UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *et. al*, *ex rel.* KREGG EVERETT, Plaintiffs, v. GENPATH DIAGNOSTICS, BIO-REFERENCE LABORATORIES, INC., and CYTOMETRY SPECIALISTS, INC., Defendants.	**10 Civ. 4212 (GBD)**

UNITED STATES OF AMERICA *ex rel.* SAMUEL RUTA and BLAIR CONROY, Plaintiffs, v. BIO-REFERENCE LABORATORIES, INC., Defendant.	**11 Civ. 3850 (GBD)**

UNITED STATES OF AMERICA, Plaintiff-Intervenor, v. BIO-REFERENCE LABORATORIES, INC., Defendant.

Plaintiff United States of America (the "United States" or the "Government"), by its attorney, Audrey Strauss, Acting United States Attorney for the Southern District of New York, brings this action against Bio-Reference Laboratories, Inc. ("BRL"), and alleges as follows:

PRELIMINARY STATEMENT

1. This is a civil fraud action brought by the United States (the "Government") against BRL pursuant to the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), and the common law to recover treble damages sustained by, and civil penalties and restitution owed to, the Government, arising from BRL's schemes to defraud the United States in connection with the submission of claims for payment to federally-funded healthcare programs.

2. As set forth more fully below, the United States alleges in this action that BRL, a company that provides laboratory testing to healthcare providers focusing on molecular diagnostics, anatomical pathology, genetics, and women's health, engaged in fraudulent reimbursement and kickback schemes that resulted in BRL improperly receiving millions of dollars from Medicare and TRICARE.

3. From 2009 through 2012, BRL knowingly and willfully billed Medicare and TRICARE for certain testing performed for hospital inpatients which should have been paid by the hospitals themselves. As a result, BRL received reimbursement from Medicare and TRICARE for tests that the federally-funded programs had already paid for, because hospitals receive payments for all items and services provided to the patient under the inpatient prospective payment system ("IPPS"), unless an exemption applies which are inapplicable here.

4. In addition, in violation of the Anti-Kickback Statute (the "AKS"), 42 U.S.C. §§ 13320a-7b(b), BRL knowingly and willfully offered and paid remuneration, in the form of a percentage of the cost of electronic medical records transition software, to physicians based on

the volume of business generated by those physicians in order to induce them to use BRL's services.

5. As a result of these fraudulent schemes, federal healthcare programs paid BRL millions of dollars to which it was not entitled.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the claims brought under the FCA pursuant to 31 U.S.C. § 3730(a) and 28 U.S.C. §§ 1331 and 1345, and over the remaining claims pursuant to 28 U.S.C. § 1345.

7. This Court may exercise personal jurisdiction over BRL pursuant to 31 U.S.C. § 3732(a), which provides for nationwide service of process.

8. Venue lies in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because BRL does business in this District.

9. No official of the United States charged with responsibility to act in the circumstances knew or should have known of the facts material to the FCA claims related to the fraudulent billing practices alleged herein prior to May 2010.

PARTIES

10. Plaintiff is the United States of America and it is suing on its own behalf and on behalf of the United States Department of Health and Human Services ("HHS") and its component agency, the Centers for Medicare and Medicaid Services ("CMS"), which administers the Medicare program; and the Department of Defense, which administers the TRICARE program.

11. Defendant BRL is a company headquartered in New Jersey that provides molecular laboratory testing services to patients through their healthcare providers. In August

2015, a subsidiary of OPKO Health Inc. ("OPKO") merged with and into BRL, with BRL surviving the merger as a wholly owned subsidiary of OPKO and continuing to provide laboratory testing.

12. Relator Kregg Everett ("Everett") is a former sales representative of BRL's subsidiary, Genpath Diagnostics. On or about May 25, 2010, Everett filed a complaint under the *qui tam* provisions of the FCA and the AKS, alleging, *inter alia*, that BRL and its division Genpath Diagnostics fraudulently billed Medicare for certain testing performed for hospital inpatients that the hospitals were required to pay themselves, in order to induce hospitals to order more testing from BRL (the "Everett Complaint").

13. Relator Samuel Ruta ("Ruta") is a former sales director for Genpath Diagnostics, a subsidiary of BRL.

14. Relator Blair Conroy ("Conroy") is a former sales manager for BRL.

15. On or about December 16, 2010, Ruta and Conroy filed a complaint in the United States District Court for the District of New Jersey under the *qui tam* provisions of the FCA, alleging, *inter alia*, that BRL, in violation of the FCA and AKS: (i) fraudulently billed Medicare for certain testing performed for hospital inpatients that the hospitals were required to pay for themselves, and (ii) engaged in a fraudulent kickback scheme by providing a percentage of the cost of medical records transition software to physicians' offices based on the volume of business generated by those offices (the "Ruta-Conroy Complaint"). On April 16, 2011, the Ruta-Conroy Complaint was transferred to this District.

BACKGROUND

I. The False Claims Act and the Anti-Kickback Statute

16. The FCA establishes treble damages liability to the United States for an individual who, or entity that, "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1)(A); or "knowingly makes, uses, or causes 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). "Knowingly" is defined to include actual knowledge, reckless disregard and deliberate indifference. 31 U.S.C. § 3729(b)(1). No proof of specific intent to defraud is required. *Id.*

17. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.

18. The AKS makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2). Violation of the AKS is a felony punishable by fines and imprisonment and can also result in exclusion from participation in federal healthcare programs. 42 U.S.C. § 1320a-7b(b)(2); 42 U.S.C. § 1320a-7(b)(7).

19. The AKS arose out of congressional concern that remuneration given to those who can influence healthcare decisions would result in goods and services being provided that are medically unnecessary, of poor quality, or even harmful to a vulnerable patient population. To protect federal healthcare programs from these harms, Congress enacted a prohibition against the payment of kickbacks in any form.

20. As emodied 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), "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]."

21. According to the legislative history of the PPACA, this amendment to the AKS was intended to clarify "that all claims resulting from illegal kickbacks are considered false claims for the purpose of civil actions under the False Claims Act, even when the claims are not submitted directly by the wrongdoers themselves." 155 Cong. Rec. S10854.

22. Compliance with the AKS, 42 U.S.C. § 1320a-7b(b), is a condition of payment under the federal healthcare programs.

II. The Federal Healthcare Programs

23. ***Medicare.*** Medicare is a federal program that provides federally subsidized health insurance primarily for persons who are 65 or older or disabled. *See* 42 U.S.C. §§ 1395 et seq. ("Medicare Program").

24. HHS is responsible for the administration and supervision of the Medicare program. CMS is an agency of HHS and is directly responsible for the administration of the Medicare program.

25. Medicare has several parts, including Part A (which is primarily for hospital-based charges) and Part B (which is primarily for physician and other ancillary services). Medicare Part A coverage is based upon a Prospective Payment System for which the hospital receives a predetermined, fixed payment for each Medicare admission.

26. Each patient is classified into a Diagnosis Related Group ("DRG"), determined by the patient's medical condition, and the hospital is paid a flat rate for each patient based on the DRG category, irrespective of the actual services provided.

27. ***TRICARE.*** TRICARE (formerly known as CHAMPUS) is part of the United States military's healthcare system, designed to maintain the health of active duty service personnel, provide healthcare during military operations, and offer healthcare to non-active duty beneficiaries, including dependents of active duty personnel and military retirees and their dependents. The military health system, which is administered by the Department of Defense ("DOD"), is composed of the direct care system, consisting of military hospitals and military clinics, and the benefit program, known as TRICARE. TRICARE is a triple-option benefit program designed to give beneficiaries a choice between health maintenance organizations, preferred provider organizations, and fee-for-service benefits.

28. The federal government reimburses a portion of the cost of laboratory testing services under TRICARE.

29. 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 generally cannot, as a matter of law, waive these co-pay or deductible requirements. 32 C.F.R. § 199.4(f)(9).

30. Providers of services to TRICARE beneficiaries are required to comply with TRICARE's program requirements, including its anti-abuse provisions. 32 C.F.R. § 199.9(a)(4). TRICARE regulations provide that claims submitted in violation of TRICARE's anti-abuse provisions can be denied. *Id.* § 199.9(b). Kickback arrangements are included within the definition of abusive situations that constitute program fraud. *Id.* §§ 199.2(b), 199.9(c)(12).

III. Billing Process Under the Clinical Lab Fee Schedule

31. In order to receive reimbursement payments from the Government for medical services covered by Medicare and TRICARE, a provider must submit claims for payment. These claims must contain CPT codes, which are a set of standardized medical codes developed and maintained by the American Medical Association that are used to identify and report the medical, surgical, and diagnostic procedures and services provided. The claims are required to reflect, among other things: (a) the code that accurately identifies the medical procedure or service; (b) the date the service was rendered; (c) the name of the patient who received the services; and (d) the name of the provider.

32. Government healthcare payors use CPT codes to determine both coverage, *i.e.*, if they will pay for the billed medical procedures and services, and reimbursement, *i.e.*, how much they will pay for the billed medical procedures and services.

33. Each procedure or service furnished to a patient has a specific CPT code. Further, each CPT code receives a certain level of reimbursement, which can vary depending on what other codes are billed. The amount of money a provider is paid by Government healthcare payors for a service rendered to a patient depends on which CPT codes are submitted as part of the corresponding claim.

34. Regarding services provided by independent clinical laboratories, CMS requires independent laboratories to bill hospitals for laboratory tests that are (a) listed by CPT code on the Clinical Lab Fee Schedule ("CLFS"), 42 C.F.R. §§ 414 *et seq*., and (b) furnished to Medicare and TRICARE inpatients.

35. Specifically, 42 C.F.R. §§ 411.15(m)(1) & (2) exclude from Medicare and TRICARE coverage a list of clinical laboratory services, provided to hospital inpatients, and the

laboratory services subject to the exclusion vary by year. 42 C.F.R. §§ 411.15(m)(1) & (2) exclude from coverage "clinical laboratory services" provided to hospital inpatients by entities other than the hospital. This prohibits any independent lab billing under the CLFS for services rendered to hospital inpatients. *See also* amended Federal Register Document (42 C.F.R. § 411.15(m) and 58 FR 3066, May 26, 1993)).

36. CMS requires independent laboratories to bill hospitals directly rather than Medicare or TRICARE for certain services provided to inpatients and listed on the CLFS, because hospitals receive payments for all items and services provided to the patient under the inpatient prospective payment system, unless an exemption applies. As a result, Medicare has already effectively paid for the inpatient testing through the DRG (diagnosis-related groups) payment system. Through the DRG, Medicare pays hospitals a flat rate per case for inpatient hospital care, so that efficient hospitals are rewarded and inefficient hospitals have an incentive to become more efficient.

IV. Remuneration Under the AKS

37. As noted above, the AKS makes it illegal for individuals or entities to knowingly and willfully "offer[] or pay[] remuneration (including any kickback, bribe, or rebate) . . . to any person to induce such person . . . to purchase, . . . order, . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C. § 1320a-7b(b)(2).

38. 42 C.F.R. § 1001.952(y)(5) provides that "remuneration" under the AKS consists of "nonmonetary remuneration," such as "items and services in the form of software or information technology," where "the eligibility of a beneficiary for the items of services," or "the

amount or nature of the items or services, is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties."

39. This prohibits an independent laboratory from donating to its clients any portion of the costs for "software or information technology," where the determination is directly based on the volume of business generated by that client.

FACTUAL ALLEGATIONS

I. BRL's Fraudulent Billing Practices under the Clinical Lab Fee Schedule

40. From 2009 through 2012, BRL knowingly and fraudulently billed Medicare and TRICARE for certain testing that was (i) listed on the CLFS and (ii) performed on beneficiaries who were hospital inpatients at the time of service.

41. Specifically, from 2009-2012, a percentage of BRL's Medicare and TRICARE billing originating from hospitals consisted of testing performed on hospital inpatients and listed on the CLFS.

42. For example, from 2009-2012, BRL did not bill Triad of Alabama/Flowers Hospital in Dothan, Alabama ("Triad"), for any inpatient testing whatsoever. As a result, during that time period, BRL improperly billed Medicare and TRICARE for testing BRL performed for Triad and its associated pathology practices on behalf of Medicare or TRICARE beneficiaries.

43. BRL knew this was occurring and took no steps to stop it. In 2009, BRL's requisition form – the form BRL provided to hospitals to order tests for their patients – did not contain any place for a hospital to indicate whether the patient was an inpatient or an outpatient. Accordingly, BRL claims processing personnel could not distinguish between patients who were inpatients or outpatients and thus billed federal healthcare programs for inpatient testing.

44. Indeed, on January 27, 2010, the Director of Genpath Accounts Receivable wrote to management, "I'm afraid that we can end up billing Medicare for hospital patients." Other BRL employees noted in January 2010 that "there is some serious confusion [] on what can and cannot be billed for hospital patients."

45. But as of at least January 2010, BRL management had a clear understanding of the necessity to bill hospitals – and not CMS – for clinical codes on the CLFS. As a Senior Vice President of BRL stated in an email in January 2010, "Under NO circumstances can [BRL] EVER bill Medicare/Medicaid for any test [under the CLFS]."

46. Nevertheless, despite this "major confusion," the requisition forms remained the same – without a way to indicate whether the patient was an inpatient.

47. This was intentional. During a March 10, 2011, company meeting, BRL executives explicitly told the salesforce that it was not BRL's job to send hospitals any bills for inpatient testing.

48. This practice continued, as BRL, knowing that this practice was illegal, recklessly failed to distinguish between testing performed on hospital inpatients and listed on the CLFS, and testing performed on patients on an outpatient basis and listed on the CLFS.

49. As a result, from 2009 through at least 2012, BRL knowingly and fraudulently billed Medicare and TRICARE for hospital inpatient testing listed on the CLFS. Indeed, BRL submitted thousands of claims for reimbursement under the CLFS for testing performed on hospital patients which should have been billed to the hospitals instead.

50. The federal healthcare programs would not have paid these claims for reimbursement had they known that the tests were performed on hospital inpatients and thus covered by the DRG.

51. This practice resulted in BRL receiving hundreds of thousands of dollars in reimbursement from federal health care programs to which it was not entitled.

II. BRL's Kickback Scheme

52. Despite the prohibition outlined in 42 C.F.R. § 1001.952(y)(5), BRL had a practice – directed from the very top – that conditioned the provision of electronic medical record technology ("EMR") to physicians' offices on the volume of business generated by the practice.

53. BRL provided remuneration to physicians' offices by paying a percentage of costs for EMR in order to induce physicians to order BRL tests for Federal healthcare program beneficiaries.

54. From 2009 through 2012, BRL provided a percentage of the cost of free electronic medical records transition software ("EMR Software") to physicians' offices based on the volume of business generated by those offices.

55. Specifically, from 2009 through 2012, BRL engaged in a practice – at the direction of its management – entitled the "3 to 1 calculation," meaning that BRL conditioned the provision of free payment for EMR Software to physicians' offices on whether a physician's office would generate revenue equal to three times the value of the EMR Software BRL provided.

56. For example, on January 24, 2009, a BRL employee, in an internal email to BRL management, applied the 3 to 1 calculation to a particular physician's office in Somerville, New Jersey, and suggested that BRL provide the EMR Software, but noted, "You find the legal way to say that. I don't feel they will make us put it in writing."

57. Also in 2009, another BRL employee, in an internal email to management, explained that a practice in Paramus, New Jersey, wanted BRL to donate the costs of EMR Software. A Senior Vice President replied, "12 month volume and cash receipts." After reviewing the revenue and payment history for the practice, the executive stated, "No EMR donation[.]"

58. In October 2009, responding to a BRL employee's separate request for an EMR Software donation to a particular practice in Scottsdale, Arizona, a Senior Vice President replied, "If we make the EMR donation for $42,500, [] that would yield $243,000 less expenses of $137,000 or net before lab costs, overhead and commission . . . . . $106,000. So, my question is, would YOU spend $137,000 to get $106,000[?]"

59. In August 2010, a BRL salesperson requested two donations of $20,000 over a two year period to a particular practice in North Carolina; the Director of Sales for Genpath approved the request after requesting and reviewing the practice's business volume.

60. Similarly, on June 7, 2011, BRL management evaluated a BRL salesperson's request for payment for an EMR Software donation to a particular physician's office in Los Angeles, California, and directed that salesperson to "[b]uild volume to meet 3x rule."

61. Likewise, an internal BRL memorandum dated June 30, 2011, notes that the "3 to 1 calculation" means that if the cost of EMR Software is $50,000, BRL would require $150,000 in gross revenue generated by that practice in order to donate the cost of the EMR Software.

62. During this timeframe, BRL provided payment for EMR Software based on this formula to sixty-nine separate physicians' offices throughout the United States.

63. This provision of the cost of EMR Software to physicians' offices constitutes kickbacks, causing false claims to be submitted to federal healthcare programs for tests ordered by the physicians who received these kickbacks.

64. The federal healthcare programs would not have paid claims submitted by BRL for testing ordered by these physician's offices had they known of the illegal kickbacks.

65. As a result of this conduct, BRL received millions of dollars to which it was not entitled.

CLAIMS FOR RELIEF

FIRST CLAIM

Violation of the False Claims Act: Presenting False Claims for Payment (31 U.S.C. § 3729(a)(1)(A))

66. The Government incorporates by reference each of the preceding paragraphs as if fully set forth in this paragraph.

67. The Government seeks relief against BRL under Section 3729(a)(1)(A) of the False Claims Act.

68. Through the acts set forth above, BRL knowingly, or acting with deliberate ignorance or reckless disregard for the truth, presented, or caused to be presented, false or fraudulent claims for payment to federal healthcare programs in connection with laboratory testing services provided by BRL.

69. The federal healthcare programs made payments to BRL because of the false or fraudulent claims.

70. If the federal healthcare payors had known that the claims presented for payment were for tests that were inaccurately billed or resulted from illegal kickbacks, they would not have paid the claims.

71. By reason of these false or fraudulent claims, the Government has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

SECOND CLAIM

Violations of the False Claims Act: Use of False Statements (31 U.S.C. § 3729(a)(1)(B))

72. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

73. The Government seeks relief against BRL under 31 U.S.C. § 3729(a)(1)(B).

74. Through the acts set forth above, BRL knowingly, or acting with deliberate ignorance or reckless disregard for the truth, made, used, and caused to be made and used, false records and statements material to the payment of false or fraudulent claims by federal healthcare programs.

75. BRL made and/or caused to be made numerous false records and statements, including claims with false certifications of compliance with applicable federal and state laws and regulations.

76. If the federal healthcare payors had known that the records and statements were false, they would not have paid the claims.

77. By reason of these false records and statements, the Government has sustained damages in a substantial amount to be determined at trial, and is entitled to treble damages plus a civil penalty for each violation.

THIRD CLAIM

Unjust Enrichment

78. The Government incorporates by reference each of the preceding paragraphs as if fully set forth herein.

79. Through the acts set forth above, BRL has received payments to which it was not entitled and therefore was unjustly enriched. The circumstances of these payments are such that, in equity and good conscience, BRL should not retain those payments, the amount of which is to be determined at trial.

WHEREFORE, the Government respectfully requests judgment to be entered against BRL as follows:

a. On the First and Second Claims (FCA violations), a judgment for treble damages and civil penalties to the maximum amount allowed by law;

b. On the Third Claim (unjust enrichment), a judgment for damages to the extent allowed by law; and

c. Granting the Government costs and such further relief as the Court may deem proper.

Dated: September 9, 2020
New York, New York

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