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FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

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SEALED

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA

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U.S. DISTRICT COURT
SOUTHERN DISTRICT OF CALIFORNIA

UNITED STATES OF AMERICA and
THE STATE OF CALIFORNIA *ex rel.*
Stephanie La Fleur and Corinne Vause, and
STEPHANIE LA FLEUR and CORINNE VAUSE,
individually,

Plaintiffs,

v.

GENOMEDX BIOSCIENCES CORP.,

Defendant.

RMC

DEPUTY

DOCKET NO.

FILED UNDER SEAL
PURSUANT TO
31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

17 CV 1959 L WVG

COMPLAINT AND DEMAND FOR JURY TRIAL

Plaintiffs and *qui tam* Relators Stephanie La Fleur and Corinne Vause, by and through their undersigned counsel JTB Law Group, LLC and Law Office of Mann & Elias, allege of personal knowledge as to their observations and actions, and on information and belief as to all else, as follows:

I.

PRELIMINARY STATEMENT

1. Relators Stephanie La Fleur and Corinne Vause ("Relators") bring a *qui tam* action on behalf of the United States of America (the "United States") under the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (the "FCA"), the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) (the "AKS"), and the common law to recover treble the damages actually sustained by, and civil penalties and restitution owed to, the United States as a result of a scheme by Defendant to commit fraud.

2. Relators also bring a *qui tam* action on behalf of the State of California ("California") under the California Insurance Frauds Prevention Act, Cal. Ins. Code §§ 1871 *et*

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seq. (the “CIFPA”) and the common law to recover treble the damages actually sustained by, and civil penalties and restitution owed to, California and other insurers as a result of a scheme by Defendant to commit fraud.

3. Defendant GenomeDx Biosciences Corp. (“GenomeDX”) is a biotechnology company that provides genomic testing for the purpose of assessing patients’ risk for diseases.

4. Defendant has submitted claims to and received payments from Medicare and other insurers for performing its genomic tests.

5. A substantial amount of these payments were obtained through fraudulent means because Defendant submitted claims for tests that were:

- a. conducted without meeting the requirements necessary for health insurance coverage;
- b. not medically necessary; and/or
- c. induced by offers of remuneration in violation of the AKS.

6. In carrying out this fraud, Defendant knowingly (a) presented or caused to be presented false claims to obtain payments; (b) made or caused to be made or used false records or statements material to these false claims; (c) conspired to cause these claims to be presented and/or these records or statements to be made or used; and (d) made, used, or caused to be made or used, a false record or statement material to an obligation to pay or transmit money or property, or knowingly concealed or knowingly and improperly avoided or decreased an obligation to pay or transmit money or property.

7. This Complaint has been filed *in camera* and under seal pursuant to 31 U.S.C. § 3730(b)(2). It will not be served on Defendant unless and until the Court so orders. A copy of the Complaint, along with written disclosure of substantially all material evidence and information that Relators possesses, has been served upon the Attorney General of the United

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States and on the United States Attorney for the Southern District of California pursuant to 31 U.S.C. § 3730(b)(2) and Fed. R. Civ. P. 4(d), and on the San Diego County District Attorney and the California Insurance Commissioner pursuant to Cal. Ins. Code § 1871.7(e)(2).

**II.
JURISDICTION AND VENUE**

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331, because this action is brought for violations of the False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (as amended), a federal statute.

9. The Court has subject matter jurisdiction over the CIFPA claims pursuant to 31 U.S.C. § 3732(b).

10. The Court has subject matter jurisdiction over the common law claim pursuant to 28 U.S.C. § 1345.

11. The Court has personal jurisdiction over Defendant because Defendant (a) is a resident of, and is licensed to transact and does transact business in, this District; and (b) has carried out its fraudulent scheme in this District.

12. Venue is proper in this District pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391 (b)(2), because Defendant can be found in, is licensed to do business in, and transacts or has transacted business in this District, and the events and omissions that give rise to these claims have occurred in this District.

13. The Complaint has been filed within the period prescribed by 31 U.S.C. §§ 3731(b) and 3730(h)(3), and Cal. Ins. Code 1871.7(l).

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**III.
NO PUBLIC DISCLOSURE;
DIRECT AND INDEPENDENT KNOWLEDGE
OF VIOLATIONS OF THE FALSE CLAIMS ACT**

14. There has been no public disclosure, relevant under 31 U.S.C. § 3730(e), or Cal. Ins. Code § 1871.7(h)(2)(A), or of the “allegations or transactions” in this Complaint.

15. Relators make the allegations in this Complaint based on their own knowledge, experience and observations.

16. Relators are the original source of the information on which the allegations herein are based, have direct and independent knowledge of such information, and have voluntarily disclosed such information to the United States and the State of California before filing this action.

**IV.
THE PARTIES**

A. Plaintiff the United States

17. Plaintiff the United States of America brings this action by and through Relators Stephanie La Fleur and Corinne Vause. At all times relevant to this Complaint, the United States, acting through the Centers for Medicare & Medicaid Services (“CMS”), has reimbursed Defendant for the provision of various medical services and treatments for eligible individuals through the Medicare program. Thus, the United States brings this action on behalf of its agencies, CMS and HHS, and on behalf of the Medicare program.

B. Plaintiff the State of California

18. The California Insurance Fraud Prevention Act (the “CIFPA”) allows any interested person to bring a civil lawsuit for violations of Cal. Pen. Code § 550 on behalf of that person and the State of California. Accordingly, Plaintiffs and Relators La Fleur and Vause

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allege that Defendant has violated Cal. Pen. Code § 550 and bring this action on behalf of the State of California.

C. Plaintiffs and Relators La Fleur and Vause

19. Relators La Fleur and Vause also bring this action on behalf of themselves, the United States, and the State of California.

20. La Fleur and Vause are citizens of the United States, and at all relevant times have been residents of San Diego County, California.

21. La Fleur has been employed in Defendant's member and regulatory appeals department since December 2015. Starting approximately April 2017, her job duties expanded to include provider appeals and prior authorizations. She is currently a supervisor of regulatory clinical appeals.

22. Vause has been employed by Defendant as a billing manager since December 2016.

E. Defendant

23. Defendant GenomeDx Biosciences Corp. is a corporation organized and existing under the laws of the State of Delaware.

24. The address of Defendant's principal office in the State of California is 10355 Science Center Drive, Suite 240, San Diego, CA 92121.

25. The address of Defendant's headquarters is 201-1595 West 3rd Avenue, Vancouver, BC Canada V6J1J8.

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**V.
DEFENDANT'S FRAUDULENT ACTS**

A. Defendant's Decipher Test

26. Defendant's flagship service is the Decipher post-operation genomic test (herein, "Decipher Post-op") also referred to as "Decipher GC" and "Decipher assay," which measures the activity of genes in prostate tumors to assess the risk of cancer recurrence.

27. Defendant conducts this test on tissue samples obtained during radical prostatectomies ("RPs").¹

28. The Medicare Administrative Contractor ("MAC") for Jurisdiction E, Noridian Healthcare Solutions, LLC,² has granted the Decipher Post-op limited Medicare coverage pursuant to 42 U.S.C. 1395ff(f)(2)(B).³

29. Noridian granted coverage under Local Coverage Determination ("LCD") ID L36343, titled "MoIDX-CDD: Decipher® Prostate Cancer Classifier Assay," attached hereto as **Exhibit A**.

30. The Decipher Post-op is the only test Defendant conducts which is covered by Medicare.

B. Defendant Obtained Payments for Decipher Post-op Tests That Did Not Meet Coverage Requirements

31. Under the LCD, Noridian will pay for the Decipher Post-op test only when certain conditions are met, including the requirement that the "Patient must have achieved initial PSA [prostate-specific antigen] nadir (defined as undetectable PSA) within 30 days of RP [radical

¹ A radical prostatectomy is the surgical removal of the prostate gland and surrounding tissue.

² A MAC is a private health care insurer awarded a geographic jurisdiction to process medical claims for Medicare beneficiaries. MAC jurisdictions can be found at <https://www.cms.gov/Medicare/Medicare-Contracting/Medicare-Administrative-Contractors/Downloads/AB-MAC-Jurisdiction-Map-Dec-2015.pdf>.

³ Defining a local coverage determination as "a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered."

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prostatectomy] surgery.” **Exhibit A**, at 4. In other words, Medicare will only pay for the test when it is conducted on a patient whose prostate-specific antigens have dropped to undetectable levels within 30 days of his surgery.

32. Despite this requirement, Defendant routinely conducted and billed Medicare and other insurers for Decipher Post-ops without evidence that the patient had met this condition.

33. Many of these patients failed to actually achieve PSA nadir. *See Exhibit B* (emails discussing billing, dated Aug. 28, 2017).

34. Furthermore, the LCD also requires that the Decipher Post-op be performed “on a patient’s RP specimen.” **Exhibit A**, at 4. In other words, Medicare will pay only for tests performed on tissue samples obtained from radical prostatectomies.

35. Disregarding this requirement, Defendant has routinely billed Medicare and other insurers for tests conducted on pre-surgical biopsy samples.

36. Defendant refers to the test as the “Decipher Biopsy” when conducted on pre-surgical biopsy tissue samples. *See Exhibit C* (Decipher brochure).

37. Defendant has sought but not yet obtained a Local Coverage Determination for the Decipher Biopsy. As of the filing of this Complaint, the Decipher Biopsy is not covered by Medicare.

38. Nevertheless, Defendant has knowingly and intentionally submitted claims to Medicare and other insurers for Decipher Biopsies.

39. In making these claims, Defendant took steps to mislead Medicare and other insurers into believing that the Decipher Biopsies were actually Decipher Post-ops that were covered by Medicare.

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40. Defendant submits claims for *both* the Decipher Post-op and the Decipher Biopsy under Current Procedural Terminology (“CPT”)⁴ code 81479, which is used to identify “Unlisted molecular pathology procedure[s].” See **Exhibit A**, at 5. Thus, the MAC and other insurers are not able to tell from the coding which claims should be paid and which should not.

41. To further disguise its fraud, Defendant supports its Decipher Biopsy claims (and its appeals of denials of claims) with documentation that the claims are for the Decipher Post-op. Relator La Fleur observed and reported to Defendant’s director the submission of these misleading documents, stating:

I also noticed that all the documents such as the LCD, Medicare Fee Schedule and the NCCN [National Comprehensive Cancer Network] guidelines that go out for the RP test where [*sic*] being sent for the biopsy test. I realized Brittany was sending these with the appeals long ago and Vicki and I told you that Brittany was doing this. The Humana that I looked into are requesting refunds as well for these.

Exhibit B, at 1; *see also* **Exhibit D** (NCCN guidelines discussing the Decipher Post-op).

42. For instance, to appeal a denial of a claim for a Decipher Biopsy, Defendant’s billing department submitted a letter that:

- a. refers to the test as the Decipher Prostate Cancer Classifier Assay, which is the LCD name for the Decipher Post-op, and not the Decipher Biopsy;
- b. states the test is based on a “post-surgical, pathologic specimen of the prostate gland,” even though the test was conducted on a pre-surgical biopsy tissue sample;
- c. references the attached NCCN guidelines,⁵ which discuss only the merits of the Decipher Post-op; and

⁴ To obtain payment from Medicare and Medicaid, providers use Healthcare Common Procedure Coding System (“HCPCS”) codes to represent the medical procedures claimed for payment. Level I HCPCS codes are identical to CPT codes. All medical procedure codes referenced in this Complaint are Level I HCPCS codes, and are thus interchangeable with CPT codes. See American Medical Association CPT®/Medicare Payment Search, *available at* <https://apps.ama-assn.org/CptSearch/> (requires an account); *see also* 2017 Medicare CPT/HCPCS Codes, *available at* <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Risk-Adjustors-Items/CPT-HCPCS.html> (last accessed Sept. 18, 2017).

⁵ See **Exhibit D**.

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- d. falsely states that the test in question is covered under LCD L36343, which provides coverage for only the Decipher Post-op.

Exhibit E (Defendant's appeal letter, dated Mar. 14, 2017).

43. Defendant has thereby fraudulently obtained payment from Medicare Advantage and commercial insurance plans to which it is not entitled.

44. On information and belief, insurers including Humana Inc. and UnitedHealth Group Inc. have discovered instances of the above fraud and sought repayment from Defendant.

45. For instance, Humana has sent a request for repayment to Defendant, stating:

According to the information provided, this is a biopsy specimen rather than RP specimen without staging or evidence of post surgical PSA nadir, all of which are required criteria for testing. Criteria for Decipher assay has not been met and will not be covered.

Exhibit F (overpayment letter from Humana, dated Apr. 10, 2017).

46. On information and belief, insurers have requested over \$1 million in repayment from Defendant for its fraudulent Decipher Biopsy claims.

C. Defendant Obtained Payment for Tests by Falsely Certifying Medical Necessity

47. The Social Security Act (the "SSA") provides: "no payment may be made under Part A or Part B [of Medicare] for any expenses incurred for items or services which ... are not reasonable and necessary...." 42 U.S.C. 1395y(a)(1)(A).

48. The SSA defines "certificate of medical necessity" as "a form or other document containing information required by the carrier to be submitted to show that an item is reasonable and necessary...." 42 U.S.C. 1395m(j)(2)(B).

2. Defendant has submitted claims for payment to Medicare Advantage and privately administered insurance plans for numerous Decipher Post-op tests based on fraudulent certificates of medical necessity.

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49. To perpetrate its fraud, Defendant instructed physicians to pre-sign blank certificates of medical necessity. Defendant would then fill in the patient's name and date of birth, and a date for the physician's signature, as needed. Defendant used these "templates" to create fraudulent certificates of medical necessity for its claims, without the physician actually signing off on the particular test underlying the claim.

50. Defendant's director Dani Fletes referred to such a fraudulent certificate in an email, stating: "Yay, another perfect example of what we want. Please enter the name, DOB and date and send." In response, Defendant's reimbursement specialist Amber Feroz stated: "And it does say : [*sic*] date signed- so the physician could have signed it weeks ago but now I am adding in todays [*sic*] date". See **Exhibit G** (emails discussing "letter of medical necessity," dated Aug. 30, 2017).⁶

51. Furthermore, Defendant has ordered and conducted tests for which there no were physicians' orders or certificates of medical necessity at all.

52. Defendant has perpetrated this fraud on a massive scale, and has received many millions of dollars in undeserved payments from both Medicare and private insurers.

53. In many cases, Defendant conducted tests on patients who:

- a. had not received prostate-related treatment in multiple years;
- b. were not suffering from prostate-related ailments at the time of testing;
and/or
- c. were unaware that tests have been ordered and conducted on their tissue samples.

⁶ Defendant refers to a certificate of medical necessity as a "letter of medical necessity" or "LMN."

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54. In addition to billing Medicare and other insurers for these unnecessary tests, Defendant bills patients for co-pays. As a result, Defendant continuously received complaints from bewildered patients who had received invoices for tests to which they did not consent.

D. Defendant Violated Medicare Advantage Waiver of Liability Guidelines

55. On multiple occasions, Defendant's claims for payments have been rejected by insurers, including Medicare and Medicare Advantage health plans.

56. A provider "is permitted to file a standard appeal for a denied claim only if the non-contract provider completes a waiver of liability statement, which provides that the non-contractor provider will not bill the enrollee regardless of the outcome of the appeal." Medicare Managed Care Manual, Chapter 13, § 60.1.1.⁷

57. Accordingly, prior to appealing its denied claims, Defendant completes waivers relinquishing its right to collect from the enrolled patients in the event the appeal is denied.

58. However, Defendant regularly reneged on these waivers. After its appeals were denied, Defendant would submit invoices to patients.

59. When the patient did not have knowledge that the services were not covered by the plan, "but the provider, practitioner, or supplier knew, or could have been expected to know, of the exclusion of the items or services, **the liability for the charges for the denied items or services rests with the provider, practitioner or supplier.**" Medicare Claims Processing Manual, Chapter 30, § 20 (emphasis added).⁸

60. Defendant knew that its tests are excluded from coverage, having received multiple denials.

⁷ Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/mc86c13.pdf> (last accessed Sept. 21, 2017).

⁸ Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c30.pdf> (last accessed Sept. 21, 2017).

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61. In contrast, many patients were not even aware that a test had been conducted on their tissues.

62. Defendant thus has no legal basis for billing patients for its denied claims. Nevertheless, Defendant has sought payment from patients whose tissue samples were tested without their consent.

E. Defendant Failed to Provide Required Notices of Non-coverage

63. As alleged above, Defendant knowingly conducted tests which were not compliant with coverage requirements. As a result, on multiple occasions, Defendant's claims were denied by Medicare and other insurers.

64. Nevertheless, Defendant continued to perform tests that did not meet coverage requirements on Medicare beneficiaries without providing such beneficiaries an Advance Beneficiary Notice of Noncoverage ("ABN"), Form CMS-R-131, attached hereto as **Exhibit H**.

65. Medicare guidelines state that a provider must issue an ABN to the patient "[p]rior to providing an item or service that is usually paid for by Medicare under Part B . . . but may not be paid for in this particular case because it is not considered medically reasonable and necessary." Medicare Claims Processing Manual, Chapter 30 § 50.1.⁹

66. Defendant knew that Medicare would not pay for Decipher Post-ops that did not meet coverage requirements because Medicare had already denied claims for such tests.

67. Defendant knew that Medicare would not pay for Decipher Biopsies disguised by Defendant as Decipher Post-ops, because Medicare had already denied claims for such tests.

68. In order to protect its profitability, Defendant made the deliberate decision not to issue ABNs prior to performing tests that it knew would not be covered.

⁹ Available at <https://www.cms.gov/Medicare/Medicare-General-Information/BNF/Downloads/ABN-CMS-Manual-Instructions.pdf> (last accessed Sept. 21, 2017).

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69. Defendant's Director of Billing Brittany Rambino stated in an email that "If we were to treat these patients as Medicare we would need a signed ABN because the service does not fall within a LCD these are non-covered and the patient [*sic*] responsibility." **Exhibit I** (emails discussing ABNs, dated Aug. 11, 2016).

70. In response, Defendant's Genomic Specialist Shihab Huq stated: "The signing of ABN's [*sic*] will kill Decipher biopsy. Neither Prolaris or Oncotype [competing brands of genomic testing] ever required patients to sign one." **Exhibit I**.

71. As a result of this and other discussions, Defendant chose not to issue ABNs as required by CMS.

**VI.
DEFENDANT VIOLATED THE ANTI-KICKBACK STATUTE
IN INDUCING ORDERS FOR ITS SERVICES**

72. To induce physicians and patients to order its tests, Defendant routinely offered to reduce or waive the coinsurance or deductible amount owed by the patients.

73. The Anti-Kickback Statement (the "AKS") provides:

Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly . . . to any person to induce such person to purchase . . . or recommend purchasing . . . 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....

42 U.S.C. § 1320a-7b(b)(2)(B).

74. In general, a discount is not a prohibited form of remuneration. However the following are specifically excluded from the discount safe harbor:

"A reduction in price applicable to one payer but not to Medicare, Medicaid, or other Federal health care programs" 42 C.F.R. 1001.952(h)(5)(iii);

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“A routine reduction or waiver of any coinsurance or deductible amount owed by a program beneficiary” 42 C.F.R. 1001.952(h)(5)(iv).

75. “Medicare payment is based on the lesser of the actual charge or the applicable fee schedule amount.” 42 C.F.R. § 414.21.

76. Defendant did not notify Medicare of its routine practice of reducing or waiving patient coinsurance or deductible amounts, and continued to bill Medicare at the full rate for its tests.

77. As a result of this practice, Defendant illegally induced physicians and patients to order tests that they would not have otherwise ordered. Defendant sought to pass the costs of these excessive tests on to Medicare, and in many cases succeeded.

78. Even more outrageously, after successfully obtaining test orders, Defendant would renege on its offered discount and bill patients for the full amount of their coinsurance or deductible payments.

79. Furthermore, on information and belief, Defendant has offered and paid cash or cash equivalents to pathology laboratories and physicians to induce orders for its tests.

80. On at least one occasion, Defendant conducted a test without a physician’s order or patient consent, and instead obtained the tissue sample directly from a pathology laboratory which stored patient tissues.

81. On information and belief, Defendant has entered into arrangements with pathology laboratories in which such laboratories will provide Defendant with tissue samples in exchange for payment from Defendant.

82. On information and belief, Defendant has entered into similar arrangements with physicians, in which physicians would order tests in exchange for payment from Defendant.

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83. On multiple occasions, Defendant obtained orders from physicians belonging to independent practice associations (“IPAs”), and who are compensated on a capitation basis.¹⁰ Because these physicians provide their services at personal financial risk, they typically do not order expensive tests such as those offered by Defendant without financial incentives.

84. On one occasion, Relators observed that Defendant had sent a check in the amount of \$10,000.00 to a urology clinic whose physicians had ordered tests from Defendant.

**VII.
THE LEGAL FRAMEWORK**

A. The False Claims Act

85. The False Claims Act, 31 U.S.C. §§ 3729 *et seq.*, (the “FCA”), reflects Congress’s objective to “enhance the Government’s ability to recover losses as a result of fraud against the Government.” S. Rep. No. 99-345, at 1 (1986). As relevant here, the FCA establishes treble damages liability for an individual or entity that:

(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 claim;

(C) conspires to commit a violation of subparagraph (A) [or] (B)... [or]

* * *

(G) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government

31 U.S.C. § 3729(a)(1).

¹⁰ In a capitated plan, a physician is paid a fixed amount of money per patient in advance. This sum, or capitation rate, is determined using factors such as local costs and average utilization of services and the risk factor of the patient. A portion of capitation payments is initially withheld in collective “risk pools,” which are used to cover medical expenses. Any budget surpluses from the risk pool are distributed to physicians, who are thus incentivized to keep costs low.

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55. The FCA defines a “claim” to include, in pertinent part:

(A) ... any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that –

(i) is presented to an officer, employee, or agent of the United States; or

(ii) is made to a *contractor, grantee, or other recipient*, if the money or property is to be spent or used on the Government’s behalf or to advance a Government program or interest, and if the United States Government –

(I) provides or has provided *any portion* of the money or property requested or demanded; or

(II) *will reimburse such contractor, grantee, or other recipient for any portion of the money or property* which is requested or demanded ...

Id § 3729(b)(2) (emphasis added).

56. “Knowing,” within the meaning of the FCA, is defined to include reckless disregard and deliberate indifference. *Id* § 3729(b)(1).

57. An “obligation” within the meaning of the FCA includes “[a]ny overpayment retained by a person after the deadline for reporting and returning the overpayment specified in” 42 C.F.R. § 401.305(b).

58. In addition to treble damages, the FCA also provides for assessment of a civil penalty for each violation or each false claim.¹¹

59. The FCA provides for payment of a percentage of the United States’ recovery to a private individual who brings suit on behalf of the United States (the “Relator”) under the FCA. *See* 31 U.S.C. § 3730(d).

¹¹ 31 U.S.C. § 3729(a)(1)(G) provides 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 (28 U.S.C. 2461 note; Public Law 104-410). The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, 28 U.S.C. 2461 note, substituted a different statutory formula for calculating inflation adjustments on an annual basis. On February 3, 2017, the Department of Justice promulgated a Final Rule increasing the penalty for FCA violations occurring after November 2, 2015. For such penalties assessed after February 3, 2017, the minimum penalty is \$10,957 and the maximum is \$21,916. *See* 28 C.F.R. § 85.5; 82 F.R. 9131 (February 3, 2017).

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B. The Medicare Program

Program Overview; Provider Enrollment

60. In 1965, Congress enacted Title XVIII of the Social Security Act, known as the Medicare program, to pay for certain healthcare services provided to certain segments of the population. Entitlement to Medicare is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 1395 *et seq.*

61. HHS, through CMS, administers the Medicare program.

62. Part B of the Medicare program authorizes payment of federal funds for outpatient health services, including diagnostics tests. *See generally* Medicare Benefit Policy Manual *at* Chapter 15.¹²

63. CMS enters into agreements with healthcare providers such as Defendant to establish their eligibility to participate in the Medicare program. Individuals or entities who are participating providers in Medicare, such as Defendant, may seek reimbursement from CMS for services rendered to patients who are program beneficiaries.

64. During all times relevant herein, to become an authorized participant in Medicare Part B, a provider has been required to certify as follows:

I agree to abide by the Medicare laws, regulations and program instructions that apply to this supplier. ... I understand that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations, and program instructions ..., and on the supplier's compliance with all applicable conditions of participation in Medicare.

Medicare Enrollment Application: Clinics/Group Practices, CMS Form-855B, at 31.¹³

¹² Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf> (last accessed September 18, 2017).

¹³ Available at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms855b.pdf> (last accessed September 18, 2017).

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The Medicare Advantage Program

65. In lieu of coverage under Part A or Part B of Medicare, referred to collectively as Original Medicare, eligible beneficiaries can choose to receive coverage under Medicare Advantage Plans, or Part C plans.

66. Under Medicare Advantage, CMS is authorized to contract with private insurers to offer a variety of health plan options for beneficiaries, including coordinated care plans (collectively, “Medicare Advantage Plans” or “MAPs”). MAPs provide all Original Medicare benefits, and most offer additional benefits as well.¹⁴

67. CMS funds MAPs using a process established in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “MMA”).¹⁵ Pursuant to this process, CMS pays a monthly “capitation” payment to each MAP for each of that plan’s enrolled beneficiaries.¹⁶ The MAP, in turn, pays the capitation payment to the enrollee’s doctor or medical practice, after retaining a percentage fee for administration.

The Medicare Claims Process

68. In order to receive reimbursement from Medicare, providers such as Defendant must submit a claim form. *See* Form CMS-1500, attached hereto as **Exhibit J**.¹⁷ That claim form requires the provider to make the following certification:

In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete ... 3) I have provided or will provide sufficient information required to allow the government to make an

¹⁴ See CMS website: <https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/>.

¹⁵ Enacted in December 2003. See Medicare Managed Care Manual, Chapter 7 – Risk Adjustment, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.html>; see also Medicare Managed Care Manual, Chapter 8 - Payments to Medicare Advantage Organizations, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.html>.

¹⁶ *Id.*, Medicare Managed Care Manual, Chapter 8, § 10 “General Payment Rules.”

¹⁷ Exhibit J is a true and correct copy of Form CMS-1500 (approved OMB-0938-1197 form 1500 (02-12)), available at <https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1500.pdf> (last accessed June 7, 2017).

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informed eligibility and payment decision; 4) this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment. . . 5) the services on this form were medically necessary

Id., at 2.

69. A provider may also submit the electronic equivalent of this claim form, which contains a substantially similar certification.

70. The submission of such a certification, if false, is a violation of the FCA. 31 U.S.C. § 3729(a).

71. Each such false certification is a separate violation of the FCA.

C. The California Insurance Fraud Prevention Act

72. The California Insurance Fraud Prevention Act (the "CIFPA") is similar to the FCA, but instead covers claims made to private insurance companies. *See* Cal. Ins. Code § 1871.7.

73. The CIFPA establishes civil liability for violating Cal. Pen. Code § 550, prohibiting the filing of fraudulent insurance claims. *See* Cal. Ins. Code § 1871.7(b).

74. Cal. Pen. Code § 550(b) provides:

It is unlawful to do, or to knowingly assist or conspire with any person to do, any of the following:

(1) Present or cause to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.

(2) Prepare or make any written or oral statement that is intended to be presented to any insurer or any insurance claimant in connection with, or in support of or opposition to, any claim or payment or other benefit pursuant to an insurance policy, knowing that the statement contains any false or misleading information concerning any material fact.

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75. For each violation of the CIFPA, California assesses civil penalties not less than five thousand dollars (\$5,000) and not more than ten thousand dollars (\$10,000), plus an assessment of not more than three times the amount of each claim. *See* Cal. Ins. Code § 1871.7(b).

76. The CIFPA also provides for payment of a percentage of California's recovery to a private individual who brings suit on behalf of California (the "Relator") under the CIFPA. *See* Cal. Ins. Code § 1871.7(g).

D. The Anti-Kickback Statute

77. The Anti-Kickback Statute (the "AKS") prohibits offering, paying, soliciting, or receiving anything of value to induce services for which payment made be made under a Federal health program.

78. A violation of the AKS is, in turn, a violation of the FCA. *See* 42 U.S.C. § 1320a-7b(g) ("[A] claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31" – *i.e.*, the FCA).

**VIII.
FIRST CLAIM FOR RELIEF
FEDERAL FALSE CLAIMS ACT: PRESENTATION OF FALSE CLAIMS**

79. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

80. Throughout the statutory period, Defendant presented claims to CMS and its contractor for:

- a. tests that were not performed according to Medicare coverage requirements, but that Defendant presented as meeting such requirements using false and misleading documents;

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- b. tests that were not medically necessary, but that Defendant presented as medically necessary using false and misleading documents; and
- c. tests that were illegally induced through offers of remuneration in violation of the AKS.

81. Defendant knew that these tests were not covered by Medicare, but chose not to issue patients the required ABNs.

82. To appeal claims denied by Medicare Advantage, Defendant waived its right to collect payments from beneficiaries. However, Defendant reneged on its waiver and billed patients anyway.

83. For each of its claims for reimbursement, Defendant certified that the information it was providing was true, accurate and complete; and that the claim complied with all applicable Medicare laws, regulations, and instructions for payment.

84. Each such representation was false, for the reasons described above.

85. Accordingly, Defendant knowingly presented false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(1) (2000), and, as amended, 31 U.S.C. § 3729(a)(1)(A).

86. The submission by Defendant of these false claims caused CMS to pay out monies that CMS would not have paid if it had known of the falsity of Defendant's claims and certifications.

87. Each false or fraudulent claim thus submitted for payment by CMS is a separate violation of the FCA.

88. By reason of the false or fraudulent claims that Defendant knowingly presented, the United States has been damaged in a substantial amount, to be proven at trial. Relators therefore respectfully request an order awarding the United States treble damages plus a civil

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monetary penalty for each violation, and awarding Relators the maximum award permitted under 31 U.S.C. § 3730(d).

**IX.
SECOND CLAIM FOR RELIEF
FEDERAL FALSE CLAIMS ACT: MAKING OR USING
FALSE RECORD OR STATEMENT TO CAUSE FALSE CLAIM TO BE PAID**

89. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

90. As described above, throughout the statutory period, Defendant knowingly used false records and statements when it submitted these claims for payment, including false documentation that Defendant's tests complied with coverage requirements.

91. Accordingly, Defendant knowingly used false records or statements material to false or fraudulent claims for payment in violation of 31 U.S.C. § 3729(a)(1)(B).

92. The submission of these false records or statements caused CMS to pay out monies that CMS would not have paid if it had known of the falsity of Defendant's records or statements.

93. Each submission of a false record or statement is a separate violation of the FCA.

94. By reason of the false or fraudulent records or statements that Defendant knowingly submitted, the United States has been damaged in a substantial amount, to be proven at trial. Relators therefore respectfully request an order awarding the United States treble damages plus a civil monetary penalty for each violation, and awarding Relators the maximum award permitted under 31 U.S.C. § 3730(d).

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X.

**THIRD CLAIM FOR RELIEF
FEDERAL FALSE CLAIMS ACT: CONSPIRING TO SUBMIT FALSE CLAIMS**

95. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

96. As set forth above, Defendants' directors and other employees conspired with each other and unnamed parties to seek and obtain payments by submitting claims based on fraudulent representations and records.

97. Accordingly, Defendant knowingly conspired to defraud the United States by getting false or fraudulent claims allowed or paid, in violation of 31 U.S.C. § 3729(a)(3) (1986), and conspired to commit violations of 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), in violation of 31 U.S.C. § 3729(a)(1)(C) (2009).

98. By reason of the false or fraudulent claims that Defendant conspired to get allowed or paid, or by reason of its conspiracy to violate 31 U.S.C. §§ 3729(a)(1)(A) and 3729(a)(1)(B), the United States has been damaged in a substantial amount, to be proven at trial. Relators therefore respectfully request an order awarding the United States treble damages plus a civil monetary penalty for each violation, and awarding Relators the maximum award permitted under 31 U.S.C. § 3730(d).

XI.

**FOURTH CLAIM FOR RELIEF
FEDERAL FALSE CLAIMS ACT:
IMPROPERLY AVOIDING AN OBLIGATION TO PAY
OR TRANSMIT MONEY TO THE GOVERNMENT**

99. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

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100. Defendant knew or had reason to know that it had been overpaid by Medicare for tests that did not meet the requirements for reimbursement under the Local Coverage Determination (“LCD”).

101. Defendant was on notice of this overpayment as soon as private insurers denied its claims and started seeking refunds.

102. Nevertheless, Defendant continued to submit to and receive payment from CMS for claims that did not meet LCD requirements.

103. Under 42 U.S.C. 1320a-7k(d), Defendant was obligated to report and return each overpayment to the MAC, and to notify the MAC in writing of the reason for the overpayment, “by the later of (A) ... 60 days after the date on which the overpayment was identified; or (B) the date any corresponding cost report is due”

104. 42 C.F.R. § 401.305(a)(2) provides: “A person has identified an overpayment when the person has, or should have through the exercise of reasonable diligence, determined that the person has received an overpayment and quantified the amount of the overpayment.”

105. As a result of the fraud described herein, Defendant has received overpayments from the MAC which Defendant failed to return.

106. Each failure to comply with the obligations of 42 U.S.C. 1320a-7k(d) is a separate violation of 31 U.S.C. § 3729(a)(1)(G).

107. By reason of Defendant’s violations of 31 U.S.C. § 3729(a)(1)(G), the United States has been damaged in a substantial amount, to be proven at trial. Relators therefore respectfully request an order awarding the United States treble damages plus a civil monetary penalty for each violation, and awarding Relators the maximum award permitted under 31 U.S.C. § 3730(d).

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**XII.
FIFTH CLAIM FOR RELIEF
CALIFORNIA INSURANCE FRAUD PREVENTION ACT:
PRESENTATION OF FALSE CLAIMS**

108. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

109. Throughout the statutory period, Defendant presented claims to private insurance carriers in California for:

- a. tests that were not performed according to Medicare coverage requirements, but that Defendant presented as meeting such requirements using false and misleading documents;
- b. tests that were not medically necessary, but that Defendant presented as medically necessary using false and misleading documents; and
- c. tests that were illegally induced through offers of remuneration in violation of the AKS.

110. For each of its claims for reimbursement, Defendant committed, knowingly assisted in, or conspired to commit the following:

- a. present or cause to be presented a statement in support of a claim for payment knowing that the statement contains false or misleading information concerning a material fact, in violation of Cal. Pen. Code § 550(b)(1); and
- b. prepare or make a statement intended to be presented to any insurer in support of a claim for payment, knowing that the statement contains false or misleading information concerning a material fact, in violation of Cal. Pen. Code § 550(b)(2).

111. For each such violation of Cal. Pen. Code § 550, Defendant is liable for civil damages under the CIFPA, Cal. Ins. Code § 1871.7(b).

112. By reason of the false or fraudulent statements that Defendant prepared or presented, or assisted or conspired to prepare or present, California insurance carriers have been damaged in a substantial amount, to be proven at trial. Relators therefore respectfully request an

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order awarding California treble damages plus a civil monetary penalty for each violation, and awarding Relators the maximum award permitted under Cal. Ins. Code § 1871.7(g)(1)(A)(i).

**XIII.
SIXTH CLAIM FOR RELIEF
UNJUST ENRICHMENT**

113. Relators repeat and re-allege all preceding paragraphs of the Complaint inclusive, as if fully set forth herein.

114. As set forth above, the United States and California insurance carriers issued payments to Defendant based on Defendant's claims submitted using fraudulent records.

115. The circumstances of Defendant's receipt of these monies from the United States and California insurance carriers, in an amount to be determined at trial, are such that, in equity and in good conscience, Defendant should not be permitted to retain such monies.

116. By reason of Defendant's unjust enrichment, Relators respectfully request an order requiring Defendant to disgorge all monies it received as a result of the illicit scheme described herein.

PRAYER FOR RELIEF

WHEREFORE, Relators respectfully request that this Court enter judgment in their favor and that of the United States and California, and against Defendant, granting the following:

- (A) On the First, Second, Third and Fourth Claims for Relief (violations of the FCA, 31 U.S.C. §§ 3729(a)(1)(A), 3729(a)(1)(B), 3729(a)(1)(C), and 3729(a)(1)(G)), an award to the United States for treble its damages, in an amount to be determined at trial, plus a statutory penalty for each violation of the FCA;
- (B) On the First, Second, Third and Fourth Claims for Relief, an award to the United States for its costs pursuant to 31 U.S.C. § 3729(a)(3);
- (C) On the First, Second, Third and Fourth Claims for Relief, an award to Relators in the maximum amount permitted under 31 U.S.C. § 3730(d);

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- (D) On the Fifth Claim for Relief (violations of the CIFPA, Cal. Ins. Code § 1871.7(b)), an award to California for treble damages, in an amount to be determined at trial, plus a statutory penalty for each violation of the CIFPA;
- (E) On the Fifth Claim for Relief, an award to California for its costs pursuant to Cal. Ins. Code § 1871.7(g)(1)(A)(ii);
- (F) On the Fifth Claim for Relief, an award to Relators in the maximum amount permitted under Cal. Ins. Code § 1871.7(g)(1)(A)(i);
- (G) On the Sixth Claim for Relief (Unjust Enrichment); an award for the damages sustained by the United States and California, and amounts of monies illegally obtained from the United States and California and retained by Defendant, plus interest, costs, and expenses;
- (H) And on all Claims for Relief,
 - 1. An award to Relators of the reasonable attorneys' fees, costs, and expenses they incurred in prosecuting this action;
 - 2. Awards to the United States, California, and to Relators for their costs of court;
 - 3. Awards to the United States, California, and to Relators for pre- and post-judgment interest at the rates permitted by law; and
- (I) An award of such other and further relief as this Court may deem to be just and proper.

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DEMAND FOR TRIAL BY JURY

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Relators demands trial by jury on all questions of fact raised by the Complaint.

Dated:

Respectfully submitted,

JTB LAW GROUP, LLC
(Lead Counsel)

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CERTIFICATE OF SERVICE

I hereby certify that on September 26, 2017, I caused a true copy of the Complaint in the matter captioned *United States of America and California ex rel. Stephanie La Fleur and Corinne Vause v. GenomeDx Biosciences Corp.* to be served upon the following, along with written disclosure of substantially all material evidence and information possessed by Relators:

by hand delivery to

Alana W. Robinson
United States Attorney
Southern District of California
United States Attorney's Office
880 Front Street, Room 6293
San Diego, California 92101-8893

by hand delivery to

Summer Stephan
San Diego County District Attorney
330 W. Broadway
San Diego, CA 92101

by USPS Registered Mail, Return Receipt Requested, to

Dave Jones
California Insurance Commissioner
California Department of Insurance
Government Law Bureau
300 Capitol Mall, Suite 1700
Sacramento, CA 95814

by USPS Registered Mail, Return Receipt Requested, to

Office of the Attorney General of the United States
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

/s/ Imad Y. Elias
Imad Y. Elias