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SUPERIOR COURT FOR THE STATE OF CALIFORNIA

FOR THE COUNTY OF LOS ANGELES

AZIKE NTEPHE, an individual, DIANE FENCL, an individual,

Plaintiffs,

vs.

DR. ALI MESIWALA, an individual; DR. DEVIN K. BINDER, an individual; DR. TY THAIYANANTHAN, an individual; THE SOUTHERN CALIFORNIA CENTER FOR NEUROSCIENCE AND SPINE; THE CENTER FOR NEUROSCIENCE AND SPINE; and DOES 1 through 100, inclusive,

Defendants.

Case No.: KC065457
[Assigned to Hon. Samantha P. Jessner in Dept. 93]

First Amended Complaint for:

1. Fraudulent Concealment
2. Breach of Fiduciary Duty
3. Failure to Obtain Informed Consent
4. Intentional Misrepresentation
5. Medical Negligence
6. Violation of Bus. & Prof. Code §§ 17200 et seq.
7. Loss of Consortium

Demand for Jury Trial

Complaint filed: January 18, 2013

Plaintiffs allege based on their personal knowledge with respect to their own acts and on information and belief with respect to all other matters:

GENERAL ALLEGATIONS

1.

INTRODUCTION

1. Physicians have a legal, moral and ethical obligation to disclose to their patients any unusual financial interest that they have in their patient's treatment. This is absolutely necessary to ensure that patients are fully informed about their treatment options – including any financial motivations that may be affecting their physician's recommended treatment.

2. Dr. Ali Mesiwala ("Dr. Mesiwala") is a surgeon who implants medical devices in which he has a financial interest in his patients. Dr. Mesiwala performed a multiple level decompression fusion on Azike Ntephe ("Azike") on or about October 16, 2009. Dr. Mesiwala used medical devices from a company or companies in which he had a financial interest in Azike's surgery, but he concealed this from Azike. As a result, Azike underwent Dr. Mesiwala's recommended surgery and remained under Dr. Mesiwala's care for the past several years.

3. Dr. Mesiwala is involved in a Physician Owned Distributorship, which is commonly referred to as a "POD." In PODs, physicians form business arrangements with medical device companies in which the doctors implant medical devices from the companies in their patients and then share in the profits generated by the sale of the devices. Because of the legal, ethical and patient safety problems involved in PODs, a few weeks ago the Office of the Inspector General for the United States issued a Special Fraud Alert regarding PODs. The Fraud Alert addresses attributes and practices of PODs that "produce substantial fraud and abuse risk and pose dangers to patient safety." A copy of the Special Fraud Alert is attached as Exhibit "A".

4. In addition to concealing his use of medical devices in which he had a financial interest from Azike, Dr. Mesiwala also provided sub-standard post-operative care to Azike following spinal fusion surgery on or about October 16, 2009. Dr. Mesiwala ignored and ultimately downplayed the presence of a dislodged spinal cage in Azike's spinal canal, concealed and misled plaintiff about the relevance of the disconnected rods and screws and dislodged spinal

cage to Azike's overall condition and symptoms of extreme pain, failed to recommend an appropriate fix for the dislodged spinal cage and disconnected rods and screws, and recommended a surgical procedure that was inappropriate given the issues with the disconnected rods and screws and dislodged cage in Azike's spine. As a result of Dr. Mesiwala's treatment falling below the standard of care, his misrepresentations regarding the dislodged spinal cage and disconnected rods and screws in Azike's spine, and his misrepresentations and concealment regarding his financial relationship with the companies that manufactured the hardware he implanted in Azike's spine, Azike has endured years of intense, near-constant pain, and a deterioration in his physical condition that has rendered him almost unrecognizable to his friends and family.

2.

THE PARTIES

5. Plaintiff Azike Ntephe ("Azike") is a 68-year-old man. At all relevant times to this action, plaintiff has been a resident of Claremont, California, in the County of Los Angeles.

6. Plaintiff Diane Fencl ("Diane") is Azike's wife. At all relevant times to this action, plaintiff has been a resident of Claremont, California.

7. Defendant Dr. Ali Mesiwala ("Dr. Mesiwala") is a neurosurgeon at the Southern California Center for Neuroscience and Spine and at the Center for Neuroscience and Spine. He is a resident of Claremont, California, in the County of Los Angeles.

8. Defendant Dr. Devin K. Binder ("Dr. Binder") is or was a neurosurgeon at the Center for Neuroscience and Spine at times relevant to this action.

9. Defendant Dr. Ty Thaiyananthan ("Dr. Thaiyananthan") is or was a neurosurgeon at the Center for Neuroscience and Spine at times relevant to this action.

10. Defendant Center for Neuroscience and Spine is a California Corporation, with an agent for service of process in California, which does business in California, and is subject to the jurisdiction of this court.

11. Defendant Southern California Center for Neuroscience and Spine is located in the same office as the Center for Neuroscience and Spine. Defendant Southern California for

Neuroscience and Spine appears to be legally connected to the Center for Neuroscience and Spine, and does not appear to be an independently legally registered California corporation.

12. Plaintiffs are informed and believe that defendants were in a joint venture to provide the services that are the subject of this lawsuit.

13. The true names and capacities, whether individual, corporate, associate or otherwise, of defendants named herein as Does 1 through 100, inclusive, are unknown to plaintiffs, who therefore sue said defendants by such fictitious names. Each of the defendants named herein as a Doe is responsible in some manner for the events and happenings hereinafter referred to, and some of plaintiffs' damages as herein alleged were proximately caused by such defendants. Plaintiffs will seek leave to amend this complaint to show said defendants' true names and capacities when the same have been ascertained.

14. At all times mentioned herein, each of the defendants was the agent or employee of each of the other defendants, or an independent contractor, or joint venturer, and in doing the things herein alleged, each such defendant was acting within the purpose and scope of said agency and/or employment and with the permission and consent of each other defendant.

3.

FACTUAL BACKGROUND

15. On or about October 16, 2009, Azike underwent surgery for a multiple level decompression fusion by his neurosurgeon, Dr. Mesiwala. Spinal cage, rods and screws were to be installed in Azike's spine during this surgery. However, unbeknownst to Azike, the spinal cage, rods and screws Dr. Mesiwala installed in Azike's back came from a medical device company or companies in which Dr. Mesiwala had a financial interest. Prior to installing these devices in Azike's spine, Dr. Mesiwala did not tell Azike that he had a financial interest in the company or companies providing the devices for Azike's spine. Nor did Dr. Mesiwala obtain Azike's consent to use hardware in Azike's back from companies in which Dr. Mesiwala had a financial interest. In fact, Azike would not have consented to the surgery, or to be treated by Dr. Mesiwala if he had known Dr. Mesiwala was concealing the fact that he planned to use devices from companies in which he had a financial interest in Azike's surgery.

16. Following the October 16, 2009 surgery, Azike remained in the hospital, first at Pomona Valley Hospital Medical Center in the Intensive Care Unit, and then at Casa Colina Hospital in the in-patient unit, until on or about November 10, 2009 when he was discharged. Azike went in for a follow up appointment with Dr. Mesiwala on or about November 24, 2009. Dr. Mesiwala reminded Azike and Diane that given the magnitude of the surgery, it would take 12-18 months for Azike to realize the full benefits of the surgery. Dr. Mesiwala cautioned Azike to have reasonable expectations for his recovery and advised him to be patient.

17. Azike had x-rays of his T8-S1 fusion on or about December 3, 2009, and another follow up appointment on December 3, 2009. Dr. Mesiwala assured Azike and Diane that "from a surgical perspective" Azike was doing well. Azike went in for additional x-rays on January 14, 2010, and had a follow-up appointment on January 21, 2010. Dr. Mesiwala reiterated what he had told Azike in December 2009: that it normally takes one year for muscles and bones to heal following a fusion surgery like the one Azike had, and 18 months for the nerves to stabilize. Dr. Mesiwala told Azike that he was making the expected progress for three months after a decompression fusion surgery. Dr. Mesiwala did not tell Azike that x-rays from January 14, 2010 showed that the spinal cage that Mesiwala implanted had migrated into the spinal canal and that the implanted rods and screws were disconnected.

18. On or about May 18, 2010, Azike had x-rays performed on his spine as part of his ongoing care following his October 16, 2009 surgery. These x-rays show that the spinal cage Dr. Mesiwala installed at the L5-S1 section of Azike's spine had become dislodged and migrated into the spinal canal. These x-rays also showed that certain rods and screws Dr. Mesiwala installed in Azike's back had become disconnected. Dr. Mesiwala did not tell Azike that a spinal cage had become dislodged in his spinal canal, or that various rods and screws were not connected, nor did he recommend any course of action to address these problems. Dr. Mesiwala also continued to conceal his financial interest in these devices.

19. On or about October 19, 2010, Azike went to Dr. Mesiwala for his one-year follow up appointment post-operation. Prior to that appointment, on or about October 14, 2010, Azike had x-rays of his spine taken. When Azike arrived for his appointment, he learned that he would

only be seeing Nurse Practitioner Ray Smith ("Smith"), rather than Dr. Mesiwala himself. During the appointment, Azike and his wife Diane asked Smith about confusing notes on the x-rays from October 14, 2010 that stated "posterior rods do not appear connected to the pedicle screws in S1." Smith was unable to answer questions about this.

20. Following this appointment, Azike scheduled an appointment to see Dr. Mesiwala to discuss his x-rays from October 14, 2010. Azike met with Dr. Mesiwala on November 18, 2010 and explicitly asked him about the x-ray report from October 14, 2010 that stated the "posterior rods do not appear connected to the pedicle screws in S1." Dr. Mesiwala answered that this issue was not a concern because the hardware (the rods and screws) were only there to provide initial support for the development and growth of the fusion, but were not needed in the long term. He also told Azike that even though the hardware is not needed in the long term, no one undertakes surgery to remove the hardware; rather, the hardware is just left inside the patient. Azike accepted and trusted Dr. Mesiwala's explanation completely as the sound medical advice of a trained neurosurgeon. Dr. Mesiwala continued to hide the fact that he used medical devices from a company in which he had a financial interest in Azike's surgery.

21. The x-rays of Azike's spine from October 14, 2010 also show that a spinal cage had become dislodged and had migrated into Azike's spinal canal. Dr. Mesiwala did not inform Azike that the x-rays showed the dislodged spinal cage, and he did not recommend any course of treatment to correct the problem at that time.

22. During Azike's appointment on November 18, 2010, Azike also described new pains he was experiencing. Dr. Mesiwala told Azike during this appointment that his ongoing pain was likely due to nerve damage developed prior to the October 2009 surgery, and he recommended a spinal cord stimulator as the best way to treat Azike's ongoing pain. Dr. Mesiwala also told Azike that he had healed from a bony standpoint, and that there was no evidence of instability. Dr. Mesiwala noted in his records that Azike "continues to have flexed forward gait" and "continues to have disconnection of the rod at the S1 level" but failed offer any explanation or treatment to remedy this.

23. By April 2011, Azike's pain was increasing. Azike scheduled an appointment to

see Dr. Mesiwala, and told Dr. Mesiwala that he was experiencing severe pain, numbness and tingling in both lower extremities. During this appointment, Dr. Mesiwala told Azike again that the spinal cord stimulator was Azike's best option for reducing his pain. Dr. Mesiwala did not give any indication that the dislodged spinal cage or disconnected rods and screws could be causing Azike's pain. Dr. Mesiwala did not recommend any treatment or interventions for correcting the dislodged spinal cage, the disconnected rods and screws in Azike's back or the flexed forward gait.

24. Due to increasing, unmanageable pain, Azike underwent surgery on October 21, 2011 to have a spinal cord stimulator implanted into his spine. Following the implant, Azike's ambulation began to deteriorate and he would lose balance when walking. He also began to demonstrate signs of proprioception. Azike's mobility began to deteriorate markedly beginning on or about November 24, 2011. He became unable to stand up and experienced episodes of falling.

25. On November 28, 2011, at the suggestion of Jeff Fairley at the Body Center, Diane rented a motorized wheelchair for home use to protect Azike's safety. Azike went to see Dr. Mesiwala the following day, on November 29, 2011 for assessment of his new problems. Dr. Mesiwala did not conduct any neurologic exams or suggest that any tests be ordered, nor did he suggest that the dislodged spinal cage and disconnected rods and screws in Azike's back should be corrected. Instead, he told Azike that his problems were the result of pressure on the paddle at T8-9 and that a "simple" correction—a minor laminectomy at T8-9—should fix Azike's new mobility problems.

26. Azike went in on Friday, December 2, 2011, to have the laminectomy performed. Azike's proprioception did not improve over the weekend following surgery, and he began experiencing urinary issues. After spending about 3 weeks time at a rehabilitation facility, Casa Colina, Azike returned home on or about December 28, 2011. He was wheelchair bound.

27. In approximately May 2012, Azike began to experience a further decline in his strength and increase in his pain level. Azike went to see Dr. Mesiwala on approximately June 12, 2012 to discuss this problem. Dr. Mesiwala expressed confidence that Azike would likely

have continued improvement and changes in his sensation and strength over the next year. Dr. Mesiwala indicated that he wanted to further evaluate Azike's spinal canal to ensure that no other problems existed that could be causing Azike's current symptomology, with no mention of the dislodged cage, disconnected rods, or the flexed forward gait. Dr. Mesiwala ordered a CT scan.

28. On July 13, 2012, Azike experienced a serious bout of pain, accompanied by profuse sweating and extreme weakness. He called his wife Diane, worried that he was going to die. Azike was transported via ambulance to the Pomona Valley Hospital Medical Center. Diane contacted Dr. Mesiwala and explained Azike's symptoms. Dr. Mesiwala returned her call, and reported based on an image he had viewed of Azike's spine that there was a gaseous vacuum at L5-S1. He text messaged Diane a picture of the image, with a message noting a "black void" at the L5-S1 disc space, and he noted that the disc above was filled with graft material.

29. On August 3, 2012, Azike initiated a follow up with Dr. Mesiwala to review the CT scan he had ordered in June 2012. Dr. Mesiwala told Azike that there was non-fusion at L5-S1, and that he needed to do a "simple" surgery—an anterior lumbar interbody fusion with a Medtronic cage with a graft using bone morphogenetic proteins. Dr. Mesiwala also told Azike that although the cage that was previously installed in his spine had migrated , was not causing any problems, he would go ahead and remove it since he would be conducting surgery anyway. This was the first time Dr. Mesiwala had mentioned the dislodged cage. He recommended an L5-S1 anterior lumbar interbody fusion. As a result, Azike suffered from constant, excruciating pain that prevented him from walking without assistance as a result of Dr. Mesiwala's substandard care and treatment. His pain was so intense at night that he could not sleep without a sleep aid.

30. On March 19, 2009, Dr. Mesiwala had Azike sign a "Medical Device/Study Consent" form. This form stated that Dr. Mesiwala had a financial interest in Kronos Spine, NuVasive Inc. and Hoffman Surgical. The form stated that if Dr. Mesiwala recommended a medical device for Azike that was produced by a company in which Dr. Mesiwala had a financial interest, that Dr. Mesiwala would first specifically inform Azike of that fact and would provide him with alternative devices made by other manufacturers. This form also stated that Azike had

the right to elect not to use a device made by any company in which Dr. Mesiwala had a financial interest. In fact, Dr. Mesiwala never informed Azike that he planned to use medical devices in Azike's surgeries that were produced by companies in which Dr. Mesiwala had a financial interest, nor did Dr. Mesiwala offer Azike the option of using devices from companies in which Dr. Mesiwala did not have a financial interest. Dr. Mesiwala used medical devices in which he had a financial interest in Azike's surgeries but never obtained Azike's informed consent to do so. Dr. Mesiwala intentionally concealed from Azike, throughout the course of Azike's treatment, that he was using devices in Azike from companies in which he had a financial interest. Because Dr. Mesiwala's hid these facts, Azike continued to treat with Dr. Mesiwala.

31. Had Azike known that Dr. Mesiwala had a financial interest in the companies that provided the hardware Dr. Mesiwala installed in Azike's back, Azike would not have had the surgeries recommended by Dr. Mesiwala, nor would he have remained under Dr. Mesiwala's care.

FIRST CAUSE OF ACTION

(Fraudulent Concealment)

PLAINTIFFS FOR A FIRST CAUSE OF ACTION AGAINST DEFENDANTS AND DOES 1 THROUGH 100, INCLUSIVE, EXCLUDING DR. BINDER AND DR. THAIYANANTHAN, AND EACH OF THEM, FOR FRAUDULENT CONCEALMENT

32. Plaintiffs incorporate by reference each and every of the foregoing paragraphs as though set forth in full in this cause of action.

33. Azike had a patient-physician relationship with defendants. Defendants intentionally failed to disclose important facts to Azike. Specifically, defendants failed to disclose that Dr. Mesiwala had a financial interest in the company or companies that provided the hardware Dr. Mesiwala implanted in Azike's back.

34. Azike did not know that Dr. Mesiwala was using hardware in Azike's back that came from companies in which Dr. Mesiwala had a financial interest.

35. Defendants intended to deceive Azike by concealing Dr. Mesiwala's financial relationship with the companies providing the hardware for Azike's surgeries. Azike reasonably

relied on defendants' deception and remained under his care and treatment.

36. Azike has been seriously harmed by defendants' concealment, and defendants' concealment was a substantial factor in causing plaintiff's harm. As a result of defendants' concealment, Azike remained under defendants' care and was subject to defendants' sub-standard care. These surgeries and treatments have caused Azike daily, excruciating pain.

37. Dr. Mesiwala's fraudulent concealment was a substantial factor causing Azike to suffer physical harm, prolonged pain and suffering, and emotional harm. Dr. Mesiwala's fraudulent concealment was also a substantial factor causing Azike to suffer economic damages in the form of loss of present and future earning capacity, the need for additional medical care, and the costs of suit.

SECOND CAUSE OF ACTION

(Breach of Fiduciary Duty)

PLAINTIFFS FOR A SECOND CAUSE OF ACTION AGAINST DEFENDANTS AND DOES 1 THROUGH 100, INCLUSIVE, EXCLUDING DR. BINDER AND DR. THAIYANANTHAN, AND EACH OF THEM, FOR BREACH OF FIDUCIARY DUTY, ALLEGE:

38. Plaintiffs incorporate by reference each and every of the foregoing paragraphs as though set forth in full in this cause of action.

39. Defendants owed Azike a fiduciary duty. As fiduciaries, defendants had a duty of full disclosure with respect to Azike's care and treatment. Defendants breached their fiduciary duty to Azike by failing to disclose that the hardware used in Azike's surgeries was provided by a company or companies in which Dr. Mesiwala had a financial interest. Azike was harmed by defendants' breach of fiduciary duty because he did not know that defendants' judgment with respect to his care and treatment was being influenced by a profit motive. As a result of defendants' breach of fiduciary duty, Azike remained under defendants' care and was subject to defendants'' sub-standard care. These treatments have caused Azike daily, excruciating pain.

40. Dr. Mesiwala's misrepresentations were a substantial factor causing Azike to suffer physical harm, prolonged pain and suffering, and emotional harm. Dr. Mesiwala's

misrepresentations were also a substantial factor causing Azike to suffer economic damages in the form of loss of present and future earning capacity, the need for additional medical care, and the costs of suit.

THIRD CAUSE OF ACTION

(Failure to Obtain Informed Consent)

PLAINTIFFS FOR A THIRD CAUSE OF ACTION AGAINST DEFENDANTS AND DOES 1 THROUGH 100, INCLUSIVE, EXCLUDING DR. BINDER AND DR. THAIYANANTHAN, AND EACH OF THEM, FOR FAILURE TO OBTAIN INFORMED CONSENT, ALLEGE:

41. Plaintiffs incorporate by reference each and every of the foregoing paragraphs as though set forth in full in this cause of action.

42. Dr. Mesiwala performed a multiple level decompression fusion on Azike's back, during which time he installed a spinal cage and rods and screws in Azike's back. Dr. Mesiwala had a financial interest in the company that manufactured the spinal cage, rods and screws that he installed in Azike's back. Dr. Mesiwala intentionally failed to disclose to Azike his financial interest in the companies that created the hardware he installed in Azike's back. Dr. Mesiwala did not have Azike's informed consent to use hardware in Azike's back in which he had a financial interest.

43. Azike was harmed by Dr. Mesiwala's failure to obtained informed consent regarding the hardware Dr. Mesiwala used in Azike's back. Specifically, Dr. Mesiwala's failure to obtain informed consent was a substantial factor causing Azike to suffer physical harm, prolonged pain and suffering, and emotional harm. Dr. Mesiwala's failure to obtain informed consent was also a substantial factor causing Azike to suffer economic damages in the form of loss of present and future earning capacity, the need for additional medical care, and the costs of suit.

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FOURTH CAUSE OF ACTION

(Intentional Misrepresentation)

PLAINTIFFS FOR A FOURTH CAUSE OF ACTION AGAINST DEFENDANTS AND DOES 1 THROUGH 100, INCLUSIVE, EXCLUDING DR. BINDER AND DR. THAIYANANTHAN, AND EACH OF THEM, FOR INTENTIONAL MISREPRESENTATION, ALLEGE:

44. Plaintiffs incorporate by reference each and every of the foregoing paragraphs as though set forth in full in this cause of action.

45. Dr. Mesiwala made numerous false representations to plaintiff, including, but not limited to, the following:

a. Dr. Mesiwala misrepresented that he would specifically inform Azike if he planned to recommend or use any medical devices produced by companies in which he had a financial interest in Azike's surgeries.

b. Dr. Mesiwala misrepresented that he if he wanted to use medical devices from companies in which he had a financial interest in Azike's surgeries, that he would first provide Azike with the option of using medical devices not manufactured by companies in which he had a financial interest.

c. Dr. Mesiwala misrepresented that Azike would be able to elect to not use a device made by any companies in which Dr. Mesiwala had a financial interest in Azike's surgeries.

d. Dr. Mesiwala intentionally concealed from Azike that he was using medical devices in Azike's surgeries that were manufactured by companies in which Dr. Mesiwala had a financial interest;

46. Dr. Mesiwala knew or should have known that these representations were false when he made them, and/or he made these representations recklessly and without regard for their truth.

47. Dr. Mesiwala intended Azike to rely on these representations, and Azike reasonably relied on these representations as the medical advice of his neurosurgeon.

48. Dr. Mesiwala's misrepresentations were a substantial factor causing Azike to suffer physical harm, prolonged pain and suffering, and emotional harm. Dr. Mesiwala's misrepresentations were also a substantial factor causing Azike to suffer economic damages in the form of loss of present and future earning capacity, the need for additional medical care, and the costs of suit.

FIFTH CAUSE OF ACTION

(Medical Negligence)

PLAINTIFFS FOR A FIFTH CAUSE OF ACTION AGAINST DEFENDANTS AND DOES 1 THROUGH 100, INCLUSIVE, AND EACH OF THEM, FOR MEDICAL NEGLIGENCE, ALLEGE:

49. Plaintiffs incorporate by reference each and every paragraph of the General Allegations as though set forth in full in this cause of action.

50. Defendant Dr. Mesiwala had a duty of care running to Azike as his treating neurosurgeon.

51. Dr. Mesiwala deviated from applicable standards of care in his profession, and breached his duty to Azike in several ways including, but not limited to, the following:

a. Providing substandard post-operative care by failing to correct the dislodged cage in Azike's spine at L5-S1, which was first noticeable in x-rays of Azike's spine from January 2010, but which Azike did not learn about from Dr. Mesiwala until July 2012;

b. Failing to correct the disconnected rods and screws in Azike's spine;

c. Failing to adequately review and/or disregarding x-ray images and x-ray reports that showed there were issues with the rods, screws and cage he installed in Azike's spine;

d. Misleading Azike by telling him that the disconnected rods and screws in Azike's spine were unimportant;

e. Recommending an inappropriate surgical procedure—a spinal cord stimulator—given the issues with the loose rods and screws, dislodged cage

and non-fusion at L5-S1;

f. Failing to address and correct Azike's flexed forward gait due to curvature of rods causing lordosis and flat back syndrome;

52. Plaintiffs reserve the right to assert other acts and omissions that amount to negligence in the care and treatment rendered to Azike by defendants, to be further set forth as discovered during litigation.

53. The acts and omissions cited above are evidence not only for violations of the applicable standard of care, but are also compelling evidence for wanton, reckless disregard on the part of Dr. Mesiwala for the health and safety of Azike, as will be set forth in a later noticed motion seeking permission to perform discovery on and to seek punitive damages.

54. As a direct, legal and proximate result of the negligent conduct of the named defendants and each of them, Azike has suffered physical harm, prolonged pain and suffering, and emotional harm. He has also suffered economic damages in the form of loss of present and future earning capacity and the need for additional medical care and the costs of suit. Additionally, the negligent conduct caused Azike to undergo more complex treatment and surgeries, and permanent injuries.

55. The amounts to be sought for the full measure of economic and general damages will be proven at the time of trial.

SIXTH CAUSE OF ACTION

(Violation of Business & Professions Code sections 650, 650.01 (f) and 654.2 & 17200)

PLAINTIFFS FOR A SIXTH CAUSE OF ACTION AGAINST DEFENDANTS AND DOES 1 THROUGH 100, INCLUSIVE, EXCLUDING DR. BINDER AND DR. THAIYANANTHAN, AND EACH OF THEM, FOR VIOLATIONS OF BUSINESS & PROFESSIONS CODE SECTIONS 17200, ET SEQ. ALLEGE:

56. Plaintiffs incorporate by reference each and every of the foregoing paragraphs as though set forth in full in this cause of action.

57. Dr. Mesiwala installed medical devices in Azike that were manufactured by companies in which he had a financial interest without telling Azike that he planned to use these

devices prior to the surgery, and without giving Azike the option to select an alternate device made by a manufacturer in which Dr. Mesiwala did not have a financial interest. Dr. Mesiwala also profited by using medical devices in Azike in which he had a financial interest. These actions are unlawful, unfair and fraudulent. They violate Business & Professions Code §§ 650, 650.01 (f) and 654.2.

58. Dr. Mesiwala, by violating Business & Professions Code §§ 650, 650.01 (f) and 654.2, has committed acts of unfair competition as set forth in Business & Professions Code § 17200.

59. Plaintiffs are informed and believe and thereon allege that Dr. Mesiwala's acts of unfair competition are continuing in nature and respectfully requests that an injunction against Dr. Mesiwala issue to enjoin him from continuing to engage in the unfair competition alleged herein.

60. Plaintiffs have suffered an injury in fact and has lost money or property as the result of defendants' conduct. In addition, as a consequence of Dr. Mesiwala's failure to disclose his use of medical devices from a company in which he had a financial interest, and in failing to offer Azike alternative medical devices, Azike was unwittingly forced to use these medical devices that caused him to suffer physical injuries and emotional distress, all so that Dr. Mesiwala could increase his profits.

61. Plaintiffs further respectfully request that the Court order any other and further equitable relief deemed necessary by the Court.

SEVENTH CAUSE OF ACTION

(Loss of Consortium)

PLAINTIFF DIANE FENCL FOR A SEVENTH CAUSE OF ACTION AGAINST DEFENDANTS AND DOES 1 THROUGH 100, INCLUSIVE, AND EACH OF THEM, FOR LOSS OF CONSORTIUM, ALLEGES:

62. Plaintiff incorporates by reference each and every of the foregoing paragraphs as though set forth in full in this cause of action.

63. At all times mentioned in this complaint, plaintiffs were husband and wife.

64. By reason of the injuries defendants caused Azike described above, plaintiff

Diane Fencl has been deprived of the care, comfort, protection, society, support and services and consortium of her husband, and thereby has suffered general damages. As a direct and proximate result of the injuries Azike has suffered, Azike has been unable to perform the duties of a husband in that he can no longer assist with housework, participate in family, recreational or social activities with Diane, or contribute to the household income. Due to the nature of the injuries sustained by Azike and the severe physical and psychological strains they cause him, Azike is no longer able to provide plaintiff with the same love, companionship, affection, society, moral support and solace. Because of these injuries, Azike will be unable to perform these duties in the future. Diane is therefore deprived and will be permanently deprived of her spouse's consortium, all to her damage, in an amount to be established by proof at trial.

WHEREFORE, plaintiffs pray for full compensation for such tortious acts and statutory violations, including;

A. General and special damages according to proof;

B. Economic damages according to proof;

C. Reasonable attorneys' fees and costs according to proof including, but not limited to, attorneys' fees based on CCP Section 1021.5;

D. Injunctive relief;

E. Such other compensation and award as the court and the jury should find lawful and appropriate.

Dated this 9th day of May 2013, at Pasadena, California.

LAW OFFICES OF SCOTT C. GLOVSKY, APC

By: _____
SCOTT C. GLOVSKY
Attorneys for Plaintiffs

DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a trial by jury.

DATED: May 9, 2013

LAW OFFFICES OF SCOTT C. GLOVSKY, APC

By: _____

SCOTT C. GLOVSKY
Attorneys for Plaintiffs

EXHIBIT A

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).

PROOF OF SERVICE

STATE OF CALIFORNIA, COUNTY OF LOS ANGELES

I am employed in the county of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is: 100 East Corson Street, Suite 200, Pasadena, California, 91103.

On **May 9, 2013**, I served the foregoing documents described as:

First Amended Complaint for:

1. Fraudulent Concealment
2. Breach of Fiduciary Duty
3. Failure to Obtain Informed Consent
4. Intentional Misrepresentation
5. Medical Negligence
6. Violation of Bus. & Prof. Code §§ 17200 et seq.
7. Loss of Consortium

Demand for Jury Trial

on all interested parties in this action by placing [ ] the original [x]a true copy thereof enclosed in sealed envelopes addressed as follows:

[Please See Attached Service List]

[X] BY MAIL

I caused such envelope to be deposited in the mail at Pasadena, California. The envelope was mailed with postage thereon fully prepaid. I am "readily familiar" with this firm's practice of collection and processing correspondence for mailing. It is deposited with U.S. postal service on that same day in the ordinary course of business. I am aware that on motion of party served, service is presumed invalid if postal cancellation date or postage meter date is more than 1 day after date deposit for mailing in affidavit.

[ ] BY FACSIMILE ("FAX")

A copy was sent by FAX to the above-listed party.

I declare that I am employed in the office of a member of the bar of this court at whose direction the service was made. I declare under penalty of perjury under the laws of California that the above is true and correct.

Executed on **May 9, 2013** at Pasadena, California.

Roberta Liao

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