IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
BEAUFORT DIVISION

The United States of America and the States of North Carolina, California, Colorado, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Louisiana, Michigan, Minnesota, New Jersey, New York, Tennessee, Texas, Virginia and Wisconsin, *ex rel*. Scarlett Lutz, Kayla Webster, Dr. Michael Mayes and Chris Reidel, Plaintiffs, vs. Berkeley Heartlab, Inc., BlueWave Healthcare Consultants, Inc., Latonya, Mallory, Floyd Calhoun Dent, III and Robert Bradford Johnson, Defendants.	)	**CA No.: 9:14-cv-00230-RMG** (Consolidated with 9:11-cv-1593-RMG and 9:15-cv-2485-RMG)

UNITED STATES' COMPLAINT IN INTERVENTION

The United States brings this action to recover losses from false claims submitted to the Medicare and TRICARE programs as a result of the sustained fraudulent course of conduct of Defendants Berkeley Heartlab, Inc. ("Berkeley"), BlueWave Healthcare Consultants, Inc. ("BlueWave"), Floyd Calhoun Dent, III ("Dent"), Robert Bradford Johnson ("Johnson"), and Latonya Mallory ("Mallory") (collectively "Defendants"). Defendants knowingly and willfully offered and/or paid kickbacks, primarily in the form of eighty million dollars ($80,000,000.00) in improper "process and handling" fees, to induce physicians to refer blood samples to "specialty laboratories" Berkeley, Health Diagnostic Laboratories, Inc. ("HDL"), and Singulex, Inc. ("Singulex") for large panels of tests. These kickbacks resulted in false claims submitted to Medicare and TRICARE

which caused the federal government to pay more than five hundred million dollars ($500,000,000.00) to Berkeley, HDL, and Singulex. Defendants BlueWave, Johnson, Dent, and Mallory also entered into illegal contracts for commission-based payments in exchange for arranging for and recommending that physicians refer laboratory tests to HDL and Singulex that were reimbursed by Federal health care programs. The aforementioned conduct violated the Anti-Kickback Statute ("AKS"), 42 U.C.S. § 1320(a)-7b(b)(1)(A). Defendants also submitted or caused to be submitted false claims in violation of the False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, and common law.

I. NATURE OF ACTION

1. This is an action brought by Plaintiff, the United States of America ("United States" or "Government"), to recover treble damages and civil penalties under the FCA, and to recover damages under common law theories of payment by mistake and unjust enrichment.

2. Dr. Michael Mayes, Chris Riedel, Scarlett Lutz, and Kayla Webster filed three separate complaints on behalf of the United States pursuant to the *qui tam* provisions of the FCA, 31 U.S.C. § 3730(b)(1). The United States files this Complaint in Intervention as to Defendants Berkeley, BlueWave, Dent, Johnson, and Mallory, pursuant to 31 U.S.C. § 3730(b)(3).

3. From 1999 through January 2012, Berkeley provided remuneration to physicians and physician groups (collectively "physicians") to induce the referral of federal beneficiaries to Berkeley. Such remuneration was in the form of sham processing and handling fees and the waiver of TRICARE copays and deductibles.

4. Berkeley provided this remuneration with the intent to induce physician referrals of blood testing for which Berkeley sought reimbursement through two federal health care programs, Medicare and TRICARE, in violation of the AKS. Berkeley knew it was not entitled to reimbursement for claims arising out of this illegal scheme, and therefore submitted or caused to be submitted claims in violation of the FCA as well.

5. By paying kickbacks to physicians, Berkeley also induced physicians to order large panels of tests that included a significant number of medically unnecessary tests. Berkeley knew that it was not entitled to reimbursement for medically unnecessary laboratory testing services; thus, its submission of these claims also violated the FCA.

6. Between 2008 and 2010, Defendants Mallory, Johnson, and Dent – all of whom had worked for Berkeley – left that company and initiated their own kickback scheme. Mallory founded HDL, a specialty laboratory that offered the same or similar testing services as Berkeley. Johnson and Dent created BlueWave, which provided an outside sales force dedicated to marketing and selling HDL's tests and test panels. Later, BlueWave also became the outside sales force for another specialty lab, Singulex, which offered tests that were similar to those offered by Berkeley and HDL.

7. From January 2010 through July 2014, Defendants BlueWave, Johnson, Dent, and Mallory conspired to offer, arrange for, and provide remuneration to physicians to induce referrals of blood testing to HDL and Singulex, including testing that was reimbursed by Medicare and TRICARE. As with Berkeley, the remuneration was in the form of sham processing and handling fees and the waiver of TRICARE copays and deductibles.

8. Defendants BlueWave, Johnson, Dent, and Mallory offered, arranged for, and provided remuneration to physicians with the intent to induce physician referrals, in violation of the AKS, 42 U.S.C. § 1320a-7b. Defendants BlueWave, Johnson, Dent, and Mallory knew that HDL and Singulex were not entitled to reimbursement for claims arising out of this scheme; therefore, Defendants BlueWave, Johnson, Dent, and Mallory knowingly caused the submission of false and fraudulent claims, in violation of the FCA.

9. By causing kickbacks to be paid, Defendants BlueWave, Johnson, Dent, and Mallory also induced physicians to order large panels of tests that included a significant number of medically unnecessary tests. Defendants BlueWave, Johnson, Dent, and Mallory knew that HDL and Singulex were not entitled to reimbursement from Medicare or TRICARE for medically unnecessary laboratory testing services and caused the submission of such false and fraudulent claims violated the FCA.

10. In addition, BlueWave and its customer laboratories, HDL and Singulex, entered into Sales Agreements, pursuant to which HDL and Singulex paid BlueWave a commission based on a percentage of the laboratories' revenue in exchange for BlueWave's arranging for and recommending that physicians order tests that were reimbursed by federal programs. The AKS prohibits entities like BlueWave from receiving remuneration in return for "arranging for" or "recommending" the purchase or order of any "good" or "service" reimbursed by federal health programs. 42 U.S.C. § 1320a-7b(b)(1)(B). The AKS likewise prohibits HDL, Singulex, and Defendant Mallory from paying such remuneration. 42 U.S.C. § 1320a-7b(b)(1)(B). Defendants Johnson and Dent negotiated and entered into these agreements on behalf of BlueWave; Defendant Mallory negotiated and entered into such an agreement on behalf of HDL.

Defendants BlueWave, Johnson, Dent, and Mallory knowingly entered into contracts that violated the AKS. They are further liable under the FCA for knowingly causing the submission of claims to federal health care programs arising out of these illegal agreements.

11. The United States' claims against Defendants under the FCA are based upon false certifications and false or fraudulent claims that Defendants presented or caused to be presented to Medicare and TRICARE for laboratory testing services referred by physicians with whom Defendants had illegal financial relationships under the AKS.

II. JURISDICTION AND VENUE

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1345 because this action is brought by the United States as a plaintiff pursuant to the FCA.

13. This Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because the Defendants can be found in and/or have transacted business in the District of South Carolina.

14. Venue is proper in South Carolina under 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1391(b) and 1395(a) because Defendants can be found in and/or have transacted business in the district. Defendants regularly conducted substantial business within this district, maintained employees and offices within the district, and/or made significant sales within the district.

III. PARTIES

15. The United States brings this action on behalf of the Department of Health and Human Services ("HHS") and the Centers for Medicare & Medicaid Services ("CMS"), formerly known as the Health Care Financing Administration ("HCFA"), on behalf of the Medicare program, and the Defense Health Agency ("DHA") on behalf of the Civilian Health and Medical Program of the Uniformed Services ("CHAMPUS"), now known as TRICARE.

16. Relator Michael Mayes is a resident of Hilton Head Island, South Carolina. Dr. Mayes is a practicing physician, licensed to practice in the State of South Carolina. In 1999, Dr. Mayes joined Heritage Medical Partners in South Carolina.

17. Relator Chris Riedel was the Chief Executive Officer of Hunter Laboratories, Inc. and has worked for 40 years in the health care industry. Mr. Riedel is a resident of California.

18. Relator Scarlett Lutz is a resident of Florence, South Carolina and provided billing services to Dr. Lloyd Miller, a primary care physician who received tens of thousands of dollars from Berkeley, HDL, and Singulex in exchange for patient referrals.

19. Relator Kayla Webster is a resident of Timmonsville, South Carolina and worked as a Nursing Supervisor for Dr. Miller.

20. Defendant Berkeley HeartLab, Inc. is a corporation organized under the laws of the State of California, and headquartered at 839 Mitten Road, Burlingame, California 94010. From October 2007 through May 2011, Berkeley was a wholly-owned subsidiary of Celera Corporation. In May 2011, Celera Corporation was purchased by

Quest Diagnostics, Inc. From at least 1999 through January 2012, Berkeley was in the business of providing cardiovascular disease management services, including laboratory services, to physicians, medical clinics and patients throughout the United States.

21. Defendant BlueWave was founded in 2010 in Alabama by two former sales representatives at Berkeley, Defendants Johnson and Dent. Upon inception, BlueWave entered into a contract with HDL to serve as HDL's outside sales force. Shortly thereafter, BlueWave entered into a similar arrangement with Singulex to provide the same outside sales services. HDL and Singulex were BlueWave's only clients. Under those two arrangements, BlueWave was paid a percentage of HDL's and Singulex's revenues for blood tests referred by BlueWave's physician clients. BlueWave's annual revenue grew exponentially from $6,152,000.00 in 2010 to $75,217,000.00 in 2013.

22. Defendant Johnson is a co-founder, co-owner, and President of BlueWave. Johnson has been in medical sales for nearly 20 years and worked for Berkeley as a Sales Representative from 2002 through 2009. In addition to managing and controlling BlueWave since 2010, Johnson has a sales contract with BlueWave whereby BlueWave pays him commissions to sell HDL and Singulex tests. Johnson is a resident of Alabama.

23. Defendant Dent is a co-founder, co-owner, and Vice President of BlueWave. Dent has been in medical sales for nearly 20 years and worked for Berkeley as a Sales Representative from 2005 through 2009. Like Johnson, Dent has a sales contract with BlueWave whereby BlueWave pays him commissions to sell HDL and Singulex tests. Dent is a resident of South Carolina.

24. As co-founders and co-owners of BlueWave, Johnson and Dent controlled BlueWave's practices and policies, including the practice of pushing clients to order large panels of tests and of paying sham processing and handling fees to clients.

25. Johnson and Dent also each own approximately 1.5% of HDL's stock.

26. Defendant Latonya Mallory ("Mallory") was a Senior Manager of Lab Operations at Berkeley from 2006 through 2008. She left Berkeley in 2008 to start HDL and served as HDL's President and CEO from 2008 through 2014. As President and CEO, Mallory devised and implemented HDL's practice of paying sham processing and handling fees to physicians who referred blood samples to HDL for testing. Mallory owns approximately 15% of HDL's stock and received at least $26,000,000.00 from HDL in salary, bonuses, and tax distributions.

27. Various other companies, partnerships, and individuals not made defendants in this Complaint, participated as co-conspirators in the conspiracies alleged herein and performed acts and made statements in furtherance of those conspiracies.

IV. THE LAW

The False Claims Act

28. The False Claims Act provides, in pertinent part, that any person who:

> "(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent; [or]
>
> (C) conspires to commit a violation of subparagraph (A) [or] (B) ….

is liable to the United States Government [for statutory damages and such penalties as are allowed by law]." 31 U.S.C. §§ 3729(a)(1)-(3) (2006), as amended by 31 U.S.C. §§ 3729(a)(1)(A)-(C) (2010).

29. The False Claims Act further provides that "knowing" and "knowingly"

> "(A) 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; and
>
> (B) requires no proof of specific intent to defraud."

31 U.S.C. § 3729(b) (2006), as amended by 31 U.S.C. § 3729(b)(1) (2010).

30. The False Claims Act, 31 U.S.C. § 3729(a)(1), provides that any person who violates the Act is liable to the United States Government for three times the amount of damages which the Government sustains because of the act of that person, plus a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990. *See* 28 C.F.R. § 85.3(a)(9) (setting forth the current civil penalties level of not less than $5,500 and not more than $11,000 for violations of the FCA).

The Anti-Kickback Statute

31. The AKS arose out of Congressional concern that providing things of value to those who can influence healthcare 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 a vulnerable patient population. The AKS prohibits the payment of kickbacks in order to protect the integrity of Medicare, TRICARE, and other federal healthcare programs. *See* Social Security

Amendments of 1972, Pub. L. No. 92-603, §§ 242(b) and (c); 42 U.S.C. § 1320a-7b, Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142; Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

32. The AKS prohibits any person or entity from soliciting, receiving, offering, or paying any remuneration to induce a person to, or reward a person for referring, recommending, or arranging for the purchase of any item 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
>
> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person–
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

33. The AKS not only prohibits outright bribes to a physician, but also prohibits offering or paying for any remuneration to a physician that has, as one purpose, inducement of the physician's referrals to federal health care programs. Claims that include items or services resulting from a violation of the AKS are false or fraudulent under the FCA. 42 U.S.C. §1320a-7b(g).

34. The Office of Inspector General for the United States Department of Health and Human Services ("HHS-OIG") has published safe harbor regulations that define arrangements that are not subject to the AKS because the practice would be unlikely to result in fraud or abuse. Safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

35. One such statutory safe harbor protects some arrangements between an entity and an independent contractor, but only if the arrangement meets all seven standards. Specifically, the arrangement must (1) be in writing and signed by the parties; (2) cover all services provided by the independent contractor, and specify those services; (3) for part-time work, set forth the schedule, length, and exact charge for the intervals of work; (4) span at least one year; (5) set in advance the aggregate compensation, which must be fair market value and not be determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties; (6)

not involve services that involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law; and (7) cover aggregate services that do not exceed those reasonably necessary to accomplish the commercially reasonable purpose of the services. 42 C.F.R. § 1001.952(d). Defendants' arrangements cannot qualify for this safe harbor because the aggregate compensation was not set in advance, the compensation exceeded fair market value, and the amount of the compensation was determined in a way that took into account the volume and value of the referrals between the Defendants and other parties.

36. There is another safe harbor to the AKS for payments by an employer to its *bona fide* employees. 42 U.S.C. § 1320a-7b(b)(3)(B); 42 C.F.R. § 1001.952(i). The term "employee," as used in the AKS safe harbor, "has the same meaning" as the Internal Revenue Code's definition of "employee," found in 26 U.S.C. § 3121(d)(2). 42 C.F.R. § 1001.952(i). The Internal Revenue Code provides, in relevant part, that an "employee" is "any individual who, under the usual common law rules applicable in determining the employer-employee relationship, has the status of an employee." 26 U.S.C. § 3121(d)(2). Defendants cannot meet this AKS safe harbor because, as stated in the contract and under the common law rules for determining the employer-employee relationship, BlueWave, Johnson, Dent, and the other BlueWave consultants were not *bona fide* employees of HDL or Singulex.

37. HHS-OIG specifically did not extend protection under the *bona fide* employee safe harbor to arrangements with independent contractors because of the "existence of widespread abusive practices by salespersons who are independent contractors and, therefore, who are not under appropriate supervision and control."

Medicare and State Health Care Programs; Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35952, 35981 (July 29, 1991).

HHS-OIG Fraud Alerts and Opinions

38. Pursuant to 42 U.S.C. § 1320a-7d(b), the Secretary of the HHS, in consultation with the Attorney General, is authorized to issue advisory opinions on specific topics, including what constitutes prohibited remuneration under 42 U.S.C. § 1320a-7b(b), and whether any activity or proposed activity could result in the imposition of sanctions or exclusion from participation in federal health care programs. 42 U.S.C. § 1320a-7d(b)(2).

39. HHS-OIG has issued a number of fraud alerts on problematic arrangements involving the provision of clinical laboratory services.

40. HHS-OIG has stated that "[w]henever a laboratory offers or gives to a source of referrals anything of value not paid for at fair market value, the inference may be made that the thing of value is offered to induce the referral of business." OIG Special Fraud Alert: Arrangements for the Provision of Clinical Laboratory Services (Issued October 1994), *available at* ttps://oig.hhs.gov/fraud/docs/alertsandbulletins/121994.html.

41. HHS-OIG has issued several advisory opinions on problematic arrangements related to clinical laboratory services. For instance, in HHS-OIG Advisory Opinion 05-08, HHS-OIG considered whether a laboratory's proposal to pay physicians for the collection of blood samples and to provide free blood drawing supplies would potentially constitute grounds for the imposition of sanctions related to the commission of acts described in the AKS. HHS-OIG explained that the laboratory's offer to pay the physicians for collecting blood samples carried a "substantial risk that the Lab would be

offering the blood draw remuneration to the physicians in exchange for referrals." Because the physicians would receive free blood-drawing supplies and up to twice the amount Medicare pays for collecting blood samples, HHS-OIG concluded that "the compensation provides an obvious benefit to the referring physician and it may be inferred that this benefit would be in exchange for referrals." HHS-OIG Advisory Opinion No. 05-08 (Posted June 13, 2005), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao0508.pdf.

42. HHS-OIG Advisory Opinion 05-08 also noted that the AKS safe harbor requires, in relevant part, that the "aggregate compensation paid for the services be set in advance" but that any arrangement involving payments from blood laboratories that are "paid on a per-patient basis" would not be covered by the safe harbor because the compensation would not be set in advance. HHS-OIG Advisory Opinion No. 05-08 (Issued August 2005), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2005/ao05_08.pdf.

43. HHS-OIG has also prohibited commission-based sales agreements for independent contractors. *See e.g.*, HHS-OIG Advisory Opinion No. 99-3 (Issued March 1999), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_3.htm; HHS-OIG Advisory No. Opinion 10-23 (Issued October 2010), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2010/AdvOpn10_23.pdf.

44. In HHS-OIG Advisory Opinion No. 99-3, HHS-OIG noted that "any compensation arrangement between a seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute." HHS-

OIG Advisory Opinion No. 99-3 (Issued March 1999), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1999/ao99_3.htm.

45. Similarly, HHS-OIG Advisory Opinion No. 98-10 stated that "percentage compensation arrangements are potentially abusive, however, because they provide financial incentives that may encourage overutilization of items and services and may increase program costs." HHS-OIG Advisory Opinion No. 98-10 (Issued March 1998), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_10.htm. The opinion also noted that arrangements that are "based on a percentage of the volume or value of business generated between the parties" and that involve "active marketing, including direct contacts" are particularly problematic. *Id*.

46. In 2010, HHS-OIG issued another opinion, again rejecting a similar arrangement. HHS-OIG stated:

> Marketing fees paid on the basis of successful orders for items or services are inherently subject to abuse because they are linked to business generated by the marketer. Because the Requestor receives a fee each time its marketing efforts are successful, the Requestor's financial incentive to arrange for or recommend the Hospital's sleep testing facility is heightened. The more test orders the Requestor's marketing efforts generate, the more fees the Requestor receives.

HHS OIG Advisory Op. No. 10-23 (posted Nov. 4, 2010), *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2010/AdvOpn10-23.pdf.

The Medicare Program

47. In 1965 Congress enacted Title XVIII of the Social Security Act, which established the Medicare Program to provide health insurance for the elderly and disabled.

48. Payments from the Medicare Program come from a trust fund – known as the Medicare Trust Fund – which is funded through payroll deductions taken from the work force and from government contributions.

49. Medicare now has four parts: Part A (Hospital Insurance); Part B (Medical Insurance); Part C (Managed Care Plans); and the Part D (Prescription Drug) Program.

50. This case involves claims submitted to Medicare Part B.

51. Medicare Part B (Medical Insurance) helps cover doctors' services and outpatient care, including emergency care. Part B helps pay for covered health services and supplies, but only when they are medically necessary for the diagnosis or treatment of illness or injury. 42 U.S.C. § 1395y(a)(1)(A).

52. Medical care is "medically necessary" when it is ordered or prescribed by a licensed physician or other authorized medical provider, and Medicare agrees that the care is necessary and proper. Services or supplies that are needed for the diagnosis or treatment of a medical condition must meet the standards of good medical practice in the local area where the physician practices.

53. Medicare Part B pays for clinical laboratory testing performed by companies such as Berkeley, HDL, and Singulex. These independent laboratories perform testing on specimens (also known as "samples") from patients referred to the independent laboratory by their physicians.

54. In order to bill the Medicare Program, a provider must submit an electronic or hard-copy claim form called CMS 1500. When the CMS 1500 is submitted, the provider certifies that the services in question were "medically indicated and necessary for the health of the patient."

55. Medicare does not cover purely prophylactic lipid testing or lipid screening:

> Routine screening and prophylactic testing for lipid disorder are not covered by Medicare. While lipid screening may be medically appropriate, Medicare by statute does not pay for it. Lipid testing in asymptomatic individuals is considered to be screening regardless of the presence of other risk factors such as family history, tobacco use, *etc*.
>
> Once a diagnosis is established, one or several specific tests are usually adequate for monitoring the course of the disease. Less specific diagnoses (for example, other chest pain) alone do not support medical necessity of these tests.

National Coverage Determination on Lipid Testing National Coverage Determination (NCD) for Lipid Testing (190.23) (Implemented on March 11, 2005), *available at* http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=102&ncdver=2&bc=AAEAAAAAAAAA&.

56. When a patient is placed on dietary therapy or prescribed medication for high cholesterol, Medicare pays for periodic lipid testing. Medicare will cover "[a]ny one component of the panel or a measured LDL may be medically necessary up to six times the first year for monitoring dietary or pharmacologic therapy. . . . If no dietary or pharmacological therapy is advised, monitoring is not necessary." *Id*. Medicare also pays for lipid testing once annually for patients on "long term anti-lipid dietary or pharmacologic therapy and when following patients with borderline high total or LDL cholesterol levels." *Id*.

57. A physician who orders clinical laboratory services "must maintain documentation of medical necessity in the beneficiary's medical record." 42 C.F.R. § 410.32(d)(2).

58. The majority of laboratory testing services are paid by Medicare on a fee-for service ("FFS") basis. Medicare pays for most outpatient clinical laboratory services based on the Clinical Laboratory Fee Schedule, in accordance with Section 1833(h) of the Social Security Act. The Medicare payment to the laboratory is the lesser of the laboratory's actual charge, the local fee for a geographic area, or a national limit. Under the Clinical Laboratory Fee Schedule, the amount paid to the laboratory is usually the National Limitation Amount (NLA). *See* Medicare Claims Processing Manual [Pub. 100-4] Chapter 16 – Laboratory Services, Section 20, *available at* http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf.

59. A clinical laboratory that provides testing services submits claims directly to Medicare.

60. In addition to payment for the laboratory testing service itself, CMS may make a separate payment to providers for collection of the blood specimen. Medicare reimburses medical providers a specimen collection fee for drawing a blood sample through venipuncture (*i.e.*, inserting into a vein a needle with syringe or vacutainer to draw the specimen). Section 1833(h)(3) of the Act; Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.

61. A physician who performs the blood draws on their own patients for blood samples that are then sent to independent laboratories reports the service with Healthcare

Common Procedure Coding System ("HCPCS") Code 36415, "collection of venous blood by venipuncture."

62. For all relevant times herein, the venipuncture fee for Medicare was $3.00.

63. Medicare does not pay the collection ("blood draw") fee to anyone who has not actually extracted the specimen. Only one collection fee is allowed for each blood draw, regardless of the number of vials of blood drawn. Medicare Claims Processing Manual, Chapter 16 - Laboratory Services, Section 60.1.

The TRICARE Program

64. The federal government reimburses a portion of the cost of laboratory testing services under TRICARE. TRICARE is a medical benefits program established by federal law. 10 U.S.C. § 1071-1110b.

65. TRICARE covers eligible beneficiaries, which, *inter alia*, includes active duty members of the Uniformed Services and their dependents as well as retired members of the Uniformed Services and their dependents. TRICARE is administered by the Defense Health Agency.

66. 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* 10 C.F.R. 199.4(a)(1)(i) and applicable definitions at *Id*. 199.2.

67. TRICARE requires a referral and/or prescription from the beneficiary's physician for laboratory tests.

68. Some TRICARE options require participating members to pay a co-pay and/or to meet a deductible. 32 C.F.R. § 199.4(f). A provider of services cannot, as a matter of law, waive these co-pay or deductible requirements. 32 C.F.R. § 199.4(f)(9).

V. FACTUAL BACKGROUND

A. BLOOD LABORATORIES AND BLOOD TESTING

69. Berkeley, HDL, and Singulex are clinical laboratories that specialize in cardiovascular health and advanced lipid testing.

70. Advanced lipid tests are generally more expensive than basic cholesterol and blood tests and often result in significantly higher profit margins for the laboratories that provide such tests.

71. For instance, Medicare pays HDL well over $1,000 when physicians refer a patient for HDL's Initial Comprehensive CVD Baseline Assessment panel. Further, Medicare pays HDL over $600 for every CVD/Metabolic Follow-Up Profile that is referred—a panel that many HDL customers ordered four times a year for each of their patients who received such testing.

72. Advanced lipid tests are marketed as being useful for detecting, preventing, and managing coronary heart disease. Senior citizens covered by Medicare make up a large percentage of the population that receive such testing.

73. Partly because the profit margins on advanced lipid testing are so substantial and also because these specialized tests have such limited clinical utility and

would normally only be ordered for a small percentage of the population, competing laboratories like Berkeley, HDL, and Singulex resorted to illegal kickback schemes to poach customers from their rivals and to induce referrals from a substantially larger portion of the population than medically necessary.

B. BERKELEY DEVISES AND IMPLEMENTS KICKBACK SCHEME

74. No later than 1999, Berkeley implemented a nationwide scheme to pay physicians and physician groups a kickback disguised as a draw fee for every sample referred to Berkeley's laboratories.

75. Between 1999 and 2005, Berkeley induced referrals by paying physicians and physician groups a "draw fee" of up to $20.00 for every sample referred to Berkeley—a sum that far exceeded the $3.00 draw fee permitted by CMS.

76. On June 13, 2005, HHS-OIG publically posted HHS-OIG Advisory Opinion No. 05-08, which made clear that payments by laboratories to physicians for blood sample collection could, in certain circumstances, constitute improper remuneration under the AKS. More specifically, HHS-OIG advised that arrangements between laboratories and physicians in which laboratories paid physicians for the collection of blood samples carried a "substantial risk that the Lab would be offering the blood draw remuneration to the physicians in exchange for referrals" and that "the compensation provides an obvious benefit to the referring physician and it may be inferred that this benefit would be in exchange for referrals." HHS-OIG Advisory Opinion No. 05-08.

77. HHS-OIG Advisory Opinion No. 05-08 noted that, in order for an arrangement to qualify under the personal services and management safe harbor, the

aggregate compensation would need to be set in advance. The arrangement discussed in HHS-OIG Advisory Opinion No. 05-08 involved paying physicians on a per-patient bases, and HHS-OIG opined that the compensation in such an arrangement was problematic because it could not be set in advance. In this way, HHS-OIG Advisory Opinion No. 05-08 put Berkeley, and other laboratories, on notice that any arrangement that involved payments on a per-patient basis would not qualify under the personal services safe harbor of the AKS.

78. In response to the publication of HHS-OIG Advisory Opinion No. 05-08, Berkeley did not stop or alter its payments to physicians for each sample collected, but instead changed the payment in name only, from a draw fee of $7.50-$11.50 to a $3.00 draw fee and a $4.50-$8.50 "processing and handling fee" or "P&H fee." Berkeley ignored HHS-OIG Advisory Opinion No. 05-08's warnings about per-patient payments.

79. Between 2005 and January 2012, Berkeley continued offering and paying processing and handling fees, albeit at the reduced rate of $7.50, with a few accounts receiving as much $11.50.

80. The payment of processing and handling fees had the intended effect. Physicians who received P&H fees from Berkeley made substantial referrals to Berkeley.

81. For instance, in 2010, Berkeley paid Dr. Bodo Brauer tens of thousands of dollars in processing and handling fees in exchange for approximately $570,843.31 worth of referrals.

82. Also in 2010, Berkeley paid Dr. Jeffrey Gladden tens of thousands of dollars in processing and handling fees in exchange for approximately $556,825.98 worth of referrals.

83. In 2009, Berkeley paid Dr. Rex Butler tens of thousands of dollars in processing and handling fees in exchange for approximately $384,366.72 worth of referrals.

84. Between 2005 and 2011, Berkeley paid approximately six million dollars ($6,000,000) in processing and handling fees to physicians and physicians groups nationwide in exchange for referrals yielding roughly ninety-six million dollars ($96,000,000) in Medicare and TRICARE reimbursement.

85. Berkeley executives encouraged sales representatives to reference the processing and handling fees in their sales pitches to potential clients as a means of inducing physicians to, and then rewarding physicians for, those referrals.

86. Berkeley executives also understood that the processing and handling fees "could potentially help close the deal for more business."

87. When HDL entered the blood laboratories market in 2009, Berkeley was paying $7.50 in processing and handling fees to most of its referring physicians.

88. In response to the competition HDL posed, Berkeley executives and sales representatives internally advocated for increasing processing and handling fees as a means of retaining clients who were leaving Berkeley for HDL because HDL paid more than twice as much as Berkeley did per sample.

89. Berkeley executives also understood that terminating processing and handling fees would "be a deal breaker" for "some accounts" and that "guillotining the entire program would hurt."

90. Roughly eight (8) months after being acquired by Quest Diagnostics, Inc. Berkeley stopped paying processing and handling fees in early 2012, but only after losing

a significant amount of business to laboratories like HDL and Singulex that were paying significantly higher processing and handling fees.

91. Berkeley's market share continued to decrease rapidly after it stopped paying processing and handling fees, and Berkeley no longer operates as an independent laboratory providing advanced lipid testing.

C. MALLORY, JOHNSON, AND DENT LEAVE BERKELEY AND EXECUTE ILLEGAL SALES AGREEMENT WITH HDL

92. In 2008, as Berkeley's practice of paying processing and handling fees was helping Berkeley achieve its highest gross revenues, Defendant Mallory resigned from her position as Berkeley's Senior Manager of Lab Operations to start her own clinical laboratory specializing in advanced lipid testing, HDL.

93. Mallory was the CEO of HDL from 2008 until she resigned in 2014.

94. HDL began to perform and bill for laboratory tests in 2009.

95. In late 2009, Defendants Johnson and Dent, who had been sales representatives at Berkeley, left the company to found Defendant BlueWave.

96. From late 2009 through early 2010, Mallory, Johnson, and Dent discussed and ultimately agreed that Johnson and Dent would lead a group of independent, non-employee, sales representatives to promote and market HDL's tests.

97. In January 2010, Johnson and Dent incorporated BlueWave to act as the formal sales and marketing entity that would contract with HDL.

98. At all relevant times herein, Johnson and Dent each owned 50% of BlueWave.

99. For most relevant times herein, BlueWave had only three employees. Johnson is the President, Dent is the Vice President, and they have on occasion employed an administrative assistant.

100. The remainder of BlueWave's sales force consists of approximately 34 independent contractors, including both corporate entities and individuals.

101. In April 2010, Mallory, on behalf of HDL, and Johnson and Dent, on behalf of BlueWave, executed a sales agreement, which was dated January 4, 2010, wherein BlueWave would serve as HDL's exclusive outside sales force in certain enumerated states: Alabama, South Carolina, Mississippi, Tennessee, Georgia, Florida, North Carolina, Louisiana, and Texas ("the HDL Sales Agreement").

102. The HDL Sales Agreement provided that, if BlueWave met certain sales goals, BlueWave would "have a right of first refusal to expand the Territory into other states in which [HDL] plans to do business."

103. Pursuant to the HDL Sales Agreement, HDL appointed BlueWave "as its contractor to perform certain sales services for" HDL, "including the sale of various laboratory tests and services of [HDL] to physicians and medical groups."

104. More specifically, BlueWave agreed to "use its best efforts to maximize" specific sales goals.

105. In return, HDL agreed, *inter alia*, to pay physicians between $18-$21 in process and handling fees.

106. The HDL Sales Agreement stated that:

> [BlueWave] shall act as and be deemed to be an independent contractor for all purposes of this Agreement and shall not act, nor shall [BlueWave] be deemed to be, an agent, employee or servant of [HDL]. This Agreement

> is not intended to be one of hiring under the provisions of any workers' compensation or any other law, and shall not be so construed. [BlueWave] has sole responsibility for making an [sic] payment for local, state, federal or international tax purposes.

107. Also pursuant to the HDL Sales Agreement, HDL paid BlueWave a monthly base fee, plus a "commission equal to. . . 13.8% of the revenue collected by HDL from sales" in BlueWave's territory. For the 18 months beginning after September 30, 2011, BlueWave was to be paid an "Increased Commission" that was "equal to . . . 19.8% of the revenue collected by [HDL] from sales" in the same territory. For the remaining time, HDL paid BlueWave "a commission equal to sixteen and eight tenths percent (16.8%) of the revenue collected by [HDL]." The Agreement also conveyed shares in HDL to Dent and Johnson as individuals.

108. Between January 2010 and January 2015, BlueWave and HDL performed under the HDL Sales Agreement, and, by January 2015, BlueWave served as a large, independent sales and marketing force for HDL in forty-seven states and the District of Columbia.

109. BlueWave arranged for and recommended that physicians order laboratory tests from HDL. Indeed, BlueWave arranged for physicians to order 753,062 samples in 2012 and 868,381 samples from HDL in 2013.

110. In return for the samples being referred, HDL paid BlueWave approximately $6,898,661.00 in commissions in 2010.

111. In return for the samples being referred, HDL paid BlueWave approximately $21,054,588.00 in commissions in 2011.

112. In return for the samples being referred, HDL paid BlueWave approximately $74,368,756.00 in commissions in 2012.

113. In return for the samples being referred, HDL paid BlueWave approximately $67,087,513.00 in commissions in 2013.

114. In return for the samples being referred, HDL paid BlueWave approximately $54,126,642.00 in commissions in 2014.

115. As sales increased exponentially, BlueWave's commissions also increased dramatically.

116. HDL's commission payments to BlueWave were nothing more than thinly disguised kickbacks made in violation of the AKS. The commissions paid by HDL to BlueWave did not fall within any of the safe harbors enumerated in the AKS. More specifically, because BlueWave and its officers, employees, and independent contractors, including Johnson and Dent, were not employed by HDL, the employment safe harbor to the AKS did not apply.

117. Under the HDL Sales Agreement, BlueWave, Johnson, and Dent's compensation varied depending on the volume and value of the referrals that BlueWave arranged for or referred to HDL for testing.

118. In other words, the more HDL tests that BlueWave, Johnson, and Dent's customers referred, the more money BlueWave, Johnson, and Dent would make.

119. Between October 2009 and July 2014, Medicare and TRICARE paid HDL approximately $333,000,000.00 for tests referred by physicians who received processing and handling fees.

120. Defendant Mallory knowingly and willfully arranged for the payment of remuneration to BlueWave, Johnson, and Dent in exchange for their arranging for or recommending that physicians order HDL's testing, including testing that was reimbursable by Medicare and TRICARE.

121. Furthermore, BlueWave, Johnson, and Dent knowingly and willfully solicited and received remuneration, totaling more than $223,000,000.00, that was meant to induce them to arrange for or to recommend the purchasing or ordering of HDL's tests that might be paid for in full or in part by federal health care programs.

D. BLUEWAVE, JOHNSON, AND DENT EXECUTE ILLEGAL SALES AGREEMENT WITH SINGULEX

122. On June 1, 2010, two months after entering into the HDL Sales Agreement, BlueWave, Johnson, and Dent executed a very similar sales agreement with Singulex. This agreement named BlueWave as Singulex's outside sales force ("the Singulex Sales Agreement").

123. In part because the HDL Sales Agreement included a Covenant Not to Compete, BlueWave consulted with Mallory on the terms of the Singulex Sales Agreement and the specific panel of tests that BlueWave would sell for Singulex. Mallory approved of the terms in the Singulex Sales Agreement.

124. Pursuant to the Singulex Sales Agreement, BlueWave was paid a monthly commission of 24% of Singulex's revenue collected from sales generated by BlueWave as BlueWave's fee for arranging for or recommending to doctors that they refer patients' blood testing to Singulex.

125. Johnson, Dent, and BlueWave's sales representatives were not employees of Singulex.

126. Singulex's tests were paid for in part by Medicare and TRICARE.

127. The more Singulex panels that BlueWave, Johnson, and Dent sold, the more money BlueWave, Johnson, and Dent would make.

128. In return for the samples being referred, Singulex paid BlueWave approximately $152,883.00 in commissions in 2010.

129. In return for the samples being referred, Singulex paid BlueWave approximately $3,084,935.00 in commissions in 2011.

130. In return for the samples being referred, Singulex paid BlueWave approximately $7,347,354.00 in commissions in 2012.

131. In return for the samples being referred, Singulex paid BlueWave approximately $8,217,174.00 in commissions in 2013.

132. Pursuant to the Singulex Sales Agreement, BlueWave, Johnson, and Dent knowingly and willfully solicited and received remuneration meant to induce them to arrange for or to recommend purchasing or ordering Singulex's tests that were paid for in part by federal or state health care programs.

133. As such, BlueWave, Johnson, and Dent knowingly and willfully solicited and received remuneration meant to induce them to arrange for or to recommend the purchasing or ordering of Singulex's tests that might be paid for in full or in part by federal or state health care programs.

E. BLUEWAVE, JOHNSON, AND DENT EXECUTE ILLEGAL AGREEMENTS WITH BLUEWAVE'S SALES REPRESENTATIVES

134. In order to market tests on behalf of HDL and Singulex, BlueWave, Johnson, and Dent also negotiated illegal agreements with BlueWave's independent sales contractors. BlueWave paid its sales contractors a portion of the kickbacks it received

from HDL and Singulex to market and sell HDL and Singulex tests to physicians and medical groups around the country in violation of the AKS.

135. For example, Dent signed an independent contractor agreement with BlueWave effective April 1, 2011, in which BlueWave named Dent's marketing company, HisWay of South Carolina, Inc., as its representative in South Carolina, parts of North Carolina, and Augusta, Georgia, to market and sell HDL and Singulex tests ("the HisWay Sales Agreement").

136. Pursuant to the HisWay Sales Agreement, BlueWave paid HisWay a quarterly commission of 6% of revenues collected from sales HisWay generated for HDL and 10% of revenues collected from sales HisWay generated for Singulex as its fee for arranging for or recommending to doctors that they refer patients' blood testing to HDL and Singulex.

137. Similarly, Johnson signed an independent contractor agreement effective April 1, 2011, in which BlueWave named Johnson's marketing company, Royal Blue, Inc., as its representative in Alabama, Mississippi, Tennessee, part of Georgia, and the Florida panhandle to market and sell HDL and Singulex tests ("the Royal Blue Sales Agreement").

138. Pursuant to the Royal Blue Sales Agreement, BlueWave paid Royal Blue a quarterly commission of 2% of revenues collected from sales Royal Blue generated for HDL and 3.33% of revenues collected from sales Royal Blue generated for Singulex as its fee for arranging for or recommending to doctors that they refer patients' blood testing to HDL and Singulex.

139. HisWay and Royal Blue employees, including Dent and Johnson, were not employees of HDL or Singulex.

140. BlueWave paid HisWay and Royal Blue for their marketing of HDL and Singulex tests using the illegal remuneration BlueWave was paid by HDL and Singulex.

141. BlueWave executed more than 30 such independent contractor agreements with individuals and corporations founded and operated by individual independent contractors.

142. The independent contractors, including Dent for HisWay and Johnson for Royal Blue, performed under the agreements with BlueWave to arrange for and recommend HDL and Singulex laboratory tests.

143. Mallory knew about these independent contractors and that BlueWave was splitting its revenues with the independent contractors to induce them to arrange for or recommend purchasing or ordering of HDL tests that might be paid for in full or in part by federal health care programs.

144. Under these independent contractor agreements, the compensation varied depending on the volume and value of the referrals the sales representatives had in arranging for or recommending the purchasing or ordering of HDL and Singulex laboratory tests.

145. BlueWave tracked the number of samples attributable to each independent contractor as well as the revenue generated by those samples to HDL and Singulex from third party payors, including federal healthcare programs. BlueWave in turn paid commissions to the contractors based upon the revenue generated from those samples to HDL and Singulex.

146. The more tests the sales representatives arranged for or recommended, the more money BlueWave, Johnson, Dent, and Mallory made.

147. Pursuant to the various independent contractor agreements, BlueWave, Johnson, Dent, and Mallory knowingly and willfully facilitated, paid, solicited and received remuneration meant to induce the arranging, recommending, purchasing, or ordering of HDL and Singulex tests that might be paid for in full or in part by federal or state health care programs.

F. MALLORY, BLUEWAVE, JOHNSON AND DENT IMPLEMENT THEIR OWN KICKBACK SCHEME

148. Competition in the cardiovascular laboratory testing industry is fierce.

149. For the most part, the laboratories competing in this industry all offered the same assortment of tests.

150. In order to induce physicians to order HDL's tests, Mallory, Johnson, and Dent decided to adopt and enhance the "process and handling fee" scheme being employed by Berkeley.

151. While she worked at Berkeley, Mallory helped Berkeley rationalize the amount of the processing and handling fees it was paying to physicians by conducting a time and motion study on her own to determine the amount of time it took to process and handle the blood samples.

152. While they worked at Berkeley, Johnson and Dent promoted the processing and handling fees that Berkeley was paying in order to generate sales.

153. Soon after leaving Berkeley, Mallory, Johnson, and Dent implemented a similar processing and handling fees scheme at HDL but increased the fee amount by more than 100%. Whereas Berkeley was paying approximately $7.50 to physicians in

late 2009, HDL opted to pay physicians a processing and handling fee of $17.00 for every sample referred.

154. Beginning in 2009 and continuing at least until July 2014, BlueWave, Johnson, Dent, Mallory, and their co-conspirators conspired to offer or directly offered referring physicians remuneration in the form of: (1) paying physicians excessive fees for every blood specimen sent to HDL for testing, and (2) routinely waiving copayments and deductibles for TRICARE patients.

155. BlueWave's contract with HDL and Singulex required HDL and Singulex to pay physicians a minimum of $18.00 in processing and handling fees (including a $3.00 draw fee) for every sample referred to HDL and Singulex.

156. Ultimately, HDL paid a total of $20.00 to physicians for every sample—a $3.00 draw fee and $17.00 for processing and handling. BlueWave, Johnson, Dent, and Mallory all knew that $17.00 was more than twice as much as competitors were paying for the processing and handling portion of the payment.

157. Ultimately, Singulex paid a total of $13.00 to physicians for every sample—a $3.00 draw fee and $10.00 for processing and handling. BlueWave, Johnson, Dent, and Mallory all knew that physicians who ordered tests from both HDL and Singulex on the same patient would be receiving $33.00, more than four times as much as competitors were paying.

158. BlueWave, Johnson, Dent, and Mallory deliberately doubled, and in many instances more than quadrupled, their competitors' payments in order to induce additional referrals and to steal business from rivals.

159. In their sales pitches, BlueWave sales representatives touted how much more HDL paid in processing and handling fees than competitor laboratories were paying.

160. For example, Leonard Blasko, an independent contractor working with BlueWave, met with a physician on January 27, 2012. During that meeting, Mr. Blasko not only went into great detail about the benefits of the $20.00 processing and handling fees, he also called up another BlueWave sales representative, Charles Maimone, who mentioned to the physician that he could get an additional $13.00 if he ordered a Singulex panel in addition to an HDL panel.

161. The processing and handling fees took into account the volume and value of the business generated by the physician.

162. The more specimens the physician sent to HDL, the more money HDL paid the physician.

163. Similarly, the more specimens the physician sent to Singulex, the more money Singulex paid the physician.

164. BlueWave, Johnson, Dent, and Mallory promoted processing and handling fees to referring physicians as a revenue generator.

165. For instance, on June 16, 2010, a BlueWave sales representative emailed a potential client and explained: your "practice has the potential to draw close to 100 panels a week if we were to include all other insurances we were not able to include previously. Therefore, 100 panels a week would result in a revenue stream for the office of $2000 (100 x 20 panels) per week." He added, "this would far outweigh any rent money an

outside laboratory could legitimately compensate the office to assist in collecting blood specimens."

166. For some physician practices, processing and handling payments totaled over $100,000 a year.

167. For instance, from 2011 through 2012, HDL paid $234,740.00 to the Colorado Springs Family Practice in exchange for $1,687,567.43 in Medicare referrals.

168. In 2012, HDL paid $107,660.00 to Dr. Lawrence A. May in exchange for $1,077,300.25 in Medicare referrals.

169. From 2011 through 2012, HDL paid $185,840.00 to the Family Physicians of Spartanburg practice in South Carolina in exchange for $4,665,340.69 in Medicare referrals.

170. From 2011 through 2012, HDL paid $189,237.00 to the Keowee Primary Care & Internal Medicine practice in South Carolina in exchange for $3,525,319.13 in Medicare referrals

171. Between 2010 and 2014, BlueWave, on behalf of Mallory and HDL, paid physicians and physician groups roughly $68,000,000.00 in processing and handling fees.

172. BlueWave, Johnson, Dent, and Mallory could afford to offer such high processing and handling fees because Defendants promoted the ordering of large panels of tests, many of which were medically unnecessary, which generated substantially more revenue than ordering only those tests that were medically necessary for each patient.

173. HDL promoted baseline and follow-up panels as well as panels customized for a specific doctor.

174. BlueWave, Johnson, Dent, and Mallory promoted HDL's "baseline" and "follow up" panels.

175. In South Carolina the baseline panel included as many as 20 or more individual blood tests, including a number of one-time genetic tests. The "follow up" panel was smaller and omitted the genetic tests, but still included as many as 15 or more tests.

176. Depending on the patient, many of the tests ordered in the baseline panel and the follow up panel were medically unnecessary.

177. In South Carolina, HDL billed federal health care providers as much as $3,000 to $4,000 per panel.

178. Mallory, Johnson, Dent, and BlueWave encouraged physicians to order a follow up baseline panel every three months.

179. For the customized panels, BlueWave sales representatives met directly with the ordering physician and presented the physicians with "recommended custom panels" consisting of dozens of tests that would be ordered on every sample submitted to HDL.

180. BlueWave, Johnson, and Dent sent out periodic reminders to BlueWave sales representatives with instructions to "make a concerted effort" to add additional tests "to each of your customers panels," or with directives to push newer and more expensive tests such as the CYP2C19 test.

181. Physicians were required to order multiple tests in order to get the processing and handling fees.

182. For instance, in the aforementioned January 27, 2012 meeting between Mr. Blasko and a potential customer physician, the physician was specifically told that he can only get the processing and handling fees if he orders the full panel.

183. As another inducement, Mallory, Johnson, Dent, and BlueWave advertised HDL's waiver of copayments and deductibles for all patients, including TRICARE patients. Defendants offered to waive TRICARE copayments and deductibles, and did waive them, to induce TRICARE patients to agree to testing by HDL and Singulex.

184. The combined effects of the processing and handling kickbacks and the waiver of copays and deductibles kickbacks worked to generate millions of referrals and HDL's profits soared. For example, HDL starting testing in the fall of 2009 and by April 2011 it was receiving approximately 7,000 blood samples a week. By November 2012, HDL was receiving over 28,000 samples a week. By 2013, hundreds of thousands of blood samples from physicians' offices across the country were arriving on a weekly basis.

185. There were so many blood samples coming in that HDL got its own Federal Express mailing code. *See* Richmond Times Dispatch article, 2/6/12.

186. In February 2012 Mallory told the Richmond Times Dispatch, "[w]e run about 60,000 tests a day. We have been growing at a rate of about 5% a week for the last 23 months." *Id.*

187. The scheme was so effective that HDL was able to poach at least 75 high-referring physicians from Berkeley within 12 months of implementing the scheme.

188. Those 75 physicians referred $28,312,635.73 in Medicare reimbursements to HDL in 2011 and 2012 alone.

189. Mallory, Johnson and Dent directly profited from the kickback scheme they instituted.

190. From 2009 through July 2014, HDL collected approximately $333,000,000.00 from Medicare and TRICARE related to claims that were tainted by the processing and handling fees.

191. Mallory's salary and bonuses were directly tied to HDL's profits, and she personally collected at least $26,00,000.00 in salaries, bonuses, and stock distributions between 2009 and 2014.

192. Between 2010 and 2014, BlueWave received commission payments from HDL totaling more than $223,000,000.00.

193. Between 2010 and 2013, BlueWave received commission payments from Singulex totaling more than $18,800,000.00.

194. As joint owners of BlueWave, Johnson and Dent each received 50% of all net profits generated from BlueWave's improper contracts with HDL and Singulex. Upon information and belief, the government estimates that Johnson and Dent each received at least $58,000,000.00 from BlueWave distributions.

195. Johnson also profited from his direct sales of HDL and Singulex tests to physicians through his company Royal Blue.

196. Dent similarly profited from his direct sales of HDL and Singulex tests to physicians through his company HisWay.

G. WHILE DEFENDANTS' REAPED HUNDREDS OF MILLIONS IN TESTING FEES FROM FEDERAL PROGRAMS, DEFENDANTS' KICKBACKS CORRUPTED MEDICAL JUDGMENT AND PROMOTED THE OVERUTILIZATION OF TESTS

197. Defendants' kickback scheme induced physicians to order tests from the laboratory that provided them with remuneration (and frequently the laboratory that provided the highest remuneration), rather than the laboratory that provided the best, most clinically appropriate service.

198. Defendants' kickback scheme induced physicians to order more tests than were medically necessary because the amount of the physician's remuneration was tied to the volume or value of business generated by the physician.

199. For example, Berkeley encouraged Dr. Mayes to order tests in pre-packaged "panels" rather than specifically choosing individual tests to run on each patient. These panels included genetic tests like the CYP2C19 "Plavix" test, ApoE and KIF-6, and the hormone test NTproBNP, that are not appropriate for most patients.

200. BlueWave, Johnson, Dent, and Mallory promoted that physicians run unnecessary genetic testing on all patient blood samples held by HDL in storage, which Mallory said "alone could result in almost a million extra for us."

201. In one instance, Mallory wanted the CYP2C19 genetic test to be run on all of the stored blood from patients for a South Carolina physician "by the end of July so that the reimbursement will hit us in September when we will need it to pay our next settlement fees to [Berkeley]."

202. BlueWave, Johnson, Dent, and Mallory also successfully encouraged physicians to include the CYP2C19 genetic test on the standard and custom panels that doctors submitted to HDL.

203. As a result, the CYP2C19 test was unnecessarily performed on thousands of patients despite the fact that its sole utility is detecting whether a patient has an extremely rare gene that makes the drug Plavix ineffective. The CYP2C19 test was performed on thousands of patients who were not and would not be taking Plavix.

H. DEFENDANTS KNEW THAT THEIR SCHEME WAS WRONGFUL

204. At all times relevant to the Complaint, Defendants participated in the kickback scheme knowing that at least one of the purposes of the remuneration was to induce and reward referrals of laboratory tests to Berkeley, HDL, and Singulex.

205. Berkeley, BlueWave, Johnson, Dent, and Mallory knew of the remuneration, and at times directly and personally authorized the payment of remuneration in exchange for referrals of tests.

206. Mallory approved, on a case by case basis, HDL's payment of a higher processing and handling fee for certain physicians in order to get them to switch to HDL from competitors.

207. For example, Mallory approved a request from an HDL Account Manager to pay an increased processing and handling fee to a physician who requested to be paid more after speaking with a colleague who was also paid more than the established rate. According to the HDL Account Manager, the physician's colleague "was a prime example of a doctor who cranked it out when offered the higher [processing and handling fees]."

208. Defendants knowingly attempted to disguise the illegal remuneration by calling it a "processing and handling" or "P&H" fee and encouraging the use of these phrases.

209. Johnson at one point told Mallory and Dent "I want to refocus that this is an [sic] ph fee not a draw fee. One word makes it legal the other illegal."

210. Defendants received emails from physician practices and their attorneys asserting that the processing and handling fees were kickbacks.

211. Even though Defendants claimed that the processing and handling payments were just meant to reimburse the practice for the time spent processing and handling the blood samples, Mallory authorized and HDL paid some physicians directly rather than the physicians' practice. HDL also mailed checks directly to a physician's house rather than to his practice.

212. BlueWave sales representatives, trained by Johnson and Dent, marketed processing and handling fees to physicians as an additional revenue stream.

213. For example, a BlueWave sales representative in Maryland told a practice that it would receive "$20 per patient per draw" called a "process and handling agreement," which was "significantly higher than the typical $2.76 reimbursement." The sales representative explained further that "[a]s long as 2 or more tests are ordered" HDL would pay the practice $20 and so "[w]ith two offices and 10 providers you can see how much revenue this could create" for the practice. The BlueWave representative later forwarded this email to Mallory.

214. BlueWave sales representatives in Nevada and Washington encouraged physicians to order more tests by putting together charts calculating how much "P&H Missed Potential" revenue a practice had. For one practice the missed projected revenue was $145,000 per year.

215. BlueWave sales representatives also promoted the additional revenue physicians could generate for follow-up office visits. They recommended follow up visits to review the test results for which the physician could "bill one level to two levels higher for the office visit . . . generating an additional $60 to $85 per patient . . . $546,000 per year."

216. At the instruction of Johnson, Dent, and Mallory, BlueWave sales representatives sold potential clients by hyping the additional revenue stream those clients would reap from the processing and handling fees.

217. BlueWave sales representatives even went so far as to provide mathematical equations showing how much extra a doctor would make each month by ordering certain numbers of tests.

218. Berkeley, BlueWave, and Johnson encouraged sales representatives to target physicians that were "money hungry doctors."

219. If a physician was not satisfied with just the processing and handling fee from HDL, BlueWave, Johnson, and Dent encouraged sales representatives to offer to send blood to multiple labs in order for the physician to get paid multiple processing and handling fees.

220. For example, when one physician asked if HDL would pay him more fees per test, the BlueWave representative told the doctor that the doctor could get an additional $13.00 if he also ordered tests from Singulex, without even explaining the Singulex testing to him.

221. Mallory, Johnson, and Dent were personally aware of this practice and encouraged the sales representatives to do it.

Count I
(False Claims Act: Presentation of False Claims)
(31 U.S.C. § 3729(a)(1) (claims up to and through May 19, 2009)
and 31 U.S.C. § 3729(a)(1)(A) (claims from and after May 20, 2009))

222. The United States incorporates by reference Paragraphs 1 through 220 above as if fully set forth in this Paragraph.

223. Defendants Berkeley, BlueWave, Johnson, Dent, and Mallory knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States for blood testing that were false as a result of illegal kickbacks in the form of processing and handling fees paid for each sample referred to the laboratory.

224. Defendants Berkeley, BlueWave, Johnson, Dent, and Mallory knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States for blood testing that were false as a result of illegal kickbacks in the form of waived copays and deductibles for each sample referred to the laboratory and billed to TRICARE.

225. Defendants Berkeley, BlueWave, Johnson, Dent, and Mallory knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States for blood testing that were false because the tests were medically unnecessary.

226. Defendants BlueWave, Johnson, Dent, and Mallory knowingly presented or caused to be presented false or fraudulent claims for payment or approval to the United States for blood testing that were false as a result of illegal kickbacks in the form of fees that HDL and Singulex paid to BlueWave, Johnson, and Dent in exchange for arranging for and recommending that physicians order tests that were reimbursed by federal programs.

227. By virtue of the false or fraudulent claims that Defendants Berkeley, BlueWave, Johnson, Dent, and Mallory made or caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

Count II
(False Claims Act: Presentation of False Statements Material to False Claims)
(31 U.S.C. § 3729(a)(2) (claims up to and through May 19, 2009)
and 31 U.S.C. § 3729(a)(1)(B) (claims from and after May 20, 2009))

228. The United States incorporates by reference Paragraphs 1 through 226 above as if fully set forth in this Paragraph.

229. Defendants Berkeley, BlueWave, Johnson, Dent, and Mallory knowingly made or caused to be made false records or statements material to false or fraudulent claims.

230. Defendants Berkeley, BlueWave, Johnson, Dent, and Mallory knowingly made or caused to be made false bills, requests for reimbursement, requisition forms, and records of services that were obtained by means of illegal kickbacks and were material to the payment or approval of claims by federal programs.

231. Defendants Berkeley, BlueWave, Johnson, Dent, and Mallory knowingly made or caused to be made false bills, requests for reimbursement, requisition forms, and records of services for medically unnecessary tests that were material to the payment or approval of claims by federal programs.

232. By virtue of the false or fraudulent statements that Defendants BlueWave, Johnson, Dent, and Mallory made or caused to be made, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be

determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

Count III
(False Claims Act: Conspiracy to Present False Claims)
(31 U.S.C. § 3729(a)(3) (claims up to and through May 19, 2009) and 31 U.S.C. § 3729(a)(1)(C) (claims from and after May 20, 2009))

233. The United States incorporates by reference Paragraphs 1 through 231 above as if fully set forth in this Paragraph.

234. Defendants BlueWave, Johnson, Dent, Mallory and their co-conspirators knowingly entered into one or more conspiracies to present or cause to be presented false or fraudulent claims for payment or approval to the United States for blood testing that were false as a result of illegal kickbacks in the form of processing and handling fees paid for each sample referred to the laboratory.

235. Defendants BlueWave, Johnson, Dent, Mallory and their co-conspirators knowingly entered into one or more conspiracies to present or cause to be presented false or fraudulent claims for payment or approval to the United States for blood tests that were false because the tests were medically unnecessary.

236. Defendants BlueWave, Johnson, Dent, Mallory and their co-conspirators knowingly entered into one or more conspiracies to present or cause to be presented false or fraudulent claims for payment or approval to the United States for blood testing that were false as a result of illegal kickbacks in the form of fees that HDL—authorized by Mallory—and Singulex paid to BlueWave, Johnson, and Dent in exchange for arranging for and recommending that physicians order tests that were reimbursed by federal programs.

237. By virtue of the false or fraudulent claims that Defendants BlueWave, Johnson, Dent, Mallory and their co-conspirators conspired to present or cause to be presented, the United States suffered damages and therefore is entitled to treble damages under the False Claims Act, to be determined at trial, plus civil penalties of not less than $5,500 and up to $11,000 for each violation.

Count IV
(Payment by Mistake of Fact)

238. The United States incorporates by reference Paragraphs 1 through 236 above as if fully set forth in this Paragraph.

239. This is a claim for the recovery of monies paid by the United States to Defendants as a result of mistaken understandings of facts.

240. The false claims which Defendants submitted to the United States' agents were paid by the United States based upon mistaken or erroneous understandings of material fact.

241. The United States, acting in reasonable reliance on the truthfulness of the claims and the truthfulness of Defendants' certifications and representations, paid Defendants certain sums of money to which they were not entitled, and Defendants are thus liable to account and pay such amounts, which are to be determined at trial, to the United States.

Count V
(Unjust Enrichment)

242. The United States incorporates by reference Paragraphs 1 through 240 above as if fully set forth in this Paragraph.

243. This is a claim for the recovery of monies by which Defendants have been unjustly enriched.

244. By obtaining government funds to which they were not entitled, Defendants were unjustly enriched, and are liable to account and pay such amounts, or the proceeds therefrom, which are to be determined at trial, to the United States.

PRAYER FOR RELIEF

WHEREFORE, the United States demands and prays that judgment be entered in its favor against Defendants, jointly and severally, as follows:

I. On the First Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, together with all such further relief as may be just and proper.

II. On the Second Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, together with all such further relief as may be just and proper.

III. On the Third Count under the False Claims Act, for the amount of the United States' damages, trebled as required by law, and such civil penalties as are permitted by law, together with all such further relief as may be just and proper.

IV. On the Fourth Count for payment by mistake, for the amounts the United States paid by mistake, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

V. On the Fifth Count for unjust enrichment, for the amounts by which Defendants were unjustly enriched, plus interest, costs, and expenses, and for all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States demands a jury trial in this case.

Respectfully submitted,

BENJAMIN C. MIZER

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