supervision of attorney David Finkelstein in connection with a false claims law investigation, hereby certify that at the time of _____, on the _____day of _____, 2013, I personally served Civil Investigative Demand No. 13-338 on _____, by delivering _____ an executed copy of such Demand at:

_____

_____

_____

I declare under penalty of perjury that the foregoing is true and correct. Executed on this _____ day of _____, 2013.

Signature_____

Title_____

Attachment A: Instructions

Except as otherwise provided in these instructions, this Civil Investigative Demand (CID) requires the production of all documents responsive to one or more of the attached specifications which are in your possession, custody, or control regardless of where located.

This subpoena refers to the time period from January 1, 2006, through the date of service of this CID unless otherwise specified, and calls for the production of all documents dated, created, maintained, or held by you at any time during that time frame. The documents to be produced pursuant to this subpoena shall include all documents prepared, sent, dated, received, in effect, or which otherwise came into existence at any time during the relevant time period unless another time period is specified in a request.

You are required to produce the originals of all documents and other items that are responsive, in whole or in part, to this CID including all marginalia, post-its, and any attachments, whether referred to or incorporated by the documents. As a courtesy, copies of documents requested by the CID will be accepted in response to the CID provided that the original documents will be made available upon request to False Claims Act Investigators, Custodians, or Deputy Custodians.

To the extent that documents are found in file folders and other similar containers that have labels or other identifying information, the documents shall be produced with such file folder and label intact.

To the extent that documents are found attached to other documents, by means of paperclips, staples, or other means of attachment, such documents shall be produced together in their condition when found.

Electronically stored information (ESI) shall be produced in compliance with the specifications given in Attachment B.

No document called for by this subpoena shall be destroyed, modified, redacted, removed, or otherwise made inaccessible, except insofar as documents are withheld under a claim of privilege in compliance with the instructions herein.

To the extent that documents responsive to this subpoena once were, but no longer are, in the possession, custody, or control of you, this request requires production of all existing indices, lists, or documents in your possession, custody, or control that reflect the transfer or destruction of, or references to, such documents.

When a requested document contains both privileged and non-privileged material, the non-privileged material must be disclosed to the fullest extent possible. If a privilege is asserted with regard to a part of the material contained in a document, the party claiming the privilege must clearly indicate the portions as to which privilege is claimed. When a document has been redacted or altered in any fashion, identify as to each

document the reason for the redaction or alteration. Identify the redactions on the privilege log described herein. Any redaction must be clearly visible on the redacted document and marked accordingly (use of the word "REDACTION" within or adjacent to the redaction box).

If you withhold any document on the ground of any legal privilege, provide a privilege log or index setting forth: (a) the type of document (e.g., letter, memorandum, contract, etc.); (b) the date of the document; (c) the title of the document; (d) the names, address, and position of each author of the document and of any person who assisted in its preparation; (e) the names, address, and position of each addressee or recipient of the document or any copies of it; (f) the number of pages; (g) a brief description of the subject matter; (h) the paragraph of the subpoena to which it is responsive; and (i) the factual and legal basis(es) for the claim of privilege or grounds for non-production asserted with respect to the document.

The singular form of a noun or pronoun shall be considered to include within its meaning the plural form as well, and vice versa.

All present tenses of verbs or verb forms shall be considered to include within their meaning the future and past tenses as well, and vice versa.

The words "or" and "and" are inclusive, referring to anyone or more of the disjoined words or phrases, and "any" and "all" also include "each and every."

Definitions

"YOU" and "YOUR" mean the person or entity to whom this demand is issued.

"RELIANCE" means Reliance Medical Systems, LLC, any entity names and any variations thereof, its subsidiaries, parents, affiliates, segments, regions, divisions, groups, related companies, joint ventures, and partnerships, any and all predecessor or successor entities, and any and all present or former owners, members, officers, directors, representatives, employees, consultants, contractors, or agents acting or purporting to act or appearing to act on behalf of RELIANCE, whether or not their actions were authorized by Reliance or were within the proper scope of their authority. RELIANCE includes without limitation: Kronos Spinal Technologies, LLC; Apex Medical Technologies, LLC; Quality Spinal Innovations, LLC; Spine Design Associates, LLC; Spine Biologics, LLC; Spine Genesis Industries, LLC; Spine Matrix Technologies, LLC; Embassy Spinal Technologies, LLC; Millennium Spinal Technologies, LLC; Fortress Surgical, LLC; and Vista Spinal Solutions, LLC.

"RELIANCE INVESTORS" means anyone who at any time had an ownership interest in RELIANCE, including without limitation: Brett Barry, Adam Pike, Mark Zidek, Jason Baty, Larry Sager, John Hoffman, Ali Mesiwala, M.D.; Gowriharan Thalyananthan, M.D.; David Lundin, M.D.; Aria Sabit, M.D.; Sean Xie, M.D.; Eric Oberlander, M.D.; Horace Mitchell, M.D.; Kelly Scrantz, M.D.; Frasier

Landerneau, M.D.; and Greg Fautheree, M.D.; Robert Berry ,M.D.; Reed Fogg, M.D.; Junius Clawson, M.D.; Howard Reichman, M.D.; James Loddengaard, M.D.; Tiffany Rogers, M.D.; James Hamada, M.D.; Raed Ali, M.D.; Eric Lin, M.D.; Fardad Mobin, M.D.; Sanjay Khurana, M.D.; Ali Najafi, M.D.; Jae Chon, M.D.; Ramin Bagheri, M.D.; Erik Westerlund, M.D.; David Greenwald, M.D.; Bruce Ramsey, M.D.; John H. Pulliam, M.D.; Phillip Esce, M.D.; Chris Chittum, M.D.; Robert Josey, M.D.; Irvin Sahni, M.D.; Kamshad Raisadeh, M.D.; Ramin Raisadeh, M.D.; and Choll Kim, M.D.

"POD" means any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices, including without limitation companies that purport to design or manufacture their own devices or instrumentation.

The term "remuneration" has the meaning identified in 42 C.F.R. § 411.351.

The term "document" is defined in its broad and literal sense, including, but not limited to, all items identified in Rule 34(a)(1) of the Federal Rules of Civil Procedure, and necessarily means and includes, without limitation, electronically-stored information (ESI), including: computer data (whether or not now existing or reflected on "hard copy" documents), handwritten, printed, typewritten, recorded, electromagnetic, graphic, or photographic matter, or sound reproduction (however produced or reproduced) including, but not limited to, emails, writings, correspondence, reports, memoranda, stenographic or handwritten notes, newspapers, periodicals, files, minutes or transcripts of proceedings, instructions, orders, reports, records, complaints, papers, bills, invoices, receipts, shipping or transportation orders or receipts, diaries, calendars, date books, journals, telephone logs, computer printouts, contracts, diagrams, charts, and data of any description relating to the transactions, occurrences, and events in question. The term "document" refers to any original or non-identical copy, whether different from the original because of notes made on or attached to such copy or otherwise.

The term "concerning" means referring to, relating to, discussing, analyzing, regarding, constituting, showing, identifying, or pertaining to, whether directly or indirectly, and should be interpreted broadly to include Documents that might not otherwise come within the scope of a Specification.

The term "communication" shall mean any transmission or exchange of information between two or more persons, orally, in writing, or electronically, including without limitation conversations or discussions whether by chance or by design, and by any means, including by electronic media.

"And" as well as "or" shall be construed shall be read in both the conjunctive and the disjunctive (i.e., "and/or"). The singular form of a word shall be construed to include within its meaning the plural form of the word, and vice versa. And the use of any tense of any verb shall be considered also to include all other tenses.

Attachment B: Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

Collection of Electronically Stored Information (ESI)
Careful consideration should be given to the methodology, implementation and documentation of ESI collection to ensure that all responsive data and metadata are preserved in the collection process.

1. **Specification Modifications**
Any modifications or deviations from the Production Specifications may be done only with the express permission of the Department of Justice (the "Department"). Any responsive data or documents that exist in locations or native forms not discussed in these Production Specifications remain responsive and, therefore, arrangements should be made with the Department to facilitate their production.

2. **Production Format of ESI and Imaged Hard Copy**
Responsive ESI and imaged hard copy shall be produced in the format outlined below. All ESI, except as outlined below in sections 9 – 18, shall be rendered to type TIFF image format, and accompanied by a Concordance® Image Cross Reference file. All applicable metadata (see section 3 below) shall be extracted and provided in Concordance® load file format.

a. **Image File Format:** All images, paper documents scanned to images, or rendered ESI, shall be produced as 300 dpi single-page TIFF files, CCITT Group IV (2D Compression). Documents should be uniquely and sequentially Bates numbered with an endorsement burned into each image.
- All TIFF file names shall include the unique Bates number burned into the image.
- Each Bates number shall be a standard length, include leading zeros in the number, and be unique for each produced page.
- All TIFF image files shall be stored with the ".tif" extension.
- Images should be able to be OCR'd using standard COTS products, such as LexisNexis LAW PreDiscovery™.
- All pages of a document or all pages of a collection of documents that comprise a folder or other logical grouping, including a box, should be delivered on a single piece of media.
- No image folder shall contain more than 2000 images.

b. **Concordance® Image Cross Reference file:** Images should be accompanied by a Concordance® Image Cross Reference file that associates each Bates number with its corresponding single-page TIFF image file. The Cross Reference file should also contain the image file path for each Bates numbered page.
- Image Cross Reference Sample Format:

```
ABC00000001,OLS,D:\DatabaseName\Images\001\ ABC00000001.TIF,Y,,,
ABC00000002,OLS,D:\DatabaseName\Images\001\ ABC00000002.TIF,,,,
ABC00000003,OLS,D:\DatabaseName\Images\001\ ABC00000003.TIF,,,,
ABC00000004,OLS,D:\DatabaseName\Images\001\ ABC00000004.TIF,Y,,,
```

c. **Concordance® Load File:** Images should also be accompanied by a "text load file" containing delimited text that will populate fields in a searchable, flat database environment. The file should contain the required fields listed below in section 3.

- ASCII text delimited load files are defined using the following delimiters:

Field Separator	*^ or Code 094*
Text Qualifier	*| or Code 124*
Substitute Carriage Return or New Line	*~ or Code 013*

Attachment B: Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

- The text file should also contain hyperlinks to applicable native files, such as Microsoft Excel or PowerPoint files.
- There should be one line for every record in a collection.
- The load file must contain a field map/key listing the metadata/database fields in the order they appear within the data file. For example, if the data file consists of a First Page of a Record (starting Bates), Last Page of a Record (ending Bates), Document ID, Document Date, File Name, and a Title, then the structure may appear as follows:

  |BEGDOC#|^|ENDDOC#|^|DOCID|^|DOCDATE|^|FILENAME|^|TITLE|

- The extracted/OCR text for each document should be provided as a separate single text file. The file name should match the BEGDOC# or DOCID for that specific record and be accompanied by the .txt extension.

3. Required Metadata/Database Fields

- A "✓" denotes that the indicated field should be present in the load file produced.
- "Other ESI" includes non-email or hard copy documents, including but not limited to data discussed in sections 6-9, and 12-18 below.

Field name	Field Description	Field Type	Field Value	Hard Copy	E-Mail	Other ESI
COMPANY	Company/Organization submitting data	Full Text	Unlimited	✓	✓	✓
BOX#	Submission/volume/box number	Note Text	10	✓	✓	✓
CUSTODIAN	Custodian(s)/Source(s) - format: Last, First or ABC Dept	Multi-Entry	Unlimited	✓	✓	✓
AUTHOR	Creator of the document	Note Text	160			✓
BEGDOC#	Start Bates (including prefix) - No spaces	Note Text	60	✓	✓	✓
ENDDOC#	End Bates (including prefix) - No spaces	Note Text	60	✓	✓	✓
DOCID	Unique document Bates # or populate with the same value as Start Bates (DOCID = BEGDOC#)	Note Text	60	✓	✓	✓
PGCOUNT	Page Count	Integer	10	✓	✓	✓
PARENTID	Parent's DOCID or Parent's Start Bates (for EVERY document including all Child documents)	Note Text	60	✓	✓	✓
ATTACHIDs	Child document list; Child DOCID or Child Start Bates	Multi-Entry	60	✓	✓	✓
ATTACHLIST	List of Attachment Bates numbers	Multi Entry	Unlimited		✓	✓
BEGATTACH	Start Bates number of first attachment	Note Text	60	✓	✓	✓
ENDATTACH	End Bates number of last	Note	60	✓	✓	✓

Attachment B: Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

Field name	Field Description	Field Type	Field Value	Hard Copy	E-Mail	Other ESI
	attachment	Text				
PROPERTIES	Privilege notations, Redacted, Document Withheld Based On Privilege	Multi-Entry	Unlimited	✓	✓	✓
RECORD TYPE	File, E-mail, Attachment, or Hard Copy	Note Text	60	✓	✓	✓
FROM	Author - format: Last name, First name	Note Text	160		✓	✓
TO	Recipient- format: Last name, First name	Multi-Entry	Unlimited		✓	✓
CC	Carbon Copy Recipients - format: Last name, First name	Multi-Entry	Unlimited		✓	✓
BCC	Blind Carbon Copy Recipients - format: Last name, First name	Multi-Entry	Unlimited		✓	✓
SUBJECT	Subject/Document Title	Note Text	Unlimited		✓	✓
DOCDATE	Document Date/Date Sent - Format YYYY/MM/DD	Date Keyed	YYYY/MM/DD			✓
BODY	E-mail body, Other Electronic Document Extracted text, or OCR	Full Text	Unlimited	✓	✓	✓
TIMESENT	Time e-mail was sent	Time	10		✓	
DATECRTD	Date Created	Date	YYYY/MM/DD		✓	✓
DATESVD	Date Saved	Date	YYYY/MM/DD		✓	✓
DATEMOD	Date Last Modified	Date Keyed	YYYY/MM/DD		✓	✓
DATERCVD	Date Received	Date	YYYY/MM/DD		✓	
DATEACCD	Date Accessed	Date	YYYY/MM/DD		✓	✓
FILESIZE	File Size	Note Text	10			✓
FILENAME	File name - name of file as it appeared in its original location	Full Text	Unlimited			✓
APPLICATION	Application used to create native file (e.g. Excel, Outlook, Word)	Note Text	160		✓	✓
FILEPATH	Data's original source full folder path	Full Text	Unlimited		✓	✓
NATIVELINK	Current file path location to the native file	Full Text	Unlimited		✓	✓
FOLDERID	E-mail folder path (e.g. Inbox\Active) or Hard Copy container information (e.g. Folder or binder name)	Full Text	Unlimited	✓	✓	
PARAGRAPH	Subpoena/request paragraph number to which the document is responsive	Multi-Entry	Unlimited	✓	✓	✓

Attachment B: Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

Field name	Field Description	Field Type	Field Value	Hard Copy	E-Mail	Other ESI
HASH	Hash value (used for deduplication or other processing) (e-mail hash values must be run with the e-mail and all of its attachments)	Note Text	Unlimited		✓	✓
MESSAGEHEADER	Email header. Can contain IP address	Full Text	Unlimited		✓	
ATTACHMCOUNT	Number of attachments to an email	Note Text	10		✓	
FILETYPE	Identifies the application that created the file	Note Text	160		✓	✓
COMMENTS	Identifies whether the document has comments associated with it	Note Text	10		✓	✓

4. **De-duplication, Near-Duplicate Identification, Email Conversation Threading and Other Culling Procedures**
De-duplication of exact copies within a custodian's data may be done, but all "filepaths" must be provided for each duplicate document. The recipient shall not use any other procedure to cull, filter, group, separate or de-duplicate, etc. (i.e., reduce the volume of) responsive material before discussing with and obtaining the written approval of the Department. All objective coding (e.g., near dupe ID or e-mail thread ID) shall be discussed and produced to the Department as additional metadata fields.

5. **Hidden Text**
All hidden text (e.g. track changes, hidden columns, mark-ups, notes) shall be expanded and rendered in the image file. For files that cannot be expanded the native files shall be produced with the image file.

6. **Embedded Files**
All non-graphic embedded objects (Word documents, Excel spreadsheets, .wav files, etc.) that are found within a file shall be extracted and produced. For purposes of production the embedded files shall be treated as attachments to the original file, with the parent/child relationship preserved.

7. **Image-Only Files**
All image-only files (non-searchable .pdfs, multi-page TIFFs, Snipping Tool [and other] screenshots, etc., as well as all other images that contain text) shall be produced with associated OCR text and metadata/database fields identified in section 3 for "Other ESI."

8. **Hard Copy Records**
   a. All hard copy material shall reflect accurate document unitization including all attachments and container information (to be reflected in the PARENTID, ATTACHID, BEGATTACH, ENDATTACH and FOLDERID). Unitization in this context refers to identifying and marking the boundaries of documents within the collection, where a document is defined as the smallest physical fastened unit within a bundle. (e.g., staples, paperclips, rubber bands, folders, or tabs in a binder.) The first document in the collection represents the parent document and all other documents will represent the children.
   b. All documents shall be produced in black and white TIFF format unless the image requires color. An image "requires color" when color in the document adds emphasis to information in the document or is itself information that would not be readily apparent on the face of a black and white image. Images identified as requiring color shall be produced as color 300 dpi single-page JPEG files.

Attachment B: Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

c. All objective coding (e.g., document date or document author) should be discussed and produced to the Department as additional metadata/database fields.

9. **Production of Spreadsheets and Presentation Files.** All spreadsheet and presentation files (e.g. Excel, PowerPoint) shall be produced in the unprocessed "as kept in the ordinary course of business" state (i.e., in native format). *See* section 18 below. The file produced should maintain the integrity of all source, custodian, application, embedded and related file system metadata. No alteration shall be made to file names or extensions for responsive native electronic files.

10. **Production of Email Repositories**
Email repositories, also known as email databases (e.g., Outlook .PST, Lotus .NSF, etc.), can contain a variety of items, including: messages, calendars, contacts, tasks etc. For purposes of production, responsive items shall include the "Email" metadata/database fields outlined in section 3, including but not limited to all parent items (mail, calendar, contacts, tasks, notes, etc.) and child files (attachments of files to email or other items) with the parent/child relationship preserved. Email databases from operating systems other than Microsoft Exchange shall be produced after consultation with and written consent of the Department about the format for the production of such databases.

11. **Production of Items Originally Generated in E-Mail Repositories but Found and Collected Outside of Email Repositories, i.e., "Stand-alone" Items**
Any parent email or other parent items (e.g., calendar, contacts, tasks, notes, etc.) found and collected outside of email repositories (e.g., items having extensions like .MSG, .HTM, .MHT, etc.), shall be produced items with the "Email" metadata fields outlined in section 3, including but not limited to any attachments, maintaining the family (parent/child) relationship.

12. **Production of Instant Messenger (IM), Voicemail Data, Audio Data, Video Data, etc.**
The responding party shall identify, collect, and produce any and all data which is responsive to the requests which may be stored in audio or video recordings, cell phone/PDA/Blackberry/smart phone data, voicemail messaging data, instant messaging, text messaging, conference call data and related/similar technologies. However, such data, logs, metadata or other files related thereto, as well as other less common but similar data types, shall be produced after consultation with and written consent of the Department about the format for the production of such data.

13. **Productions of Structured Data**
Prior to any production of responsive data from a structured database (e.g., Oracle, SAP, SQL, MySQL, QuickBooks, etc.), the producing party shall first provide the database dictionary and a list of all reports that can be generated from the structured database. The list of reports shall be provided in native Excel (.xls) format.

14. **Productions of Structured Data from Proprietary Applications**
Prior to any production of structured data from proprietary applications (e.g., proprietary timekeeping, accounting, sales rep call notes, etc.) the producing party shall first provide the database dictionary and a list of all reports that can be generated from the structured database. The list of reports shall be produced in native Excel (.xls) format.

15. **Production of Photographs with Native File or Digitized ESI**
Photographs shall be produced as single-page .JPG files with a resolution equivalent to the original image as it was captured/created. All .JPG files shall have extracted metadata/database fields provided in a Concordance® load file format as outlined in section 3 for "Other ESI."

Attachment B: Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

16. **Images from which Text Cannot be OCR Converted**
An exception report shall be provided when limitations of paper digitization software/hardware or attribute conversion do not allow for OCR text conversion of certain images. The report shall include the electronic Bates, document id or Bates number(s) corresponding to each such image.

17. **Format of ESI from Non-PC or Windows-based Systems**
If responsive ESI is in non-PC or non-Windows-based Systems (e.g., Apple, IBM mainframes and UNIX machines), the ESI shall be produced after discussion with and written consent of the Department about the format for the production of such data.

18. **Production of Native Files (When Applicable Pursuant to These Specifications)**
Productions of native files, as called for in these specifications, shall have extracted metadata/database fields provided in a Concordance® load file format as defined in the field specifications for "Other ESI" as outlined in section 3.

a. ESI shall be produced in a manner which is functionally useable by the Department. The following are examples:
   - AutoCAD data, e.g., .DWG, .DXF, shall be processed/converted and produced as single-page .JPG image files and accompanied by a Concordance® Image formatted load as described above. The native files shall be placed in a separate folder on the production media and linked by a hyperlink within the text load file.
   - GIS data shall be produced in its native format and be accompanied by a viewer such that the mapping or other data can be reviewed in a manner that does not detract from its ability to be reasonably understood.
   - Audio and video recordings shall be produced in native format and be accompanied by a viewer if such recordings do not play in a generic application (e.g., Windows Media Player).

19. **Bates Number Convention**
All images should be assigned Bates numbers before production to DOJ. The numbers should be "endorsed" (or "burned in") on the actual images. Native files should be assigned a single bates number for the entire file. The Bates number shall not exceed 30 characters in length and shall include leading zeros in the numeric portion. The Bates number shall be a unique name/number common to each page (when assigned to an image) or to each document (when assigned to a native file). If the Department agrees to a rolling production, the naming/numbering convention shall remain consistent throughout the entire production. There shall be no spaces between the prefix and numeric value. If suffixes are required, please use "dot notation." Below is a sample of dot notation:

PREFIX0000001	PREFIX0000003
PREFIX0000001.001	PREFIX0000003.001
PREFIX0000001.002	PREFIX0000003.002

20. **Media Formats for Storage and Delivery of Production Data**
Electronic documents and data shall be delivered on any of the following media:
a. CD-ROMs and/or DVD-R (+/-) formatted to ISO/IEC 13346 and Universal Disk Format 1.02 specifications.
b. External hard drives, USB 2.0 (or better) or eSATA, formatted to NTFS format specifications.
c. Storage media used to deliver ESI shall be appropriate to the size of the data in the production.
d. Media should be labeled with the case name, production date, Bates range, and producing party.

Attachment B: Specifications for Production of ESI and Digitized ("Scanned") Images ("Production Specifications")

21. **Virus Protection and Security for Delivery of Production Data**
Production data shall be free of computer viruses. Any files found to include a virus shall be quarantined by the producing party and noted in a log to be provided to the Department. Password protected or encrypted files or media shall be provided with corresponding passwords and specific decryption instructions. No encryption software shall be used without the written consent of the Department.

22. **Compliance and Adherence to Generally Accepted Technical Standards**
Production shall be in conformance with standards and practices established by the National Institute of Standards and Technology ("NIST" at www.nist.gov), U.S. National Archives & Records Administration ("NARA" at www.archives.gov), American Records Management Association ("ARMA International" at www.arma.org), American National Standards Institute ("ANSI" at www.ansi.org), International Organization for Standardization ("ISO" at www.iso.org), and/or other U.S. Government or professional organizations.

23. **Read Me Text File**
All deliverables shall include a read me text file at the root directory containing: total number of records, total number of images/pages or files, mapping of fields to plainly identify field names, types, lengths and formats. The file shall also indicate the field name to which images will be linked for viewing, date and time format, and confirmation that the number of files in load files matches the number of files produced.

24. **Exception Log**
An Exception Log shall be included documenting any production anomalies utilizing the electronic Bates number (document id or control numbering) assigned during the collection, processing and production phases.

-XXX-

Attachment C: Documents Requested

You are required by this Demand to produce any and all of the following documents in your possession, custody or control:

1. Documents sufficient to identify your education and professional background.

2. Documents concerning any PODs in which you have invested at any time, including without limitation RELIANCE.

3. Documents concerning RELIANCE, including without limitation:

   a. documents provided by you to RELIANCE;
   b. documents provided to you by RELIANCE;
   c. documents concerning payments from RELIANCE to you;
   d. documents concerning payments from you to RELIANCE;
   e. Documents concerning communications or meetings between you and RELIANCE, or between you and any actual or potential RELIANCE investor.

4. Medical Records and all other documents pertaining to all patients that you have treated at any time using RELIANCE products.

5. Documents reflecting any communications with any state or other licensing authority concerning your practice of medicine.

Attachment D: Interrogatories

1. Identify all privately held companies of which YOU are the owner or part-owner, including the principal business address and phone, place of incorporation, and the identities of the other owners, officers, and directors, and their business and residential address and phone numbers.

2. Identify YOUR assets, including assets owned jointly, including:

    a. All checking accounts by location, including the value of all accounts;
    b. All savings accounts by location, including the value of all accounts;
    c. All investment accounts through which YOU hold stocks, bonds, mutual fund shares, or other securities, including the value of all accounts;
    d. All real estate, including address, contract price, principal amount still owing, and amount of next payment due;
    e. All life insurance policies, including company, face amount, and cash surrender value;
    f. All real and personal property owned by YOUR spouse or dependent valued in excess of $10,000;
    g. All transfers of property valued in excess of $10,000 that YOU have made within the last three years, including transfers by loan, gift, or sale.

Attachment E: Primary Areas of Inquiry

1. Your background, training, and licensure.

2. Spinal fusion surgery generally, including without limitation:

    a. Protocols for determining a patient is a good candidate for spinal fusion;
    b. Risks associated with spinal fusion;
    c. Standard(s) of care associated with specific spinal fusion procedures;
    d. Particular spinal fusion surgeries that you have performed.

3. RELIANCE devices generally, including without limitation the design of such devices and your contribution, if any, to this design.

4. Communications with patients about RELIANCE, including without limitation communications concerning your financial interest in RELIANCE.

5. Communications with health care facilities about RELIANCE products, including without limitation your financial interest in RELIANCE.

6. Communications with RELIANCE, including without limitation:

    a. Communications concerning investment risk;
    b. Communications concerning actual, expected, or possible returns;
    c. Communications concerning the requirements for investment;
    d. Communications concerning RELIANCE's compliance with Federal health care statutes and regulations, including without limitation the Anti-Kickback Statute;
    e. Communications concerning your utilization of RELIANCE products in surgeries;
    f. Communications about payments or other benefits provided to you by RELIANCE;
    g. Communications with other RELIANCE INVESTORS.

7. Patients' health outcomes of surgeries you have performed, including without limitation surgeries involving RELIANCE devices.

8. Medical records of your patients on whom you have used RELIANCE products.

9. Communications with any state or other licensing authority concerning your practice of medicine.

Kuntz Declaration, Exhibit B

AMENDED AND RESTATED OPERATING AGREEMENT OF Apex Medical Technologies, LLC

THIS AGREEMENT (this "Agreement") is between EVOLVE MEDICAL, INC., a Texas corporation, SEAN XIE, M.D. A MEDICAL CORPORATION, a California corporation, ARIA SABIT, a California corporation, PIKE INDUSTRIES, INC., a Florida corporation, and BERRY MEDICAL ENTERPRISES, INC., a Florida corporation as members of Apex Medical Technologies, LLC, a Florida limited liability company.

RECITALS

The parties to this Agreement are all of the initial members of Apex Medical Technologies, LLC, a Florida limited liability company (the "Company"). The parties intend by this Agreement to define their rights and obligations with respect to the Company's governance and financial affairs and to adopt regulations and procedures for the conduct of the Company's activities. Accordingly, they agree as follows:

ARTICLE 1: DEFINITIONS

1.1 Scope. For purposes of this Agreement, unless the language or context clearly indicates that a different meaning is intended, capitalized terms have the meanings specified in this Article 1.

1.2 Defined Terms.

(a) "Act" means the Florida Limited Liability Company Act.

(b) "Affiliate," with respect to a Person, means (1) a Person that, directly or indirectly, through one or more intermediaries, controls, is controlled by or is under common control with the Person, (2) a Person who owns or controls at least ten percent of the outstanding voting interests of the Person, (3) a Person who is an officer, director, manager or general partner of the Person, or (4) a Person who is an officer, director, manager, general partner, trustee or owns at least ten percent of the outstanding voting interests of a Person described in clauses (1) through (3) of this sentence.

(c) "Agreement" means this agreement, including any amendments.

(d) "Articles" means the articles of organization filed with the Office of the Secretary of State to organize the Company as a limited liability company, including any amendments.

(e) "Available Funds," for a Taxable Year, means the Company's gross cash receipts from any source, less the sum of (1) payments of principal, interest, charges and fees then due pertaining to the Company's indebtedness; (2) expenditures incurred incident to the usual conduct of the Company's business; and (3) amounts reserved to meet the reasonable

current and anticipated needs of the Company's business.

(f) "Bankruptcy," with respect to a Member, means (1) the Member's general assignment for the benefit of creditors, (2) the filing of a petition or answer seeking for the Member any reorganization, arrangement, composition, readjustment, liquidation, dissolution, protection or similar relief in any state or federal bankruptcy, insolvency, reorganization or receivership proceeding or (3) the filing of an answer or other pleading admitting or failing to contest the material allegations of a petition filed against the Member in any state or federal bankruptcy, insolvency, reorganization or receivership proceeding.

(g) "Capital Account" of a Member means the capital account maintained for the Member in accordance with Article 4.5.

(h) "Capital Investment" of a Member means an amount equal to the excess of the cumulative value of the Member's Contributions of cash and property over the cumulative value of all prior Distributions to the Member out of the Member's Capital Investment pursuant to Article 4.4. For purposes of this definition, the value of any Contribution or Distribution of property in kind is as recorded on the Company's books at the time of the Contribution or Distribution.

(i) "Code" means the Internal Revenue Code of 1986, as amended.

(j) "Company" means Apex Medical Technologies, LLC and any successor limited liability company.

(k) "Competing Activity" means an activity that competes with or is benefitted by the Company's present or prospective activities. A passive investment in an Entity engaged in a Competing Activity is itself a Competing Activity only if the investor and the Entity are Affiliates.

(l) "Contribution" means anything of value that a Member contributes to the Company as a prerequisite for or in connection with membership, including any combination of cash, property, services rendered, a promissory note or any other obligation to contribute cash or property or render services.

(m) "Dissolution," with respect to an Entity, means (1) the filing of articles of dissolution on the Entity's behalf, (2) the Entity's administrative dissolution, unless the Entity is reinstated within the time period prescribed by applicable law or (3) any other event that initiates the Entity's winding up under applicable law.

(n) "Dissociation" means a complete termination of a Member's membership in the Company in consequence of an event described in Article 3.9.

(o) "Distribution" means the Company's direct or indirect transfer of money or other property with respect to Membership Units, other than (1) issuance of Membership Units, (2) issuance of evidence of indebtedness, (3) reasonable compensation for past or present services or (4) reasonable payments made in the ordinary course of business pursuant to a bona fide retirement plan or other benefits program.

(p) "Effective Date," with respect to this Agreement, means the date on which the Company's existence as a limited liability company begins, as prescribed by the Act.

(q) "Entity" means an association, relationship or artificial person through or by means of which an enterprise or activity may be lawfully conducted, including, without limitation, a domestic or foreign corporation, nonprofit corporation, limited liability company, general partnership, limited partnership, business trust, association, trust, estate, joint venture, cooperative or governmental unit.

(r) "Incapacity," with respect to a Member or Manager, means impairment by reason of mental illness, mental deficiency, physical illness or disability, chronic use of drugs, chronic intoxication or other cause to the extent the Member or Manager lacks sufficient understanding or capacity to make or communicate responsible decisions.

(s) "Manager" means a Person, whether or not a Member, who is vested with authority to manage the Company in accordance with Article 5.

(t) "Member" means an initial Member and any Person who subsequently is admitted as an additional or substitute Member after the Effective Date, in accordance with Article 3. 1(b).

(u) "Membership Units" means a Member's interest in the Company, consisting of the Member's right to share in Profits, receive Distributions, participate in the Company's governance, approve the Company's acts, participate in the designation and removal of a Manager and receive information pertaining to the Company's affairs. The Membership Units of the initial Members are set forth in Article 3.1(a). Changes in Membership Units after the Effective Date, including those necessitated by the admission and Dissociation of Members, will be reflected in the Company's records. The allocation of Membership Units reflected in the Company's records from time to time is presumed to be correct for all purposes of this Agreement and the Act.

(v) "Minimum Gain" means minimum gain as defined in sections 1.704-2(b)(2) and 1.704-2(d) of the Regulations.

(w) "Person" means a natural person or an Entity.

(x) "Profit," as to a positive amount, or "Loss," as to a negative amount, means, for a Taxable Year, the Company's net taxable income or loss for the Taxable Year, as determined in accordance with section 703(a) of the Code, with the following adjustments: (1) all items required to be separately stated pursuant to section 703(a)(1) of the Code will be accounted for in the aggregate, (2) any income that is exempt for federal income tax purposes will be included; and (3) any item that is specially allocated pursuant to Article 4.2(b) will be disregarded.

(y) "Regulations" means proposed, temporary or final regulations promulgated under the Code by the Department of the Treasury, as amended.

(z) "Tax Percentage," for a Taxable Year, means the sum of (1) the highest federal income tax rate applicable to the taxable income of an individual and (2) the highest state income tax rate applicable to the taxable income of an individual resident.

(aa) "Taxable Year" means the Company's taxable year as determined in accordance with Article 6.2.

(bb) "Transfer," as a noun, means a transaction or event by which ownership of Membership Units is changed, including, without limitation, a sale, exchange, distribution, abandonment, gift, devise or foreclosure. "Transfer," as a verb, means to effect a Transfer.

(cc) "Transferee" means a Person who acquires Membership Units by Transfer from a Member or another Transferee and is not admitted as a Member in accordance with Article 3.1(b).

ARTICLE 2: THE COMPANY

2.1 Status. The Company is a Florida limited liability company organized under the Act.

2.2 Name. The Company's name is Apex Medical Technologies, LLC.

2.3 Term. The Company's existence commenced on the Effective Date and will continue until terminated under this Agreement.

2.4 Purposes. Building upon the significant experience and familiarity that the Physician Members will have in performing spinal implant surgeries, the Company will focus on advancing and improving existing and new technologies in the practice of spinal surgery, with an emphasis on developing more cost-effective methods to improve products and procedures that will result in better patient outcomes. In addition, the Company is organized for any lawful business or purpose allowed by the Act, including, without limitation, to acquire by purchase, exchange, lease or otherwise real and personal property of every kind, character and description,

wherever located, and interests of all kinds therein, and (a) to hold, own, improve, manage, operate, lease and mortgage such property; (b) to sell and/or exchange such property and interests therein; (c) to obtain, use, sell, dispose of and deal in and with such property in every other manner, either alone or in conjunction with others, as partners, members, joint venturers or otherwise; and (d) to carry on the business of managing agent, broker, finder, consultant and all other functions in connection therewith.

2.5 Designated Office and Registered Agent.

(a) Designated Office.

(1) The Company's registered office is its Designated Office.

(2) The Company at any time may change the location of its Designated Office by filing a statement of change with the Secretary of State within 30 days after the effective date of the change.

(b) Registered Office and Agent.

(1) The Company's initial registered office is located at 11313 Mandarin Ridge Lane, Jacksonville, FL 32258 and its initial registered agent at that location is Barbara Naif.

(2) The Company at any time may change the location of its registered office or the identity of its registered agent by filing a statement of change with the Secretary of State within 30 days after the effective date of the change. However, the location of the registered agent's business office must remain the same as the location of the Company's registered office.

(3) If the location of the registered agent's business office changes, the registered agent may change the location of the Company's registered office by giving written notice of the change to the Company and filing a statement of change with the Secretary of State within 30 days after the effective date of the change.

2.6 Compliance. The Company understands the need to develop and maintain a voluntary compliance program to assist the Company in preventing the submission of erroneous claims or engaging in unlawful conduct involving the Federal health care programs. The goal of voluntary compliance program will be to provide a tool to strengthen the efforts of the Company to prevent and reduce improper conduct. The following list of components, as set forth in the Office of Inspector General compliance program guidance, will form the basis of the compliance plan; Conducting internal monitoring and auditing through the performance of periodic audits; Implementing compliance and practice standards through the development of written standards and procedures; Designating a compliance officer or contact(s) to monitor compliance efforts and enforce practice standards; Conducting appropriate training and education on practice

standards and procedures; Responding appropriately to detected violations through the investigation of allegations and the disclosure of incidents to appropriate Government entities; Enforcing disciplinary standards through well-publicized guidelines.

2.6 Guiding Principals. It is Company's policy that all sales of spinal implant products comply with the Stark Law and the Anti-Kickback Statute. The following guidelines will enable the Company to conducts its operations within the law;

(a) The Company will hire and employ its own employees and contractors.

(b) The Company will manage its own inventory.

(c) The Company will have its own distinct office and warehouse space for operation of its own business.

(d) The Company's products will be shipped to the Company by the manufacturers/distributors and will be separately warehoused by the Company before resale to hospitals or surgery centers.

(e) The Company will hold any and all licenses or governmental approvals necessary for operation of its business.

(f) The investment price (i.e., price per membership Unit) offered to physician investors is not be based on the projected sales volumes generated by surgeries from the physician investors, nor is the amount being offered to physician investors reflect the anticipated sales generated from the physician investors' procedures. Any investment terms offered to non-Physician Investors is at least as favorable as those offered to physician investors, and any compensation paid to non-physician investors for management or related services is not below fair market value.

(g) No physician investor's investment interest (i.e., membership Unit) will be subject to repurchase for failure to use the Company's devices in such physician's surgeries.

(h) The physician investors will not be pressured in any way to utilize the Company's devices in their surgeries.

(i) The physician investors will not exert pressure on the hospitals or surgery centers to purchase the devices from the Company.

(j) The Company will be adequately capitalized for its operations through the capital contributions of its physician and non-physician investors and the physician investors' investments will not be nominal.

(k) The physician and non-physician investor's capital contributions will not come from the manufacturers/distributors that sell devices to the Company.

(l) No investment in the Company will be financed or guaranteed by any other investor or the Company, and no loans will be made to the physician investors from the non-physician investors.

(m) The Company will not have any financial relationships with physician investors other than the investment and product sale relationships with the Company.

(n) The use of the devices will at all times be medically necessary.

(o) The Company will not bill patients or payors (including Medicare and Medicaid) or any third parties for the devices.

(p) The Company will have written agreements with the manufacturers/distributors for purchase of the devices

(q) The Company will have written agreements with the purchasers, hospitals or surgery centers, for the sale of the devices.

(r) The purchasers, hospitals or surgery centers will be charged a fixed price based on negotiations, which will not increase with the use of more devices.

(s) The Company will generally have a fixed list of prices that will be generally available to all purchasers, hospitals or surgery centers. However, the Company may be willing to accept lower pricing if the purchaser dictates lower fixed pricing. The payments by the purchasers will not be higher than fair market value for the devices.

(t) The Company's products will be of high quality and FDA approved.

(u) The Company will not enter into any consignment arrangement with any of its vendors with respect to the Company's products; instead, any relationship between the Company and its vendors shall only consist of true sales.

(v) The return on investment received by each investor in the Company will be directly proportionate to such investor's ownership interest, without regard to the volume of devices used by such investor.

(w) The Company will not have the right to repurchase any investor's interest for failing to use the Company's products (or failing to use any particular volume of such products).

(x) To the extent case coverage is required for a surgery that involves the Company's products, the Company shall cover the costs associated with such case coverage.

ARTICLE 3: RIGHTS AND OBLIGATIONS OF MEMBERS

3.1 Identification.

(a) Initial Members. The names, addresses and Membership Units of the initial Members are as follows:

EVOLVE MEDICAL, INC. ATTN: JOHN HOFFMAN, PRESIDENT 237 SENISA DRIVE SAN ANTONIO, TX 78227	10 UNITS
SEAN XIE, M.D., A MEDICAL CORPORATION ATTN: SEAN XIE, PRESIDENT 1245 WILSHIRE BLVD #305 LOS ANGELES, CA 90017	10 UNITS
ARIA SABIT ATTN: ARIA SABIT, PRESIDENT 1495 BRODIEA AVE. VENTURA, CA 93001	10 UNITS
PIKE INDUSTRIES, INC. ATTN: ADAM A. PIKE, PRESIDENT 11313 MANDARIN RIDGE LANE JACKSONVILLE, FL 32258	10 UNITS
BERRY MEDICAL ENTERPRISES, INC. ATTN: BRET M. BERRY, PRESIDENT 514 FRANK SHAW ROAD TALLAHASSEE, FL 32312	10 UNITS

(b) Additional and Substitute Members. The Company may admit additional or substitute Members only with the approval of the Manager and Members whose aggregate Membership Units issued exceeds fifty percent (50%) of the total Membership Units issued and outstanding. A Member may withhold approval of the admission of any person for any or no reason.

(c) Rights of Additional or Substitute Members. A Person admitted as an additional or substitute Member has all the rights and powers and is subject to all the restrictions and obligations of a Member under this Agreement and the Act.

3.2 Verification of Membership Units. Within 10 days after receipt of a Member's written request, the Company will provide the Member with a statement of the Member's Membership Units. The statement will serve the sole purpose of verifying the Member's

Membership Units, as reflected in the Company's records, and will not constitute for any purpose a certificated security, negotiable instrument or other vehicle by which a Transfer of Membership Units may be effected.

3.3 Manner of Acting.

(a) Meetings.

(1) Right to Call. Any Manager or any Member or combination of Members whose Membership Units exceeds 10 percent of all of the Membership Units issued and outstanding may call a meeting of Members by giving written notice to all Members not less than 10 nor more than 60 days prior to the date of the meeting. The notice must specify the date of the meeting and the nature of any business to be transacted. If a Member fails to attend two or more consecutive meetings, then the remaining Members may elect by a majority vote of the outstanding Units to have the Company purchased the absent Members Units at the then current book value of those Units (as determined by the Company's accountant) after the Company provides such absent Member thirty (30) days notice. Each Member specifically appoints each Member, with full power of substitution, as the Member's attorney-in-fact, to act in the Member's name to execute all documents and instruments that effect or confirm the purchase of the absent Member's Units pursuant to this Agreement.

(2) Proxy Voting. A Member may act at a meeting of Members through a Person authorized by a written proxy signed by the Member and filed with the secretary of the meeting before or at the time of the meeting.

(3) Quorum. Members whose aggregate Membership Units exceed fifty percent (50%) of the total Membership Units issued and outstanding will constitute a quorum at a meeting of Members. No action may be taken in the absence of a quorum.

(4) Required Vote. Except with respect to matters for which a greater minimum vote is required by this Agreement, the vote of Members present whose aggregate Membership Units exceed fifty percent (50%) of the total Membership Units issued and outstanding will constitute the act of the Members at a meeting of Members.

(b) Written Consent. The Members may act without a meeting by written consent describing the action and signed by Members whose aggregate Membership Units exceed the minimum number of issued and outstanding Membership Units that would be necessary to take the action at a meeting at which all Members were present. The Company will give written notice of any action approved by written consent to each Member who does not

join in the written consent. The notice must contain or be accompanied by a description of the action approved by the written consent and be delivered to the Member at least five days before consummation of the action approved by the written consent.

3.4 Limitation on Individual Authority. A Member who is not also a Manager has no authority to bind the Company. A Member whose unauthorized act obligates the Company to a third party will indemnify the Company for any costs or damages the Company incurs as a result of the unauthorized act.

3.5 Negation of Fiduciary Duties. A Member who is not also a Manager owes no fiduciary duties to the Company or to the other Members solely by reason of being a Member. A Member may participate, directly or indirectly, in a Competing Activity.

3.6 Withdrawal of a Member. A Member at any time may withdraw from the Company by giving written notice to the Company and the other Members at least 60 days prior to the effective date of the withdrawal.

3.7 Expulsion of a Member.

(a) Majority Vote. The Company may expel a Member, with or without cause, but only with the approval of the Manager and Members whose aggregate Membership Units exceed eighty percent (80%) of the total Membership Units issued and outstanding. A Member's expulsion from the Company will be effective upon the Member's receipt of written notice of the expulsion.

(b) Disclosure of Proprietary Information. The Members acknowledge that the Company's patient lists, charts and records, the Company's business records and other items defined below (collectively "Proprietary Information") are confidential and derive independent economic value from not being generally known to other persons, and that such Information constitutes principal assets of the Company. Therefore, the Members agree to hold in confidence any and all Proprietary Information which the Members may at any time have access to and agree not to disclose any such Proprietary Information to any third party, except as expressly authorized herein or by the Company's Managers. The Members agree to use their best efforts to prevent disclosure of Proprietary Information to any third person or organization, and further agree that disclosure of such Proprietary Information will be made only to the Company's employees who must have access thereto in order to perform services for the Company. The Company may expel a Member upon the Member's unauthorized disclosure of Proprietary Information as determined in the Managers' sole and absolute discretion. A Member's expulsion from the Company will be effective upon the Member's receipt of written notice of the expulsion, and such notice shall specify the particular act(s) or failure(s), which is or are Company's reasons for terminating the Agreement.

(b) For Cause. The Company shall have the right to expel a Member for Cause at any time upon written notice. For purposes of this Agreement, "Cause" shall be deemed to exist in the event of a Member's: (i) material breach of his duties or covenants hereunder; (ii) self-dealing, dishonesty, fraud or misrepresentation which is intended to result in gain or personal enrichment for the Member at the expense of the Company; (iii) failure or refusal to comply with the policies, procedures, rules, standards or regulations of the Company; (iv) violation of any law or regulation applicable to the Company's business, which violation, in the reasonable good faith determination of the Company, is or is reasonably likely to be injurious to the Company; (v) indictment, conviction or plea of nolo contendere or guilty to a felony or to any crime which involves moral turpitude.

3.8 Transfer of Membership Units.

(a) Transfers Prohibited. A Member may not Transfer, directly or indirectly, any Membership Units without the Manager's and Members (whose aggregate Membership Units are at least eighty percent (80%) of the total issued and outstanding Membership Units) prior written consent. With respect to a Member that is an Entity, a change in the control of the Member is an indirect Transfer for purposes of this Article 3.8. A change in control occurs if in consequence of a Transfer of an interest in the Member any Person ceases to be an Affiliate of any other Person. Notwithstanding, the above restriction, a Member may transfer their Memberships Units to an existing Member without restriction if the Manager consents to such transfer in writing.

(b) Prohibited Transfers Void. If a Member attempts to Transfer any Membership Units in contravention of the provisions of this Article 3.8, the purported Transfer will be null and void.

(c) Transferor's Membership Status. If a Member Transfers less than all of their Membership Units, the Member's rights with respect to the transferred portion, including the right to vote or otherwise participate in the Company's governance and the right to receive Distributions, will terminate as of the effective date of the Transfer. However, the Member will remain liable for any obligation with respect to the transferred portion that existed prior to the effective date of the Transfer, including any costs or damages resulting from the Member's breach of this Agreement. If the Member Transfers all of the Membership Units, the Transfer will constitute an event of Dissociation for purposes of Article 3.9.

(d) Transferee's Status.

(1) Admission as a Member. A Member who Transfers Membership Units has no power to confer on the Transferee the status of a

Member. A Transferee may be admitted as a Member only in accordance with the provisions of Article 3.1(b). A Transferee who is not admitted as a Member has only the rights described in this Article 3.8.

(2) Rights of Non-Member Transferee. A Transferee who is not admitted as a Member in accordance with the provisions of Article 3.1(b), (i) has no right to vote or otherwise participate in the Company's governance, (ii) is not entitled to receive information concerning the Company's affairs or inspect the Company's books and records, (iii) with respect to the transferred Membership Units, is entitled to receive the Distributions to which the Member would have been entitled had the Transfer not occurred and (iv) is subject to the restrictions imposed by this Article 3.8 to the same extent as a Member.

3.9 Dissociation.

(a) Events of Dissociation. A Member's Dissociation from the Company occurs upon: (1) the Member's withdrawal or expulsion from the Company; (2) the Member's Transfer of the all of the Member's Membership Units; (3) as to a Member who is a natural person, the Member's Incapacity or death; (4) the Member's Bankruptcy; (5) as to a Member who holds Membership Units as a fiduciary, distribution of the all of the Membership Units to the beneficial owners; or (6) as to a Member that is an Entity, the Entity's Dissolution.

(b) Rights of Member Following Dissociation.

(1) If a Member's Dissociation occurs for any reason other than the Member's Incapacity or death, then, after the effective date of the Member's Dissociation, (i) the Member will have no right to vote or otherwise participate in the Company's governance and affairs, (ii) except as provided in Article 6.1(b), the Member will not be entitled to receive information concerning the Company's affairs or inspect the Company's books and records and (iii) if the event that results in the Member's Dissociation does not terminate the Member's entire interest in the Company's profits and capital, then, with respect to the interest the Member retains, the Member will be entitled to receive the Distributions to which the Member would have been entitled had the Dissociation not occurred. Except as provided in this paragraph, a dissociating Member will have no right to receive Distributions or otherwise participate in the Company's financial affairs.

(2) If a Member's Dissociation occurs by reason of the Member's Incapacity or death, the Member's legal representative may exercise the Member's rights under this Agreement and the Act for

the sole purpose of settling the Member's estate or administering the Member's property, as the case may be.

(3) Notwithstanding the foregoing provisions of this Article 3.9(b), a dissociating Member will remain liable for any obligation to the Company that existed prior to the effective date of the Dissociation, including any costs or damages resulting from the Member's breach of this Agreement.

3.10 Redemption of Dissociating Member's Interest.

(a) Optional Redemption.

(1) If a Member's Dissociation is a result of Bankruptcy, incapacity, death, dissolution, expulsion, or withdrawal, at any time within 180 days after the effective date of the Dissociation, the Company shall redeem not less than all of the Member's Membership Units on the terms set forth below.

(2) The Company shall exercise its right to redeem the Membership Units by giving written notice to the Member or the Member's successor in interest (the "seller") within the 180-day exercise period. The notice must specify the redemption price and payment terms and indicate a closing date within 60 days after the date the notice is delivered.

(b) Redemption Price.

(1) The redemption price of the Membership Units will be an amount equal to the Company's value as of the effective date of the Dissociation, multiplied by a percent, that is calculated by taking the redeemed Membership Units divided by the total Membership Units issued and outstanding.

(2) For the purpose of determining the redemption price, the Company's value will be the value determined by unanimous agreement of the Members at one-year intervals, as set forth on the Schedule of Values attached to this Agreement.

(3) If the Members fail to predetermine the Company's value for two successive years, the redemption price of the Membership Units shall be an amount equal to its fair market value as of the effective date of the Dissociation, as determined by a qualified appraiser acceptable to the Company and the seller. In determining the fair market value of the Membership Units, the appraiser shall consider only those factors that are relevant to the valuation of the interest as an interest in a going concern and shall be guided by the Business Valuation Standards of the American Society of

Appraisers.

(4) The determination of the redemption price will be made by an independent qualified appraiser selected by the Company. The Company will pay all costs associated with the determination of the redemption price.

(c) Payment Terms. The Company will pay the redemption price at the closing in the form of its promissory note in the principal amount of the purchase price payable in five equal annual installments, with interest compounded quarterly at the applicable Federal rate in effect under Code § 1274(d) for an obligation with the same terms, determined as of the date the Company gives the seller notice of the redemption.

ARTICLE 4: FINANCE

4.1 Contributions.

(a) Members Contribution. Each Member has made contributions for their acquisition of the initial Membership Units.

(b) Additional Members. A Person admitted as a Member in connection with the acquisition of Membership Units Interest directly from the Company after the Effective Date will make the Contributions specified in the agreement pursuant to which the Person is admitted as a Member.

(c) Additional Contributions.

(1) Permitted. The Company may authorize additional Contributions at such times and on such terms and conditions as it determines to be in its best interest.

(2) Required. If at any time the Company determines that its financial resources are insufficient to meet the reasonable needs of its business, it may require the Members to make additional Contributions sufficient to meet those needs. The Members will make the additional Contributions in proportion to their Membership Units. The Company must give each Member written notice of the obligation to contribute additional capital. The notice must explain the need for additional capital, specify the amount the Member is required to contribute and establish a due date that is not less than 30 days after the date of the notice; The Member will make the Contribution in immediately available funds on or before the due date specified in the notice.

(3) Default Remedies. If a Member does not contribute the Member's share of a required additional Contribution on or before the due date, the Company may (i) take such action as it considers necessary or appropriate to enforce the Member's obligation or (ii) accept Contributions from the other Members in satisfaction of the defaulting Member's obligation, in proportion to their Membership Units. If the Company accepts Contributions from other Members, the Membership Units of each Member will be adjusted to correspond to the ratio that the Capital Investment of the Member bears to the aggregate Capital Investment of all Members, adjusted to reflect the Contributions made by other Members in satisfaction of the defaulting Member's obligation.

(4) Creditors' Rights. A Member's obligation to make additional contributions extends only to the Company and may not be enforced by the Company's creditors without the Member's written consent.

(d) Contributions Not Interest Bearing. A Member is not entitled to interest or other compensation with respect to any cash or property the Member contributes to the Company,

(e) No Return of Contribution. A Member is not entitled to the return of any Contribution prior to the Company's dissolution and winding up.

4.2 Allocation of Profit and Loss.

(a) General Allocation. The Company's Profit or Loss for a Taxable Year, including the Taxable Year in which the Company is dissolved, will be allocated among the Members in proportion to their Membership Units.

(b) Special Allocations.

(1) If a Member unexpectedly receives an adjustment, allocation, or distribution described in sections 1.704-1(b)(2)(ii)(d)(4), (5) or (6) of the Regulations that creates or increases a deficit in the Member's Capital Account as of the end of a Taxable Year, a pro rata portion of each item of the Company's income, including gross income and gain for the Taxable Year and, if necessary, for subsequent years will be allocated to the Member in an amount and manner sufficient to eliminate the deficit in the Member's Capital Account as quickly as possible.

(2) If a Member would have a deficit in his or her Capital Account at the end of a Taxable Year that exceeds the sum of (i) the amount the Member is required to pay the Company pursuant to an obligation described in section 1.704-1(b)(2)(ii)(c) of the Regulations and (ii) the Member's share of Minimum Gain, a pro rata portion of each item of the Company's income, including gross income and gain, for the Taxable Year will be allocated to the Member in an amount and manner sufficient to eliminate the deficit in the Member's Capital Account as quickly as possible.

(3) If there is a net decrease in the Company's Minimum Gain during a Taxable Year, the items of the Company's income, including gross income and gain, for the Taxable Year and, if necessary, for subsequent Taxable Years will be allocated to the Members in proportion to their shares of the net decrease in Minimum Gain. If the allocation made by this paragraph would cause a distortion in the economic arrangement among the Members and it is expected that the Company will not have sufficient income to correct that distortion, the Company may seek to have the Internal Revenue Service waive the requirement for the allocation in accordance with section 1.704-2(f)(4) of the Regulations.

(4) Items of the Company's loss, deductions and expenditures described in section 705(a)(2)(B) of the Code that are characterized as "partner nonrecourse deductions" under Section 1.704-2(i) of the Regulations will be allocated to the Members according to the ratio in which the Members bear the economic risk of loss with respect to the nonrecourse liabilities to which such items are attributable.

(5) Items of income, gain, loss and deduction with respect to property contributed to the Company's capital will be allocated between the Members so as to take into account any variation between book value and basis, to the extent and in the manner prescribed by section 704(c) of the Code and related Regulations.

(6) If the special allocations required by this Article 4.2(b) result in Capital Account balances that are different from the Capital Account balances the Members would have had if the special allocations were not required, the Company will allocate other items of income, gain, loss and deduction in any manner it considers appropriate to offset the effects of the special allocations on the Members' Capital Account balances. Any offsetting allocation required by this paragraph is subject to and must be consistent with the special allocations.

(c) Effect of Transfers During Year. The Company will prorate items attributable to Membership Units that is the subject of a Transfer during a Taxable Year between the transferor and the Transferee based on the portion of the Taxable Year that elapsed prior to the Transfer.

4.3 Tax Allocations. For federal income tax purposes, unless the Code or Regulations otherwise requires, each item of the Company's income, gain, loss or deduction will be allocated to the Members in proportion to their allocations of the Company's Profit or Loss.

4.4 Distributions.

(a) Minimum Distribution to Pay Tax. Within 90 days after the close of each Taxable Year, the Company will distribute to each Member an amount equal to the product of the Tax Percentage and the Profit allocated to the Member for the Taxable Year.

(b) Remaining Available Funds. The Company will distribute to the Members, at quarterly intervals, any Available Funds remaining after providing for the Distribution required by the preceding paragraph.

(c) Allocation. Except as provided in Article 4.4(a), the Company will make all Distributions to the Members in proportion to their Membership Units.

(d) Prohibited Distributions. The Company may not make a Distribution if,

after giving effect to the Distribution, (1) the Company would not be able to pay its debts as they become due in the usual and regular course of its business or (2) the fair market value of the Company's total assets would be less than the sum of its total liabilities. The Company's determination of its capacity to make a Distribution under this Article 4.4(d) will be made as of the date and in accordance with a method authorized by section 48-2c-1005(2) of the Act.

(e) Negation of Right to Distribution in Kind. Except as provided in Article 7.2, a Member has no right to demand and receive a Distribution in a form other than cash.

(f) Obligation to Return Wrongful Distribution. If for any reason a Member receives a Distribution to which the Member, is not legally entitled, the Member will return the Distribution to the Company within 30 days after receiving notice of the wrongful Distribution.

(g) Waiver of Obligation to Return Rightful Distribution. Except to the extent required by the Act, a Member has no liability to return to the Company a Distribution to which the Member is legally entitled, regardless of the Company's inability to discharge its obligations to its Creditors.

4.5 Capital Accounts.

(a) General Maintenance. The Company will establish and maintain a Capital Account for each Member. A Member's Capital Account will be:

(1) increased by: (i) the amount of any money the Member contributes to the Company's capital; (ii) the fair market value of any property the Member contributes to the Company's capital, net of any liabilities the Company assumes or to which the property is subject; and (iii) the Member's share of Profits; and

(2) decreased by: (i) the amount of any money the Company distributes to the Member; (ii) the fair market value of any property the Company distributes to the Member, net of any liabilities the Member assumes or to which the property is subject; and (iii) the Member's share of Losses.

(b) Adjustments.

(1) Distributions in Kind. If at any time the Company distributes property in kind, it will adjust the Members' Capital Accounts to account for their shares of any Profit or Loss the Company would have realized had it sold the property at fair market value and distributed the sale proceeds.

(2) Acquisitions and Redemptions. If at any time a Person acquires

Membership Units from the Company or the Company redeems Membership Units, the Company will adjust the Members' Capital Accounts to account for their shares of any Profit or Loss the Company would have realized had it sold all of its assets at fair market value on the date of the acquisition or redemption.

(c) Transfer of Capital Account. A Transferee of Membership Units succeeds to the portion of the transferor's Capital Account that corresponds to the portion of the Membership Units that is the subject of the Transfer.

(d) Compliance with Code. The requirements of this Article 4.5 are intended and will be construed to ensure that the allocations of the Company's income, gain, losses, deductions and credits have substantial economic effect under the Regulations promulgated under section 704(b) of the Code.

ARTICLE 5: MANAGEMENT

5.1 Representative Management. The Company will be managed by Managers. The Members from time to time may establish and change the number of Managers. The names and business addresses of the Company's initial Managers are:

Adam A. Pike
11313 Mandarin Ridge Lane
Jacksonville, FL 32258

and

Bret M. Berry.
514 Frank Shaw Road
Tallahassee, FL 32312

5.2 Time Devoted to Business. A Manager will devote only the amount of time to the Company's activities as is reasonably necessary to discharge the Manager's responsibilities.

5.3 Powers and Authority. Except for matters on which the Members' approval is required by this Agreement, the Managers have full power, authority and discretion to manage and direct the Company's business, affairs and properties, including, without limitation, the specific powers conferred by the Act.

5.4 Manner of Acting.

(a) General. The Managers may act with respect to any matter within the scope of their authority at a meeting of Managers or pursuant to formal or informal procedures adopted at a meeting of Managers. Procedures that may be adopted at a meeting of Managers include, without limitation, the establishment of dates and times for regular meetings, procedures pursuant to which the Managers may approve a matter without a meeting and,

subject to the provisions of Article 5.7, the delegation of duties and responsibilities with respect to which the delegate may act without approval or ratification by the other Managers.

(b) Written Consent. The Managers may act without a meeting by written consent describing the action and signed by Managers whose voting power is at least equal to the minimum that would be necessary to take the action at a meeting at which all Managers were present. The Company will give written notice of any action approved by written consent to each Manager who does not join in the written consent. The notice must contain or be accompanied by a description of the action approved by the written consent and be delivered to the Manager at least five days before consummation of the action approved by the written consent.

(c) Required Approval. The decision of a majority in number of the Managers controls with respect to any matter arising within the scope of their authority. A Manager may be absolved from personal liability with respect to the matter by registering dissent from the decision in the Company's records within 30 days after receiving notice of the decision. A dissenting Manager will nevertheless act with the other Managers in any way necessary or appropriate to effectuate the decision of the majority.

(d) Participation by Non-Member Managers. The fact that a Manager is not also a Member in no way limits the Manager's right to vote on any matter properly within the scope of the Managers' authority under this Agreement.

5.5 Required Member Approval. Notwithstanding any other provision of this Agreement, without the approval of Members whose aggregate Membership Units exceed fifty one percent (51%) of the total Membership Units issued and outstanding, the Managers may take no action with respect to: the sale, lease, exchange, mortgage, pledge or other disposition of all or substantially all of the Company's assets; the Company's merger with or conversion into another Entity; acceptance of an additional Contribution voluntarily tendered by any Member; redemption of a Membership Units; Distributions in excess of Available Funds; and the indemnification of a Manager.

5.6 Agency Power and Authority. A Manager apparently acting for the Company in the usual course of its business has the power to bind the Company and no person has an obligation to inquire into the Manager's actual authority to act on the Company's behalf. However, if a Manager acts outside the scope of the Manager's actual authority or in contravention of a decision of the Managers, the Manager will indemnify the Company for any costs or damages it incurs as a result of the unauthorized act.

5.7 Delegation of Authority. A Manager at any time may delegate to any other Manager, in whole or in part, the delegating Manager's authority and powers to manage the Company's business, affairs and properties. Any such delegation must be effected by a written instrument that (a) specifies the scope and duration of the delegation, (b) reserves to the delegating Manager the power to revoke the delegation at any time and for any or no reason, (c)

prohibits substitution without the delegating Manager's written consent and (d) is signed by the delegating Manager and delivered to the delegate. While a delegation is in effect, the delegate may exercise the delegated authority and powers with the same force and effect as if the delegating Manager had personally joined in the exercise of the delegated authority and powers. However, the delegating Manager will not be liable for any action so taken. Delegation of a Manager's authority and powers pursuant to this Article 5.7 will not cause the delegating Manager to cease to be a Manager.

5.8 Fiduciary Duties.

(a) Standard of Care.

(1) Exculpation. A Manager will not be liable to the Company or any Member for an act or omission done in good faith to promote the Company's best interests, unless the act or omission constitutes gross negligence, willful misconduct or a knowing violation of law.

(2) Justifiable Reliance. A Manager may rely on the Company's records maintained in good faith and on information, opinions, reports or statements received from any Person pertaining to matters the Manager reasonably believes to be within the Person's expertise or competence.

(b) Conflicts of Interest.

(1) Competing Activities. A Manager may participate, directly or indirectly, in a Competing Activity.

(2) Company Opportunities. A Manager must disclose to the Company any business opportunity that the Manager believes or has reason to believe the Company would accept if brought to its attention. If the Company declines to accept the opportunity, and if the opportunity does not involve a Competing Activity, the Manager may pursue it for the Manager's own account. If the Manager fails to disclose the opportunity, the Manager will account to the Company for any income the Manager derives from the opportunity and will indemnify the Company for any loss the Company incurs as a result of the failure to disclose.

(c) Self-Dealing. A Manager may enter into a business transaction with the Company if the terms of the transaction are no less favorable to the Company than those of a similar transaction with an independent third party. Approval or ratification by Members having no interest in the transaction constitutes conclusive evidence that the terms satisfy the foregoing condition.

5.9 Indemnification and Advancement of Costs.

(a) Indemnification.

(1) Mandatory. The Company will indemnify a Manager for all expenses, losses, liabilities and damages the Manager actually and reasonably incurs in connection with the Manager's successful defense of any claim, action or proceeding arising out of or relating to the Manager's conduct of the Company's activities.

(2) Permissive. The Company may, but is not required to, indemnify a Manager for all expenses, losses, liabilities and damages the Manager actually and reasonably incurs in connection with the Manager's unsuccessful defense of any claim, action or proceeding arising out of or relating to the Manager's conduct of the Company's activities, but only if (1) the Manager's conduct was in good faith, (ii) the Manager reasonably believed that the Manager's conduct was in, or not opposed to, the Company's best interests, (iii) in the case of a criminal proceeding, the Manager had no reason to believe the Manager's conduct was unlawful, (iv) in the case of a proceeding by or in the right of the Company, the Manager was not adjudged liable to the Company and (v) in the case of any other proceeding, the Manager was not adjudged liable to any Person on the basis that the Manager derived an improper personal benefit.

(b) Advancement of Costs. The Company may, but is not required to, pay for or reimburse the expenses a Manager actually and reasonably incurs in connection with a proceeding arising out of or relating to the Manager's conduct of the Company's activities in advance of final disposition of the proceeding, but only if (1) the Manager furnishes to the Company a written affirmation of the Manager's good faith belief that the Manager has met the applicable standards of conduct described in Article 5.9(a)(2), (2) the Manager furnishes to the Company a written, signed undertaking to repay the advance if it is ultimately determined that the Manager did not meet such standards of conduct and (3) the Company determines that the facts then known by it would not preclude indemnification under this Article 5.9.

5.10 Compensation. The Managers will not receive compensation for services rendered to or on behalf of the Company in excess of his proportionate Membership distributions, if any. The Company will reimburse each Manager for reasonable expenses properly incurred on the Company's behalf.

5.11 Tenure.

(a) Term. A Manager will serve until the earlier of (1) the Manager's resignation; (2) the Manager's removal; (3) the Manager's Bankruptcy; (4) as to a Manager who is a natural person, the Managers Incapacity or death;

and (5) as to a Manager that is an Entity, the Manager's dissolution.

(b) Resignation. A Manager at any time may resign by written notice delivered to the Members at least 30 days prior to the effective date of the resignation.

(c) Removal. The Members at any time may remove a Manager, with or without cause, but only with the approval of Members whose aggregate Membership Units is at least ninety percent (90%) of the total issued and outstanding Membership Units

(d) Vacancy. If a Manager for any reason ceases to act, the Members will promptly elect a successor, to serve until a successor is elected and qualified.

ARTICLE 6: RECORDS AND ACCOUNTING

6.1 Maintenance of Records.

(a) Required Records. The Company will maintain at its Designated Office such books, records and other materials as are reasonably necessary to document and account for its activities, including, without limitation:

(1) a current list, in alphabetical order, of the full name and last-known business, residence or mailing address of each Member and Manager;

(2) a copy of the Articles;

(3) copies of any signed powers of attorney pursuant to which the Articles were signed,

(4) a copy of the writing required of the Company's organizer pursuant to the Act;

(5) copies of the Company's federal, state and local income tax returns and reports for the three most recent Taxable Years;

(6) copies of the Company's financial statements for the three most recent tax years;

(7) a copy of this Agreement, including any amendments; and

(8) copies of any minutes of each meeting of the Members and of any written consents of the Members.

(b) Authorized Access.

(1) Each current or former Member or Manager is entitled to inspect and copy, during regular business hours at the Company's Designated Office, any of the records described in Article 6.1 (a) after first giving the Company written notice at least five business days before the inspection and copying is to occur. However, a former Member or Manager is entitled to inspect and copy only those records that pertain to the period of the former Member's or Manager's tenure as a Member or Manager or are reasonably necessary to enable the former Member or Manager to establish a claim or defense in a controversy with the Company, any Member or Manager or any other Person.

(2) An authorized agent or attorney of a current or former Member or Manager has the same rights of inspection and copying as such current or former Member or Manager.

(3) Any costs associated with the production or reproduction of the Company's records will be borne and paid in advance by the requesting current or former Member or Manager.

(c) Confidentiality. No current or former Member or Manager will disclose any information relating to the Company or its activities to any unauthorized person or use any such information for his or her or any other Person's personal gain or for any other improper purpose.

6.2 Financial Accounting.

(a) Accounting Method. The Company will account for its financial transactions using a method of accounting determined by the Managers in compliance with the Act.

(b) Taxable Year. The Company's Taxable Year is the Company's annual accounting period, as determined by the Managers in compliance with the Act.

6.3 Reports.

(a) Members. As soon as practicable after the close of each Taxable Year, the Company will prepare and send to the Members such reports and information as are reasonably necessary to (1) inform the Members of the results of the Company's operations for the Taxable Year and (2) enable the Members to completely and accurately reflect their distributive shares of the Company's income, gains, deductions, losses and credits in their federal, state and local income tax returns for the appropriate year.

(b) Periodic Reports. The Company will complete and file any periodic reports required by the Act or the law of any other jurisdiction in which the Company is qualified to do business.

6.4 Tax Compliance.

(a) Withholding. If the Company is required by law or regulation to withhold and pay over to a governmental agency any part or all of a Distribution or allocation of Profit to a Member; and

(1) the amount withheld will be considered a Distribution to the

(2) if the withholding requirement pertains to a Distribution in kind or an allocation of Profit, the Company will pay the amount required to be withheld to the governmental agency and promptly take such action as it considers necessary or appropriate to recover a like amount from the Member, including offset against any Distributions to which the Member would otherwise be entitled.

(b) Tax Matters Partner. The Company will designate a Member to act as the "Tax Matters Partner" pursuant to Section 6231(a)(7) of the Code. The Company may remove any Tax Matters Partner, with or without cause, and designate a successor to any Tax Matters Partner who for any reason ceases to act. A Member is eligible to serve as the Tax Matters Partner only if (1) the Member is then serving as a Manager or (2) no Member is then serving as a Manager. The Tax Matters Partner will inform the Members of all administrative and judicial proceedings pertaining to the determination of the Company's tax items and will provide the Members with copies of all notices received from the Internal Revenue Service regarding the commencement of a Company-level audit or a proposed adjustment of any of the Company's tax items. The Tax Matters Partner may extend the statute of limitations for assessment of tax deficiencies against the Members attributable to any adjustment of any tax item. The Company will reimburse the Tax Matters Partner for reasonable expenses properly incurred while acting within the scope of the Tax Matters Partner's authority.

ARTICLE 7: DISSOLUTION

7.1 Events of Dissolution.

(a) Enumeration. The Company will dissolve upon the first to occur of:

(a) the date that is 99 years after the Effective Date;

(2) the vote of the Members to dissolve the Company, unless the dissolution is revoked in accordance with the provisions of the Act;

(3) any event that makes the Company ineligible to conduct its activities as a limited liability company under the Act;

(4) the Company's administrative dissolution under the Act, unless the

Company is reinstated within the time prescribed by the Act;

(5) entry of a decree of judicial dissolution pursuant to the Act; or

(6) any event or circumstance that makes it unlawful or impossible for the Company to carry on its business, unless the Company's incapacity to carry on its business is cured within 90 days after such event or circumstance.

(b) Exclusivity of Events. Unless specifically referred to in this Article 7.1, no event will result in the Company's dissolution.

7.2 Effect of Dissolution.

(a) Appointment of Liquidator. Upon the Company's dissolution, the Managers will appoint a liquidator, who may but need not be a Member. The liquidator will wind up and liquidate the Company in an orderly, prudent and expeditious manner in accordance with the following provisions of this Article 7.2.

(b) Final Accounting. The liquidator will make proper accountings (1) to the end of the month in which the event of dissolution occurred and (2) to the date on which the Company is finally and completely liquidated.

(c) Duties and Authority of Liquidator. The liquidator will make adequate provision for the discharge of all of the Company's debts, obligations and liabilities. The liquidator may sell, encumber or retain for distribution in kind any of the Company's assets. Any gain or loss recognized on the sale of assets will be allocated to the Members' Capital Accounts in accordance with the provisions of Article 4.2. With respect to any asset the liquidator determines to retain for distribution in kind, the liquidator will allocate to the Members' Capital Accounts the amount of gain or loss that would have been recognized had the asset been sold at its fair market value.

(d) Final Distribution. The liquidator will distribute any assets remaining after the discharge or accommodation of the Company's debts, obligations and liabilities to the Members in proportion to their Capital Accounts. The liquidator will distribute any assets distributable in kind to the Members in undivided interests as tenants in common. A Member whose Capital Account is negative will have no liability to the Company, the Company's creditors or any other Member with respect to the negative balance.

(e) Required Filings. The liquidator will file articles of dissolution with the Division and take such other actions as are reasonably necessary or appropriate to effectuate and confirm the cessation of the Company's existence.

ARTICLE 8: GENERAL PROVISIONS

8.1 Amendments.

(a) Required Amendments. The Company, the Manager and the Members will execute and file with the Division a certificate of amendment of the Articles when (1) there is a change in the Company's name, (2) there is a change in the character of the Company's business, as specified in the Articles, (3) there is a false or erroneous statement in the Articles, (4) there is a change in the Company's period of duration, (5) there is a change in the Company's management structure or (6) there is a change in the identity of any Manager. If any such amendment results in inconsistencies between the Articles and this Agreement, this Agreement will be considered to have been amended in the specifics necessary to eliminate the inconsistencies.

(b) Other Amendments. Any Manager or any Member may propose for consideration and action an amendment to this Agreement or to the Articles. A proposed amendment will become effective at such time as it is approved by the Managers and all Members.

8.2 Power of Attorney. Each Member appoints each Manager, with full power of substitution, as the Member's attorney-in-fact, to act in the Member's name to execute and file (a) all certificates, applications, reports and other instruments necessary to qualify or maintain the Company as a limited liability company in the states and foreign countries where the Company conducts its activities, (b) all instruments that effect or confirm changes or modifications of the Company or its status, including, without limitation, certificates of amendment to the Articles and (c) all instruments of transfer necessary to effect the Company's dissolution and termination. The power of attorney granted by this Article 8.2 is irrevocable and coupled with an interest.

8.3 Nominee. Title to the Company's assets may be held in the name of the Company or any nominee (including any Manager or any Member so acting), as the Company determines. The Company's agreement with. any nominee may contain provisions indemnifying the nominee for costs or damages incurred as a result of the nominee's service to the Company.

8.4 Investment Representation. Each Member represents to the Company and the other Members that (a) the Member is acquiring Membership Units in the Company for investment and for the Member's own account and not with a view to its sale or distribution and (b) neither the Company nor any Member or Manager has made any guaranty or representation upon which the Member has relied concerning the possibility or probability of profit or loss resulting from the Member's investment in the Company.

8.5 Notices. Any notice contemplated by this Agreement may be sent by any commercially reasonable means, including hand delivery, first class mail, facsimile, e-mail or private courier. The notice must be prepaid and addressed as set forth in the Company's records. The notice will be effective on the date of receipt or, in the case of notice sent by first class mail, the fifth day after mailing. If notice is required to be given to a Member or Manager, a written waiver signed by the Member or Manager and delivered to the Company, whether before or after the time the notice is required to be given, is the equivalent of timely notice.

8.6 Resolution of Inconsistencies. If there are inconsistencies between this Agreement and the Articles, the Articles will control. If there are inconsistencies between this Agreement and the Act, this Agreement will control, except to the extent the inconsistencies relate to provisions of the Act that the Members cannot alter by agreement. Without limiting the generality of the foregoing, unless the language or context clearly indicates a different intent, the provisions of this Agreement pertaining to the Company's governance and financial affairs and the rights of the Members upon withdrawal and dissolution will supersede the provisions of the Act relating to the same matters.

8.7 Additional Instruments. Each Member will execute and deliver any document or statement necessary to give effect to the terms of this Agreement or to comply with any law, rule or regulation governing the Company's formation and activities.

8.8 Computation of Time. In computing any period of time under this Agreement, the day of the act or event from which the specified period begins to run is not included. The last day of the period is included, unless it is a Saturday, Sunday or legal holiday, in which case the period will run until the end of the next day that is not a Saturday, Sunday or legal holiday.

8.9 Entire Agreement. This Agreement and the Articles comprise the entire agreement among the parties with respect to the Company. This Agreement and the Articles supersede any prior agreements or understandings with respect to the Company. No representation, statement
or condition not contained in this Agreement or the Articles has any force or effect.

8.10 Waiver. No right under this Agreement may be waived, except by an instrument in writing signed by the party sought to be charged with the waiver.

8.11 General Construction Principles. Words in any gender are deemed to include the other genders. The singular is deemed to include the plural and vice versa. The headings and underlined paragraph titles are for guidance only and have no significance in the interpretation of this Agreement.

8.12 Binding Effect. Subject to the provisions of this Agreement relating to the transferability of Membership Units and the rights of Transferees, this Agreement is binding on and will inure to the benefit of the Company, the Members and their respective distributees, successors and assigns.

8.13 Governing Law. Florida law governs the construction and application of the terms of this Agreement.

8.14 Counterparts. This Agreement may be executed in counterparts, each of which will be considered an original.

Signed on the respective dates set forth below, to be effective as of the Effective Date.

MEMBERS:

EVOLVE MEDICAL, INC.

SIGNED: _____
JOHN HOFFMAN, PRESIDENT
DATE: 1-7-11

SEAN XIE, M.D., A MEDICAL CORPORATION

SIGNED: _____
SEAN XIE, PRESIDENT
DATE: 1/27/11

ARIA SABIT

SIGNED: _____
ARIA SABIT, PRESIDENT
DATE: 1/27/11

PIKE INDUSTRIES, INC.

SIGNED: _____
ADAM A. PIKE, PRESIDENT
Date: 1-1-11

BERRY MEDICAL ENTERPRISES INC.

SIGNED: _____
BRET M. BERRY, PRESIDENT
Date: 1 Jan 2011

The undersigned, as the Company's initial Managers, accept the office of manager and agree to be bound by all of the terms and conditions of this Agreement.

Signed on the date set forth below, to be effective as of the Effective Date.

MANAGERS:

ADAM A. PIKE
Date: 1-1-11

BRET M. BERRY
Date: 1 Jan 2011

SCHEDULE OF VALUES

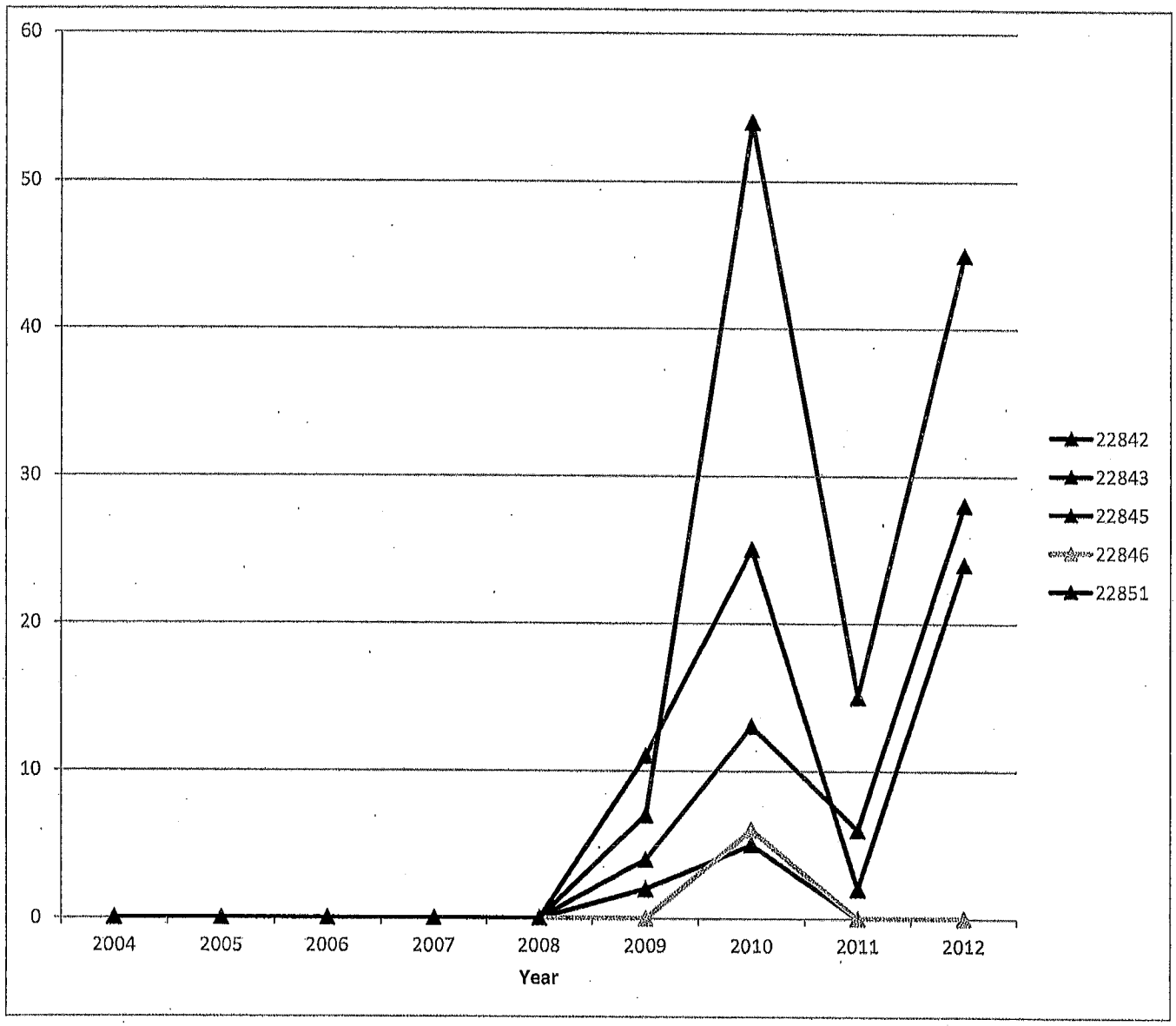
ATTACHED TO OPERATING AGREEMENT

OF

Apex Medical Technologies, LLC

Date Value Determined	Value

Kuntz Declaration, Exhibit D


60
50
40
30
20
10
0
2004
2005
2006
2007
2008
2009
2010
2011
2012
Year
22842
22843
22845
22846
22851

CLAIM LINES			2009	2010	2011	2012
posterior non-segmental	22840		1	11	2	36
wiring	22841		0	0	0	0
posterior: 3-6	22842		11	25	2	24
posterior: 7-12	22843		2	5	0	0
posterior: 13+	22844		0	0	0	0
anterior: 2-3	22845		4	13	6	28
anterior: 4-7	22846		0	6	0	0
anterior: 8+	22847		0	0	0	0
pelvic fixation	22848		0	0	0	0
reinsertion	22849		1	2	0	2
removal: posterior nonsegmental	22850		0	1	0	0
cage(s)	22851		7	54	15	45
removal: posterior segmental	22852		0	3	0	0
removal: anterior	22855		0	0	0	2

Kuntz Declaration, Exhibit E

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Attorney General of California
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Supervising Deputy Attorney General
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Attorneys for Complainant

FILED
STATE OF CALIFORNIA
MEDICAL BOARD OF CALIFORNIA
SACRAMENTO September 17, 2013
BY: ANALYST

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: ARIA OMAR SABIT, M.D. 29355 Northwestern Highway, Suite 130 Southfield, MI 48034 Physician's and Surgeon's Certificate Number A 108433 Respondent.	Case No. 05-2011-212383 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Kimberly Kirchmeyer (Complainant) brings this Accusation solely in her official capacity as the Interim Executive Director of the Medical Board of California, Department of Consumer Affairs.

2. On or about June 17, 2009, the Medical Board of California issued Physician's and Surgeon's Certificate Number A 108433 to Aria Omar Sabit, M.D. (Respondent). Said Certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 31, 2015, unless renewed.

JURISDICTION

3. This Accusation is brought before the Medical Board of California (Board), Department of Consumer Affairs, 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 pertinent 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.

"(f) . . . (i)."

5. Section 2220 of the Code states:

"Except as otherwise provided by law, the Division of Medical Quality may take action against all persons guilty of violating this chapter [Chapter 5, the Medical Practice Act]. The division shall enforce and administer this article as to physician and surgeon certificate holders, and the division shall have all the powers granted in this chapter for these purposes including, but not limited to:

"(a) Investigating complaints from the public, from other licensees, from health care facilities, or from a division of the board that a physician and surgeon may be guilty of unprofessional conduct. The board shall investigate the circumstances underlying any report received pursuant to Section 805 within 30 days to determine if an interim suspension order or temporary restraining order should be issued. The board shall otherwise provide timely disposition of the reports received pursuant to Section 805.

"(b) Investigating the circumstances of practice of any physician and surgeon where there have been any judgments, settlements, or arbitration awards requiring the physician and surgeon or his or her professional liability insurer to pay an amount in damages in excess of a cumulative total of thirty thousand dollars ($30,000) with respect to any claim that injury or damage was

proximately caused by the physician's and surgeon's error, negligence, or omission.

"(c) Investigating the nature and causes of injuries from cases which shall be reported of a high number of judgments, settlements, or arbitration awards against a physician and surgeon."

6. Section 2230.5 of the Code provides, in pertinent part:

"(a) Except as provided in subdivisions (b) and (c), and (e), any accusation filed against a licensee pursuant to Section 11503 of the Government Code shall be filed within three years after the board, or a division thereof, discovers the act or omission alleged as the ground for disciplinary action, or within seven years after the act or omission alleged as the ground for disciplinary action occurs, whichever occurs first.

"(b) . . . ."

"(c) An accusation filed against a licensee pursuant to Section 11503 of the Government Code alleging unprofessional conduct based on incompetence, gross negligence, or repeated negligent acts of the licensee is not subject to the limitation provided for by subdivision (a) upon proof that the licensee intentionally concealed from discovery his or her incompetence, gross negligence, or repeated negligent acts."

"(d) . . . (f)."

7. Section 2227 of the Code provides that a licensee who is found guilty under the Medical Practice Act may have his or her license revoked, suspended for a period not to exceed one year, placed on probation and required to pay the costs of probation monitoring, or such other action taken in relation to discipline as the Division deems proper.

8. Section 2234 of the Code, provides, in pertinent part:

"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.

"(d) Incompetence.

"(e) The commission of any act involving dishonesty or corruption which is substantially related to the qualifications, functions, or duties of a physician and surgeon.

"(f) Any action or conduct which would have warranted the denial of a certificate.

"(g) . . . (h)."

9. Section 2266 of the Code provides: "The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct."

FIRST CAUSE FOR DISCIPLINE

(Gross Negligence)

10. Respondent is subject to disciplinary action under Business and Professions Code section 2234, subdivision (b), in that he was grossly negligent in his care and treatment of patients J.S., M.S., R.S., D.B., and M.M.[1] The circumstances are as follows:

Patient J.S.

11. On or about June 26, 2009, patient J.S., a then 67-year old male, presented to the Ventura County Neurosurgical Associates (VCNA) for the evaluation of intense back pain and was referred to Respondent for surgical consultation and treatment.

[1] For privacy, the patients in the Accusation will be identified by their first and last initials. The full names will be disclosed to Respondent upon timely request for discovery pursuant to Government Code section 11507.6.

12. On or about July 10, 2009, Respondent saw J.S. at VCNA, and documented that the patient had "very severe stenosis[2] at L1 down to L5." However, the CT lumbar spine post-myelogram[3] reports "negative" findings at T12-L1, "no stenosis at L1-2," "mild canal stenosis at L2-3 and L3-4," and no stenosis at L5-S1. The only area of "severe stenosis" was reported at L4-5. Respondent also noted that J.S. had a scoliotic curvature of the spine, however, the lumbar CT myelogram and x-rays do not describe or mention scoliosis.[4] Respondent recommended surgery from L1 or L2 to L5 or S1, and ordered a discogram[5] prior to surgery.

13. On or about August 7, 2009, Respondent saw J.S. and noted that the discogram was "positive from L3-L4 to L5-S1." The L5-S1 level, however, was not included in the levels to be studied nor was that level injected with contrast dye. Further, there were no demonstrated annular[6] fissures[7] at any of the injected levels (i.e., L2-3, L3-4 nor L4-5).

14. On or about December 18, 2009, Respondent performed surgery on J.S. at Community Memorial Hospital (CMH). According to Respondent's operative report, he performed a "Posterior lateral fusion L3, L4, L5, S1. Laminectomy[8] for decompression[9] L3, L4, L5, S1. Pedicle screw fixation[10] L3, L4, L5. Allograft.[11] Autograft.[12] Fluoroscopy.[13] Repair

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[2] Stenosis is the narrowing of the vertebral canal, nerve root canals, or intervertebral foramina of the lumbar spine.

[3] A myelogram is an x-ray film taken after the injection of a radiopaque medium into the subarachnoid space to demonstrate any distortions of the spinal cord, spinal nerve roots, and subarachnoid space.

[4] Scoliosis is a side-to-side curvature of the spine.

[5] A discogram is an x-ray image produced by a discography. A discography is an examination of the intervertebral disk space using x-rays after injection of contrast media into the disk.

[6] Annular refers to shaped like or forming a ring.

[7] Fissure refers to a deep furrow, cleft, groove or slit, normal or otherwise.

[8] A laminectomy is the surgical removal of the posterior arch of a vertebra.

[9] Decompression in spinal surgery refers to the surgical relief of pressure on the spinal cord.

[10] Pedicle screw fixation, in orthopedic surgery, refers to a multicomponent device constructed from stainless or titanium-based steel, consisting of solid, grooved, or slotted plates of rods that are longitudinally interconnected and anchored to adjacent vertebrae using bolts, hooks, or screws.

[11] An allograft is a graft of tissue obtained from a donor of the same species as, but with a different genetic make-up from, the recipient, as a tissue transplant between two humans.

[12] An autograft is a graft of tissue or organ that is grafted into a new position on the body of the individual from whom it was removed.

[13] Fluoroscopy is an examination by means of a fluoroscope. A fluoroscope is a device equipped with a fluorescent on which the internal structures of an optically opaque object, such as the human body, may be continuously viewed as shadowy images formed by the different transmission of x-rays through the object.

of CSF[14] leak, creation of shunt."[15] J.S. signed a consent for an L4-5 interbody fusion with decompression and fusion from L3 to S1, however, Respondent's operative report narrative does not describe that an interbody fusion was performed at L4-5. There is no explanation for this discrepancy documented in the patient's chart. During an interview with the Board, Respondent stated that he "did not see the consent sheet" and "it was not the practice at the hospital to look at this consent sheet" before the procedure. He further stated "I would have gone off whatever I had in my . . . dictation in my office, whatever I decided I was going to do" and that he "was not going to base [the procedure] on" the consent signed by the patient. Respondent, however, failed to document any explanation for the discrepancies between the actual procedures performed and the procedures listed in the signed patient consent.

A). Respondent's operative report narrative further describes that the instrumentation was inserted from L3 to L5, excluding S1 (the sacrum) from the instrumentation construct. In explaining why the S1 level was not included in the instrumentation construct, Respondent told the Board that there was no need to perform an extensive laminectomy at that level or to expose the nerve roots. However, Respondent's operation report contradicts this and states that "[l]aminectomies were performed at L3, L4, L5, S1. All nerve roots were exposed. Foraminotomies[16] were done at all levels. Medial facetectomies[17] were also done at all levels." These procedures, however, are not supported by the post-operative lumbar x-ray which notes reports a laminectomy at L4.

B). Respondent's operative report narrative further states that a "posterolateral fusion was . . . performed at L3, L4, L5, S1." However, this is not supported by the post-operative lumbar spine x-ray reports which notes a posterior fusion from L3 to L5. Respondent failed to accurately dictate the procedures he performed during the operation and failed to correct his

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[14] CSF is an abbreviation for cerebrospinal fluid.

[15] A shunt is a passage between two natural body channels, such as blood vessels, especially one created surgically to divert or permit flow from one pathway or region to another; a bypass.

[16] Foraminotomy is the removal of the intervertebral foramen (an aperture or perforation through a bone or a membranous structure).

[17] Facetectomy is the surgical removal or excision of a facet, particularly the articular facet (a relatively small articular surface of a bone) of a vertebra.

operative report after it was transcribed.

C). Respondent further states, in his operative narrative, that "a week (sic) point in the dura was visualized ... and repaired using 4-0 silk sutures. A shunt was created for CSF egress." The creation of a shunt was also included in the operative report's list of procedures performed. There is, however, no description why a shunt was necessary when Respondent's narrative states he repaired the dura during the procedure. When questioned by the Board, Respondent admitted that he did not create a shunt during the operation, and did not "know what . . . [his statement] means." Further, he had "no idea" what he was referring to when he dictated his report and had no explanation why this information was contained in two separate portions of his operative report (i.e., the list of procedures performed section and the narrative section). Respondent failed to accurately dictate the procedures he performed during the operation and failed to correct his operative report after it was transcribed.

15. Respondent committed acts of gross negligence in his care and treatment of patient J.S. when he:

A). Performed unnecessary surgical procedures at L3 and L5-S1 without evidence of severe stenosis or other findings justifying the procedures at these levels;

B). Excluded S1, the sacrum, from the instrumentation construct when attempting to fuse the L3-S1 levels;

C). Documented that he performed various procedures during the operation which were not performed; and

D). Repeatedly failed to adequately, appropriately and accurately document the patient's chart.

Patient M.S.

16. On or about February 5, 2010, patient M.S., a then 64-year old female, presented to the Ventura County Neurosurgical Associates (VCNA) for severe pain in her left lower extremity and knee. M.S. was referred to another office for an epidural injection of her lumbar spine.

17. On or about February 18, 2010, M.S. returned to VCNA when the epidural injection failed to address her concerns. Respondent saw M.S. and recommended surgery as soon as

possible.

18. On or about February 21, 2010, M.S. presented to the Community Memorial Hospital (CMH) Emergency Department unable to ambulate. Respondent saw M.S. for a neurosurgical consult and recommended surgery the following morning. However, Respondent's pre-operative history and physical note failed to specifically detail what the radiologic findings were and which levels were involved. M.S. signed a consent for a lumbar interbody fusion at L4-5 and a posterior lumbar decompression and fusion at L4 to S1.

19. On or about February 22, 2010, Respondent performed surgery on M.S. at CMH. Respondent's operative report lists that he performed a posterior "decompression at L4, L5, S1; posterior lateral fusion L4, L5, S1; plate fixation L4, L5, S1" and "interbody fusion L5-S1." However, the post-operative CT scan report does not support this and notes laminar defects at L4 and an interbody cage and hardware at L4-5.

20. M.S. was thereafter discharged and received physical therapy. Respondent saw M.S. for a follow-up office visit on March 2, 2010, which was unremarkable.

21. In May 2010, M.S. presented to Respondent at VCNA to address the redevelopment of some of her pain. An MRI revealed increased pathology at L4-L5.

22. On or about June 19, 2010, M.S., in preparation for surgery, signed a consent for an interbody lumbar fusion of L5 to S1 with lumbar instrumentation. Respondent saw M.S. prior to the surgery and dictated a history and physical note in the patient's chart. In that note, Respondent states that M.S. had "a previous fusion from L4-L5." Respondent's plan was to "perform a full discectomy and interbody fusion at L5-S1." However, Respondent had previously decompressed, fused and instrumented L5-S1 four months earlier, according to his February 22, 2010 operative report.

A). Respondent lists, in his June 19, 2010 operative report, that he performed a "Laminectomy for decompression of the nerve roots at L4, L5, S1; lumbar discectomy L5-S1; posterolateral fusion L4, L5, and S1; pedicle screw fixation L4, L5, S1" utilizing the Apex pedicle screw system. However, there was no documented diagnosis or justification requiring a laminectomy and decompression at L4. Additionally, the L4 level was not included in the

consent M.S. signed. Respondent, however, failed to document any explanation for the discrepancies between the actual procedures performed and the procedures listed in the signed patient consent and testified that he did not review the signed consent form before the operation.

23. After the June 2010 surgery, M.S. developed right-sided foot drop and right leg pain, a new post-operative neurological complaint.[18] This should have prompted an immediate work-up and imaging to determine the cause of the problem. Several months later, however, Respondent ordered an Electromyography[19] (EMG)/Nerve Conduction Velocity[20] (NCV) study. The EMG/NCV was performed on November 23, 2010, and revealed malpositioning of the pedicle screws at L4, L5 and S1.

24. Respondent committed acts of gross negligence in his care and treatment of patient M.S. when he:

A). Failed to promptly evaluate and determine the cause of the patient's right-sided drop foot and right leg pain, a new post-operative neurological finding; and

B). Repeatedly failed to adequately, appropriately and accurately document the patient's chart.

Patient R.S.

25. On or about June 15, 2009, patient R.S., a then 57-year old female, presented to the Ventura County Neurosurgical Associates (VCNA) for severe weakness in her lower left extremity and foot, and numbness. R.S. was referred to Respondent for surgical consultation and evaluation.

26. On or about July 22, 2009, Respondent saw patient R.S. and opined that she would need a decompression with microdiskectomy at L4-5. Respondent advised her that the surgical correction of her scoliotic deformity would not relieve her symptoms. At that time, R.S. decided not to have the procedure.

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[18] All of the patient's pre-operative symptoms and findings had been limited to the left side.

[19] Electromyography (commonly referred to as EMG) is a type of test in which a nerve's function is tested by stimulating a nerve with electricity, and then measuring the speed and strength of the corresponding muscle's response.

[20] Nerve conduction velocity test (commonly referred to as NCV) is a test that measures the time it takes a nerve impulse to travel a specific distance over the nerve after electronic stimulation.

scoliosis with osteoarthritis and a prior anterior interbody fusion at L2-3.

29. On or about August 12, 2010, Respondent saw R.S. for another follow up visit. Respondent scheduled her for a two-staged operation which included "a T12 to L5 anterior release followed by a T4 to S1 decompression and fusion."

30. On or about October 19, 2010, R.S. presented to Community Memorial Hospital (CMH) and signed a consent for a lumbar interbody fusion from T12 to L5 and lumbar instrumentation and cages. At that time, R.S. also signed a consent for the second stage of the surgery scheduled to occur the following day.

A). Respondent performed the first stage of the operation on R.S. In his operative report, Respondent lists that he performed a "lumbar interbody fusion" from T12 to L5, an "interbody cage placement, L4-L5, L3-L4," structural allograft in the interbody space, L2-L3, T12-L1," arthorodesis[19]/ instrumented fusion" from T12 to L5" with allograft and autograft. However, his narrative description of the procedure does not describe the placement of any instrumentation as referenced; only cages at L3-L4 and L4-5. Additionally, the post-operative CT report does not note any hardware at these levels, only the interbody cages. Respondent, however, failed to accurately dictate the procedures he performed during the operation and failed to correct his operative report after it was transcribed.

31. On or about October 20, 2010, Respondent performed the second stage of the operation on R.S. Respondent lists, in his operative report, that he performed a "posterolateral fusion, T4, T5, T6, T7, T8, T9, T10, T11, T12, L1, L2, L3 L4, L5, L6, S1. Pedicle screw fixation, T5, T6, T7, T8, T9, T10, T11, T12, L1, L2, L3, L4, L5, L6, S1. Laminectomy for decompression of nerve roots, T4, T5, T6, T7, T8, T9, T10, T11, T12, L1, L2, L3, L4, L5, L6, S1. Partial vertebrectomy[20]-corpectomy[21], T7, T8, T10, T12, L2, L4. Correction of scoliotic deformity, thoracic, lumbar, sacral." However, the consent R.S. signed does not include partial vertebrectomies-corpectomies at any level, nor the correction of the patient's thoracic, lumbar, or

[19] Arthrodesiss is the surgical fixation of a joint by a procedure designed to accomplish fusion of the joint surfaces by promoting the proliferation of bone cells.

[20] Vertebrectomy is the excision of a vertebra.

[21] Corpectomy is the removal of a vertebra body during spinal surgery.

sacral scoliotic deformity. Respondent told the Board that he does not look at the signed consent before the procedure but goes off his own notes. There is, however, no explanation documented by Respondent for the discrepancies between the actual procedures performed and the procedures listed in the signed consent.

A). Respondent states, in his operative narrative, "that the patient has 6 lumbar vertebrae." This finding, however, is not documented in the lumbar CT scans reports, the lumbar MRI reports, nor in Respondent's operative report narrative from the previous day.

B). Respondent's operative report further states that he performed laminectomies from T4-S1 in order to facilitate de-rotation of the scoliosis curve. However, Respondent's documentation lacks sufficient specificity to justify laminectomies at all these levels. Additionally, the post-operative lumbar CT scan reports a post laminectomy at L3-4, and states that "other than the prosthetic device at L3-4, there are no extradural abnormalities appreciated." Had laminectomies of T4 down to S1 been performed, as described in Respondent's operative report, these findings should have been noted in the post-operative CT reports.

C). Respondent's operative report narrative describes performing "osteotomies" "at T6, T8, T10, T12, L2 and L4" which "entailed removal of the superior and inferior articulating facets as well as drilling into the pedicle in order to allow for derotation of the curve." This description, however, is consistent with a pedicle subtraction osteotomy, not a vertebrectomy/corpectomy as listed in his procedures performed section of the operative report. Had pedicle subtraction osteotomies been performed, as described in Respondent's operative report, these findings should have been noted in the post-operative CT reports. Additionally, the post-operative thoracic CT scan report states that notes that "despite the patient's scoliosis the central canal remains well-preserved." Respondent failed to accurately dictate the procedures he performed during the operation and failed to correct his operative report after it was transcribed.

32. Respondent committed acts of gross negligence in his care and treatment of patient R.S. when he:

A). Performed unnecessary surgical procedures at T4 to S1 without clear indication or other findings justifying the procedures;

B). Documented that he performed various procedures during the operation which were not performed; and

C). Repeatedly failed to adequately, appropriately and accurately document the patient's chart.

Patient D.B.

33. On or about October 9, 2009, patient D.B., a then 24-year old female, presented to the Emergency Department at Community Memorial Hospital (CMH) after having undergone a lumbar puncture the prior evening to rule out a subarachnoid[22] hemorrhage. Thereafter, she developed back pain and bilateral weakness of her lower extremities. An MRI of her lumbar spine revealed an epidural collection of fluid in the vertebral canal anteriorly extending from L2 through S1, presumed to be a hematoma. The study also reflected no significant herniation of the lumbar discs. Due to her complaints, a neurosurgical consultation was scheduled with Respondent who saw her that day.

A). After consultating with D.B., Respondent scheduled her for the "emergent evacuation of the epidural hematoma." Respondent's operative report lists that he performed "Laminectomies L3, L4, L5, S1; posterolateral fusion L3, L4, L5, S1; repair of cerebrospinal fluid leak; creation of shunt; evacuation of epidural hematoma; autograft." However, Respondent's consultation report and operative narrative fail to document a clear indication for performing a spinal fusion on this 24-year old woman. When questioned by the Board, Respondent conceded that there was no clear indication to fuse the patient at that time.

B). The consent D.B. signed lists the procedure as lumbar laminectomy at "L1-S1 with possible posterior lateral fusion." The consent does not include the evacuation of epidural hematoma. Respondent testified that he does not look at the signed consent before the surgery and relies on his own notes. However, Respondent failed to document an explanation in the

[22] Subarachnoid hemorrhage is bleeding between the pia mater (the innermost of the three meninges covering the brain and spinal cord) and the arachnoid (a delicate membrane interposed between the dura mater and the pia mater, separated from the latter by the subarachnoid space) of the brain.

patient's chart for the discrepancies between the actual procedures performed and the procedures listed in the signed consent.

C). Respondent's operative report states that he performed decompressive laminectomies at L3 to S1. However, this is not supported by the post-operative lumbar MRI study report which notes laminectomies at L4 and L5.

D). The narrative portion of Respondent's operative report states that the "dura was very thin in its entirety and a large area of leakage was found. This was repaired and a shunt was created to allow for passage of CSF." However, Respondent failed to describe why a shunt was necessary since he repaired the tear during the procedure. When questioned by the Board, Respondent admitted that no shunt was created during the operation and did not "know what that [statement] means." Further, he had "no idea" what he was referring to when he dictated his report and had no explanation why this information was contained in two separate portions of his operative report (i.e., the list of procedures performed section and the narrative section). Respondent failed to accurately dictate the procedures he performed during the operation and failed to correct his operative report after it was transcribed.

34. On or about October 21, 2009, D.B. returned to the emergency room for the drainage of her lumbar epidural hematoma.

35. On or about October 26, 2009, D.B. was readmitted into CMH for increased serosanguineous fluid from her surgical wound, increased back pain and right sciatica symptoms. An MRI revealed a new epidural hematoma extending from T11-12 through L2-3.

A). Respondent saw D.B. and scheduled her for the evacuation of the hemotoma that day. D.B. signed a consent for an epidural hematoma evacuation of the lumbar spine. However, Respondent's operative report lists the procedures as a "laminectomy, L1; partial laminectomy, T12, repair of dural defect; evacuation of epidural hematoma." Respondent reiterated that he does not look at the signed consent before the surgery and relies on his own notes. However, Respondent failed to document an explanation in the patient's chart for the discrepancies between the actual procedures performed and the procedures listed in the signed consent.

36. On October 28, 2009, a post-operative lumbar MRI report notes that the "epidural

hematoma has not changed" from the pre-operative image and "extends from the L3-4 level proximally to approximately T11."

37. Respondent committed acts of gross negligence in his care and treatment of patient D.B. when he:

A). Performed an unnecessary fusion of the lumbar spine without a clear indication or findings justifying the procedures performed;

B). Documented that he performed various procedures during the operation which were not performed; and

C). Repeatedly failed to adequately, appropriately and accurately document the patient's chart.

Patient M.M.

38. On or about May 24, 2010, patient M.M, a then 58-year old female, presented to Respondent at the Ventura County Neurosurgical Associates (VCNA) due to degenerative disc disease, osteoarthritis and scoliosis. Respondent stated, in a letter to the referring physician, that he told the patient if her symptoms returned he would "schedule her to undergo a minimally invasive lateral correction of her scoliotic deformity supplemented by posterior pedicle screw fixation." However, on that date Respondent completed a Surgery Scheduling Work Sheet noting that the surgery date would be in "Mid July." The work sheet further listed a two-day staged procedure as a "XLI7 L1-L2, L2-L3, L3-L4, L4-L5" and "posterior lumbar decomp./fusion" with Nuvasive instrumentation, and a "T10 - L5" on the second day with Apex instrumentation.

39. On or about July 22 and 23, 2010, M.M. was scheduled to undergo the two-day staged surgery, however, the surgery was rescheduled to the beginning of August as the patient was not feeling well.

40. On or about August 5, 2010, M.M presented to Community Memorial Hospital (CMH) and signed a consent for a anterior lumbar interbody fusion from L1 to L5 with autograft/allograft and lumbar instrumentation. Respondent's operative report, however, does not list or describe that an L1-2 anterior interbody fusion was performed that day. There is no explanation documented in the patient's chart for the discrepancies between the actual procedures

performed and the procedures listed in the signed consent. When questioned, Respondent told the Board that he does not review the signed consents before the procedure and probably never meant to perform an anterior lumbar interbody fusion at L1-L2. Respondent, however, failed to document this in the patient's chart.

41. On or about August 6, 2010, M.M. underwent the second portion of the staged procedure. Respondent's operative report lists that he performed "Laminectomy for decompression of nerve roots" from T10 to S1, a "posterolateral fusion" from T10 to S1, "pedicles screw fixation" from T10 to L5, and correction of scoliosis at T10 to S1. The post-operative x-rays and MRI reports, however, do not reflect laminectomies or fusions at S1, but pedicle screws and wires from T9 down to L5.

A). Additionally, M.M signed a consent for a "lumbar decompression and fusion" of T10 to L5 with lumbar instrumentation. Respondent testified that he does not look at the signed consent before the surgery and relies on his own notes. There is, however, no explanation documented in the patient's chart for the discrepancies between the actual procedures performed and the procedures listed in the signed consent.

B). Even though Respondent's operative report lists and described laminectomies and fusions from T10 to S1, Respondent admitted, during questioning by the Board, that he actually performed "laminotomies,"[23] not "laminectomies" as described and listed in his operative report. Respondent failed to accurately dictate and describe the actual procedures he performed and failed to correct his operative report after it was transcribed.

C). Respondent's operative report further lists and describes that the fusion extended to the S1 level. This, however, is not supported by the post-operative imaging studies which reflected pedicle screws and wires from T9 down to L5. Respondent, however, failed to accurately report this in his operative report. Additionally, when performing long segment fusions for scoliosis correction that extends to or near the lumbosacral junction, the fusion

[23] A laminotomy is the excision of a portion of a vertebral lamina resulting in enlargement of the intervertebral foramen for the purpose of relieving pressure in a spinal nerve root. A laminectomy is the surgical removal of the posterior arch of a vertebra.

construct should incorporate the sacrum to avoid the creation of a lever-arm effect at the lumbosacral junction. Respondent, however, failed to include the sacrum (S1) in the instrumentation construct during the second procedures and failed to provide a clear rationale for failing to do so. Respondent also failed to accurately dictate the procedures he performed during the operation and failed to correct his operative report after it was transcribed.

42. Respondent committed acts of gross negligence in his care and treatment of patient M.M. when he excluded the sacrum (S1) from the instrumentation construct when attempting to perform a long segment scoliosis deformity correction surgery.

SECOND CAUSE FOR DISCIPLINE

(Repeated Negligent Acts)

43. Respondent is subject to disciplinary action under Business and Professions Code section 2234, subdivision (c), in that that he committed repeated negligent acts in his care and treatment of patients J.S., M.S., R.S., D.B., and M.M. The circumstances are as follows:

44. Paragraphs 11 through 14C, 16 through 23, 25 through 31C, 33 through 36, and 38 through 41C, inclusive, above are incorporated herein by reference as if fully set forth.

Patient J.S.

A). Performed unnecessary surgical procedures at L3 and L5-S1 without evidence of severe stenosis or other findings justifying the procedures at these levels;

B). Excluded S1, the sacrum, from the instrumentation construct when attempting to fuse the L3-S1 levels;

C). Documented that he performed various procedures during the operation which were not performed; and

D). Repeatedly failed to adequately, appropriately and accurately document the patient's chart.

Patient M.S.

A). Failed to promptly evaluate and determine the cause of the patient's right-sided drop foot and right leg pain, a new post-operative neurological finding; and

B). Repeatedly failed to adequately, appropriately and accurately document the patient's

chart.

Patient R.S.

A). Performed unnecessary surgical procedures at T4 to S1 without clear indication or other findings justifying the procedures;

B). Documented that he performed various procedures during the operation which were not performed; and

C). Repeatedly failed to adequately, appropriately and accurately document the patient's chart.

Patient D.B.

A). Performed an unnecessary fusion of the lumbar spine without a clear indication or findings justifying the procedures performed;

B). Documented that he performed various procedures during the operation which were not performed; and

C). Repeatedly failed to adequately, appropriately and accurately document the patient's chart.

Patient M.M.

A). Excluded the sacrum (S1) from the instrumentation construct when attempting to perform a long segment scoliosis deformity correction surgery; and

B). Repeatedly failed to adequately, appropriately and accurately document the patient's chart.

THIRD CAUSE FOR DISCIPLINE

(Dishonest and Corrupt Acts)

45. Respondent is subject to disciplinary action under Business and Professions Code section 2234, subdivision (e), in that committed dishonest and corrupt acts in his care and treatment of patients J.S., M.S., R.S., D.B. and M.M. The circumstances are as follows:

46. Paragraphs 11 through 14C, 16 through 23, 25 through 31C, 33 through 36, and 38 through 41C, inclusive, above are incorporated herein by reference as if fully set forth.

///

treatment of patients J.S., M.S., R.S., D.B. and M.M. The circumstances are as follows:

46. Paragraphs 11 through 14C, 16 through 23, 25 through 31C, 33 through 36, and 38 through 41C, inclusive, above are incorporated herein by reference as if fully set forth.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Maintain Accurate and Adequate Records)

47. Respondent is subject to disciplinary action under Business and Professions Code section 2266 in that he failed to maintain adequate and accurate records in his care and treatment of patients J.S., M.S., R.S., D.B., and M.M. The circumstances are as follows:

48. Paragraphs 11 through 14C, 16 through 23, 25 through 31C, 33 through 36, and 38 through 41C, inclusive, above are incorporated herein by reference as if fully set forth.

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's and Surgeon's Certificate Number A 108433, issued to Aria Omar Sabit, M.D.

2. Revoking, suspending or denying approval of his authority to supervise physicians assistants, pursuant to section 3527 of the Code;

3. If placed on probation, ordering Respondent 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: September 17, 2013

KIMBERLY KIRCHMEYER
Interim Executive Director
Medical Board of California
Department of Consumer Affairs
State of California
Complainant

LA2013607634
61085544.docx

Kuntz Declaration, Exhibit F

VERIFIED RETURN OF SERVICE

I, DEWEY POWELL, an employee of the United States working under the direction and supervision of attorney David Finkelstein in connection with a false claims law investigation, hereby certify that at the time of 9:45 AM, on the 16th day of AUGUST, 2013, I personally served Civil Investigative Demand No. 13-338 on ARIA SABET, by delivering ARIA SABET an executed copy of such Demand at:

McLAREN - LAPEER REGION - COMMUNITY MEDICAL GRP
MEDICAL BRAIN & SPINE
1254 N. MAIN ST SUITE 1B
LAPEER MI 48446

I declare under penalty of perjury that the foregoing is true and correct. Executed on this 16th day of AUGUST, 2013.

Signature D Powell

Title SPECIAL AGENT

Kuntz Declaration, Exhibit G

Finkelstein, David M. (CIV)

From: Jonathan Frank <jfrank@jackiergould.com>
Sent: Monday, September 09, 2013 4:24 PM
To: Finkelstein, David M. (CIV)
Subject: Aria Sabit CID

David,

Your subpoena found its way to me, and I'll be representing Dr. Sabit. Due to scheduling issues (his and mine), and the fact that many of the documents are in the hands of third parties, we would like to set the response date at October 18 if possible, with the deposition to occur in the 30 days after that. To confirm what Jonathan Golding told you, Dr. Sabit does intend to comply with the subpoena, but please give me your thoughts about how to deal with HIPAA. See 45 CFR 164.512(f)(1)(ii)(C).

Jonathan Frank

JONATHAN B. FRANK, P.C.
OF COUNSEL TO JACKIER GOULD, P.C.

121 WEST LONG LAKE ROAD
SECOND FLOOR
BLOOMFIELD HILLS, MI 48304
OFFICE: (248) 433-2589
CELL: (248) 320-8361
FRANK@JACKIERGOULD.COM
WWW.FRANKPC.COM
WWW.JACKIERGOULD.COM

Kuntz Declaration, Exhibit H

Finkelstein, David M. (CIV)

From: Jonathan Frank <jfrank@jackiergould.com>
Sent: Friday, November 08, 2013 12:59 PM
To: Finkelstein, David M. (CIV)
Cc: Dwight Bostwick (dbostwick@zuckerman.com); Di Dio, Arthur (CIV)
Subject: RE: CID No. 13-338

David,

I just wanted to let you know I got this and I'm not avoiding you. I've had two appeal briefs, a deposition, an answer to a patent suit, and a presentation to a group of new lawyers this week, so I've had to move some work to next week, including responding to the CID. You will have the response by next Friday.

Jon

JONATHAN B. FRANK, P.C.
OF COUNSEL TO JACKIER GOULD, P.C.

121 WEST LONG LAKE ROAD
SECOND FLOOR
BLOOMFIELD HILLS, MI 48304
OFFICE: (248) 433-2589
CELL: (248) 320-8361
FRANK@JACKIERGOULD.COM
WWW.FRANKPC.COM
SUPER LAWYERS

From: Finkelstein, David M. (CIV) [mailto:David.M.Finkelstein@usdoj.gov]
Sent: Friday, November 08, 2013 12:36 PM
To: Jonathan Frank
Cc: Di Dio, Arthur (CIV)
Subject: CID No. 13-338

Dear Jonathan,

Dr. Sabit was served personally with DOJ's Civil Investigative Demand No. 13-338 on August 16, 2013. The CID sets a deadline for response of September 16, 2013.

You first contacted me by email on September 9, 2013. In that email, you indicated that you represented Dr. Sabit in connection with the CID. You also stated that Dr. Sabit "intend[s] to comply with the subpoena" and requested that we "set the response date at October 18." We agreed to your proposed October 18 response date. The October 18 deadline came and went without Dr. Sabit producing a single document, providing any legitimate reason for his failure to do so, or communicating a firm date by which he intended to comply with the CID.

On November 5, 2013, we met in person to discuss, among other things, Dr. Sabit's failure to comply with the CID. In that meeting, we reiterated our request that Dr. Sabit comply with his CID obligations and commit to a firm date by which to respond.

You responded by email the following day, expressing a general desire to provide us information and documents "as quickly as possible," but your response did not actually provide any specific information or documents and did not include a specific commitment to do so.

That same day, we responded to your email and repeated our position that we need to know where you object, the basis for your objection(s), and – where you do not object – when you expect to produce.

You have not responded to that email.

We write in a final effort to resolve whatever disagreements we may have – which you still have not identified – concerning Dr. Sabit's obligations under the CID. Please produce all responsive documents in Dr. Sabit's possession no later than Friday November 15, or unambiguously state your basis for objecting to production. If we do not have your response by then, we will consider seeking relief from the court.

Regards,
David

David M. Finkelstein
Trial Attorney
Fraud Section | Civil Division
U.S. Department of Justice
601 D Street, NW
Washington, D.C. 20004
202.616.2971
David.M.Finkelstein@usdoj.gov

Kuntz Declaration, Exhibit I

Civil Investigative Demand – Documentary Material, Interrogatories, and Oral Testimony

UNITED STATES DEPARTMENT OF JUSTICE
Washington, D.C. 20530

Civil Investigative
Demand No. 13-338

Dr. Aria Sabit's Responses to Documents Requested

1. Documents sufficient to identify your education and professional background.

   ANSWER: A current C.V. is attached.

2. Documents concerning any PODs in which you have invested at any time, including without limitation RELIANCE.

   OBJECTION: This request is overbroad in the use of the word "concerning." Subject to that objection, Dr. Sabit does not intend to adopt the characterization that Reliance is a POD. Moreover, you have indicated that the Department of Justice is investigating potential civil and criminal violations of the False Claims Act by Reliance and/or Dr. Sabit. We understand that at least part of the focus of DOJ's investigation(s) relates to Dr. Sabit's relationship with Reliance, his communications with Reliance and his medical procedures. Given this, Dr. Sabit invokes his right under the Fifth Amendment not to produce documents or to provide testimony in response to this document request on the grounds that, rightly or wrongly, Dr. Sabit's act of producing such documents or providing such testimony in these subject areas may be used by the DOJ, correctly or incorrectly, in an effort to incriminate him.

3. Documents concerning RELIANCE, including without limitation:

   a. documents provided by you to RELIANCE;
   b. documents provided to you by RELIANCE;
   c. documents concerning payments from RELIANCE to you;
   d. documents concerning payments from you to RELIANCE;
   e. documents concerning communications or meetings between you and RELIANCE, or between you and any actual or potential RELIANCE investor.

   LIMITATION: Pursuant to an agreement between the parties, this request does not include documents in Dr. Sabit's possession or control that were provided by Reliance after issuance of this CID.

OBJECTION: This request is overbroad in the use of the word "concerning." For the reasons stated in response to document request number 2, Dr. Sabit asserts his right under the Fifth Amendment to not produce documents in response to this request.

4. Medical records and all other documents pertaining to all patients that you have treated at any time using RELIANCE products.

   OBJECTION: For the reasons stated in response to document request number 2, Dr. Sabit asserts his right under the Fifth Amendment to not produce documents in response to this request. Notwithstanding this, we note that Dr. Sabit is not in possession or control of documents related to his practice in California and that documents related to his practice in Michigan are in the possession and control of the hospitals in Michigan where the procedures were performed.

5. Documents reflecting any communications with any state or other licensing authority concerning your practice of medicine.

   ANSWER: Dr. Sabit has documents responsive to this request and is willing to produce them so long as he receives a commitment by the DOJ that his production of documents responsive to this limited request will not constitute a waiver of his right to assert the Fifth Amendment in response to any request for testimony on any subject or his right to assert the Fifth Amendment in response to any other request for the production of documents.

Dr. Aria Sabit's Answers to Interrogatories

1. Identify all privately held companies of which YOU are the owner or part-owner, including the principal business address and phone, place of incorporation, and the identities of the other owners, officers, and directors, and their business and residential address and phone numbers.

   ANSWER: None.

2. Identify YOUR assets, including assets owned jointly, including:

   a. All checking accounts by location, including the value of all accounts;
   b. All savings accounts by location, including the value of all accounts;
   c. All investment accounts through which YOU hold stocks, bonds, mutual fund shares, or other securities, including the value of all accounts;
   d. All real estate, including address, contract price, principal amount still owing, and amount of next payment due;
   e. All life insurance policies, including company, face amount, and cash surrender value;

f. All real and personal property owned by YOUR spouse or dependent valued in excess of $10,000;
g. All transfers of property valued in excess of $10,000 that YOU have made within the last three years, including transfers by loan, gift, or sale.

OBJECTION: This request is overbroad and seeks private confidential information not reasonably calculated to lead to the discovery of admissible evidence unless and until a judgment is entered. Dr. Sabit also asserts his right under the Fifth Amendment to not answer this question for the reasons set forth in response to request for documents number 2 above.

Respectfully submitted,

JONATHAN B. FRANK, P.C.

By: _____
Jonathan B. Frank (P42656)
Attorney for Aria O. Sabit, M.D.

Dated: November 18, 2013

ARIA SABIT, M.D.

29355 Northwestern Highway
Suite 130
Southfield, MI 48034
bregma@yahoo.com
(586) 601-8404 / (248) 440-7101

NEUROSURGEON

PROFESSIONAL DEVELOPMENT AND EXPERIENCE

Attending Neurosurgeon, Michigan Brain & Spine Physicians Group, PLLC

Director of Neurosurgery/Spine Surgery, Doctors Hospital of Michigan

Director of Neurosurgery, McLaren/Lapeer Regional Hospital

Staff Neurosurgeon, DMC Sinai Grace Hospital

Staff Neurosurgeon, DMC Receiving Hospital

Staff Neurosurgeon, DMC Harper Hospital

Staff Neurosurgeon, DMC Huron Valley- Hospital

Staff Neurosurgeon, Community Memorial Hospital, Ventura, CA
June 2009 – January, 2011

Residency
2003 – 2008

Internship in General Surgery, UMDNJ
2002-2003

In folded Endovascular Fellowship
2007 – 2008

Board Eligible

SPINE: Performed over 550 major spinal operations with Drs. Robert Heary and Ira Goldstein. These procedures included. TLIFs, PLIFs, ALIFs, XLIFs, deformity correction for scoliosis, anterior and posterior cervical instrumentation, OC fusions, decompressions and microdisectomies. Majority of the prior procedures were done using minimally invasive approaches with instrumentation. Capable of managing traumatic spinal injuries;

VASCULAR: Spent one year dedicated in the angiography suite learning diagnostic angiography as well as a variety of interventional procedures for the treatment of aneurysms, AVMs, strokes and tumors. Eighty percent (80%) experience in endovascular pathology and

twenty percent (20%) operative. Also involved with the interventional service during residency and the end of chief year, completed 240 angiograms/interventions.

ONCOLOGY: Learned operative treatment of primary and metastatic tumors, which included skull base lesions as well as stereotactic radiosurgery. University of Medical and Dentist of New Jersey was one of the first centers with an intra-operative MRI.

PERIPHERAL NERVE: Capable of managing most peripheral nerve injuries and disorders. Performed multiple surgeries for Baclofen Pumps, Morphine Pumps and Vagal Nerve Stimulators.

TRAUMA: Newark, NJ is a trauma heavy residency. Performed 6-8 craniotomies a week for trauma. The Neurosurgery ICU was managed by the Neurosurgery Chief Resident; therefore we were trained and taught critical care at a very high level.

RESEARCH

1. Correction of Post-Surgical Kyphosis. Heary, Robert, Sabit, Aria, Book Chapter. In Press 2010.
2. Hemorrhagic Complications of External Ventricular Drain Placement Maniker, A. Vaynman, A. Karimia, R. Sabit, A., Neurosurgery 2006.
3. Digital Subtraction Angiography in Evaluation of SAH, Prestigiacomo, C., Sabit, A. Podium Presentation at AANS 2007. Submitted to JNS 2008.
4. Use of CT Angiography in Evaluation of Angio Negative SAH Poster Presentation, AANS 2006.
5. Virtual Reality Modeling of Spinal Fusion. Presentation at World Spine Congress 2007.

Research Interests: Deformity Spine Surgery
Image Guided Neurosurgery
Minimally Invasive Spine Surgery
Neuro Critical Care

EDUCATION

Medical College of Virginia, 1997-2002
Medical Degree with honors

ARIA SABIT, M.D.

Virginia Commonwealth University, 1993-1997
Bachelors Degree in Economics

Eagle Advancement Institute in PSTIM Training, May, 2011
Certified in Pulse Stimulation Treatment (PSTIM)

PROFESSIONAL SOCIETIES: AANS, CNS, Society of Lateral Access Surgeons

REFERENCES

Dr. Murali Guthikonda, MD
(877) 486-7978

Dr. Hazem A. Eltahawy, MD
(877) 486-7978

Dr. Robert Bootor
(810) 662-5500

Kuntz Declaration, Exhibit J

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF VENTURA

IN RE: SABIT CASES,	CASE NO. 56-2012-415094
	(Hon. Rebecca S. Riley)

The Video Deposition of ARIA OMAR SABIT, M.D. taken by the Plaintiffs, pursuant to Notice, before Elizabeth A. Tubbert, RPR, (CSR-4248), a Notary Public within and for the County of Oakland, (acting in Wayne County), State of Michigan, at 39111 West Six Mile Road, Livonia, Michigan, on Monday, November 12, 2012.

APPEARANCES:

GLICKMAN & GLICKMAN
BY: STEVEN C. GLICKMAN, Esq.
9460 Wilshire Boulevard, Suite 330
Beverly Hills, CA 90212-2732
(310) 273-4040

Appearing on behalf of Plaintiffs Charles P. Shinn and Laura Shinn

MAGANA, CATHCART & MCCARTHY
BY: CLAY ROBBINS, III, Esq.
1801 Avenue of the Stars, Suite 600
Los Angeles, CA 90067
(310) 553-6630

Appearing on behalf of Plaintiffs Lawrence Derwin and Jennifer Derwin; Teresa Flores and Angel Flores; Ryan Shiells and Elizabeth Shiells; Guy Wysinger and Lynne Wysinger

Q Do you have any ownership interest in a physician-owned distributorship for medical devices?

A No.

Q Does any company that you have an interest in have a similar arrangement?

A No.

Q Have you ever been compensated by a medical instrument manufacturer for use of their devices?

A No.

Q Besides NuVasive, if you could, list for me while you were at CMH what other instrumentation manufacturers for spinal fusion you used.

A At least 20.

Q Okay. Do you remember the names of any of them?

A No. Those all would be in the OR records but I used at least 20 different companies.

Q And why is that?

A Your first couple of years you are trying to figure out what it is that you really like and what you don't like and what fits best with you. So you use as much as possible. In your training you use certain things and you're really not allowed to make decisions on what you should use. So once you get out you try to use as many different things as possible so you can become comfortable with one company or another.

Q The arrangement that you had with Abou-Samra as far as compensation goes didn't essentially change from the employee contract to the independent contractor contract, did it?

A That's correct.

Q Do you know anybody running a device company out of Bountiful, Utah?

A Not off the top of my head.

Q Do you recall receiving any correspondence from a company based in Bountiful, Utah that's in the medical device business?

A Not off the top of my head.

Q Would there be any reason for a Bountiful, Utah company to have ordered correspondence with your name on it?

A I'm not sure what that means.

Q Can you think of any reason, since you don't recall now, but can you think of any reason why a company in Utah would have correspondence with your name on it?

MR. GUTERMAN: The question is argumentative. Calls for speculation.

MR. COATS: Vague and ambiguous.

JUDGE ALBRACHT: Overruled. You may answer.

A Again, I don't know what you mean has my name on it.

SUPERIOR COURT OF THE STATE OF CALIFORNIA

FOR THE COUNTY OF VENTURA

CHARLES P. SHINN and LAURA, SHINN, Plaintiffs, vs. ARIA OMAR SABIT, M.D.; ARIA SABIT, M.D., A PROFESSIONAL CORPORATION; VENTURA COUNTY NEUROSURGICAL ASSOCIATES MEDICAL GROUP; MOUSTAPHA ABOU-SAMARA, M.D., a Professional Corporation; COMMUNITY MEMORIAL HOSPITAL and DOES 1 through 100, inclusive, Defendants.	Case No. 56-2011-00400004-CU-MM-VTA Volume I

VIDEOTAPED DEPOSITION OF ARIA OMAR SABIT, M.D.

Southfield, Michigan

Monday, August 27, 2012

Reported by: Laurel A. Jacoby
CSR No. 5059, RPR
NDS Job No.: 150833

of bone.

Q. And what other instrumentation did you want from Spineology?

A. They had a clamp. I'm not sure if it was their clamp or they used another instrument company to provide a clamp that would allow for posterior fixation as well.

Q. Did you personally make any money depending on what instrumentation was being used?

A. No.

Q. How about did the group make any money depending on what instrumentation was being used?

MR. COVNER: Objection; calls for speculation.

MR. WEND: Join.

BY MR. GLICKMAN:

Q. If you know.

A. I don't know about the rest of the group. I did not.

Q. In other words, if you use a Spineology or NuVasive or one of the other companies, did that make any difference to you --

A. No.

Q. -- financially?

11:37:36 A. No.

11:37:37 Q. You originally had the assistant -- there's a name written in and crossed out. Who is that?

11:37:45 A. Julie Shirk. She was a nurse, what's called a RNFA registered nurse first assist I think is what she was.

11:38:02 Q. Okay. And why did you pick her to be the assistant?

11:38:06 A. I usually use either the primary care physicians who referred the patients, that was the custom at Community Memorial Hospital, or I would use one of the nurses, whoever was available. So that's why.

11:38:21 Q. Okay. And then Dr. Westra's name is written in there?

11:38:25 A. Yes.

11:38:26 Q. Do you know how that happened that there was a change?

11:38:28 A. I think he was available for the surgery so that's why his name would have been written in there.

11:38:33 Q. Okay.

11:38:35 A. I have a page that I need to take.

11:38:37 MR. GLICKMAN: Why don't we go off the record for a second.

SUPERIOR COURT FOR THE STATE OF CALIFORNIA

FOR THE COUNTY OF VENTURA

ANDRE CASTRO,

Plaintiff,

vs. Case No. 56-2011-00406540-CU-MM-VTA

ARIA OMAR SABIT, M.D.; ARIA OMAR SABIT, M.D., a professional corporation; MOUSTAPHA ABOU-SAMRA, M.D.; MOUSTAPHA ABOU-SAMRA, M.D., a professional corporation; COMMUNITY MEMORIAL HEALTH SYSTEM, a corporation; and DOES 1 through 100,

Defendants.

The Deposition of ARIA SABIT, M.D.,

Taken at 2501 World Gateway Place,

Detroit, Michigan,

Commencing at 8:41 a.m.,

Monday, September 9, 2013,

Before Kimberly H. Kaplan, CSR-5096, RPR.

A. Yes.
Q. And so how was it as a surgeon that you would go about choosing who's going to provide the hardware?
A. Well, you know, I rotated between Zimmer, NuVasive. I think I may have used Stryker as well. DePuy -- I don't remember if I was using DePuy at that time. Apex. Medtronic.
Q. So was there any -- was there -- we know ultimately with Mr. Castro it was Apex and Reliance, but was there any -- is there any medical reason why you would choose Apex and Reliance over any of the other providers?
A. No.
Q. Okay. Do you know, as you sit here today, then why it was that you ended up using Apex and Reliance as opposed to NuVasive or Spineology or any of the other providers?
A. Spineology, that's another one I use.
No, I don't.
Q. And how was it -- do you know pre-surgery the sizes of the hardware that you're going to use in terms of screw size or the bar size, anything like that? How do you choose the sizes of the hardware?
A. Well, there is a standard set that comes in with all available options.

back?

(The following portion of the record was read by the reporter at 11:23 a.m.:

Q. "Were you going to make any additional money because of the hardware being used, either through an ownership interest in Apex or an agreement with Apex? Anything like that?")

MR. GUTERMAN: Same objections, but go ahead and answer.

THE WITNESS: So I -- I own stocks in a variety of companies. Doing a spinal surgery on Andre Castro did not dictate that I would make money or lose money dependent on how any company performs.

BY MR. ANDERSON:

Q. Okay. So nothing specifically because you used Apex, Reliance you were going to receive a distribution or a check for X amount of money?

A. That's correct.

Q. When you were providing care and treatment to Mr. Castro did you believe that anyone had been negligent in his care or treatment?

A. When I was?

Q. Yes.

A. No.

Kuntz Declaration, Exhibit K

In Re:

Oral Testimony of
BRET BERRY

Pursuant to Civil Investigative
Demand No. 13-38

VOLUME II

March 7, 2013
9:36 a.m.

Location: United States Attorney's Office
185 South State Street, 3rd Floor
Salt Lake City, Utah 84111

Reporter: Teri Hansen Cronenwett
Certified Realtime Reporter, Registered Merit Reporter

A. Yes.

Q. We've been talking a lot about Apex Medical or one of its former investors.

A. Yes.

Q. Where was Apex Medical?

A. Apex Medical was northern L.A. area, I guess. So it was -- I guess, central L.A. and Ventura were the two areas. And then we moved out to Michigan briefly, but then that's when we cut ties with Dr. Sabit.

Q. How long were you in Michigan?

A. Maybe a handful of months, not very long. It was -- because that's when we started learning more about what had happened in California and realizing that we need to cut ties.

Q. How did you get into hospitals in Michigan?

A. We had a local rep up there.

Q. Who was your local rep?

A. That would be better for John. He was in charge of that.

Q. How did you have a local rep, because it doesn't seem like you're anywhere close to Michigan otherwise?

A. We're not. But John, because it was his responsibility, would fly out there and interview different people, and so he hired one.

and researched a little bit more.

Q. And what did John tell you?

A. John told us that there was some other patient issues.

Q. Tell you about patient deaths?

A. He did not say patient deaths, I don't believe.

Q. Have you since learned about patient deaths?

A. I believe through you, yes.

Q. Maybe you heard that Adam heard?

A. Adam may have -- yes. My point is, we heard that there was more to the story than just his partner making life difficult for him. And that's when we tried to get more from him, and it was hard to communicate with him, and that's when we decided we needed to just vote him out.

Q. Have you heard from him since?

A. I don't believe so.

Q. And he never cashed the check?

A. I'd have to check our register. I don't know if he did or not.

Q. Did you affirmatively pull out of those hospitals? Did you stop him from doing cases using your product?

A. We pulled our product.

Kuntz Declaration, Exhibit L

Subject: Re: sabit rooker

From: aria sabit ([redacted])

To: [redacted];

Date: Wednesday, June 9, 2010 10:37 AM

Hi Bret
Thanks for the "Sabit". Did John contact you about the taps? I needed something more tapered at the end. The pedicle finder has a very small diameter tip. The tap usually does not fit into the hole created without disrupting the bone. It may be cheaper to just buy a couple of taps rather than altering the ones we have currently. thanks.
aria

--- On **Tue, 6/8/10, Bret Berry** <[redacted]> wrote:

> From: Bret Berry [redacted]
> Subject: sabit rooker
> To: "Lauramn Turner" <[redacted]>
> Cc: "Adam Pike" [redacted], "John Hoffman" [redacted]>,
> "Aria Sabit" <[redacted]>
> Date: Tuesday, June 8, 2010, 10:24 PM
>
> LT,
> Here are the CAD files for the add-on to Sabit's rooker. This assembly will be welded on to our existing rocker. Let me know where to ship the rocker I have from Melissa. I would think Doug or Josh would be best for this.
> Thanks
> Bret
>
> Bret M. Berry
> [redacted]

Kuntz Declaration, Exhibit M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Special Fraud Alert: Physician-Owned Entities

March 26, 2013

I. Introduction

This Special Fraud Alert addresses physician-owned entities that derive revenue from selling, or arranging for the sale of, implantable medical devices ordered by their physician-owners for use in procedures the physician-owners perform on their own patients at hospitals or ambulatory surgical centers (ASCs). These entities frequently are referred to as physician-owned distributorships, or "PODs."[1] The Office of Inspector General (OIG) has issued a number of guidance documents on the general subject of physician investments in entities to which they refer, including the 1989 Special Fraud Alert on Joint Venture Arrangements[2] and various other publications. OIG also provided guidance specifically addressing physician investments in medical device manufacturers and distributors in an October 6, 2006 letter.[3] In that letter, we noted "the strong potential for improper inducements between and among the physician investors, the entities, device vendors, and device purchasers" and stated that such ventures "should be closely scrutinized under the fraud and abuse laws."[4] This Special Fraud Alert focuses on the specific attributes and practices of PODs that we believe produce substantial fraud and abuse risk and pose dangers to patient safety.

II. The Anti-Kickback Statute

One purpose of the anti-kickback statute is to protect patients from inappropriate medical referrals or recommendations by health care professionals who may be unduly influenced by financial incentives. Section 1128B(b) of the Social Security Act (the Act) makes it a criminal

---

[1] The physician-owned entities addressed in this Special Fraud Alert are sometimes referred to as "physician-owned companies" or by other terminology. For purposes of this Special Fraud Alert, a "POD" is any physician-owned entity that derives revenue from selling, or arranging for the sale of, implantable medical devices and includes physician-owned entities that purport to design or manufacture, typically under contractual arrangements, their own medical devices or instrumentation. Although this Special Fraud Alert focuses on PODs that derive revenue from selling, or arranging for the sale of, implantable medical devices, the same principles would apply when evaluating arrangements involving other types of physician-owned entities.

[2] Special Fraud Alert: Joint Venture Arrangements (August 1989), *reprinted at* 59 Fed. Reg. 65,372, 65,374 (Dec. 19, 1994).

[3] Letter from Vicki Robinson, Chief, Industry Guidance Branch, Department of Health and Human Services, OIG, Response to Request for Guidance Regarding Certain Physician Investments in the Medical Device Industries (Oct. 6, 2006).

[4] Id.

offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services reimbursable by a Federal health care program. When remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. Violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment up to 5 years, or both. Conviction will also lead to exclusion from Federal health care programs, including Medicare and Medicaid. OIG may also initiate administrative proceedings to exclude persons from the Federal health care programs or to impose civil money penalties for fraud, kickbacks, and other prohibited activities under sections 1128(b)(7) and 1128A(a)(7) of the Act.

III. Physician-Owned Distributorships

Longstanding OIG guidance makes clear that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute. The anti-kickback statute is violated if even one purpose of the remuneration is to induce such referrals.

OIG has repeatedly expressed concerns about arrangements that exhibit questionable features with regard to the selection and retention of investors, the solicitation of capital contributions, and the distribution of profits. Such questionable features may include, but are not limited to: (1) selecting investors because they are in a position to generate substantial business for the entity, (2) requiring investors who cease practicing in the service area to divest their ownership interests, and (3) distributing extraordinary returns on investment compared to the level of risk involved.

PODs that exhibit any of these or other questionable features potentially raise four major concerns typically associated with kickbacks—corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition. This is because the financial incentives PODs offer to their physician-owners may induce the physicians both to perform more procedures (or more extensive procedures) than are medically necessary and to use the devices the PODs sell in lieu of other, potentially more clinically appropriate, devices. We are particularly concerned about the presence of such financial incentives in the implantable medical device context because such devices typically are "physician preference items," meaning that both the choice of brand and the type of device may be made or strongly influenced by the physician, rather than being controlled by the hospital or ASC where the procedure is performed.

We do not believe that disclosure to a patient of the physician's financial interest in a POD is sufficient to address these concerns. As we noted in the preamble to the final regulation for the safe harbor relating to ASCs:

> ...disclosure in and of itself does not provide sufficient assurance against fraud and abuse...[because] disclosure of financial interest is often part of a testimonial, i.e., a reason why the patient should patronize that facility. Thus, often patients

> are not put on guard against the potential conflict of interest, i.e., the possible effect of financial considerations on the physician's medical judgment.

See 64 Fed. Reg. 63,518, 63,536 (Nov. 19, 1999). Although these statements were made with respect to ASCs, the same principles apply in the POD context.

OIG recognizes that the lawfulness of any particular POD under the anti-kickback statute depends on the intent of the parties. Such intent may be evidenced by a POD's characteristics, including the details of its legal structure; its operational safeguards; and the actual conduct of its investors, management entities, suppliers, and customers during the implementation phase and ongoing operations. Nonetheless, we believe that PODs are inherently suspect under the anti-kickback statute. We are particularly concerned when PODs, or their physician-owners, exhibit any of the following suspect characteristics:

- The size of the investment offered to each physician varies with the expected or actual volume or value of devices used by the physician.
- Distributions are not made in proportion to ownership interest, or physician-owners pay different prices for their ownership interests, because of the expected or actual volume or value of devices used by the physicians.
- Physician-owners condition their referrals to hospitals or ASCs on their purchase of the POD's devices through coercion or promises, for example, by stating or implying they will perform surgeries or refer patients elsewhere if a hospital or an ASC does not purchase devices from the POD, by promising or implying they will move surgeries to the hospital or ASC if it purchases devices from the POD, or by requiring a hospital or an ASC to enter into an exclusive purchase arrangement with the POD.
- Physician-owners are required, pressured, or actively encouraged to refer, recommend, or arrange for the purchase of the devices sold by the POD or, conversely, are threatened with, or experience, negative repercussions (e.g., decreased distributions, required divestiture) for failing to use the POD's devices for their patients.
- The POD retains the right to repurchase a physician-owner's interest for the physician's failure or inability (through relocation, retirement, or otherwise) to refer, recommend, or arrange for the purchase of the POD's devices.
- The POD is a shell entity that does not conduct appropriate product evaluations, maintain or manage sufficient inventory in its own facility, or employ or otherwise contract with personnel necessary for operations.
- The POD does not maintain continuous oversight of all distribution functions.
- When a hospital or an ASC requires physicians to disclose conflicts of interest, the POD's physician-owners either fail to inform the hospital or ASC of, or actively conceal through misrepresentations, their ownership interest in the POD.

These criteria are not intended to serve as a blueprint for how to structure a lawful POD, as an arrangement may not exhibit any of the above suspect characteristics and yet still be found to be unlawful. Other characteristics not listed above may increase the risk of fraud and abuse

associated with a particular POD or provide evidence of unlawful intent. For example, a POD that exclusively serves its physician-owners' patient base poses a higher risk of fraud and abuse than a POD that sells to hospitals and ASCs on the basis of referrals from nonowner physicians.

The anti-kickback statute is not a prohibition on the generation of profits; however, PODs that generate disproportionately high rates of return for physician-owners may trigger heightened scrutiny. Because the investment risk associated with PODs is often minimal, a high rate of return increases both the likelihood that one purpose of the arrangement is to enable the physician-owners to profit from their ability to dictate the implantable devices to be purchased for their patients and the potential that the physician-owner's medical judgment will be distorted by financial incentives. Our concerns are magnified in cases when the physician-owners: (1) are few in number, such that the volume or value of a particular physician-owner's recommendations or referrals closely correlates to that physician-owner's return on investment, or (2) alter their medical practice after or shortly before investing in the POD (for example, by performing more surgeries, or more extensive surgeries, or by switching to using their PODs' devices on an exclusive, or nearly exclusive basis).

We are aware that some PODs purport to design or manufacture their own devices. OIG does not wish to discourage innovation; however, claims—particularly unsubstantiated claims—by physician-owners regarding the superiority of devices designed or manufactured by their PODs do not disprove unlawful intent. The risk of fraud and abuse is particularly high in circumstances when such physicians-owners are the sole (or nearly the sole) users of the devices sold or manufactured by their PODs.

Finally, because the anti-kickback statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction, hospitals and ASCs that enter into arrangements with PODs also may be at risk under the statute. In evaluating these arrangements, OIG will consider whether one purpose underlying a hospital's or an ASC's decision to purchase devices from a POD is to maintain or secure referrals from the POD's physician-owners.

IV. Conclusion

OIG is concerned about the proliferation of PODs. This Special Fraud Alert reiterates our longstanding position that the opportunity for a referring physician to earn a profit, including through an investment in an entity for which he or she generates business, could constitute illegal remuneration under the anti-kickback statute. OIG views PODs as inherently suspect under the anti-kickback statute. Should a POD, or an actual or potential physician-owner, continue to have questions about the structure of a particular POD arrangement, the OIG Advisory Opinion process remains available. Information about the process may be found at: http://oig.hhs.gov/faqs/advisory-opinions-faq.asp.

To report suspected fraud involving physician-owned entities, contact the OIG Hotline at http://oig.hhs.gov/fraud/report-fraud/index.asp or by phone at 1-800-447-8477 (1-800-HHS-TIPS).