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

United States of America *ex rel*. Dr. Michael Mayes, Plaintiffs, vs. Berkeley HeartLab, Inc., Quest Diagnostics Incorporated, and Bluewave Healthcare Consultants, Inc., Defendants.	Case No. 9:14-cv-00230-RMG (Consolidated with 9:11-cv-1593-RMG and 9:15-cv-2485-RMG) **FOURTH AMENDED *QUI TAM* COMPLAINT OF DR. MICHAEL MAYES STATING ONLY HIS NON-INTERVENED CLAIMS AGAINST QUEST DIAGNOSTICS INC. FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT** **JURY TRIAL DEMANDED**

I. INTRODUCTION

1. This is a consolidated action in which the United States has intervened in whole or part in three whistleblower cases filed under the *qui tam* provisions of the federal False Claims Act to recover damages and civil penalties on behalf of the United States of America arising from false and/or fraudulent records, statements and claims made and caused to be made by Defendants and/or their agents, employees, and co-conspirators in violation of the False Claims Act, 31 U.S.C. §§ 3729 *et seq*. ("the FCA").

2. Plaintiff Michael Mayes ("Relator") filed his original complaint in this action with this Court on June 30, 2011. Case No. 9:11-cv-1593-RMG. He subsequently amended his complaint three times while his action remained under seal and was being investigated by the United States for purposes of making an intervention decision. Ultimately, Dr. Mayes named as defendants in his *qui tam* action Berkeley HeartLab, Inc. ("Berkeley"); Quest Diagnostics,

Incorporated ("Quest"); BlueWave Healthcare Consultants, Inc. ("BlueWave"); Singulex, Inc. ("Singulex"); and Health Diagnostic Laboratory, Inc. ("HDL").

3. While his claims were under investigation by the United States two additional *qui tam* actions were filed by other whistleblowers ("relators") that overlap in part with the allegations Dr. Mayes made in his action. Prior to the filing of this Fourth Amended Complaint, former defendants to Dr. Mayes' and the other relators' actions Singulex and HDL settled claims with the United States and the other relators and were dismissed from all three *qui tam* actions. Thereafter, on June 5, 2015, this Court consolidated all three cases into the present action.

4. After further investigation, the United States filed a complaint in intervention as to all three consolidated actions on August 7, 2015, as authorized under the FCAt. In doing so, the United States intervened in Dr. Mayes' allegations against Berkeley and BlueWave and declined to intervene in Dr. Mayes' allegations against Quest.

5. In light of the United States' recently announced intervention to become a co-plaintiff in Dr. Mayes' allegations against Berkeley and BlueWave and to decline intervention in Dr. Mayes' claims against Quest, *qui tam* Plaintiff Michael Mayes, through his attorneys, hereby amends his Complaint only as against defendant Quest. This amendment is done both to distinguish the pleading of Relator's non-intervened claims from the claims in which the United States has intervened (and has now filed and served its Complaint in Intervention as to all remaining defendants in this Relator's action other than Quest) and to update Relator's non-intervened allegations against Quest based on newly acquired information and new factual developments. The amendments in this Fourth Amended Complaint are not intended to alter Relator's claims for relief against Berkeley and BlueWave, as continue to be set forth in his Third Amended Complaint. However, Relator recognizes–in accordance with §§3730(c)(1) and 3731(c) of the FCA, which assign the United States "primary responsibility for prosecuting [an] action" in which it intervenes and permit the United States, in exercising that responsibility, to file a new complaint to state its claims as it deems best–that United States' Complaint in Intervention now should be understood to control the substantive claims against Berkeley and

BlueWave that appear in Relator's Third Amended Complaint. Therefore, for his non-intervened claims against Quest, Dr. Mayes alleges, based upon personal knowledge, relevant documents, and information and belief, as follows:

II. SUMMARY OF ALLEGATIONS

6. Relator re-alleges and incorporates by reference the allegations contained in paragraphs 3 – 11 of the United States' Complaint in Intervention as if fully set forth herein,[1] and further alleges as follows:

7. Defendant Quest acquired Defendant Berkeley in May 2011. At Quest's direction, Berkeley continued to pay draw fee kickbacks to at least some physicians and physician practice groups until at least January 2012. However, because Quest recognized that without the illegal payments many physicians would reduce the number of tests ordered from Berkeley or cease using Berkeley entirely, Berkeley and Quest began offering several new forms of remuneration in exchange for providers' continued business. These kickbacks, which Quest representatives acknowledge were developed in an effort to "get around" the draw fee restrictions, include paying the salaries of providers' phlebotomists, leasing space from providers, providing valuable software services and paying exorbitantly high draw fees for commercially insured patients.

8. In or about August 2013, Berkeley went out of business. Quest now offers, in identical or substantially similar forms, over a dozen valuable lab tests and/or lab panels previously offered by Berkeley that Quest did not offer prior to its acquisition of Berkeley. Upon information and belief, after Dr. Mayes' original complaint in this action was filed, Quest stripped Berkeley of various valuable assets, including the intellectual and physical property associated with those valuable tests and panels formerly offered by Berkeley, without paying fair market value for those assets. Quest stripped these assets with full notice not only of Berkeley's illegal payment of kickbacks prior to Quest's acquisition of Berkeley, and not only of its own

[1] A copy of the United States' Complaint in Intervention shall be served on Quest with this Fourth Amended Complaint of Relator Mayes.

continuation and modification of those kickbacks, but also with notice of the government's investigation or the high probability of government investigation into the allegations in this complaint.

9. Based on the foregoing, *qui tam* Plaintiff Michael Mayes seeks, through this action, to recover damages and civil penalties arising from the false or fraudulent records, statements and/or claims that Quest knowingly made or caused to be made, itself or that it is jointly liable for having conspired with Berkeley to make, in connection with their fraudulent scheme.

III. PARTIES

10. Plaintiff Michael Mayes is a resident of Hilton Head Island, South Carolina. Dr. Mayes attended Temple School of Medicine in Philadelphia, Pennsylvania and completed his residency in Internal Medicine at Temple Hospital in 1997 where he was recognized as the Most Outstanding Resident in his class. In 1999, Dr. Mayes joined Heritage Medical Partners in South Carolina. He first learned of the fraudulent conduct described in this complaint when he was associated with that practice.

11. 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 August 2013, Berkeley was in the business of providing cardiovascular disease management services, including laboratory services, to physicians, medical clinics and patients throughout the United States.

12. Defendant Quest Diagnostics Incorporated is a corporation organized under the laws of the State of Delaware with its headquarters at 3 Giralda Farms, Madison, New Jersey 07940. Quest provides diagnostic testing services for cancer, cardiovascular disease, infectious disease, and neurological disorders. Quest operates a nationwide specimen collection network including approximately 2,000 patient service centers and approximately 3,000 phlebotomists in

physician offices. In 2011, Quest processed approximately 146 million test requisitions, generating net revenues of $7.5 billion. Since May of 2011, Quest has been the parent company for defendant Berkeley and, in that capacity, assumed an active role in perpetuating and refining the unlawful inducements Berkeley used to gain lab test referrals. More recently, Quest has stripped Berkeley of most of its valuable assets, leaving Berkeley unable to satisfy any potential judgment against it in this action.

IV. JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, 28 U.S.C. § 1367, and 31 U.S.C. § 3732, the last of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730.

14. This Court has personal jurisdiction over Quest pursuant to 31 U.S.C. § 3732(a) because that section authorizes nationwide service of process and because Quest has minimum contacts with the United States. Moreover, Quest can be found in and/or has transacted business in the District of South Carolina.

15. Venue is proper in the District of South Carolina pursuant to 28 U.S.C. §§ 1391(b) and 1395(a) and 31 U.S.C. § 3732(a) because Quest can be found in and transacts business in this district. At all times relevant to this Complaint, Quest regularly conducted substantial business within this district, maintained employees and offices in this district, and/or made significant sales within this district.

V. THE LAW

A. The False Claims Act

16. Relator re-alleges and incorporates by reference the allegations contained in paragraphs 28 – 30 of the United States' Complaint in Intervention as if fully set forth herein.

B. The Anti-Kickback Statute

17. Relator re-alleges and incorporates by reference the allegations contained in paragraphs 31 – 37 of the United States' Complaint in Intervention as if fully set forth herein.

C. HHS-OIG Fraud Alerts and Opinions

18. Relator re-alleges and incorporates by reference the allegations contained in paragraphs 38 – 46 of the United States' Complaint in Intervention as if fully set forth herein.

D. The Medicare Program

19. Relator re-alleges and incorporates by reference the allegations contained in paragraphs 47 – 63 of the United States' Complaint in Intervention as if fully set forth herein.

E. The TRICARE Program

20. Relator re-alleges and incorporates by reference the allegations contained in paragraphs 64 – 68 of the United States' Complaint in Intervention as if fully set forth herein.

VI. BACKGROUND ON BLOOD TESTING

A. Blood laboratories and blood testing

21. Relator re-alleges and incorporates by reference the allegations contained in paragraphs 69 – 73 of the United States' Complaint in Intervention as if fully set forth herein.

B. Quest now offers Berkeley's historical test offerings

22. Prior to Quest's acquisition of Berkeley,[2] Berkeley provided over 35 clinical diagnostic tests. Berkeley offered a wide variety of tests that were, under certain circumstances, clinically useful for patients demonstrating risk factors for cardiovascular disease. Those tests included, among others:

a. Apolipoprotein B (ApoB);

b. Lipoprotein (a) (Lp(a)),

c. ApoE Genotype,

d. KIF6 Genotype,

e. Lp-PLA2,

f. C-Reactive Protein-hs (highly sensitive CRP),

g. NT-proBNP,

[2] For simplicity, this remainder of this complaint will refer to Quest's acquisition of Berkeley to mean Quest's acquisition of Berkeley through Quest's May 2011 acquisition of Berkeley's then-parent company, Celera.

h. CYP2C19 Genotype (the Plavix test),

i. Fibrinogen,

j. Homocysteine,

k. 9p21 Genotype,

l. LPA Genotype,

m. Omega 3 and 6 fatty acid test,

n. LDL-S3GGE

o. HDL-S10GGE

23. Berkeley continued to offer these tests for some time after acquisition by Quest. In August 2013 Berkeley ceased operations. Quest now offers the above-named tests or tests that are substantially similar to them.[3] Relator is personally aware that Quest offers these tests through his interactions with Quest sales representatives.

VII. ALLEGATIONS

A. Defendants Berkeley and BlueWave, and former Defendants HDL and Singulex Knowingly Devised and/or Implemented Kickback Schemes to Induce Referrals

24. Relator re-alleges and incorporates the allegations contained in paragraphs 74 – 221 of the United States' Complaint in Intervention as if fully set forth herein.

B. Defendant Quest Conspired with Berkeley and Continued to Implement the Berkeley Kickback Scheme after Acquiring Berkeley

25. Relator re-alleges and incorporates the allegations contained in paragraph 90 of the United States' Complaint in Intervention as if fully set forth herein, and further alleges as follows:

26. Following Quest's acquisition of Berkeley's parent company in May 2011, Berkeley and Quest continued to pay physicians the excessive draw fees Berkeley had promised through the end of January 2012.

[3] Quest has renamed the LDL-S3GGE and HDL-S10GGE tests to "Cardio IQ Lipoprotein Subfraction" and "Cardio IQ Lipoprotein Fractionation," and also offers the "Cardio IQ Advanced Lipid Panel," which incorporates multiple former Berkeley offerings.

27. Immediately following the acquisition, the draw fee invoices continued to bear the Berkeley logo and the draw fee payments were made via Berkeley checks. On December 27, 2011, Berkeley issued a letter to HMP informing the physicians that it would terminate the draw fee payment program as of January 31, 2012. On January 10, 2012, Quest representative Marc Biemiller met with the HMP physicians to discuss the program's end. Mr. Biemiller explained to the practice that the legal department at Quest insisted that the draw fee policy change because the Government was "starting to crack down." Biemiller reported that the "drawing fee payments" were to cease after January 31, 2012 for all providers, with the exception of hospitals which Berkeley continued to pay $25 per patient referral. Upon information and belief, despite acknowledging the illegality of the excessive blood drawing fees, Quest made no plans to disclose to CMS the countless unlawful payments that Berkeley and Quest had previously made and never volunteered such information to CMS.

28. Although Biemiller acknowledged that the termination of the draw fees stemmed from Quest's concerns about the legality of the program, Quest did not cease the payments immediately. Instead, it continued to pay physicians for referrals through the end of January 2012. Payment records confirm that Quest knew of, and ultimately directly participated in the kickback payments: the final two payments, dated February 15, 2012 and March 19, 2012, were identified as "BHL – BLOOD DRAWS," but issued by Quest. Moreover, as explained in greater detail below, shortly after the announcement in December 2011 that Quest planned to terminate Berkeley's excessive draw fee payments, Quest suggested several methods through which it could pay the physicians kickbacks in less obvious forms in order to make up for the loss of the draw fee income.

29. On facts alleged and on information and belief, Quest and Berkeley worked together to pay physicians inflated draw fees, which they knew to be illegal forms of remuneration.

30. Additionally, when explaining how Berkley draw fee payments to physicians were being eliminated under Quest's ownership of the company, Biemiller noted the existence of

$25 draws that Berkley had been paying hospitals and the fact that such payments would continue.

C. Quest and Berkeley Offered Providers Additional Remuneration to Induce Patient Referrals After Berkeley's Draw Fee Payments to Physicians Were Terminated

31. As explained above, Quest terminated Berkeley's draw fee program January 31, 2012, ending the $11.50 per patient referral payments to providers. Although the termination of the draw fee kickbacks should have marked a step in the right direction, Quest and Berkeley developed a plan to replace the draw fees with several new forms of illegal remuneration. As Biemiller told the HMP physicians on January 10, 2012, Quest recognized that the "drawing fees" incentivized provider referrals to Berkeley and that the termination of those payments would adversely affect the number of Berkeley tests that physicians ordered. Thus, Quest developed ways to try to "get around" the draw fee restrictions (*i.e.*, continue providing kickbacks to physicians). Biemiller explained openly and directly that Quest offered these new forms of remuneration for the purpose of providing alternate compensation to those physicians who would be losing the Berkeley draw fee revenue. On the basis of these facts, and on information and belief, Quest and Berkeley have offered and provided these kickbacks to providers nationwide.

32. Principally, Quest offered to begin paying the full salary of Heritage Medical Partners' phlebotomist, Robin Spikes. Under the terms of the offer made to and ultimately accepted by HMP, Quest took over payment of the entirety of the phlebotomist's salary and expenses. As of July 13, 2012, Ms. Spikes was officially employed by Quest. Under the new arrangement, Ms. Spikes technically worked out of Quest's building, however, the building was located directly across the parking lot from HMP's offices, and Quest actually leased the space from HMP. Furthermore, in exchange for the physicians' promise to continue referring patients to Berkeley for testing, Quest promised HMP that Ms. Spikes would perform the blood draws for all the lab tests HMP ordered, even the basic test panels that HMP performed in their offices.

33. Under such an arrangement the only change for the medical practice is the source of financing for the phlebotomist. Thus, the salary payments essentially function as monetary gifts from Quest, or as kickbacks to the practice.

34. Under certain circumstances, providers may be given the use of a laboratory paid phlebotomist without implicating the Anti-Kickback Statute; however, such a provider-laboratory arrangement must abide by certain guidelines. As explained in an OIG Special Fraud Alert, "[w]hile the mere placement of a laboratory employee in the physician's office would not necessarily serve as an inducement prohibited by the anti-kickback statute, the statute is implicated when the phlebotomist performs additional tasks that are normally the responsibility of the physician's staff" because 'a strong inference arises that he or she is providing a benefit in return for the physician's referral to the laboratory.'" Dep't of Health and Human Services, Office of Inspector Gen., Special Fraud Alert, 59 Fed. Reg. 65,372, 65,377 (Dec. 19, 1994). OIG has since cited this Special Fraud Alert analysis as an extension of the broader principle that "[i]f the intent of providing free goods or services is to induce or reward referrals of Federal health care program business, the anti-kickback statute would be violated." Dep't of Health and Human Services, Office of Inspector Gen., Advisory Opinion No. 98-16 (Nov. 3, 1998), *available at* http://oig.hhs.gov/fraud/docs/advisoryopinions/ 1998/ao98_16.htm.

35. Quest's offer to begin paying the salary of a practice's phlebotomist is not consistent with the permissible laboratory-provider arrangement explained by the OIG. The fact that Quest took over the salary payments of the physician group's existing employee, rather than merely offering the services of a Quest employee, raises red flags. More significant, however, is the fact that Quest explicitly offered this benefit to physicians in order to induce continued referrals. This alone renders Quest's salary payment offer a direct violation of the Anti-Kickback Statute.

36. Quest also offered to make up lost draw fee revenue in other ways, including leasing more than 200 square feet of office space from HMP. Quest told the physicians that it would use this space for Berkeley's 4myheart program. No specific rental price was offered, but

even if Quest were to have leased the space at a price reflecting fair market value, this arrangement would still have violated the Anti-Kickback Statute as the lease and consequent rental payments were offered for the purpose of providing revenue to physicians who would have been expected to reciprocate with lab referrals to Berkeley.

37. Additionally, Quest offered to seamlessly integrate HMP's electronic medical records system with Quest's system, allowing the physicians immediate access to their patient's lab results. Biemiller explained that this would be a "valuable benefit" to HMP, offered by Quest at no cost. The Anti-Kickback Statute contains a safe harbor protecting the provision of "software or information technology…used predominantly to create, maintain, transmit, or receive electronic health records." 42 C.F.R. § 1001.952(y). However, the safe harbor protection does not apply if the "eligibility of the recipient…is determined in a manner that directly takes into account the volume or value of referrals or other business generated between the parties." *Id.* at § 1001.952(y)(5). Additionally, the software integration that Quest offered would likely not meet the safe harbor's requirement that the technology "contain[] electronic prescribing capability." *Id.* at § 1001.952(y)(10).

38. Quest further offered to make up for the loss of the draw fee remuneration paid for referrals of government-insured patients by paying the physicians hugely inflated draw fees for their commercial insurance patients. Certain private insurers are willing to pay exorbitant fees for certain blood draw collections and Quest has offered to pass those high draw fee payments on to the physicians. For example, according to Biemiller, Blue Cross Blue Shield reimburses $560 for each Plavix Test, of which almost $200 is designated as the draw fee. Even more egregiously, when Relator asked how they could be paid draw fees if Quest were paying the salary of HMP's phlebotomist, Biemiller assured him that it would not be a problem, and Quest would "pass through" the nearly $200 fee each time an HMP physician ordered a Plavix Test for a commercial insurance patient.

39. Quest's payment of phlebotomists' salaries, leasing of office space, integration of electronic medical records systems and payment of exorbitantly high drawing fees for

commercial patients all constitute illegal inducements in violation of the Anti-Kickback Statute. Quest agreed with Berkeley to provide these kickbacks, and submit or cause the submission of the resulting claims to government health care programs in violation of the FCA.

D. Quest Stripped Berkeley of Valuable Assets at Less Than Fair Market Value while on Notice of Berkeley's Probable Liability for Violations of the Anti-Kickback Statute and the False Claims Act

40. As described above, prior to its acquisition by Quest, Berkeley offered 35 separate blood tests largely focusing on cardiovascular health. It was Berkeley's ownership and expertise relating to these valuable tests that drove Celera to acquire Berkeley in or about 2007 for approximately $195 million. Several of these tests made Celera a potentially valuable acquisition target, and in fact Quest specifically mentioned Berkeley's test offerings as an important strategic asset in its $344 million acquisition of Celera in May 2011.

41. Berkeley continued to provide lab tests at its facility through 2013. Although the number of tests it processed was dramatically reduced as a result of BlueWave, HDL, and Singulex siphoning physician referrals through far greater draw fee payments, Berkeley nevertheless continued to generate significant revenues. Quest, as Berkeley's parent company, was largely the beneficiary of these revenues. Furthermore, despite Quest's knowledge that Berkeley had engaged in illegal draw fee payments, and despite Quest's knowledge of potential liability to the government for these actions (as expressed when Marc Biemiller noted to HMP that Quest's legal department insisted that the draw fee policy change because the Government was "starting to crack down"), and despite Quest's own involvement in some of those payments, Quest nevertheless failed to maintain adequate cash reserves within Berkeley to satisfy a potential judgment against Berkeley.

42. Relator therefore also believes and alleges that, through minimum appropriate pre-purchase due diligence, Quest knew about or through reckless disregard and/or willful blindness failed to discover Berkeley's use of unlawful kickback payments to physicians as a principal component of Berkeley's marketing strategy. Quest nevertheless agreed with Celera

and Berkeley to go forward with the purchase without insisting that such misconduct be stopped and/or that it be disclosed to the United States and remedied.

43. Upon information and belief, including Relator's personal interactions with Quest representatives as described below, after Berkeley ceased operations in 2013 Quest stripped Berkeley of the intellectual and physical property relating to at least 15 valuable lab tests and one lab panel. This stripping has left Berkeley undercapitalized, and therefore Relator alleges that Quest did not provide fair market value in return for the property it received from Berkeley.

44. In May 2015 Relator received a packet of information from Solstas Labs, a subsidiary of Quest Diagnostics acquired in early 2014. In that packet, Solstas provided Relator with information regarding several tests formerly provided by Berkeley and now provided through Solstas and Quest, including the KIF6 gene test, the LPA-Aspirin works gene test, the 9p21 gene test, the ApoE gene test, and the Lp-PLA2 gene test. Review of Quest's website at the time of this filing shows that Quest currently advertises the 15 lab tests listed above at paragraph 22, all of which formerly belonged to Berkeley. To Relator's understanding and belief based on his experience with Quest and its sales representatives, none of these tests were offered by Quest prior to its acquisition of Berkeley, nor were they offered by Solstas prior to its acquisition by Quest in early 2014. Upon information and belief, Quest siphoned these assets from Berkeley with full knowledge of Berkeley's potential liability to the government, but Quest did not pay fair market value for these tests.

45. Similarly, in September 2015, Quest Representative Damien Heffernan visited Relator's offices to discuss Quest's lab offerings. Mr. Heffernan has been a Quest representative for approximately six years. Approximately two and a half years ago, Mr. Heffernan began promoting Berkeley's products on behalf of Quest. Mr. Heffernan noted in a sales pitch to Relator on September 9, 2015 that "I sell the Berkeley offering, which we've [*i.e.*, Quest] now re-branded as CardioIQ." Mr. Heffernan further noted that his visit was to educate Relator "that the offering was still available through Quest, the Berkeley offering." When Relator asked whether all the previous Berkeley labs were still available through Quest, Mr. Heffernan

responded: “Essentially yes, except SLOCO1B1 Gene, which is exclusive to Boston Heart Lab. The marketing version [now employed by Quest] is more of a scaled down of what Berkeley used to do.” When Relator further inquired whether Quest still offers the Berkeley KIF6, ApoE Genotype test, Mr. Heffernan said that they do. Mr. Heffernan then guided Relator through the Quest reimbursement sheet, noting the former Berkeley tests and stating, “right here are all the genetic tests that you’re talking about as well.” When Relator asked whether Quest still offers the Berkeley LP-PLA 2 test, Mr. Heffernan replied, “That’s a good test,” and further noted that Quest continued to offer Berkeley’s Omega 3, insulin, and vitamin D testing options.

46. When Relator again asked whether Quest continued to offer the Berkeley tests, Mr. Heffernan replied, “Yeah. The only difference with what you see here is the methodology for which their doing lipid fractionation has changed.” The lipofraction test essentially separates the cholesterol particles by charge and size, with each unique particle consisting of a cholesterol sub-class. Mr. Heffernan noted that Quest was usually only generating three sub-classes of cholesterol results, unlike Berkeley which previously offered significantly more sub-classes. However, Mr. Heffernan noted that “There were some old guys, old Berkeley guys, like [Relator] probably who maybe liked a bunch of that data. We [*i.e.*, Quest] could still make that happen for you if it’s something that you want to, and when I say that I mean resulting all the HDL and LDL analysis.” Relator confirmed, “So you can still do the Berkeley [tests],” to which Mr. Heffernan replied, “Still be done.”

47. Ultimately, Mr. Heffernan stressed the continuation not only of Berkeley’s tests, but the manner in which Quest conducted those tests. Mr. Heffernan noted, “I don’t think much has changed from the Berkeley days.” When Relator asked why Quest engaged in the rebranding rather than just keeping the Berkeley name, Mr. Heffernan replied “I’ll tell you what. I thought the same thing…. I think, my personal take is, is that Quest tries to sell the complete package of Quest. It molds this in as one thing, as opposed to a Boston Heart or Atherotech or an HDL where this is all they do.” Relator reiterated his understanding that Quest nevertheless kept the Berkeley labs, to which Mr. Heffernan replied, “Yeah.”

Count I
False Claims Act
31 U.S.C. §§ 3729(a)(1)(A)

48. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 47 above as though fully set forth herein.

49. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

50. By virtue of the acts described above, Defendant Quest knowingly presented or caused to be presented false or fraudulent claims to the United States Government for payment or approval.

51. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Defendant Quest, paid and continues to pay the claims that would not be paid but for Defendant's illegal conduct.

52. By reason of Defendant's acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

53. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein.

Count II
False Claims Act Conspiracy (Quest)
31 U.S.C. § 3729(a)(1)(c)

54. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 47 above as though fully set forth herein.

55. This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, *et seq.*, as amended.

56. By virtue of the acts described above, defendant Quest Diagnostics Incorporated knowingly entered into a conspiracy with defendant Berkeley HeartLab, Inc. to present or cause to be presented false or fraudulent claims to the United States Government for payment or

approval and, thereafter, to seek to evade financial responsibility by Berkeley or Quest for Berkeley's role in such misconduct by stripping Berkeley of assets and transferring the value of such assets to other Quest-related entities without fair consideration to Berkeley or proper regard to the known liabilities Berkeley faced for its misconduct to the United States and potential FCA whistleblowers.

57. The Government, unaware of the falsity of the records, statements and claims made or caused to be made by Quest's conspiracy with Berkeley, paid and continues to pay the claims that would not be paid but for those Defendants' illegal conduct.

58. By reason of those Defendants' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

59. Additionally, the United States is entitled to the maximum penalty of up to $11,000 for each and every violation alleged herein.

VIII. PRAYER

WHEREFORE, *qui tam* Relator Dr. Mayes prays for judgment, jointly and severally, against Defendants Quest and Berkeley as follows:

60. That Defendants cease and desist from violating 31 U.S.C. § 3729 *et seq.*;

61. That this Court enter judgment against Defendants in an amount equal to three times the amount of damages the United States has sustained because of Defendants' actions, plus a civil penalty of not less than $5,500 and not more than $11,000 for each violation of 31 U.S.C. § 3729;

62. That Dr. Mayes be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act;

63. That Dr. Mayes be awarded all costs of this action, including attorneys' fees and expenses; and

64. That Dr. Mayes recover such other relief as the Court deems just and proper.

IX. DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, *qui tam* Relator Dr. Mayes hereby demands a trial by jury.

Respectfully submitted,

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