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15	IN THE UNITED STATES DISTRICT COURT					
16	FOR THE DISTRICT OF ARIZONA					
17	1					
18	United States ex rel. Radhakrishnan, et al.,	No. CV-20-00176-PHX-GMS <b>LEAD CASE</b>				
19	Plaintiffs,	Consolidated with:				
20	V.	No. CV-21-00010-PHX-SPL				
21	Yury Gampel, et al.,	No. CV-21-01206-PHX-GMS				
22	Defendants.	UNITED STATES' COMPLAINT				
23	United States <i>ex rel</i> . Terry, <i>et al.</i> ,	IN INTERVENTION				
24	• • • • • • • • • • • • • • • • • • • •	(FALSE CLAIMS ACT; PAYMENT				
25	Plaintiffs, v.	BY MISTAKE; UNJUST ENRICHMENT)				
<ul><li>26</li><li>27</li></ul>	Modern Vascular of Glendale, LLC, et al.,					
28	Defendants.					
	- -	1 -				

1 United States ex rel. Katherine Diggins, et al.,
2 Plaintiffs,
3 v.
4 Modern Vascular LLC, et al.,
5 Defendants.

Medicare, TRICARE, and other federal health care programs, like all consumers of health care goods and services, necessarily expect and depend on health care providers to make independent decisions grounded in clinical criteria, sound science, and their patients' best interests. Kickbacks and other illegal financial incentives, like those paid and received by Defendants in this case, have long been prohibited because of their potential to corrupt the clinical judgment of medical professionals. *See United States v. Starks*, 157 F.3d 833, 838 (11th Cir. 1998) ("the giving or taking of kickbacks . . . is hardly the sort of activity a person might expect to be legal"); *United States v. Neufeld*, 908 F. Supp. 491, 496 (S.D. Ohio 1995) ("Taking bribes . . . is an inherently wrongful activity and one of which a physician should be particularly aware."). Persons and entities such as Defendants, who offer, pay, or accept bribes and kickbacks in doing business with federal health care programs, forfeit their privilege to bill those programs.

## **INTRODUCTION**

- 1. The United States brings this action pursuant to the False Claims Act, 31 U.S.C. §§ 3729-3733 ("FCA"), seeking treble damages and civil penalties, and under common law and equitable theories of recovery.
- 2. Defendant Yury Gampel, a chiropractor, is the founder and former Chief Executive Officer ("CEO") of a franchise of office-based labs ("OBL") located in Arizona, New Mexico, Colorado, Texas, Indiana, Kansas, Mississippi, Missouri, Tennessee, and Virginia operating under the name Modern Vascular (collectively, the "Modern Vascular OBLs"). The Modern Vascular OBLs each its own separate legal entity focus on the treatment of peripheral arterial disease ("PAD"), particularly through an aggressive use of

vascular intervention procedures, such as angioplasty and atherectomy.

- 3. Defendant Nobility Management, LLC, provides management services to the Modern Vascular OBLs. Defendants Modern Vascular Management, LLC; Modern Vascular Management East, LLC; and Modern Vascular Management West, LLC, offer IT and management support to Modern Vascular OBLs. Defendants Modern Vascular, LLC, and Modern Vascular of South Florida, LLC, are corporations controlled by Gampel that have various ownership interests in Modern Vascular OBLs. Through Modern Vascular, LLC, and Modern Vascular of South Florida, LLC, and in his own capacity, Gampel is the majority owner of the Modern Vascular OBLs. (These entities that own and manage the Modern Vascular OBLs are referred to collectively below as "Modern Vascular Corporate.")
- 4. Gampel and Modern Vascular Corporate designed and implemented a fraud scheme at Modern Vascular OBLs at the expense of patients and federal payors. In particular, Gampel and Modern Vascular Corporate provided remuneration to physician investors in Modern Vascular OBLs to induce those investors to refer patients to the Modern Vascular OBLs.
- 5. More specifically, Gampel and Modern Vascular Corporate opened Modern Vascular OBLs in new markets where referring physicians and vascular surgeons had established relationships. Prior to opening an OBL in a particular location, Gampel sought out up to 20 local physicians usually podiatrists and pain management physicians who traditionally referred to vascular surgeons and offered each up to a two percent ownership interest in the OBL in order to induce the physicians to refer to the OBL. Gampel and Modern Vascular Corporate selected these particular physicians (hereinafter "physician-investors") to offer ownership investment because Gampel and Modern Vascular Corporate identified them as potential high-referral sources. Once they invested in an OBL, Gampel and Modern Vascular Corporate further required the physician-investors to make referrals to Modern Vascular OBLs as a condition for remaining as a physician-investor. Gampel and Modern Vascular Corporate therefore devised a scheme to establish immediate and

substantial revenue for new OBLs by paying distributions to the physician-investors to induce them to refer patients to the OBLs and reward them for the referrals.

- 6. Gampel and Modern Vascular Corporate also hired interventional radiologists or vascular surgeons as employees of newly-established Modern Vascular OBLs to run the clinics. Gampel and Modern Vascular Corporate then placed enormous pressure on each new Modern Vascular OBL, and its staff, to perform a target number of invasive procedures on the patients referred to the Modern Vascular OBLs. As Modern Vascular Corporate's Chief Medical Officer Steve Berkowitz told a reporter for the *Arizona Republic*, "If you run a pizza joint and you're not selling enough pizzas, you're not going to stay in business."
- 7. From January 1, 2017, through at least June 30, 2022 (the "relevant time period"), in violation of the FCA, Defendants submitted, and caused to be submitted, tens of millions of dollars in false or fraudulent claims to federal health care programs, including the Medicare and TRICARE programs, by offering and providing illegal remuneration to health care providers to induce referrals to the Modern Vascular OBLs in violation of the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b. To induce referrals, Gampel and Modern Vascular Corporate provided remuneration to physician-investors in the form of equity ownership interests in an OBL, which also included distributions, the prospect of future distributions, and/or the prospect of a cash-out of the equity ownership amounts when the Modern Vascular OBLs were sold. During the relevant time period, Modern Vascular OBLs received over \$50 million from Medicare Part B alone for claims submitted for patients referred by physician-investors in violation of the FCA.
- 8. The AKS arose out of concern by Congress that certain types of financial incentives, or items of value, could improperly influence or even corrupt the medical decision-making of physicians and other health care providers, resulting in federal funds being diverted to pay for goods and services that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population.
  - 9. As evident from disclosures made to potential investors in Modern Vascular

- OBLs, Defendants knew of the AKS and FCA, understood the AKS's prohibition on offering or paying money to induce or reward referrals, and understood the FCA's prohibition on submitting or causing to be submitted claims resulting from kickbacks. Modern Vascular Corporate's investor disclosures also detail the AKS "small entity safe harbor," discussed below.
- 10. Gampel, Modern Vascular Corporate, and the Modern Vascular OBLs put their own greed over compliance with the law to enhance their profitable schemes. During the relevant time period, Modern Vascular Corporate and the Modern Vascular OBLs submitted and received reimbursement for over \$50 million in false claims to Medicare Part B and TRICARE that were tainted by kickbacks and should not have been paid.

## **JURISDICTION AND VENUE**

- 11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1345, and 1367(a).
- 12. The Court may exercise personal jurisdiction over Defendants under 31 U.S.C. § 3732(a) because each Defendant resides, previously resided in, and/or transacted business in this district during the relevant time period.
- 13. Venue is proper in the District of Arizona under 31 U.S.C. § 3732 and 28 U.S.C. § 1391(b) because Defendants transact or transacted business in this district, and a substantial part of the events giving rise to this action occurred in this district.

## **PARTIES**

## I. The United States

14. The United States brings this action on behalf of the Department of Health and Human Services ("HHS"), which, through the Centers for Medicare and Medicaid Services ("CMS"), administers Medicare and Medicaid; and on behalf of the Department of Defense ("DOD"), which, through the Defense Health Agency ("DHA"), administers the TRICARE program ("TRICARE").

## II. Relators

15. Relator Jay Radhakrishnan is a resident of the State of Texas. Dr.

Radhakrishnan is a board-certified interventional radiologist who has never been employed by any Defendant.

- 16. Relator William Julien is a resident of the State of Florida. Dr. Julien is a board-certified interventional radiologist who has never been employed by any Defendant.
- 17. In January 2020, Relators Radhakrishnan and Julien filed the first of these consolidated actions, *United States ex rel. Radhakrishnan, et al. v. Yury Gampel, et al.*, CV-20-00176-PHX-GMS (D. Ariz.), alleging violations of the FCA on behalf of themselves and the United States pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).
- 18. Relator David Terry is a resident of the State of Arizona. Dr. Terry is a board-certified vascular surgeon who has never been employed by any Defendant.
- 19. Relator Chandrahas Patel is a resident of the State of Arizona. Dr. Patel is a cardiothoracic surgeon who has never been employed by any Defendant.
- 20. Relator Lannery Lauvao is a resident of the State of Arizona. Dr. Lauvao is a board-certified vascular surgeon who has never been employed by any Defendant.
- 21. In January 2021, Relators Terry, Patel, and Lauvao filed the second of these consolidated actions, *United States ex rel. Terry, et al. v. Modern Vascular of Glendale, LLC*, CV-21-00010-PHX-SPL (D. Ariz.), alleging violations of the FCA on behalf of themselves and the United States pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1).
- 22. Relator Katherine Diggins is a resident of the State of Colorado. Diggins is a former vascular surgery physician's assistant who was employed by Defendant Modern Vascular of Denver, LLC.
- 23. In July 2021, Relator Diggins filed the third of these consolidated actions, *United States ex rel. Jane Doe, et al.*, v. *Modern Vascular LLC, et al.*, CV-21-01206-PHX-GMS (D. Ariz.), alleging violations of the FCA on behalf of herself, the United States, and various states pursuant to *qui tam* provisions under state law. On September 15, 2022, those states declined to intervene.

## III. Defendants<sup>1</sup>

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24. Defendant Yury Gampel is a chiropractor and resident of Florida. During the relevant time period, or portions thereof, Gampel owned and/or controlled the other Defendants in this matter. For the vast majority of the relevant time period, Gampel portrayed himself as the CEO of Modern Vascular Corporate. On the Modern Vascular Corporate website, Gampel currently promotes himself as the "Founder and Board Chairman of Modern Vascular." Gampel principally owns and controls Nobility Management, LLC; Modern Vascular, LLC; Modern Vascular of South Florida, LLC; Modern Vascular Management, LLC; Modern Vascular Management - East, LLC; and Modern Vascular Management – West, LLC. Throughout his involvement with these entities, Gampel remained active in, and knowledgeable of, the management, operational, investment, and treatment decisions and activities of each of these entities. In effect, Gampel is the owner and controller of each of the individual Modern Vascular OBLs, and he holds that ownership interest in his own capacity and through Modern Vascular, LLC, and Modern Vascular of South Florida, LLC. Five Modern Vascular OBLs are owned and operated within the State of Arizona (Modern Vascular Institute, LLC; Modern Vascular of Mesa, LLC; Modern Vascular of Glendale, LLC; Modern Vascular of Sun City, LLC; and Modern Vascular of Tucson, LLC).

25. Defendant Nobility Management, LLC, is a limited liability corporation authorized and existing under the laws of the State of California, doing business in Arizona at 1846 East Innovation Park Drive, Suite 100, Oro Valley, Arizona 85755. Nobility Management, LLC, purports to provide billing and collection services to the Modern

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<sup>&</sup>lt;sup>1</sup> In its order consolidating these cases, the Court instructed that "[a]ll future pleadings shall be . . . captioned as referenced above" (Doc. 24). In compliance with this order, the United States lists all named defendants, including additional defendants beyond those named in the referenced *qui tam* actions, in this section rather than including them in the caption as Local Rule of Civil Procedure 7.1(a)(3) would otherwise require. *See Bias v. Moynihan*, 508 F.3d 1212, 1223 (9th Cir. 2007) ("Broad deference is given to a district court's interpretation of its local rules.").

- Vascular OBLs, which pay five percent of their revenues to Nobility Management, LLC, for these services. Gampel is the majority owner of Nobility Management, LLC. Modern Vascular OBLs are required to contract with Nobility Management, LLC, to provide management, billing, and collection services. Nobility Management, LLC, claims to provide human resources, billing, credentialing, and legal support to OBLs. Nobility Management, LLC, makes cash distributions to investors in the Modern Vascular OBLs.
- 26. Defendant Modern Vascular, LLC, is a limited liability corporation authorized and existing under the laws of the State of Arizona with its principal place of business at 4650 East Cotton Center Boulevard, Suite 120, Phoenix, Arizona 85040. Gampel is the primary owner of Modern Vascular, LLC. Modern Vascular, LLC, does not purport to provide any management services to OBLs, describing itself as a company that holds equity ownership interests in various Modern Vascular OBLs. Modern Vascular, LLC, is the principal owner of nearly all of the Modern Vascular OBLs. Modern Vascular OBLs license the federal trademark of "Modern Vascular" from Modern Vascular, LLC, on a non-exclusive non-transferrable basis. In investor agreements Modern Vascular, LLC, is listed as the "seller" of the shares in Modern Vascular OBLs that it owns, and the investor pays the investment funds to Modern Vascular, LLC; Gampel signs as Modern Vascular, LLC's authorized representative.
- 27. Defendant Modern Vascular of South Florida, LLC, is a limited liability corporation authorized and existing under the laws of the State of Florida with its principal place of business in Aventura, Florida. Modern Vascular of South Florida, LLC, does not purport to provide any management services to OBLs, describing itself as an affiliate of Modern Vascular, LLC, and a holding company that is an equity owner in various Modern Vascular OBLs. Modern Vascular of South Florida, LLC, is the principal owner of the Modern Vascular OBLs not principally owned by Modern Vascular, LLC, including Modern Vascular of Sun City, LLC, a limited liability corporation authorized and existing under the laws of the State of Arizona with its principal place of business in Surprise, Arizona. Modern Vascular of South Florida, LLC, was formed in 2018. Gampel is the

- primary owner of Modern Vascular of South Florida, LLC, and was named as its manager upon creation, though Nobility Management was named as the manager in its public filings. In effect, Gampel is the owner and controller of each of the individual Modern Vascular OBLs, and he holds that ownership interest in his own capacity and through Modern Vascular, LLC, and Modern Vascular of South Florida, LLC.
- 28. Defendant Modern Vascular Management, LLC, is a limited liability corporation authorized and existing under the laws of the State of Delaware, doing business in Arizona at 4650 East Cotton Center Boulevard, Suite 120, Phoenix, Arizona 85040. Modern Vascular Management, LLC, purports to have worked on the Modern Vascular design since its inception. Gampel is its CEO and owner. Modern Vascular Management, LLC, purports to perform many services for Modern Vascular OBLs, including contracting, accounting, legal support, cash management, payroll administration, benefits administration support, insurance support, and credentialing. In exchange for its services to Modern Vascular OBLs, OBLs are required to pay Modern Vascular Management, LLC, eight percent of their revenues. Modern Vascular Management, LLC, further claims to provide IT support, administration of policy and procedures, and corporate trainers and regional supervisors that work with the Modern Vascular OBLs.
- 29. Defendant Modern Vascular Management West, LLC, is a limited liability corporation authorized and existing under the laws of the State of Delaware, doing business in Arizona at 4650 East Cotton Center Boulevard, Suite 120, Phoenix, Arizona 85040. Gampel is the owner. Modern Vascular Management West, LLC, purports to be the successor name to Modern Vascular Management, LLC. In exchange for its services to Modern Vascular OBLs, OBLs are required to pay Modern Vascular Management West, LLC, eight percent of their revenues.
- 30. Defendant Modern Vascular Management East, LLC, is a limited liability corporation authorized and existing under the laws of the State of Delaware. Gampel is the owner. Modern Vascular Management East, LLC, purports to perform many services for Modern Vascular of Kansas, LLC, including contracting, accounting, legal support, cash

management, payroll administration, benefits administration support, insurance support, and credentialing. In exchange for its services to Modern Vascular of Kansas, LLC, that OBL is required to pay Modern Vascular Management – East, LLC, eight percent of its revenues.

- 31. Defendant Modern Vascular Institute, LLC, is a limited liability corporation authorized and existing under the laws of the State of Arizona with its principal place of business in Mesa, Arizona. Modern Vascular Institute, LLC, was formed in 2017 with its manager listed as Nobility Management, LLC. Modern Vascular Institute, LLC, operated an OBL located at 2919 South Ellsworth Road #115, Mesa, Arizona 85212. The principal owner of Modern Vascular Institute, LLC, is Modern Vascular, LLC.
- 32. Defendant Modern Vascular of Mesa, LLC, is a limited liability corporation authorized and existing under the laws of the State of Arizona with its principal place of business in Mesa, Arizona. Modern Vascular of Mesa, LLC, operated an OBL located at 535 East McKellips Road #111, Mesa, Arizona 85203. Modern Vascular of Mesa, LLC, was formed in 2017 with its manager listed as Nobility Management, LLC. The principal owner of Modern Vascular of Mesa, LLC, is Modern Vascular, LLC.
- 33. Defendant Modern Vascular of Glendale, LLC, is a limited liability corporation authorized and existing under the laws of the State of Arizona with its principal place of business in Glendale, Arizona. Modern Vascular of Glendale, LLC, was formed in 2017 with its manager listed as Gampel. Modern Vascular of Glendale, LLC, operated an OBL located at 11851 North 51st Avenue, Building G #110, Glendale, Arizona 85304. The principal owner of Modern Vascular of Glendale, LLC, is Modern Vascular, LLC.
- 34. Defendant Modern Vascular of Sun City, LLC, is a limited liability corporation authorized and existing under the laws of the State of Arizona with its principal place of business in Surprise, Arizona. Modern Vascular of Sun City, LLC, was formed in 2019 with its manager listed as Nobility Management, LLC. Modern Vascular of Sun City, LLC, operated an OBL located at 14733 West Mountain View Boulevard, Building F, Surprise, Arizona 85374. The principal owner of Modern Vascular of Sun City, LLC, is

Modern Vascular, LLC.

- 35. Defendant Modern Vascular of Tucson, LLC, is a limited liability corporation authorized and existing under the laws of the State of Arizona with its principal place of business in Tucson, Arizona. Modern Vascular of Tucson, LLC, was formed in 2018 with its manager listed as Nobility Management, LLC. Modern Vascular of Tucson, LLC, operated an OBL located at 2171 West Orange Grove, Tucson, Arizona 85741. The principal owner of Modern Vascular of Tucson, LLC, is Modern Vascular, LLC.
- 36. Defendant San Antonio Vascular Specialists Corp. d/b/a Modern Vascular is a limited liability corporation authorized and existing under the laws of the State of Texas with its principal place of business in San Antonio, Texas. San Antonio Vascular Specialists Corp. d/b/a Modern Vascular was formed in 2019 with its manager listed as Gampel. San Antonio Vascular Specialists Corp. d/b/a Modern Vascular operated locations at 9819 Huebner Road, Building 4, San Antonio, Texas 78240 and 718 Lexington Avenue, San Antonio, Texas 78212. The principal owner of San Antonio Vascular Specialists Corp. d/b/a Modern Vascular is Modern Vascular, LLC.
- 37. Defendant Fort Worth Vascular Specialists Corp. d/b/a Modern Vascular is a limited liability corporation authorized and existing under the laws of the State of Texas with its principal place of business in Fort Worth, Texas. Fort Worth Vascular Specialists Corp. d/b/a Modern Vascular was formed in 2019 and listed its manager as Modern Vascular Management, LLC. Fort Worth Vascular Specialists Corp. d/b/a Modern Vascular operated an OBL at 5750 Stratum Drive, Fort Worth, Texas 76137. The principal owner of Fort Worth Vascular Specialists Corp. d/b/a Modern Vascular, LLC.
- 38. Defendant Modern Vascular of Denver, LLC, is a limited liability corporation authorized and existing under the laws of the State of Colorado with its principal place of business in Thornton, Colorado. Modern Vascular of Denver, LLC, was formed in 2019 and listed Modern Vascular Management, LLC, as its manager. Modern Vascular of Denver, LLC, operated an OBL at 9441 Huron Street, Thornton, Colorado 80260. The principal owner of Modern Vascular of Denver, LLC, is Modern Vascular, LLC.

- 39. Defendant Modern Vascular Navajo, LLC, is a limited liability corporation authorized and existing under the laws of the State of New Mexico with its principal place of business in Albuquerque, New Mexico. Modern Vascular Navajo, LLC, was formed in 2018 and listed Nobility Management, LLC, as its manager. Modern Vascular Navajo, LLC, operated an OBL at 7800 Constitution Avenue Northeast, Albuquerque, New Mexico 87110. The principal owner of Modern Vascular Navajo, LLC, is Modern Vascular of South Florida, LLC.
- 40. Defendant Modern Vascular of Fairfax, LLC, is a limited liability corporation authorized and existing under the laws of the Commonwealth of Virginia with its principal place of business in Fairfax, Virginia. Modern Vascular of Fairfax, LLC, was formed in 2018. Modern Vascular of Fairfax, LLC, operated an OBL at 2812 Old Lee Highway #100 B-D, Fairfax, Virginia 22031. The principal owner of Modern Vascular of Fairfax, LLC, is Modern Vascular, LLC.
- 41. Defendant Modern Vascular of Houston, LLC, is a limited liability corporation authorized and existing under the laws of the State of Texas with its principal place of business in Richmond, Texas. Modern Vascular of Houston, LLC, was formed in 2020 and listed its manager as Modern Vascular Management, LLC. Modern Vascular of Houston, LLC, operated an OBL at 7103 South Peak Road, Richmond, Texas 77407. The principal owner of Modern Vascular of Houston, LLC, is Modern Vascular, LLC.
- 42. Defendant Modern Vascular of Indianapolis, LLC, is a limited liability corporation authorized and existing under the laws of the State of Indiana with its principal place of business in Fort Wayne, Indiana. Modern Vascular of Indianapolis, LLC, was formed in 2020 and listed its manager as Modern Vascular Management, LLC. Modern Vascular of Indianapolis, LLC, operated an OBL at 8704 North Meridian Street, Indianapolis, Indiana 46560. The principal owner of Modern Vascular of Indianapolis, LLC, is Modern Vascular, LLC.
- 43. Defendant Modern Vascular of Southaven, LLC, is a limited liability corporation authorized and existing under the laws of the State of Mississippi with its

- 1 principal place of business in Southaven, Mississippi. Modern Vascular of Southaven,
- 2 | LLC, was formed in 2019 and listed its manager as Modern Vascular Management West,
- 3 LLC. Defendant Modern Vascular of Southaven, LLC, operated an OBL at 55 Physicians
- 4 | Lane, Southaven, Mississippi 38671. On investor documents, "Modern Vascular, LLC, an
- 5 | Arizona Limited Liability Company" is listed as the seller of shares of Modern Vascular of
- 6 Southaven, LLC, to investors. The principal owner of Modern Vascular of Southaven, LLC,
- 7 is Modern Vascular of South Florida, LLC.
- 8 44. Defendant Modern Vascular of St. Louis, LLC, is a limited liability
- 9 corporation authorized and existing under the laws of the State of Missouri with its principal
- 10 place of business in Creve Coeur, Missouri. Modern Vascular of St. Louis, LLC, was
- 11 formed in 2020 and listed its manager as Modern Vascular Management, LLC. Modern
- 12 Vascular of St. Louis, LLC, operated an OBL at 641 North New Ballas Road, Creve Coeur,
- 13 Missouri 63141. The principal owner of Modern Vascular of St. Louis, LLC, is Modern
- 14 Vascular, LLC.
- 15 45. Defendant Modern Vascular of Kansas, LLC, is a limited liability
- 16 | corporation authorized and existing under the laws of the State of Kansas with its principal
- 17 place of business in Overland Park, Kansas. Modern Vascular of Kansas, LLC, was formed
- 18 in 2020 and listed its manager as Modern Vascular Management East, LLC. Modern
- 19 Vascular of Kansas, LLC, operated an OBL at 5320 College Boulevard, Overland Park,
- 20 Kansas 66211. The principal owner of Modern Vascular of Kansas, LLC, is Modern
- 21 Vascular, LLC.

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## LEGAL BACKGROUND

## I. The False Claims Act

- 24 | 46. The FCA makes it unlawful for any person to submit, directly or indirectly,
- 25 | false or fraudulent claims for payment to the Government. See 31 U.S.C. §§ 3729, et seq.
- 26 The United States alleges liability under two of the FCA's seven liability provisions.
- 27 47. First, under its "presentment provision," the FCA prohibits knowingly
- presenting, or causing to be presented, a false or fraudulent claim for payment or approval.

31 U.S.C. § 3729(a)(1)(A). Thus, liability under 31 U.S.C. § 3729(a)(1)(A) attaches when a defendant (a) made, or caused to be made, a claim (b) that was false or fraudulent (c) knowing of its falsity.

- 48. Second, the FCA prohibits knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim. 31 U.S.C. § 3729(a)(1)(B). Thus, liability under 31 U.S.C. § 3729(a)(1)(B) attaches when a defendant (a) made, used, or caused to be made or used, a record or statement that was (b) knowingly false and (c) material to a false or fraudulent claim.
- 49. The term "knowingly" under the FCA means that a person, with respect to information, (i) has actual knowledge of the information, (ii) acts in deliberate ignorance of the truth or falsity of the information, or (iii) acts in reckless disregard of the truth or falsity of the information. 31 U.S.C. § 3729(b). No proof of specific intent to defraud is required to show that a person acted knowingly under the FCA. *Id*.
- 50. Under the FCA, the term "claim" means any request or demand for money, whether under a contract or otherwise, presented to an officer, employee, or agent of the United States. 31 U.S.C. § 3729(b)(2)(A)(i). A "claim" is also a request or demand for money made to a contractor or other recipient if (a) the money is to be spent or used on the Government's behalf or to advance a Government program or interest and (b) if the Government provides, has provided, or will reimburse such contractor or other recipient for any portion of the money requested or demanded. 31 U.S.C. § 3729(b)(2)(A)(ii).
- 51. The FCA defines "material" objectively to mean "having a natural tendency to influence, or be capable of influencing, the payment or receipt of property." 31 U.S.C. § 3729(b)(4). The Supreme Court reaffirmed the natural tendency test materiality test even as to subsection (a)(1)(A), which does not explicitly use the term and described a holistic approach to analyzing it. *See Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 181-82, 1996 (2016).
- 52. Violations of the FCA subject the defendant to mandatory civil penalties per FCA violation, plus three times the amount of damages that the Government sustains as a

result of the defendant's actions. 31 U.S.C. § 3729(a).

## II. Medicare

- 53. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for the costs of certain health care services. *See* 42 U.S.C. §§ 1395, *et seq.* HHS, through CMS, is responsible for administering and supervising the Medicare program.
- 54. Entitlement to Medicare is based on age, disability, or affliction with endstage renal disease. 42 U.S.C. §§ 426, 426-1, 426A. Individuals who are insured under Medicare are referred to as Medicare "beneficiaries."
- 55. The Medicare program consists of four parts: A, B, C, and D. Part B covers outpatient care, including physician services and ancillary services, such as clinical laboratory services, furnished by physicians and other providers and suppliers. 42 U.S.C. § 1395k.
- 56. Medicare Part B only covers services, including diagnostic laboratory services, that are reasonable and necessary for the diagnosis or treatment of an illness. *See* 42 U.S.C. § 1395y(a)(1)(A) ("[N]o payment may be made under [Medicare] part A or part B... for any expenses incurred for items or services... which... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member[.]"); 42 C.F.R. § 411.15(k)(1).
- 57. Medicare regulations require providers and suppliers to certify that they meet, and will continue to meet, the requirements of the Medicare statute and regulations. 42 C.F.R. § 424.516(a)(1).
- 58. To participate in the Medicare program as a new enrollee, group practices and clinical laboratories must submit a Medicare Enrollment Application, Form CMS-855B. These entities must also complete Form CMS-855B to change information or to reactivate, revalidate, and/or terminate Medicare enrollment.
  - 59. Form CMS 855-B requires, among other things, signatories to certify:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier . . . . I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the supplier's compliance with all applicable conditions of participation in Medicare.

\* \* \*

I will not knowingly present or cause to be presented a false or fraudulent claim for payment by Medicare, and I will not submit claims with deliberate ignorance or reckless disregard of their truth or falsity.

See https://www.cms.gov/Medicare/CMS-Forms/CMS-

Forms/Downloads/cms855b.pdf (last visited December 12, 2022).

- 60. An authorized official must sign the "Certification Section" in Section 15 of Form CMS-855B, which "legally and financially binds [the] supplier to all of the laws, regulations, and program instructions of the Medicare program." *Id*.
- 61. The National Provider Identifier ("NPI") is a standard and unique health identifier for health care providers. All providers and practitioners must have an assigned NPI number prior to enrolling in Medicare.
- 62. Typically, physicians are compensated for the services they provide Medicare patients on a fee-for-service basis as determined by Medicare's fee schedule. 42 U.S.C. § 1395w-4. To obtain compensation, physicians must deliver a compensable service, certify that the service was medically necessary for the health of the patient, certify that the service was personally furnished by the physician (or under his or her immediate supervision), and determine the appropriate diagnosis and procedure code to describe the problem and service for billing.
- 63. The Medicare statute requires that each request for payment or bill submitted for an item or service payable under Medicare Part B include the name and NPI for the referring physician. 42 U.S.C. § 1395l(q)(1).
  - 64. To obtain Medicare reimbursement for certain outpatient items or services,

providers and suppliers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent, known as the 837P format. Among the information the provider or supplier includes on a CMS 1500 or through the 837P format are certain five-digit codes, including Current Procedural Terminology Codes ("CPT codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought, and the NPI of the "rendering provider" and the "referring provider or other source."

- 65. During the relevant time period, federal regulations designated and continue to designate CPT and HCPCS codes as the standard codes to be used for physician services and other health care services. 45 C.F.R. § 162.1002(a)(5), (c)(1).
- 66. When submitting claims to Medicare, providers certify on the CMS 1500, among other things, that (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information on the claim form is "true, accurate, and complete"; and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under applicable Federal and State laws."
- 67. After a February 2012 revision to the CMS 1500, providers further certify that their claims comply "with all applicable Medicare . . . laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as the Stark Law)." CMS 1500 also requires providers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."
- 68. Similarly, when enrolling to submit claims electronically, providers certify that they will submit claims that are "accurate, complete, and truthful." *Electronic Data Interchange (EDI) Enrollment Form*, Ctrs. For Medicare & Medicaid Servs., https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf

(last visited December 12, 2022).

- 69. A health care provider is prohibited from knowingly presenting or causing to be presented claims for items or services that the person knew or should have known were not medically necessary, or were false or fraudulent. 42 U.S.C. §§ 1320a-7a(a)(1); 1320a-7(b)(7) (permitting exclusion of providers for the foregoing violations).
- 70. A provider has a duty to familiarize itself with the statutes, regulations, and guidelines regarding coverage for the Medicare services it provides. *Heckler v. Cmty. Health Servs. of Crawford Ctnv., Inc.,* 467 U.S. 51, 64 (1984).
- 71. Because it is not feasible for the Medicare program, or its contractors, to review medical records corresponding to each of the millions of claims for payment it receives from providers, the program relies on providers to comply with Medicare requirements and to submit truthful and accurate certifications and claims.
- 72. Generally, once a provider submits a CMS 1500, or the electronic equivalent, to the Medicare program, the claim is paid directly to the provider, in reliance on the foregoing certifications, without any review of supporting documentation, including medical records.
- 73. During the relevant time period, Defendants billed Medicare under Part B for medical services including, but not limited to, atherectomy and angioplasty, by submitting claims for reimbursement.

## III. TRICARE

- 74. TRICARE is a medical benefits program established by federal law. 10 U.S.C. §§ 1071-1110b. TRICARE covers eligible beneficiaries, including active-duty members of the Uniformed Services and their dependents as well as retired members of the Uniformed Services and their dependents. The federal government reimburses a portion of the cost of health care services and prescription medications provided to TRICARE beneficiaries. TRICARE is administered by the DHA.
- 75. TRICARE covers only medically necessary inpatient and outpatient care. TRICARE defines medically necessary care as services or supplies provided by a hospital,

physician, and/or other provider for the prevention, diagnosis, and treatment of an illness, when those services or supplies are determined to be consistent with the condition, illness, or injury; provided in accordance with approved and generally accepted medical or surgical practice; not primarily for the convenience of the patient, the physician, or other providers; and not exceeding (in duration or intensity) the level of care which is needed to provide safe, adequate, and appropriate diagnosis and treatments. *See* 32 C.F.R. § 199.4(a)(1)(i) and applicable definitions at 32 C.F.R. § 199.2.

- 76. TRICARE regulations also provide that TRICARE may deny payment in "abuse situations." 32 C.F.R. § 199.9(b). To avoid abuse situations, providers are obligated to provide services and supplies under TRICARE that are: "Furnished at the appropriate level and only when and to the extent medically necessary . . . ; of a quality that meets professionally recognized standards of health care; and, supported by adequate medical documentation as may reasonably be required under this part . . . to evidence the medical necessity and quality of services furnished, as well as the appropriateness of the level of care." *Id*.
- 77. Under TRICARE regulations, to be "appropriate," medical care must be "[f]urnished economically"—i.e., "in the least expensive level of care or medical environment adequate to provide the required medical care." 32 C.F.R. § 199.2.
- 78. As with Medicare, providers submit claims to TRICARE using the CMS 1500 or an electronic equivalent. Providers therefore make the same certifications in submitting claims to TRICARE as they do when submitting claims to Medicare.
- 79. Because it is not feasible for the TRICARE program, or its contractors, to review medical records corresponding to each of the claims for payment it receives from providers, the program relies on providers to comply with TRICARE requirements and relies on providers to submit truthful and accurate certifications and claims.
- 80. During the relevant time period, Defendants billed TRICARE for medical services including, but not limited to, atherectomy and angioplasty, by submitting claims for reimbursement.

## IV. The Anti-Kickback Statute

- 81. The AKS arose out of Congressional concern that providing things of value to those who can influence health care decisions may corrupt their professional judgment and result in federal funds being diverted to pay for goods and services that are medically unnecessary, of poor quality, or even harmful to patients. Thus, Congress passed the AKS "to protect patients and the federal health care programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions." Department of Health and Human Services, Office of Inspector General ("OIG") Fact Sheet, November 1999 (https://oig.hhs.gov/documents/compliance/851/safefs.htm (last visited December 12, 2022)).
- 82. The AKS "seeks to ensure that referrals will be based on sound medical judgment and that providers will compete for business based on quality and convenience, instead of paying for . . . [referrals]." OIG Advisory Op., No. 98-16 (Nov. 3, 1998). The AKS is intended to prevent arrangements that can lead to the distortion of medical decision-making, overutilization of services and supplies, increased costs to federal healthcare programs, and unfair competition. *See* 65 Fed. Reg. 59,434, 59,440 (Oct. 5, 2000).
- 83. The AKS prohibits the payment of kickbacks in order to protect the integrity of Medicare, TRICARE, and other federal health care programs. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, § 242(b)-(c), 86 Stat. 1329, 1419-20; 42 U.S.C. § 1320a-7b; Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, 91 Stat. 1175 (1977); Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93, 101 Stat 680.
- 84. The AKS prohibits any person or entity from soliciting, receiving, offering, or paying any remuneration as an inducement or reward for referring, recommending, ordering, or arranging for the purchase of any item or service for which payment may be made in whole or in part by a federal health care program. In pertinent part, the statute provides:

b. Illegal remunerations

interest in generating business for the company in which he or she invests. *See* OIG Advisory Op., No. 97-5 (Oct. 6, 1997); *see also* Special Advisory Bulletin: Contractual Joint Ventures, 68 Fed. Reg. 23,148, 23,150 (April 30, 2003).

- 86. The AKS's legislative history confirms Congress' intent to interpret the nature of the remuneration broadly: "the substance rather than simply the form of a transaction should be controlling." *See* 123 Cong. Rec. 30,280 (1977) (statement of Rep. Rostenkowski).
- 87. While the corruptive power of kickbacks can and does result in care that is medically unnecessary, more costly than necessary, of poor quality, or even harmful to a vulnerable patient population, the harm from kickbacks is sometimes difficult to detect and may be impossible to monitor. For this reason, Congress enacted the AKS as a *per se* prohibition against the payment and receipt of kickbacks in any form, regardless of a particular impact on quality of care. Accordingly, the AKS does not require proof of overutilization or poor quality of care.
- 88. The AKS is violated if any one purpose of the remuneration is to induce or reward referrals of federal health care program business. 66 Fed. Reg. 856, 918 (Jan. 4, 2001).
- 89. Congress codified an amendment to the AKS in the Patient Protection and Affordable Care Act of 2010 ("PPACA"), Pub. L. No. 111-148, § 6402(f), 124 Stat. 119 (codified at 42 U.S.C. § 1320a-7b(g)). The amendment makes clear that the knowing submission of an AKS-tainted claim also violates the FCA: "[A] claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the FCA]."
- 90. Based on the legislative history of the PPACA, this amendment further clarifies "that all claims resulting from illegal kickbacks are considered false claims for the purposes of civil actions under the [FCA], even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854 (statement of Sen. Kaufman).

- 91. Accordingly, compliance with the AKS is material to the Government's decision to pay a claim under federal health care programs. Compliance with the AKS is also a condition of payment under federal health care programs.
- 92. Violating the AKS may subject an individual or entity to exclusion from participation in federal health care programs, civil monetary penalties of \$100,000 per violation, and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose. 42 U.S.C. § 1320a-7a(a)(7) (civil penalties for violation of the acts proscribed by 42 U.S.C. § 1320a-7b(b)).
- 93. The United States has filed suit under the FCA on several occasions to pursue individuals who offer kickbacks and health care providers who accept them, further underscoring the materiality of AKS and FCA violations based on kickbacks.

## A. AKS "Safe Harbors"

- 94. The AKS contains several safe harbors to the prohibition against providing compensation in exchange for referrals. When the OIG established the first AKS safe harbors, it explained that "the payment practices described in these safe harbor provisions would be prohibited" by the AKS, but for their inclusion in the safe harbors. 56 Fed. Reg. 35952, 35958 (July 29, 1991). The OIG was aware of "widespread abuse in many joint ventures" and believed "a large number of these newly formed entities are designed to have physicians as investors specifically to induce them to use the entity in which they had invested." *Id.* at 35966. Consequently, the OIG included "significant safeguards to minimize any corrupting influence the investment interest may have on the physician-investor's decision where to refer a patient," and emphasized that this safe harbor provision would only provide protection when the standards were met "by all investors in the entity." *Id.* at 35966-67.
- 95. One safe harbor to the prohibition against providing compensation in exchange for referrals is often referred to as the "small entity safe harbor." 42 C.F.R § 1001.952(a)(2). The safe harbor is narrowly tailored to prevent improper economic inducements from being disguised as ordinary investments. To meet this safe harbor, an

entity possessing investment interests held by either active or passive investors must meet all of eight applicable standards, including:

- (iii) The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity.
- (iv) There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor.
- (vi) No more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors.

42 C.F.R. § 1001.952(a)(2).

- 96. An active investor may be (1) an individual or entity who is responsible for day-to-day management of an entity and who is a bona fide general partner in a partnership under the Uniform Partnership Act, or (2) an individual or entity who agrees in writing to undertake liability for the actions of the entity's agents acting within the scope of their agency. 42 C.F.R. § 1001.952(a)(4). A "passive investor" is defined as "an investor who is not an active investor." 42 C.F.R. § 1001.952(a)(4). The investment interest safe harbor standards "must be met by all the investors in the entity," and when one class of investors qualifies for protection and the other does not, "safe harbor protection is not given to payments to any investors in the entity." Medicare and State Healthcare Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,967 (July 29, 1991).
- 97. Regarding subsection (iv), the "focus of the inquiry in this standard is where the business and clients are coming from. In other words, the revenues are tainted and may not exceed 40 percent of total revenues if they are derived 'from referrals \*\*\* or business otherwise generated from investors." Medicare and State Health Care Programs: Fraud

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and Abuse; Clarification of the OIG Safe Harbor Anti-Kickback Provisions, 59 Fed. Reg. 37,202, 37,204 (July 21, 1994).

98. In adopting the AKS safe harbors, the OIG expressly declined to adopt safe harbor protections for certain actions. For example, the OIG declined to protect the "vague concepts" of "substantial compliance," "technical violations," or "de minimis payments," choosing instead to establish bright lines about the conduct that would be immune from government action. 56 Fed. Reg. 35,952, 35,954 (July 29, 1991).

#### В. **OIG Advisory Opinions**

- 99. Individuals and entities may seek an advisory opinion from the OIG to determine whether a specific business arrangement constitutes grounds for the imposition of sanctions under the AKS. See 62 Fed. Reg. 7350 (Feb. 19, 1997). Individuals and entities contemplating a business arrangement that could violate the AKS may avoid unnecessary risk by describing the arrangement and asking the OIG for an advisory opinion.
- In one of the first advisory opinions issued, the OIG provided guidance to a radiology group and a hospital system contemplating a joint venture. OIG Advisory Opinion No. 97-5 (Oct. 6, 1997). The OIG cautioned that, "the major concern is that the profit distributions to investors in the joint venture, who are also referral sources to the joint venture, may potentially represent remuneration for those referrals." *Id.* at 7. Further:

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

*Id.* at 10.

#### C. **OIG Special Fraud Alerts And Related Guidance**

101. The OIG issues Special Fraud Alerts to discuss "trends of health care fraud

and certain practices of an industry-wide character." 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994). The purpose of these alerts is "to provide general guidance to the health care industry" and to offer "additional insight to the Medicare carrier and fraud units in identifying health care fraud schemes." *Id.* at 65, 373.

- 102. In 1989, the OIG issued a Special Fraud Alert that discussed arrangements that presented the strong potential for an AKS violation where a physician joint venture arrangement was "intended not so much to raise investment capital legitimately to start a business, but to lock up a stream of referrals from the physician investors and to compensate them indirectly for those referrals." OIG, Special Fraud Alert: Joint Venture Arrangements (OIG-89-4), *reprinted in* 59 Fed. Reg. 65,372, 65,373 (Dec. 19, 1994).
- 103. The 1989 Special Fraud Alert expressed the OIG's concerns over joint ventures in which physicians could benefit financially from their own referrals. The 1989 Special Fraud Alert identified the following particular areas of concern, among others: (1) recruiting and retaining only physicians who are in a position to make referrals, (2) requiring only nominal physician investments and providing returns that are disproportionately large in relation to business risk, and (3) employing a "shell" structure that outsources business operations to an ongoing entity. *Id*.
- 104. In 2003, the OIG reiterated the concerns expressed in the 1989 Special Fraud Alert in a 2003 Special Advisory Bulletin concerning the "proliferation of arrangements between those in a position to refer business, such as physicians, and those providing items . . . for which Medicare . . . pays." OIG, Special Advisory Bulletin on Contractual Joint Ventures, *reprinted in* 68 Fed. Reg. 23,148 (Apr. 30, 2003).

## **DEFENDANTS' FRAUDULENT KICKBACK SCHEME**

- 105. Gampel, through Modern Vascular Corporate, used a fraudulent kickback scheme to maximize profits at Modern Vascular OBLs at the expense of patients and federal payors.
- 106. Each Modern Vascular OBL is organized as a separate limited liability corporation, in which either Modern Vascular, LLC, or Modern Vascular of South Florida,

LLC, is the majority owner and other investors have small ownership interests. A document titled "Preliminary Year-End Report" for 2018 ("2018 Year-End Report") authored by Modern Vascular Corporate's Vice President of Legal and Compliance Mark Rabinovich explained the ownership structure of each Modern Vascular OBL:

Each subsidiary is generally owned by two groups of investors. Class B (the "founder" class) usually consists of one <u>non-physician</u> owner (MVLLC [Modern Vascular, LLC] or MVSF [Modern Vascular of South Florida, LLC], as the case may be). Class A (the "minority investor" class) consists of various investors, some or all of whom are in the position to refer patients to the facility. While both Class A and Class B members have voting rights on company-wide matters, the Class B has a controlling voting interest.

- 107. Each Modern Vascular OBL has an NPI, which is used to bill Medicare and TRICARE for services rendered to federal health care beneficiaries.
- 108. Gampel and Modern Vascular Corporate provided remuneration to physician-investors invested in Modern Vascular OBLs to induce those physician-investors to refer patients to the Modern Vascular OBLs, and also to reward them for previous referrals, in violation of the AKS. As explained in the 2018 Year-End Report:

A typical minority (Class A) investor owns up to two percent (2%) in a given Modern Vascular subsidiary. As described below, a subsidiary is optimally expected to generate from \$3,000,000 to \$4,000,000 of income during a fiscal year, which means that a typical 2% investor will be allocated from \$60,000 to \$80,000 of the Company's income.

Gampel and Modern Vascular Corporate provided remuneration to physicianinvestors through these ownership interests, but also through distributions, the prospect of future distributions, and a potential cash-out of the equity ownership amounts when Gampel sold the Modern Vascular OBLs.

109. Gampel and Modern Vascular Corporate sought to induce large numbers of patient referrals from Modern Vascular OBL investors to Modern Vascular OBLs through multiple mechanisms, including demanding patient referrals from Modern Vascular OBL investors, requesting specific numbers of patient referrals from investors, publishing and

distributing investor referral numbers, and pursuing new physician-investors positioned to make or influence large numbers of patient referrals.

- 110. Modern Vascular Corporate and the Modern Vascular OBLs then submitted or caused the submission of false claims to Medicare and TRICARE that resulted from the AKS violations.
- I. Gampel And Modern Vascular Defendants Sold Ownership Interests In Modern Vascular OBLs To Physician-Investors To Induce Referrals From The Physician-Investors.
  - a. Gampel And Modern Vascular Corporate Offered Ownership Interests In A Modern Vascular OBL To Physicians With Referring Potential And Required A Referral Commitment.
- 111. Gampel and Modern Vascular Corporate opened Modern Vascular OBLs in new markets where referring physicians and vascular surgeons had established referral relationships. To grow quickly, prior to opening a Modern Vascular OBL, Gampel identified up to 20 physicians usually podiatrists and pain management physicians who traditionally referred to vascular surgeons and offered each up to a two percent ownership interest in the OBL.
- 112. Modern Vascular Corporate and Gampel identified physician referrals as the key to the success of the lab. To induce and reward referrals, they offered high-referring physicians ownership investment in the OBL. For example, on September 5, 2018, Gampel emailed potential investors in the Modern Vascular of Fairfax, LLC, OBL stating that "I will need two commitments" from each physician-investor:
  - 1. The first commitment is a signed copy of the agreements back with a \$15,000 check or 2% shareholding for each of you in this company. This is a small amount that every physician can afford. The investment barrier has been set very low. The potential rewards are very high.
  - 2. The second, and more important, is a commitment that you all have the ability to send 3-5 patient referrals for vascular workup per week.
- Explaining Modern Vascular Corporate's business model later in the email, Gampel

proclaimed "this commitment to refer is the key to the success of the lab . . . . In order to get into the black and to good distributions [sic] as soon as possible we need your commitment for a strong start."

113. In a December 2019 investor meeting attended by Physician-Investor 1, Modern Vascular Corporate's management told investors that the more patients investors referred to Modern Vascular OBLs, the more money they would make.

## b. Gampel And Modern Vascular Corporate Required Physician-Investors To Continue Referring To Remain Investors.

- 114. Physician-investors were also required to make referrals to Modern Vascular OBLs as a condition for remaining as an investor. For example, Physician-Investor 1 was "bought out" of his investment because of his lack of referrals. Physician-Investor 1 had referred one to two patients per month to a Modern Vascular OBL and Gampel told Physician-Investor 1 that he wanted four to five referrals per week. Physician-Investor 1 stated that was not possible because his patients were already well-managed and, consequently, did not require invasive procedures. In December 2019, Gampel informed Physician-Investor 1 that he was no longer an investor due to lack of referrals.
- 115. Modern Vascular Corporate required investors to refer patients or run the risk of losing shares due to lack of referrals. Gampel told Physician-Investor 2 that investing in Modern Vascular OBLs was not a retirement plan and that the investor was required to refer patients to meet projected numbers.

## c. Gampel And Modern Vascular Corporate Pressured Physician-Investors For Additional Referrals By Tracking And Communicating Referral Numbers.

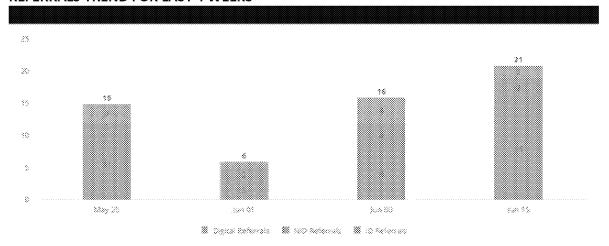
- 116. Modern Vascular Corporate tracked its sources of referrals made and distributed this information to the investors. For example, Physician-Investor 3 received monthly emails tracking his referral numbers.
- 117. Investors in the Modern Vascular of Fairfax, LLC, OBL received emails from Modern Vascular Corporate employees tracking referrals. For example, an email sent

on August 20, 2020, to three investors with the subject line "Follow Up-Modern Vascular," stated, "Referrals last week were overall solid. . . . However; this week has been about half of expectation. The expectation Yury put out was 2-3 a week."

Vascular OBLs. For example, on March 13, 2020, Dr. Luis Nadal, the managing physician of Modern Vascular Sun City, LLC, emailed numerous Modern Vascular Corporate officers and employees, including Gampel, explaining that "[h]ere is the data compiled according to Investor Doc -vs- non Investor doc status. All of this information was obtained directly from the daily procedure log sheets that are generated daily, as well as the incoming referral sheets that are faxed electronically." Dr. Nadal then proceeded to explain "several interesting observations" he learned from the data, including certain investors "who are by far under referrers relative to the group at large. So one third (33%) of the investor pool is poorly engaged." Dr. Nadal went on to explain that he had attempted to reach out to these investors.

119. Modern Vascular Corporate closely tracked weekly referral rates and sent the physician-investors summaries to keep pressure on investors. For example, on June 22, 2020, Modern Vascular Corporate's Executive Vice President Ernest Tepman sent an email with the subject line "Sun City Weekly Email" to referring investors in the Modern Vascular of Sun City, LLC, OBL. Modern Vascular Corporate's Chief Operating Officer Steve Springborn, Gampel, and other Modern Vascular Corporate officers were copied on the email. In the email, Tepman ran through the total number of referrals for the past week, noting that "[l]ast week referrals continued on an upward trend overall for the past 3 weeks as the clinic has again surpassed the weekly average of 17. The running sum of referrals for June so far is 43 as compared to June of 2019 was 71." (Bold and underline in original.) Springborn provided the investors a bar graph illustration of the referring trend for the previous four weeks:

### **REFERRALS TREND FOR LAST 4 WEEKS**



Finally, Springborn informed the investors of the Sun City OBL's "Weekly Clinic Goals": "\*\*\*The weekly clinic goals for referrals received and procedures completed is as follows ... Referrals: 50-55."

120. On March 2, 2018, Nobility Management's Chief Information Officer Clark Warren emailed Gampel, Modern Vascular Corporate's Director Tim Murphy, and other people affiliated with Nobility Management to explain their referral tracking system: "I have put new referral tracking spreadsheets in your respective site file systems (in the trackers folders) . . . . Please do the following and ask Yury [Gampel] and Tim [Murphy] for direction if you have specific questions about how they want you using the updated trackers. Please track all investor doctor and non-investor doctor referrals in the DOCTORS tab of the tracker."

121. Gampel and Modern Vascular Corporate also put some investors through a "trial period" to see how many patients the physician would refer before offering an investment interest. Depending on how many patients were referred, Gampel and Modern Vascular Corporate might offer a one or two percent investment. For example, an email from September 5, 2019, opens with a podiatrist informing Modern Vascular Corporate's Executive Vice President Ernest Tepman that he has "a colleague that I would like to get involved and invest" and then asking "[i]s the opportunity open to new doctors?" Tepman replied, "As you understand we are not in need of capital, but for the right partner we'd be

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27 28 open to a conversation. What's his name? How about he refers to the Fairfax lab for 90 days, sees what we do, gets a sense for outcomes, and we get to see how things look with him and it's [sic] a win-win we revisit then?"

- 122. On November 4, 2019, the podiatrist emailed Tepman again and stated, "I am including [Doctor 1] who is the new associate at our practice in Oxon Hill Maryland. I am reducing some of my hours there and he will be picking them up and wanted to put you two in touch to see if he can try the 90 day trial period with you guys." That same day, Tepman forwarded the email to Gampel and stated, "I don't think these are incrementally new referrals – meaning in my understanding [the podiatrist] is just giving his current patients to an associate, so not sure new shares are warranted . . . what do you think?" Gampel replied, "He can start referring but no guarantee of shares. Too early." Later that day, Tepman emailed Doctor 1 and stated that he would connect Doctor 1 to the Modern Vascular of Fairfax, LLC, OBL's physician liaison and "she'll stop by and explain the referral process."
- On December 14, 2019, Doctor 1 emailed Tepman stating, "I hope you are doing well, just wanted to follow up and get some up dates [sic]." Tepman then emailed Modern Vascular Corporate's COO Steve Springborn and asked, "Hey Steve Can we please look up [Doctor 1] referral patterns?" Springborn replied: "He started referring in November. November = 6. Dec = 3."
- 124. On December 16, 2019, Tepman emailed Doctor 1 back and stated, "We traditionally do 3-6 month trial [sic] to see how things transpire. Let's keep the communication going and revisit in a month or two."
- 125. Doctor 1 continued to make referrals to the Modern Vascular of Fairfax, LLC, OBL, including at least one referral in early 2020 using a Modern Vascular Corporate PAD evaluation and referral form discussed below at paragraph 135.
- 126. On March 2, 2020, Tepman emailed Springborn and stated, "How can I see this does referrals – [Doctor 1]? He wants to be an ID, we told him we'll do a trial period. Please let me know."

127. On March 3, 2020, Tepman emailed Gampel and stated, "Yury, you remember we put [Doctor 1] on ID 'trial period.' So he would be one of the top 5-6 referring guys in Fairfax based on his referring patterns, and I think he'd be a good addition. What do you think we offer him full 2% (as for Fairfax guys, spread among SC, Tucson, Albuquerque) or 1%?"

- 128. On March 10, 2020, Tepman emailed Doctor 1 and stated, "Wanted to let you know that we are in the process of preparation of subscription packages for you. I am not sure if you are aware of the structure that Fairfax docs have, it's a bit different from what we do elsewhere due to unique [sic] nature of Virginia laws. Once We'll [sic] send you the package, feel free toc all [sic] me and I'll explain."
- 129. On July 30, 2020, Doctor 1 emailed Tepman stating, "It has been a while since I heard from you and I like [sic] to follow up on our prior communication! Per your prior e mail the trial traditionally takes 4-6 month [sic], however I have been working with Modern Vascular group for about 8-9 months and I have not received any updates about the subscription. Please advise."
- 130. On August 10, 2020, Modern Vascular of Fairfax, LLC, OBL's Clinical Liaison Kristi Austin emailed Tepman stating, "After reviewing [Doctor 1]'s numbers, here are the stats for referrals. He sent over 8 in January, 6 in February, March through July only 4. I know a lot of this has to do with Covid. They started seeing a greatly reduced number of patients again starting in June. I believe the first of the year numbers are more accurate regarding his referral patterns." On August 13, 2020, Tepman forwarded this August 10 email to Gampel.

## d. Physicians Who Referred To Modern Vascular Of Fairfax, LLC, OBL Were Offered Investment Interests In Other OBLs.

131. For one OBL – Modern Vascular of Fairfax, LLC – Modern Vascular Corporate and Gampel employed a different version of their scheme, purportedly to circumvent the law. Gampel stated in an investor meeting that investments were needed to open a Virginia clinic, but that Modern Vascular Corporate had hired a law firm and the

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investors would invest in Modern Vascular OBLs in the Western United States so as not to violate the law. However, Modern Vascular Corporate selected those investors based on their ability to refer to the Modern Vascular of Fairfax, LLC, OBL.

Modern Vascular Corporate expected the Modern Vascular of Fairfax, LLC, OBL investors to refer to the clinics in their geographic area in return for the dividends they disbursed. On September 5, 2019, Tepman emailed certain investors in the Modern Vascular of Fairfax, LLC, OBL, copying Gampel, with the subject line "Modern Vascular additional partnership interests." Tepman stated that the investors receiving the email were being offered an additional interest in OBLs in Sun City, Tucson, and Albuquerque. Tepman stated, "We have faith and trust in you, that although these labs are not in your back yard and you'll be benefitting from the efforts and energies of partners just like you in those areas, you will reciprocate and put same effort and energy into supporting your home lab - Modern Vascular of Fairfax." (Bold in original.) Tepman went on to say, "I can't stress enough that participation of ALL partners is critical to the success of this venture, I think all would agree that Modern Vascular has been living up to its part of the promise, this is the opportunity for you to do the same." (Bold in original.)

That the Defendants' scheme relied on physician-investors referring patients to the OBLs was known throughout the defendant companies, far beyond just Gampel. For example, on June 30, 2020, Kristi Austin, the Modern Vascular of Fairfax, LLC, OBL Clinical Liaison, emailed Leslie Gibbs, Modern Vascular Corporate's Chief Marketing Officer, stating that "[m]y IDs [investor referrers] are not directly invested in Fairfax Clinic but others in our company (Va Commonwealth Law). Not having as much skin in the game places this area in a position to need 2x as many IDs. In other words twice as the highest number invested in other MV clinics doing same procedure and volume potentialdemographic and other factors." Gibbs responded, "I agree, not having a go to group of IDs is a handicap for managing tough periods."

# e. Gampel And Modern Vascular Corporate Also Encouraged Referrals Through Aggressive Treatment Guidance.

134. Modern Vascular Corporate also sought to inflate the population visiting its clinics by instructing referring doctors – including physician-investors – that they needed to refer patients to Modern Vascular OBLs who may have had minimal or no need to see a specialist. Specifically, Modern Vascular Corporate distributed "Peripheral Arterial Disease Evaluations" to potential physician referrers that, if followed, would result in an extremely high percentage of patients being automatically referred to Modern Vascular OBLs.

135. For example, the Modern Vascular of Denver, LLC, OBL circulated the following PAD evaluation referral form:

# Peripheral Arterial Disease Evaluation (PAD)

American Diabetes & Heart Associations Latest Recommendations Incorporated in Score Short

Patient Name:		DOB:		ated in Score Sheet
	PATIENT HEALTH HISTORY		Score:	
	Have Diabetes?		7	
	Have any Wounds or Ulcers on foot or lower leg?		6	
	Over 65 yrs?		6	
74	Over 50 yrs?		4	
	EVER Smoked?			5
45	Ever had Lower Extremity Revascularization?		5	
	Have history of Hypertension?			4
	Ever feel Resting Leg Pain or Foot Pain?		4	
09	Is one foot ever Colder than the other?		4	
$\leq$ $\leq$	Have Neuropathy?		4	
2>	Have High Cholesterol?		3	
	Ever had a Heart Attack or Stent?		3	
		То	tal Added Score:	
				**************************************

\*\*\* If Patient Scores Above 10, Refer for Vascular Evaluation. Check \*\*\* (Patient may be at risk for PAD & should receive an arterial screening immediately.)

#### DENVER:

9441 Huron Street Thornton, CO 80260 **P: 720-617-7333 F: 720-627-8845** 

## \*\*\*INCLUDE\*\*

- ☐ Insurance☐ Demographics

Following the guidance in referral forms such as these, any patient over the age of 65 who had ever smoked would automatically be sent to Modern Vascular OBLs for PAD evaluation.

136. In October 2019, Gampel and senior Modern Vascular Corporate officers participated in strategic planning sessions with an outside advisor. In anticipation of those sessions, a strategic planning survey developed from the participants was created titled "2019-2022 Strategic Planning Survey – Modern Vascular" ("2019-2022 Strategic Planning Survey"). In the "Final V.1.0 Master Compilation" draft of the 2019-2022 Strategic Planning Survey, various responses were gathered concerning aspects of Defendants' business. Under "Opportunities" in the 2019-2022 Strategic Planning Survey, Modern Vascular Corporate listed "Maximize Investor Docs (ID's) process via PAD screening tool implementation." Modern Vascular Corporate then listed "Threats: the Greatest Threats for MODERN VASCULAR right now – that might decrease sales, profits, or market share, and/or inhibit/erode our competitive position our productivity, and/or threaten our liability or longevity." (Bold and underline in original.) Included among these "threats" was "[b]usiness model reliance on ID's," a recognition of the critical importance of physician-investors to the business model of Modern Vascular OBLs.

137. The 2019-2022 Strategic Planning Survey also contained a section titled "To Increase Sales and Profitability: If you were solely responsible for increasing Sales Revenues and Profitability at Modern Vascular right now, what would you do to ensure success from your efforts?" Listed first is "I would focus on increasing referrals from ID's via implementation for PAD evaluation tools into the patient flow of their practice. Attempt to do that with non ID friendly referral sources." In a section discussing the "single most important goal" for each quarter, listed first for the fourth quarter of 2019 is "Implement PAD evaluation tool referral process in all ID's practices."

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# f. In Addition To The Investment Opportunity, Gampel And Modern Vascular Corporate Rewarded Referrals By Making Distributions And The Prospect Of An Equity Cash-Out.

138. Once Gampel and Modern Vascular Corporate determined that a distribution to investors was warranted based on the performance of the OBL to which the investors referred, Nobility Management, LLC, would pay a dividend to physician-investors. These dividends were paid to physician-investors to induce them to refer more patients to Modern Vascular OBLs. For example, on June 26, 2020, Modern Vascular Corporate's Executive Vice President Ernest Tepman emailed various investors in the Modern Vascular of Sun City, LLC, OBL, including Gampel, with the subject line "Notice of Distribution MVSC." The email stated: "Dear Investors: We hope that this email finds you well. In June, Modern Vascular of Sun City, LLC has operated in accordance with our expectations. We performed 46 procedures month-to-date and are scheduled to perform 18 procedures in the next two weeks. Accordingly, we have elected to declare a distribution this month. The total amount distributed is \$150,000.00." (Bold in original.) Modern Vascular of Sun City, LLC, OBL physician-investors received their distributions that day.

139. Also on June 26, 2020, Tepman sent an email to various investors in the Modern Vascular of Tucson LLC, OBL, including Gampel, with the subject line "Notice of Distribution MVT." The email stated: "Dear Investors: We hope that this email finds you well. In June, **Modern Vascular of Tucson, LLC** has operated in accordance with our expectations. We performed 44 procedures month-to-date and are scheduled to perform 26 procedures in the next two weeks. Accordingly, we have elected to declare a distribution this month. The total amount distributed is \$100,000.00." Modern Vascular of Tucson, LLC, OBL physician-investors received their distributions that day.

140. Physician-investors in Modern Vascular OBLs were also induced by the prospect of a big pay day from the future sale of the Modern Vascular OBLs in which they invested. For example, Physician-Investor 4 was told that Modern Vascular Corporate had a plan to eventually sell the business; as such, the more profitable the company, the better the buyout would be, and the more money physician-investors would get.

141. In an email sent on October 11, 2018, by a prospective physician-investor (and on which Gampel was cc'd) to other prospective investors, the prospective physician-investor stated: "Yury [Gampel] has also made it clear from the beginning that the goal of the center is to sell to a private equity firm in the next 2-3 years. In that scenario, the investors will get a huge payout as well."

# II. Gampel And The Modern Vascular Defendants Acted Knowingly and Willfully.

- 142. Gampel, Modern Vascular Corporate, and the Modern Vascular OBLs were familiar with the relevant AKS requirements, which Modern Vascular Corporate and the Modern Vascular OBLs referenced in documents. For example, disclosures sent by Modern Vascular Corporate to physician-investors stated that ownership of a Modern Vascular OBL "is limited to meet the anti-kickback statute's small business safe harbor." Documents also aver that "[t]he operation of each Modern Vascular facility is subject to numerous State and Federal laws, rules, and regulations, including without limitation the Anti-Kickback Statute set forth in 42 U.S.C. § 1320a-7b (including the statutory exceptions and safe harbor regulations promulgated thereunder)."
- 143. Similarly, in disclosures to investors, Modern Vascular OBLs stated: "Safe Harbors. While the Modern Vascular group expends considerable efforts to assure that its operations are in accordance with 'safe harbors' established by governmental entities, the Company cannot guarantee that all safe harbor requirements will be satisfied at all times."
- 144. Nevertheless, despite familiarity with the requirements of the AKS, Gampel and Modern Vascular Corporate constantly worked to pressure investors to increase their referrals, even though they knew it violated the AKS. In order to obscure their illegal conduct, especially after learning of the United States' investigation, Gampel and Modern Vascular Corporate often relied on verbal communications to convey referral requirements.
- 145. For example, in an email sent on November 3, 2020, that referenced a prior conversation with Gampel, a potential investor explained, "[T]hank you for inviting me to your vascular venture-however after thinking about it I will not be able to contribute 3-5 patients a week that you are requiring. The location is way out for me." Seeking to distance

himself from his verbal comments, Gampel replied, "There is no requirement at all. But we understand your reluctance and the distance."

146. To continue their scheme, Gampel and Modern Vascular Corporate misrepresented the nature of their business model when needed. On June 21, 2021, Gampel sent an email to investors in Modern Vascular OBLs with the subject line "Message from CEO." In that email, Gampel addressed an article published in Searchlight New Mexico alleging that Modern Vascular Corporate and Modern Vascular OBLs violated the AKS and performed unnecessary medical procedures (<a href="https://searchlightnm.org/modern-vascular-faces-lawsuits-in-arizona-new-mexico/">https://searchlightnm.org/modern-vascular-faces-lawsuits-in-arizona-new-mexico/</a>). Gampel stated: "You know that we do not require referrals as a condition of you being an investor in Modern Vascular and our main source of referrals is the relentless marketing of Modern Vascular clinics in local communities. In fact, far less than 50% of our referrals come from investor physicians." Gampel misrepresented the volume of referrals that came from investors, knowing that physician-investor referrals were a significant driver of business and, for some OBLs, accounted for more than 50 percent of referrals.

# III. Modern Vascular Corporate And Modern Vascular OBLs Submitted Or Caused The Submission Of Claims To Medicare Part B And TRICARE In Violation Of The AKS.

147. Modern Vascular Corporate and Modern Vascular OBLs submitted or caused the submission of claims for payment to Medicare that violated the AKS and therefore were false claims under the FCA. By way of illustration, for each of the following claims, Modern Vascular Corporate and/or Modern Vascular OBLs submitted a claim to Medicare Part B for the treatment of a patient who was referred to a Modern Vascular OBL by a physician-investor during the time in which the physician-investor was actively invested in the OBL (with the exception of the Modern Vascular of Fairfax, LLC, OBL, where the physician-investors invested in out-of-state Modern Vascular OBLs while referring to the Fairfax location, as described above in paragraphs 131-133):

1 2 3 4	Modern Vascular OBL	Referring Physician- Investor	Patient	Approx. Date of First Billed Claim	Estimated Medicare Payments to Modern Vascular from Medicare Part B
5 6	Modern Vascular Institute, LLC	Dr. A.S.	Patient 1	1/15/2019	\$18,341.33
7	Modern Vascular Institute, LLC	Dr. J.V.	Patient 2	7/18/2018	\$10,421.70
9	Modern Vascular Institute, LLC	Dr. B.A.	Patient 3	4/8/2019	\$6,594.75
10	Modern Vascular of Mesa, LLC	Dr. R.A.	Patient 4	2/20/2018	\$16,863.47
11	Modern Vascular of Mesa, LLC	Dr. B.N.	Patient 5	7/16/2019	\$16,858.09
13	Modern Vascular of Mesa, LLC	Dr. D.G.	Patient 6	1/26/2021	\$14,204.03
14 15	Modern Vascular of Glendale, LLC	Dr. J.H.	Patient 7	9/18.2018	\$16,0412.04
6	Modern Vascular of Glendale, LLC	Dr. T.P.	Patient 8	12/05/2017	\$15,991.38
.8	Modern Vascular of Glendale, LLC	Dr. R.B.	Patient 9	6/26/2018	\$12,349.50
9	Modern Vascular of Sun City, LLC	Dr. T.U.	Patient 10	5/27/2020	\$13,454.51
20	Modern Vascular of Sun City, LLC	Dr. J.L.	Patient 11	12/10/2019	\$11,332.46
22	Modern Vascular of Sun City, LLC	Dr. D.L.	Patient 12	3/16/2020	\$11,108.62
24	Modern Vascular of Tucson, LLC	Dr. P.M.	Patient 13	9/4/2019	\$15,808.94
25	Modern Vascular of Tucson, LLC	Dr. B.W.	Patient 14	9/26/2019	\$13,529.09
.7	Modern Vascular of Tucson, LLC	Dr. D.B.	Patient 15	2/13/2020	\$12,613.10
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1	San Antonio Vascular	Dr. R.P.	Patient 16	0/21/2020	\$11 220 25
2	Specialists Corp. d/b/a Modern	Dr. K.P.	Patient 16	9/21/2020	\$11,320.35
3	Vascular				
4	San Antonio Vascular	Dr. R.F.	Patient 17	7/13/2020	\$11,166.23
5	Specialists Corp. d/b/a Modern Vascular				¥ = -,= = = = =
6	San Antonio		7 10	2 /0 /2 02 1	00.450.50
7	Vascular Specialists Corp. d/b/a Modern	Dr. F.A.	Patient 18	3/8/2021	\$9,458.72
8	Vascular Fort Worth				
9 10	Fort Worth Vascular Specialists Corp. d/b/a Modern	Dr. R.C.	Patient 19	3/12/2021	\$10,592.48
	Vascular				
11	Fort Worth Vascular	Dr. P.S.	Patient 20	5/28/2021	\$10,825.82
12 13	Specialists Corp. d/b/a Modern	D1. 1 .5.	Tationt 20	3/28/2021	\$10,623.62
	Vascular Fort Worth				
14 15	Vascular Specialists Corp. d/b/a Modern	Dr. M.C.	Patient 21	12/30/2020	\$13,196.75
16	Vascular Modern Vascular				
17	of Denver, LLC	Dr. A.V.	Patient 22	2/23/2021	\$19,058.04
18	Modern Vascular of Denver, LLC	Dr. D.K.	Patient 23	7/22/2020	\$12,577.95
19	Modern Vascular	D., C.S.	Datiant 24	5/20/2020	¢12.556.14
20	of Denver, LLC	Dr. G.S.	Patient 24	5/20/2020	\$12,556.14
21	Modern Vascular - Navajo, LLC	Dr. B.F.	Patient 25	3/4/2021	\$10,934.91
22	Modern Vascular	D 1111	D 11 126	C 12 0 12 0 2 1	ФО 122 20
23	- Navajo, LLC	Dr. J.W.	Patient 26	6/29/2021	\$9,133.29
24	Modern Vascular - Navajo, LLC	Dr. J.D.	Patient 27	4/8/2019	\$10,589.98
<ul><li>25</li><li>26</li></ul>	Modern Vascular of Fairfax, LLC	Dr. P.G.	Patient 28	2/20/2020	\$15,949.74
27	Modern Vascular of Fairfax, LLC	Dr. A.R.	Patient 29	10/13/2020	\$15,618.92
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Modern Vascular of Fairfax, LLC	Dr. D.K.	Patient 30	6/7/2021	\$12,401.43
Modern Vascular of Houston, LLC	Dr. B.M.	Patient 31	6/28/2021	\$10,667.71
Modern Vascular of Houston, LLC	Dr. V.W.	Patient 32	5/12/2021	\$10,639.06
Modern Vascular of Houston, LLC	Dr. N.T.	Patient 33	7/8/2021	\$9,739.70
Modern Vascular of Indianapolis, LLC	Dr. T.A.	Patient 34	8/10/2021	\$10,237.38
Modern Vascular of Indianapolis, LLC	Dr. T.M.	Patient 35	12/16/2021	\$17,724.92
Modern Vascular of Indianapolis, LLC	Dr. K.M.	Patient 36	6/23/2022	\$12,148.86
Modern Vascular of Southaven, LLC	Dr. R.A.	Patient 37	4/1/2021	\$9,414.00
Modern Vascular of Southaven, LLC	Dr. M.L.	Patient 38	8/13/2020	\$10,157.91
Modern Vascular of Southaven, LLC	Dr. C.N.	Patient 39	12/2/2021	\$13,439.34
Modern Vascular of St. Louis, LLC	Dr. L.B.	Patient 40	2/1/2022	\$9,544.67
Modern Vascular of St. Louis, LLC	Dr. J.L.	Patient 41	11/9/2021	\$16,920.10
Modern Vascular of St. Louis, LLC	Dr. C.F.	Patient 42	11/1/2021	\$15,190.01
Modern Vascular of Kansas, LLC	Dr. R.S.	Patient 43	9/30/2021	\$10,688.09
Modern Vascular of Kansas, LLC	Dr. S.R.	Patient 44	4/13/2022	\$8,638.33
Modern Vascular of Kansas, LLC	Dr. J.B.	Patient 45	9/3/2021	\$11,299.68

148. Modern Vascular OBLs also submitted claims for payment to TRICARE that

of the following claims, Modern Vascular OBLs submitted a claim for the treatment of a patient who had been referred to a Modern Vascular OBL during the time in which the physician-investor was actively invested in the OBL (with the exception of the Modern Vascular of Fairfax, LLC, OBL, where the physician-investors invested in out-of-state Modern Vascular OBLs while referring to the Fairfax location, as described above in paragraphs 131-133):

paragraphs 131-133):					
Modern Vascular OBL	Referring Physician- Investor	Patient/Procedure	Approx. Date of First Billed Claim	Estimated Medicare Payments to Modern Vascular from TRICARE	
Modern Vascular of Mesa, LLC	Dr. M.H.	Patient 46	1/10/2018	\$47,306.24	
Modern Vascular of Glendale, LLC	Dr. M.G.	Patient 47	7/29/2019	\$14,585.98	
Modern Vascular of Glendale, LLC	Dr. R.B.	Patient 48	5/28/2020	\$417.81	
Modern Vascular of Glendale, LLC	Dr. J.H.	Patient 49	7/12/2021	\$422.36	
Modern Vascular of Sun City, LLC	Dr. T.U.	Patient 50	7/9/2020	\$12,443.20	
Modern Vascular of Tucson, LLC	Dr. P.M.	Patient 51	8/13/2020	\$101.99	
Modern Vascular of Tucson, LLC	Dr. B.W.	Patient 52	10/18/2021	\$71.17	
Modern Vascular of Tucson, LLC	Dr. B.H.	Patient 53	8/31/2020	\$40.00	
Modern Vascular of Denver, LLC	Dr. M.H.	Patient 54	10/7/2021	\$101.25	
Modern Vascular of Denver, LLC	Dr. M.H.	Patient 55	6/2/2022	\$54.03	
Modern Vascular of Denver, LLC	Dr. E.K.	Patient 56	7/16/2020	\$117.45	

Modern Vascular - Navajo, LLC	Dr. J.W.	Patient 57	6/3/2019	\$6,068.40
Modern Vascular of Southaven, LLC	Dr. C.H.	Patient 58	9/10/2021	\$638.12
Modern Vascular of Southaven, LLC	Dr. M.L.	Patient 59	12/18/2020	\$9,989.89
Modern Vascular of Fairfax, LLC	Dr. S.I.	Patient 60	3/15/2022	\$70.34

### IV. Defendants' Arrangements Do Not Meet the AKS Safe Harbor Provisions.

- 149. Modern Vascular OBLs must meet all eight prongs of the AKS small entity safe harbor for that provision to apply. Each Modern Vascular OBL fails as to at least two of the prongs, and most of the OBLs fail as to at least three of the prongs.
- 150. First, Gampel, Modern Vascular Corporate, and the Modern Vascular OBLs cannot satisfy 42 C.F.R. § 1001.952(a)(2)(iii), which provides: "The terms on which an investment interest is offered to an investor who is in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity must not be related to the previous or expected volume of referrals, items or services furnished, or the amount of business otherwise generated from that investor to the entity." As detailed in Paragraphs 111 to 113 above, the terms on which an investment interest was offered by Modern Vascular Corporate and Gampel to physician-investors in a position to make or influence referrals were related to the expected volume of referrals from that physician-investor to Modern Vascular OBLs.
- OBLs did not comply with 42 C.F.R. § 1001.952(a)(2)(iv), which provides: "There is no requirement that a passive investor, if any, make referrals to, be in a position to make or influence referrals to, furnish items or services to, or otherwise generate business for the entity as a condition for remaining as an investor." As outlined in Paragraphs 114 through 115 above, Gampel and Modern Vascular Corporate required physician-investors who were not employees of Modern Vascular Corporate to refer to Modern Vascular OBLs

as a condition of remaining as investors.

152. Third, nearly all of the Modern Vascular OBLs violate 42 C.F.R. § 1001.952(a)(2)(vi), which requires that "no more than 40 percent of the entity's gross revenue related to the furnishing of health care items and services in the previous fiscal year or previous 12-month period may come from referrals or business otherwise generated from investors." To avoid undue reliance on investor-generated business, the OIG expressly carved out from the safe harbor businesses that rely on investors to generate over 40 percent of the business and profits. *See* 56 Fed. Reg. at 35,952, 35,969 (July 29, 1991).

153. Based on Medicare Part B data for Modern Vascular OBL locations from the start of their investment periods, most of the Modern Vascular OBLs did not meet this requirement. In fact, for Modern Vascular of Fairfax, LLC, and Modern Vascular of Southaven, LLC, between the opening of each OBL and December 31, 2021, more than 70 percent of the gross revenue came from claims referred by physician-investors; for Modern Vascular of Indianapolis, LLC, between May 2021 and November 2022, more than 80 percent of the gross revenue came from claims referred by physician-investors; for Modern Vascular of Denver, LLC, between its opening and December 31, 2021, more than 87 percent of the gross revenue came from claims referred by physician-investors; and for Modern Vascular of St. Louis, LLC, between its opening and December 31, 2021, approximately 90 percent of the gross revenue came from claims referred by physician-investors. But even if a Modern Vascular OBL did not violate this prong, it nevertheless does not receive the safe harbor protection because it violated prongs iii and iv.

# V. Gampel And Modern Vascular Corporate Pushed OBLs And Practitioners To Perform More Invasive Procedures, Thereby Driving Up Profits.

- 154. Gampel and Modern Vascular Corporate cultivated a culture that pushed Modern Vascular practitioners and Modern Vascular OBLs to perform an increasing number of invasive procedures, which are reimbursed by Medicare and TRICARE at a higher rate than more conservative, non-invasive treatments.
  - 155. The pressure for more invasive procedures was in service of one goal: to

generate as much revenue as possible. Specifically, an internal strategy document stated that Modern Vascular Corporate's goal was that by 2029, "[e]ach of our 50 labs does \$20MM in gross revenue, with 35% profitability."

156. For example, Gampel and Modern Vascular Corporate pressured practitioners at the Modern Vascular of Denver, LLC, OBL to put more patients "on the table," meaning putting patients on the operating table for a surgical procedure. The OBL's employees were promised a \$500 bonus if the OBL performed 16 surgeries in a week. Gampel told the OBL's surgeon and physician's assistant that Modern Vascular of Denver, LLC, OBL investors were unhappy because they were receiving a small return for their investment.

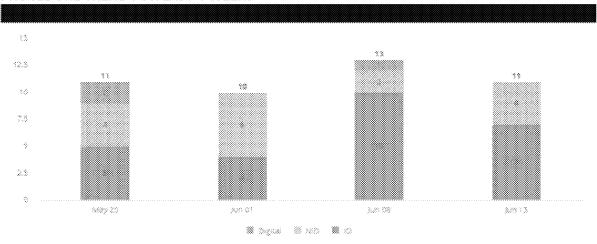
- 157. Modern Vascular Corporate put intense pressure on Modern Vascular OBLs to meet goals for the number of invasive procedures performed. For example, Dr. Kent Hootman, an interventional radiologist and the managing physician at the Modern Vascular Navajo, LLC, OBL testified at a deposition in a separate case that "[t]here was one conversation that that message was delivered to us that -- it was told to us that based upon what Modern Vascular sees throughout the country and based on our market size, we should be able to achieve an 18-procedure-per-week level."
- 158. Dr. Hootman also testified about why a nurse practitioner employed by Modern Vascular, Nurse Practitioner 1, left the company: "I was asked to review cases because upper-level management didn't think [Nurse Practitioner 1] was recommending adequate numbers of procedures, and I did those reviews several times and had discussions with him and I found for the most part that his clinical assessments were highly accurate and reasonable." When asked who in upper-level management did not feel that Nurse Practitioner 1 was recommending adequate numbers of procedures, Dr. Hootman testified, "That would have been the primary the majority owner and CEO, Yury Gampel."
- 159. Gampel and Modern Vascular Corporate incentivized Modern Vascular OBL physician-investors and vascular surgeons by offering a big pay day in an eventual sale of the company. As Dr. Hootman testified, "[w]ell, I think that's that's been Yury's model

all along was to build a successful network of these clinics, get them established; and then once it's up and running, that he would sell them off and we would have the options of participating in the equity transaction that transpires and stay on and continue working for the new entity or not, depending upon what changes with that transaction."

160. Modern Vascular Corporate expected that new PAD patients referred to Modern Vascular OBLs would receive treatment, regardless of medical need. For example, on May 14, 2021, Leslie Gibbs, Modern Vascular Corporate's Chief Marketing Officer, emailed Gampel, Tepman, and employees of the Modern Vascular of Denver, LLC, OBL stating that "[a]ll PAD patients including asymptomatic should be either recommended and scheduled for procedure or put on Medical Management, given the medical management booklet and scheduled for a follow up in no greater than 12 weeks." Gibbs is not a doctor.

161. In the June 2020 email discussed above at paragraph 119, wherein Tepman reported on referral numbers and referral goals to investors in the Modern Vascular of Sun City, LLC, OBL, Tepman also provided figures on the weekly volume of procedures, noting that, "The clinic performed 11 procedures last week and 13 the week prior. Our weekly average of procedures completed is 9. We are currently scheduled to have 11 and 9 procedures for the next two weeks. The June running sum of completed procedures is 34 as compared to June of 2019 was 28." (Bold and underline in original.) Tepman also included a bar graph illustrating how procedures trended for the previous four weeks:

#### PROCEDURE TREND FOR LAST 4 WEEKS



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Tepman then informed the investors that the "weekly clinic goals" for "procedures completed" for Modern Vascular of Sun City, LLC's OBL is "Procedures: 16-18."

162. In sum, Gampel and Modern Vascular Corporate's illegal scheme to profit by violating the AKS was to: (1) seek out physician-investors who are in a position to refer to vascular surgeons and offer them a low-cost ownership interest in a Modern Vascular OBL; (2) provide remuneration in the form of the offer of OBL equity ownership interest, and also distributions, the prospect of future distributions, and/or the prospect of a big pay day when the Modern Vascular OBLs were sold, to those physician-investors who refer patients to the Modern Vascular OBL and reward them for past referrals; (3) track referrals by physician-investors and place pressure on them to refer more patients, either verbally or with referral forms; and (4) when the patients are treated at the OBL, aggressively pursue invasive procedures, which reimburse at a higher rate.

# **COUNT I**

# (False Claims Act: Presentation Of False Claims For Payment) $(U.S.C. \S 3729(a)(1)(A))$

- 163. The United States realleges and incorporates by reference paragraphs 1 through 162.
- By virtue of the acts described above, Defendants knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to Medicare in violation of 31 U.S.C. § 3729(a)(1)(A); that is, Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment for services performed at Modern Vascular OBLs that were tainted by illegal kickbacks.
- 165. By virtue of the acts described above, Defendants knowingly presented or caused to be presented materially false or fraudulent claims for payment or approval to TRICARE in violation of 31 U.S.C. § 3729(a)(1)(A); that is, Defendants knowingly made or presented, or caused to be made or presented, to the United States claims for payment for services performed at Modern Vascular OBLs that were tainted by illegal kickbacks.

- 166. Payment of the false and fraudulent claims was a reasonable and foreseeable consequence of Defendants' conduct.
- 167. The United States was unaware of the falsity of the records, statements, and claims Defendants made, submitted, or caused to be submitted.
- 168. The false or fraudulent representations and claims Defendants knowingly made to the United States were material to the United States' decisions to make payments to Defendants.
- 169. By reason of the foregoing, the United States has been damaged in an amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false and fraudulent claim.

## **COUNT II**

# (False Claims Act: False Records Material To A False Or Fraudulent Claim) (31 U.S.C. § 3729(a)(1)(B))

- 170. The United States realleges and incorporates by reference paragraphs 1 through 162.
- 171. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements, namely, false claims and false statements about compliance with the AKS, all of which were material to false or fraudulent claims that were submitted to the United States and paid and approved by the Medicare program that were tainted by illegal kickbacks, in violation of 31 U.S.C. § 3729(a)(1)(B).
- 172. By virtue of the acts described above, Defendants knowingly made, used, or caused to be made or used, false records or statements, namely, false claims and false statements about compliance with the AKS, all of which were material to false or fraudulent claims that were submitted to the United States and paid and approved by the TRICARE program that were tainted by illegal kickbacks, in violation of 31 U.S.C. § 3729(a)(1)(B).

- 173. Defendants' false certifications and representations were made for the purpose of ensuring that the United States paid the false or fraudulent claims, which was a reasonable and foreseeable consequence of the Defendants' conduct.
- 174. The United States was unaware of the falsity of the records, statements, and claims Defendants made, submitted, or caused to be made or submitted, and, in reliance on the accuracy of these records or statements, the United States paid false or fraudulent claims.
- 175. The false and fraudulent representations and claims Defendants knowingly made to the United States were material to the United States' decisions to make payments to Defendants.
- 176. By reason of the foregoing, the United States has been damaged in an amount to be determined at trial and is entitled to recover treble damages plus a civil monetary penalty for each false and fraudulent claim.

# COUNT III (Unjust Enrichment)

- 177. The United States realleges and incorporates by reference paragraphs 1 through 162.
- 178. By virtue of the acts described above, the United States paid claims submitted to Medicare for services that were tainted by kickbacks. Defendants' receipt of payments based on their kickback schemes are such that, in equity and good conscience, Defendants should not retain those payments.
- 179. By virtue of the acts described above, the United States paid claims submitted to TRICARE for services that were tainted by kickbacks. Defendants' receipt of payments based on their kickback schemes are such that, in equity and good conscience, the Defendants should not retain those payments.
- 180. The United States had and continues to have a reasonable expectation of payment of the monies paid to Defendants based on false or fraudulent claims tainted by kickbacks.

- 181. Defendants should reasonably have expected and should reasonably be expected to pay to the United States the monies paid to Defendants based on false or fraudulent claims tainted by kickbacks.
- 182. Society's reasonable expectations of person and property would be defeated by Defendants' nonpayment to the United States of the monies paid to Defendants based on false or fraudulent claims tainted by kickbacks.
- 183. By reason of Defendants' acts, the United States has been damaged in an amount to be determined at trial.

### **COUNT IV**

### (Payment By Mistake)

- 184. The United States realleges and incorporates by reference all paragraphs 1 through 162.
- 185. The United States' agents paid the claims and statements Defendants submitted or caused to be submitted based upon mistaken or erroneous understandings of material fact.
- 186. The United States, acting in reasonable reliance on the accuracy and truthfulness of the information contained in Defendants' claims and statements, paid Defendants certain sums of money, in an amount to proven at trial, to which they were not entitled, and Defendants are thus liable to account and pay such amounts to the United States.
- 187. By virtue of the acts described above, the United States paid claims submitted to Medicare and TRICARE under the mistaken belief that those claims were not tainted by illegal kickbacks to referring physician-investors. Had the United States known those claims were tainted, it would not have paid those claims.
- 188. By reason of Defendants' acts, the United States has been damaged in an amount to be determined at trial.

1 PRAYER FOR RELIEF WHEREFORE, the United States respectfully requests that judgment be entered in 2 its favor as follows: 3 I. On Count I under the FCA, for the amount of the United States' damages to 4 be established at trial, trebled as required by law, and such civil penalties as 5 6 are authorized by law, and all such further relief the Court deems just and 7 proper. II. On Count II under the FCA, for the amount of the United States' damages to 8 9 be established at trial, trebled as required by law, and such civil penalties as are authorized by law, and all such further relief the Court deems just and 10 11 proper. III. On Count III for unjust enrichment, for the amounts by which defendants 12 were unjustly enriched, plus interest, costs, and expenses, and for all such 13 further relief as may be just and proper. 14 IV. On Count IV for payment by mistake, for the amounts the United States paid 15 16 by mistake, plus interest, costs, and expenses, and for all such further relief 17 as may be just and proper. **DEMAND FOR JURY TRIAL** 18 19 The United States demands a jury trial in this case. 20 Respectfully submitted this 13th day of December, 2022. 21 BRIAN M. BOYNTON GARY M. RESTAINO Principal Deputy Assistant Attorney General United States Attorney 22 <u>/s/ Jared S. Wiesner</u> JAMIE ANN YAVELBERG /s/ Lon R. Leavitt LON R. LEAVITT 23 NATALIE A. WAITES Assistant United States Attorney 24 JARED S. WIESNER United States Attorney's Office District of Arizona ADITHI S. GRAMA 25 Attorneys, Civil Division Two Renaissance Square United States Department of Justice 40 North Central Avenue, Suite 1800 26 P.O. Box 261, Ben Franklin Station Phoenix, Arizona 85004 Washington, D.C. 20044 Phone: (602) 514-7500 27 Phone: (202) 353-1274 28