UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* [UNDER SEAL], Plaintiffs, v. [UNDER SEAL], Defendants.	Case No.: **COMPLAINT FOR VIOLATION OF THE FALSE CLAIMS ACT [31 U.S.C. §§ 3729 *et seq.*]** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY TRIAL DEMANDED**

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

UNITED STATES OF AMERICA *ex rel.* LEIGHSA WILSON, Plaintiffs, v. VIZTEK INC., KONICA MINOLTA HEALTHCARE AMERICAS INC., JOSIP CERMIN, KEVIN BORDEN, and INFOGARD LABORATORIES INC, Defendants.	Case No. **COMPLAINT FOR VIOLATION OF THE FALSE CLAIMS ACT [31 U.S.C. §§ 3729 *et seq.*]** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)** **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiff-Relator Leighsa Wilson, through her attorneys, on behalf of the United States of America (the "Government" or the "Federal Government"), for her Complaint against Defendants Viztek, Inc. ("Viztek"), Konica Minolta Healthcare Americas, Inc. ("Konica Minolta"), Josip Cermin ("Joe Cermin" or "Cermin"), Kevin Borden ("Borden") (collectively "EHR Defendants"), and InfoGard Laboratories Inc. ("InfoGard") (collectively "Defendants") alleges based upon personal knowledge, relevant documents, and information and belief, as follows:

I. INTRODUCTION

1. This is an action 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 and employees, in violation of the federal False Claims Act, 31 U.S.C. §§ 3729-3733 ("the FCA").

2. This action alleges that Defendants caused false claims to be submitted to the Department of Health and Human Services (HHS) for federal incentive payments through the Electronic Health Record (EHR) Incentive Programs.

3. Pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), HHS established the Medicare and Medicaid EHR Incentive Programs (also known as the "Meaningful Use program"), which provided incentive payments to healthcare providers who demonstrated "meaningful use" of certified EHR technology.

4. Viztek, and its corporate parent Konica Minolta, developed and sold EHR software to healthcare providers in this judicial district. The EHR Defendants, working together with Defendant InfoGard, a certifying body for EHR software, made false representations to the United States that the EHR Defendants' software complied with the requirements for certification and for the payment of incentives under the Meaningful Use program.

5. To ensure that their product was certified and that their customers received incentive payments, Viztek and Konica Minolta: (a) falsely attested to InfoGard that their software met the certification criteria; (b) hard-coded their software to pass certification testing requirements temporarily without ensuring that the software released to customers met certification criteria; and (c) caused their users to falsely attest to using a certified EHR technology, when their software could not support the applicable certification criteria in the field.

6. Defendant InfoGard facilitated and participated in the EHR Defendants' false attestations, knowingly or with reckless disregard, certifying the EHR Defendants' software even though it was unable to meet the certification criteria.

7. The flaws in the EHR Defendants' software not only rendered the system unreliable and unable to meet Meaningful Use standards, but the flaws also created a risk to patient health and safety. Rather than spend the time and resources necessary to correct the flaws in its EHR software, the EHR Defendants opted to do nothing.

8. Since 2011, healthcare providers who used the EHR Defendants' software and attested to satisfying the Meaningful Use objectives and measures received incentive payments

through the Meaningful Use program. Had the EHR Defendants disclosed that their software did not meet the certification criteria, it would not have been certified and their customers would not have been eligible for incentive payments.

9. Corporate managers at Viztek, including Defendants Cermin and Borden, directed and participated in the conduct alleged herein.

10. The Defendants' false and fraudulent statements and conduct alleged in this Complaint violate the federal False Claims Act (FCA), 31 U.S.C. §§ 3729 *et seq*. The FCA allows any person having information about an FCA violation (referred to as a *qui tam* plaintiff or "relator") to bring an action on behalf of the Government, and to share in any recovery. The FCA requires that the complaint be filed under seal for a minimum of 60 days (without service on the defendant during that time) to allow the Government time to conduct its own investigation and to determine whether to join the suit.

11. *Qui tam* plaintiff Leighsa Wilson seeks through this action to recover all available damages, civil penalties, and other relief for the FCA violations alleged herein in every jurisdiction to which Defendants' misconduct has extended.

II. PARTIES

12. Plaintiff United States of America is the real party in interest herein. The United States, acting through HHS, administers the Medicare program, Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 (Medicare), and administers grants to states for Medical Assistance Programs pursuant to Title XIX of the Social Security Act, 42 U.S.C. §§ 1396 *et seq*. (Medicaid). The United States, acting through HHS, also administers the Meaningful Use program and a certification program for EHR technology.

13. *Qui tam* Plaintiff/Relator Leighsa Wilson ("Relator") is a resident of Greensboro, North Carolina, with ten years of experience in healthcare IT. Relator worked for Viztek from July 2014 until April 2016, during which time she was the Project Manager responsible for the EXA EHR product.

14. Defendant Viztek, Inc. is a corporate subsidiary of Konica Minolta Healthcare Americas, purchased by Konica Minolta in October 2015. Prior to the purchase, Viztek was a privately-held Florida corporation. Viztek was founded in 1999 by Defendant Josip "Joe" Cermin, Founder and President. Viztek, and now Konica Minolta, manufactures and sells hardware and digital software imaging solutions including the flagship, zero footprint, server-side EXA product line. EXA is used in radiology practices. Viztek is headquartered in Garner, North Carolina.

15. Defendant Konica Minolta Healthcare Americas, a business unit of the Japanese company Konica Minolta, Inc., is a provider of diagnostic digital radiography and ultrasound imaging, healthcare information and service-based solutions. Konica Minolta purchased Defendant Viztek in October 2015. The company is headquartered in Wayne, New Jersey.

16. Defendant Josip Cermin was the founder of Viztek and the President until its sale to Konica Minolta in October 2015. He is now the President for Healthcare IT – Americas of Konica Minolta. Mr. Cermin is a resident of North Carolina.

17. Defendant Kevin Borden was Viztek's Director of Software Implementation and Software Support from January 2012 to January 2015. He was Viztek's Vice President of Software Development from February 2015 until its sale to Konica Minolta in October 2015. He is now Vice President for Healthcare IT Software Development. Mr. Borden is a resident of North Carolina.

18. Defendant InfoGard Laboratories Inc. is a corporate subsidiary of UL LLC (itself a subsidiary of Underwriters Laboratories LLC), purchased in December 2015. Prior to the purchase, InfoGard was a privately held company. InfoGard provides testing, auditing, consulting, and certification services to IT solution providers in the Federal, Payment, and Healthcare IT markets. It has been authorized by the U.S. Department of Health and Human Services Office of the National Coordinator for Health Information Technology (ONC) to test and certify EHR Products as an ONC-Accredited Testing Laboratory and ONC-Authorized Certification Body. InfoGard is headquartered in San Luis Obispo, California.

III. JURISDICTION AND VENUE

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and 31 U.S.C. § 3732, the latter of which specifically confers jurisdiction on this Court for actions brought pursuant to 31 U.S.C. §§ 3729 and 3730. Although the issue is no longer jurisdictional after the 2009 amendments to the FCA, to Relator's knowledge there has been no statutorily relevant public disclosure of the "allegations or transactions" in this Complaint, as those concepts are used in 31 U.S.C. § 3730(e), as amended by Pub. L. No. 111-148, § 10104(j)(2), 124 Stat. 119, 901-02.

20. Moreover, whether or not such a disclosure has occurred, Relator would qualify as an "original source" of the information on which the allegations or transactions in this Complaint are based. Before filing this action, Relator voluntarily disclosed to the Government the information on which the allegations or transactions in this Complaint are based. Additionally, Relator has direct and independent knowledge about the misconduct alleged herein and that knowledge is independent of and materially adds to any publicly disclosed allegations or transactions relevant to her claims.

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

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b)-(c) and 31 U.S.C. § 3732(a) because the Defendants can be found in and/or transact business in this District, and because violations of 31 U.S.C. §§ 3729 *et seq*. alleged herein occurred within this District. At all times relevant to this Complaint, Defendants regularly conducted business within this District.

IV. STATUTORY AND REGULATORY BACKGROUND

A. The False Claims Act

23. The FCA imposes civil liability on any person who, *inter alia*: (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government a false or fraudulent claim for payment or approval; (2) knowingly makes, uses or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Government; (3) knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government; or (4) conspires to violate the FCA. 31 U.S.C. §§ 3729(a)(l)(A), (B). (C), and (G).

24. The FCA defines a "claim" to include "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 ...." *Id*. at § 3729(b)(2).

25. The FCA defines the terms "knowing" and "knowingly" to mean "that a person, with respect to information - (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. *Id*. at § 3729(b)(1)(A). The FCA does not require proof of specific intent to defraud. *Id*. at § 3729(b)(l)(B).

26. The FCA provides that the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." *Id*. at § 3729(b)(4).

27. Any person who violates the FCA is liable for a mandatory civil penalty for each such claim, plus three times the damages sustained by the Government. *Id*. at § 3729(a)(l).

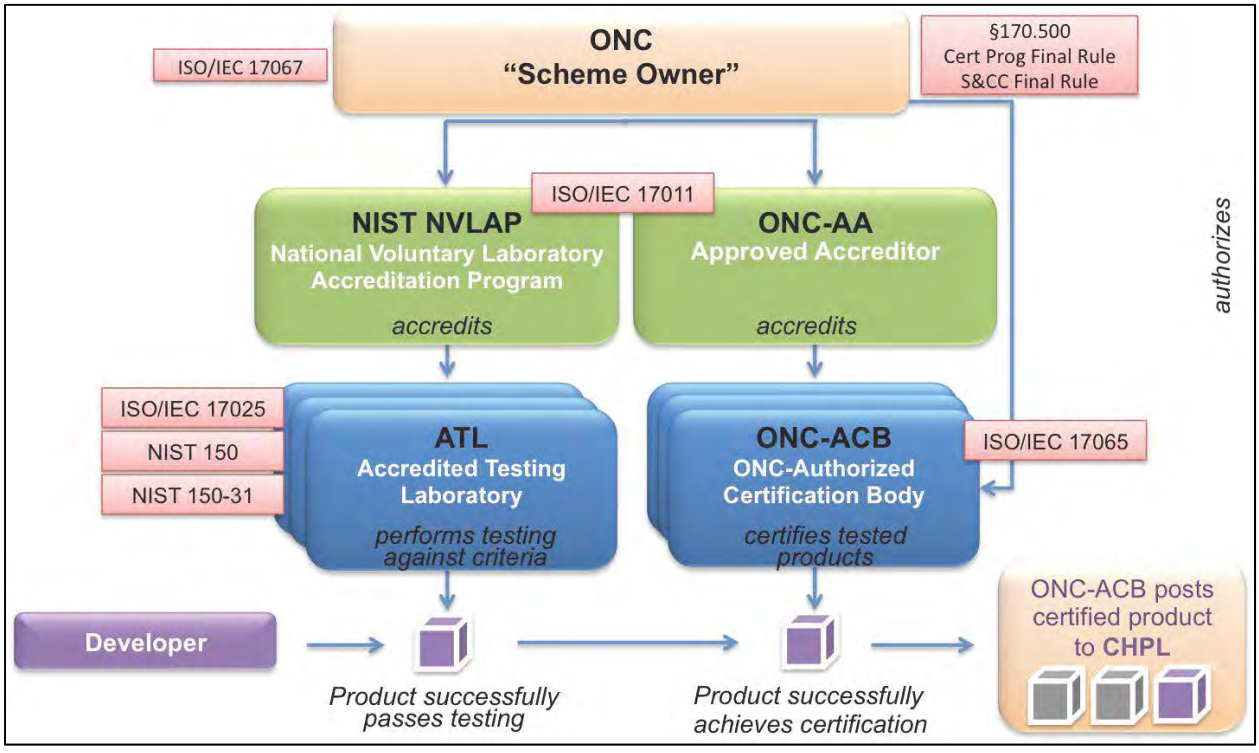
B. Certified EHR Technology and the Meaningful Use Program

28. On February 17, 2009, the HITECH Act was enacted to promote the adoption and meaningful use of certified EHR technology. Under the HITECH Act, the HHS Office of the National Coordinator for Health Information Technology (ONC) established the ONC Health IT Certification Program, a certification program for EHR technology. As part of the certification program, ONC provided for the creation of authorized certification bodies (ACB) and accredited testing laboratories (ATL) to test and certify that EHR vendors' software are compliant with the ONC-specified certification requirements. Through the Meaningful Use program CMS makes incentive payments to healthcare providers for demonstrating meaningful use of certified EHR technology.

1. ONC Authorized Certification and Testing Bodies

29. ONC does not perform conformance testing or issue certifications itself. Rather, it utilizes other organizations that it evaluates, approves, and authorizes to perform these functions on its behalf.

30. ONC created the following diagram to illustrate the process:



31. ATLs are accredited through ONC's Health Information Testing Laboratory Accreditation Program (HITLAP), which is administered by the National Voluntary Laboratory Accreditation Program (NVLAP), a part of the National Institute of Standards and Technology (NIST). NVLAP operates the accreditation process in accordance with the International Standard, ISO/IEC 17025, which provides general requirements for the competence of testing and calibration laboratories; and NIST Handbooks 150 and 150-31, which contain the technical requirements and guidance for accreditation of laboratories performing testing of health information technology. NVLAP accredited testing laboratories can then apply for ONC authorization to test health IT under the ONC Health IT Certification Program.

32. The NIST Handbooks that govern ATLs specify a comprehensive set of requirements, including the following: Laboratories shall use the ONC-Approved Test Methods and testing tools for examinations. *See* NIST, *NIST Handbook 150-31:2011, Healthcare Information Technology Testing* § 5.4.2 (2011). In addition, the laboratory must "protect all products under testing … from modifications of any kind," *NIST Handbook 150-31:2011* at § 5.8.1, and it must have "quality control procedures for monitoring the validity of tests … undertaken." NIST, *NIST Handbook 150:2006, Procedures and General Requirements* § 5.9.1 (2006).

33. ACBs are accredited by an Approved Accreditor (ONC-AA), which is chosen by ONC. To date, the American National Standards Institute (ANSI) has been the sole ONC-AA. The ONC-AA certifies companies seeking ACB status to International Standard, ISO/IEC 17065, which provides requirements for bodies certifying products, processes, and services. ONC-AA accredited certification bodies can then apply for ONC authorization to certify health IT under the ONC Health IT Certification Program.

34. A single organization may obtain both ONC ATL and ACB status, but such entities are required to develop and implement policies and procedures to maintain separation of those functions. *NIST Handbook 150-31:2011*, § 4.1.

2. Certification of EHR Software

35. To obtain certification of EHR software, EHR vendors must pass certification testing by an ATL, and attest to an ACB that their EHR product satisfies the applicable certification criteria. The 2014 Edition EHR testing criteria, at issue in this Complaint, are codified at 45 CFR 170.314. The regulation specifies 59 unique criteria, some mandatory for certification and some optional.

36. To test the criteria, the ATLs use standardized testing protocols ("test scripts"), which identify each step the vendor will be required to take during testing. ONC makes the test scripts available to vendors in advance of their testing date. *See* ONC, *Testing and Test Methods,* HealthIT.gov, http://www.healthit.gov/policy-researchers-implementers/2014-edition-final-test-method.

37. These scripts are intended to test representative aspects of the criteria under examination and are not intended to test all aspects of the criteria. The ACB relies on the accuracy and good faith of the vendor's attestations with regard to aspects of the criteria that are not directly tested.

38. After obtaining certification, an EHR vendor must maintain that certification by complying with all applicable conditions and requirements of the certification program. Among other things, the EHR product must be able to accurately, reliably, and safely perform its certified capabilities while in use in doctors' offices. EHR vendors must cooperate with the processes established by ONC for testing, certifying, and conducting ongoing surveillance and review of certified EHR technology.

3. Meaningful Use of Certified EHR Technology

39. Individual practitioners (Eligible Professionals) could qualify for up to $43,720 over five years from Medicare (ending after 2016) and up to $63,750 over six years from Medicaid (ending after 2021) in incentive payments for demonstrating meaningful use of certified EHR technology.

40. In order to qualify for incentive payments under the Meaningful Use program, Eligible Professionals were required, among other things, to: (1) use an EHR system that qualified as certified EHR technology; and (2) satisfy certain objectives and measures relating to their meaningful use of the certified EHR technology.

41. HHS implemented the certification criteria and incentive payment requirements in multiple stages. On January 13, 2010, HHS published in the Federal Register interim final rules setting forth the "2011 Edition" certification criteria and a proposed rule setting forth the "Stage 1" requirements for incentive payments. HHS finalized these rulemakings by publication in the Federal Register on July 28, 2010. In Stage 1, an Eligible Professional's use of certified EHR technology generally needed to satisfy fifteen "core objectives" and five out of ten "menu set objectives."

42. On September 4, 2012, HHS published in the Federal Register the final rules setting forth the "2014 Edition" certification criteria and "Stage 2" requirements for incentive payments. In Stage 2, an Eligible Professional's use of certified EHR technology generally needed to satisfy seventeen "core objectives" and three out of six "menu set objectives."

43. On October 16, 2015, CMS published in the Federal Register a final rule with comment period setting forth the "Modified Stage 2" requirements for incentive payments. For years 2015 through 2017, Modified Stage 2 eliminated the concept of "menu set objectives" and required all Eligible Professionals to attest to a single set of objectives and measures.

44. In October 2015, CMS also released a final rule that established Stage 3 in 2017 and beyond, which focuses on using certified EHR technology to improve quality, safety, and efficacy of health care, including promoting patient access to self-management tools and improving population health.

45. Starting in 2015, all providers were required to use technology certified to the 2014 Edition. For 2016 and 2017, providers can choose to use technology certified to the 2014 Edition or the 2015 Edition.

46. To qualify for incentive payments in each Stage of the Meaningful Use program, healthcare providers are required each year to attest that they used certified EHR technology and satisfied the applicable Meaningful Use objectives and measures. Use of certified EHR technology and satisfaction of applicable Meaningful Use objectives and measures are material to payment under the Meaningful Use program.

47. The CMS rules governing the Meaningful Use program recognize that healthcare providers rely on certification of the EHR vendor for assurance that an EHR product meets the applicable certification criteria, including that it possesses the certified capabilities that healthcare providers will need to use to achieve relevant objectives and measures, and that the software will perform in accordance with applicable certified capabilities.

48. Starting in 2017, the Medicare EHR Incentive Program was incorporated into the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program created by the Medicare Access and CHIP Reauthorization Act (MACRA), 42 U.S.C. 1395ee. MIPS is discussed further in Paragraph 54 below.

C. Certified EHR Technology and the PQRS Program

49. The Physician Quality Reporting System (PQRS) is a voluntary reporting program that provides a financial incentive for health care professionals who participate in Medicare to submit data to CMS on specified quality measures for covered Physician Fee Schedule services furnished to Medicare Part B Fee-for-Service beneficiaries.

50. For reporting years 2012 through 2014, CMS provided physicians who satisfactorily reported data on the required quality measures an incentive payment of 0.5% of their total allowed charges for the reporting year. Starting in 2015, the program applied a negative payment adjustment to practices with Eligible Professionals that do not satisfactorily report data on quality measures. The penalty was 1.5% for 2015 and increased to 2.0% for 2016 and subsequent years. Those who report satisfactorily for the 2016 program year avoid the 2018 PQRS negative payment adjustment.

51. Providers can participate in PQRS either with or without an EHR. Those who have an EHR can report PQRS data directly through their EHR.

52. The measures for PQRS are divided into two groups: Individual Measures and Measures Groups. An eligible professional may choose to report any combination of Individual Measures or choose a specific Measures Group. Measures Groups include a minimum of 6 individual measures and normally a maximum of 11 measures. The individual measures in the Measures Groups all relate to a specific diagnosis or problem such as diabetes, coronary heart disease, or others. Also, beginning in 2016, Eligible Professionals must include one cross-cutting measure.

53. The last program year for PQRS was 2016. Starting in the 2017 program year, PQRS became part of the Merit-based Incentive Payment System (MIPS) under the Quality Payment Program.

D. The Merit-based Incentive Payment System ("MIPS")

54. The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) created the Quality Payment Program to replace three programs that ended with the 2016 reporting period: the Medicare EHR Incentive Program; the PQRS program; and the Value-Based Modifier program.

55. The Quality Payment Program has two tracks: the Merit-based Incentive Payment System (MIPS) and the Advanced Alternative Payment Models (APMs).

56. MIPS payment adjustments are applied to Medicare Part B payments two years after the performance year, with 2019 being the payment adjustment year for the 2017 performance year.

57. Although as of the date of preparation of this Complaint, MIPS payment adjustments have not yet been made under the Quality Payment Program, Relator alleges based on information and belief that the practices described herein that cause false claims to be

submitted to the Government under the Meaningful Use program will cause false claims to be submitted to the Government under the Quality Payment Program.

V. ALLEGATIONS

A. Background: The Corporate Culture of Viztek

58. Defendant Joe Cermin, the founder and President of Viztek, emigrated from Croatia to the United States in 1987. After a few years attending Jacksonville University, Cermin dropped out, and spent the next decade selling and servicing computers for the business market. In 1999, Cermin decided to jump into the medical software and hardware business, founding Viztek.

59. Cermin successfully grew Viztek at a rapid rate, soon achieving tens of millions of dollars in revenue. By 2008, annual revenue was at $30 million; by 2012: $50 million. At the time of Viztek's sale to Konica Minolta in 2015, annual revenue exceeded $70 million.

60. When Relator accepted a position at Viztek in 2014, she was inspired by the company's vision and scope, and what she believed to be Joe Cermin's straight-forward goal: to get great products into the hands of doctors. Unfortunately, within a short time working at Viztek, Relator learned the truth about Joe Cermin and Viztek: it was just about the money, even at the expense of compliance with federal law and patient safety.

61. Cermin's personal style was flashy—expensive clothes, expensive cars, and expensive gadgets. His demeanor, meanwhile, was pushy and imposing. Relator witnessed firsthand as Cermin pushed the EXA EHR toward certification, "lie, beg, cheat, steal, or kill," knowing full well that it was not capable of the functionality required, and that it could affect the health and safety of actual patients out in the field.

62. Relator also observed that Cermin's style of leadership had set the tone for the rest of the company. Relator's direct boss Kevin Borden, adopted the same attitude toward EHR certification as Cermin—get it done by any means necessary. Both Cermin and Borden explicitly directed Viztek employees to cheat on the certification tests. And Viztek's lead

developer in India, Sundar, was even more direct with Relator, explaining to her that he was happy to lie, to anyone at any time, if it suited his needs.

B. Viztek and Konica Minolta Failed to Satisfy the Certification Criteria and Made False Statements in Obtaining Certification and Marketing their Software

63. Viztek Inc. has been creating and selling Picture Archiving and Communications Systems (PACS) and other medical software for over ten years. Its first major product line, Opal, was acquired in a merger with 20/20 Healthcare. In 2014, Viztek introduced the successor to Opal, its EXA software line, a web-based, zero-footprint, radiology software platform. Among the EXA modules available, Viztek offered EXA PACS, EXA RIS (radiology information system) and EXA MAMMO (mammography viewing), and full integration with its EXA EHR electronic health records product.

64. On August 26, 2015, Viztek began to undergo the testing required for its EXA EHR product to receive ONC HIT 2014 certification.

65. As a predicate to obtaining certification for its EXA EHR, Viztek submitted Attestation forms to InfoGard Laboratories, both an Office of the National Coordinator-Authorized Certification Body (ACB) and an authorized testing laboratory (ATL), representing that the EXA EHR software satisfied the 2014 Edition certification criteria and that the software was capable of performing those criteria and standards in the field.

66. While the testing was ongoing, on October 1, 2015, Konica Minolta purchased Viztek, including its EXA software line.

67. Based upon Viztek's attestations, and several months of testing between late 2015 and early 2016 performed by InfoGard, EXA EHR version 1.0 achieved 2014 Edition certification on March 16, 2016. This certification designated that Viztek's EHR software is capable of supporting eligible providers with meeting the Stage 1 and Stage 2 Meaningful Use measures required to qualify for funding under the American Recovery and Reinvestment Act (ARRA).

68. As explained more fully below, Relator alleges that Viztek could—and did—pass 2014 Edition certification testing for EXA EHR version 1.0 without fully implementing the requirements for 2014 Edition certification of the electronic health record software. Viztek did not seek to ensure that the standards, implementation specifications, and criteria were met.

C. Viztek Falsely Attested to Compliance with Certification Requirements And Hardcoded its Software to Pass Certification Testing

69. Since the start of the Meaningful Use program, eligibility for incentive payments required Eligible Professionals to use certified EHR technology. An EHR product cannot be certified unless all applicable certification criteria and standards have been met. Certification is material to payment under the Meaningful Use program.

70. Certification testing does not confirm that each criteria and standard is satisfied in full and under every conceivable scenario. Rather, testing takes a snapshot of a product's capabilities by ensuring it can pass certain pre-disclosed test cases.

71. During the course of Relator's employment with Viztek, she discovered that the company was engaging in a fraudulent scheme to obtain certification of its EXA EHR product. Relator discovered this information in the following circumstances.

72. In November 2014, Relator was hired by Viztek as a Project Manager in charge of the EXA EHR product. In that role, she worked with Viztek's development teams, and was present for and participated in the 2014 Edition Certification testing with InfoGard.

73. For the first several months of Relator's employment, no one at Viztek appeared to be seriously working on the EXA EHR product. Members of the development team in India, which was also working on other modules of the EXA platform, told Relator that they believed the EHR would not take much work because they could modify the technology from Viztek's older Opal EHR, which had passed 2011 Edition Certification.

74. As Viztek moved closer to Certification testing for its EHR, Relator was alarmed at the lack of progress made by the development team—little of the required functionality had been added. Relator frequently asked Sundar—the head of the India development team—about

specific functionality that was not working. He would either reply that it would be addressed soon or that it was already working, something Relator knew not to be the case.

75. Relator brought her concerns to the attention of her supervisors, both Kevin Borden, Vice President of Software Development, and Joe Cermin, President of Viztek. Neither appeared to take her concerns seriously. In August 2015, when InfoGard began 2014 Edition certification testing of the EXA EHR product, Viztek was not prepared.

76. As testing began, however, Cermin's deal with Konica Minolta to purchase Viztek was nearing completion, and failure to certify Viztek's flagship EXA EHR product was not an option. Cermin told Relator to get the software certified, "I don't care if you have to lie, beg, cheat, steal, or kill." Cermin indicated that if certification was not complete by February 2016, they could lose millions of dollars.

77. When Viztek was offered the choice between onsite testing or remote testing (via computer conference and screen share), Viztek chose the latter option which allowed them a better opportunity to manipulate the certification testing.

78. With the knowledge and participation of Joe Cermin, Kevin Borden, and the Viztek development team, Viztek devised several deceptive schemes to pass the 2014 Edition certification testing. Relator personally witnessed these schemes executed as she operated the onsite computer during testing; they included:

79. During testing, InfoGard followed ONC test scripts that Viztek knew would be used in advance. Rather than programming the software to retrieve the required information in any scenario, Viztek had software developers hardcode the test script information directly into the server, all for the purpose of making it appear as though Viztek had implemented the required functionality when in fact it had not.

80. During testing, another Project Manager, Jessica Rader, instructed Relator to have multiple tabs open on the testing computer, one to perform the test script and another that was configured ahead of time to show the desired result. Rader then instructed Relator to switch back and forth between the tabs without the certifying body knowing so that she could get

through particular test script workflows. Joe Cermin and Kevin Borden were present for, aware of, and agreed with the approach.

81. If the software failed to successfully perform a test script during testing—a regular occurrence—Relator was instructed by Cermin, Borden, and Rader, who were out of view of the testers but in the same room, to request breaks and pause the computer screen. During the breaks, Viztek software developers offsite would manually adjust the software making it appear to perform the required functions, when it did not in fact have the capacity to perform the functions.

82. Viztek had one, and sometimes two, development teams on call during testing for this purpose. The development teams had access to multiple builds of the EHR software running on different servers. When the EHR software was unable to successfully complete a test script, while the testing was paused, the development teams would split up and attempt to develop a workaround solution on all of the different builds at once. Whomever succeeded first, their build would be used to complete the test script.

83. On at least one occasion, the development team in India hard-coded the EHR to pass a test with XML code (the output required by the test) that it took directly from a competitor. The competitor's code was located in an examples section of an ONC 2014 Edition testing website. However, the developers had not made any adjustments to the code prior to passing it off as their own, and Relator discovered that the other company's name was still apparent within it. Relator raised this issue with Mr. Borden, but he instructed her to continue with the testing.

84. Viztek's slipshod process also, on occasion, revealed live patient data. During testing, the EXA product line was already in use, and medical data from patients was stored on the Viztek servers. Close to ten separate times, while attempting to circumvent the testing, the development team in India accidentally caused the test scripts to output the live patient data.

85. Based on the test results, InfoGard found that EXA EHR version 1.0 met the certification requirements, and InfoGard certified Viztek's software on March 16, 2014.

D. InfoGard Knew or Recklessly Disregarded the Fact That Viztek's EXA EHR Did Not Meet the Certification Criteria.

86. InfoGard's role as an ONC Certification Body and Testing Laboratory is a critical one to ensure that EHRs work properly and safely handle patient data, and that only EHRs actually meeting ONC-specified criteria are able to support Meaningful Use attestation. In regards to Viztek's EXA EHR, InfoGard abrogated that duty, certifying the product either knowing that it did not meet the required criteria, or in reckless disregard of that fact.

87. On many occasions during testing, the EXA EHR failed repeatedly to pass individual test scripts, often five or six times in a row, indicating that the software was unable to reliably meet the certification criteria. Despite this, InfoGard's testing agent, referred to in this Complaint as "PL," allowed Viztek to continue with the tests, offering unlimited breaks for Viztek to adjust its software, or to postpone the test script until a later date.

88. In addition, PL was aware that Viztek was using improper methodologies to pass some of the tests.

89. For example, on one occasion after failing multiple times on a specific test script, PL allowed the Viztek team a short break. During the break, the Viztek developers completed a workaround solution on a different build of the software, and made that the active version for testing. When testing resumed, PL noticed and mentioned that the version number shown on the screen had changed. Moreover, Relator could tell that PL understood the ramifications of the change—Viztek did not have a single version of the software able to complete the test scripts—because she subsequently admonished the Viztek team that they had to complete the testing on a single version of the software, operating on a single server. But she awarded Viztek a pass on that portion of the test, nevertheless.

90. PL noticed artifacts of Viztek's frequent server and build switches on other occasions, as well. For example, in one instance she noticed that the color scheme of the program changed, and in another she noticed that the location of non-movable items on the screen had changed location.

91. Despite these problems and the frequent test script failures, PL did not inquire further into whether the EXA EHR Version 1.0 software was, in fact, capable of completing any of the test scripts. She never investigated whether previously completed test scripts had been passed corruptly, and she did not implement any quality control measures to ensure that Viztek could not cheat going forward.

92. Relator is informed and believes that PL raised the testing issues with her direct supervisor at InfoGard, but was instructed to continue with the testing and certification.

93. Ultimately, PL certified that the EXA EHR Version 1.0 had passed the testing, allowing the product to be certified under the 2014 Edition standard.

E. Specific Criteria for Which Viztek Cheated During the EXA EHR 2014 Edition Certification Testing

94. Relator was present for all of InfoGard's 2014 Edition Certification testing of the Viztek EXA EHR software, which took place over several months. As described above, Viztek used a variety of methods to pass the certification tests, but its EXA EHR software was not actually able to meet the certification criteria. During this process, Relator observed and recorded the tests for which the EXA EHR software was unable to actually meet the Certification criteria.

95. For example, Certified EHR software must allow users to electronically record, change, and access patient demographic data including preferred language, sex, race, and date of birth. 45 CFR 170.314(a)(3). Moreover, the preferred language must be recorded in accordance with a specific standard (ISO 639-2 alpha-3 codes), specified in section (a)(3)(B). The ONC 2014 Approved Test Procedures state that the EHR technology "must be capable of recording a patient's language according to any of the languages in the standard." For purposes of the test, however, only a small sample of the languages need be shown to work, and this list of languages is available to the applicant in advance.

96. During testing, the EXA EHR did not have the capability to record all of the languages in the standard, as required. In order to defeat the test and obtain certification, Viztek

developers coded the software so it would work only for the few languages required to pass the test script.

97. Another example, Certified EHR software must enable users to electronically reconcile data that represent a patient's active medication, problem, and medication allergy list, including the ability to "simultaneously display (that is, in a single view) the data from at least two list sources in a manner that allows a user to view the data and their attributes." *Id*. at § (b)(4). The data that must be displayed are given to applicants in advance.

98. During testing, the EXA EHR did not have the capability to display the data from two sources in a single view. Instead, to create the appearance that the software could function as required, the Viztek developers manually created a screen appearing to show both sets of data. Prior to the test, they preloaded the screen in a separate tab on the testing computer, and then switched to the rigged screen at the appropriate time.

99. A final example, Certified EHR technology must provide patients with an online means to view, download, and transmit to a 3rd party a variety of data including the "Common MU Data Set," which contains a core set of information about the patient. *Id*. at § (e)(1). The data must be coded in a specific format (XML), and the testing agent observes the code outputted to verify that it is correct.

100. During testing, EXA EHR did not have the capability to create the coded data required for the test. Relator ran through the motions of creating the output code using the EXA EHR software. But since it could not create the required output, Viztek developers manually created the output code, which they submitted to the testing agent.

101. In addition, the following mandatory capabilities were not actually functional during testing:

- The ability to calculate a patient's body mass index (BMI). *Id*. at § (a)(4).
- The ability to reliably record the date that "problem list" data were entered. *Id*. at § (a)(5).
- The ability to reliably record the date that "medication list" or "medication history" data were entered. *Id*. at (a)(6).

- The ability to reliably record the severity of medication allergies or the date that medication allergy data were entered. *Id*. at § (a)(7).
- The ability to implement clinical decision support interventions. *Id*. at § (a)(8).
- The ability to reliably record smoking status or the date that smoking status data were recorded. *Id*. at § (a)(11).
- The ability to select, sort, access, and create patient lists. *Id*. at § (a)(14).
- The ability to output transition of care summaries. *Id*. at § (b)(1).
- The ability to electronically receive and incorporate laboratory tests and results. *Id*. at § (b)(6).
- The ability to create export summaries in the specified format. *Id*. at § (b)(7).
- The ability to reliably produce a numerator for tracking Clinical Quality Measures (CQMs). *Id*. at § (c)(1).

VI. CLAIMS FOR RELIEF

102. The Defendants obtained EHR certification for the EXA EHR through a series of false statements and fraudulent conduct. The EXA EHR system did not—and could not—meet both the certification criteria and the incentive payment requirements in its operation in the field, and the Defendants attempted to conceal the failure from the Government. The Defendants caused Eligible Professionals falsely to attest to using certified EHR technology and to satisfying Meaningful Use objectives and measures and to submit false information on their attestations requesting incentive payments.

103. Through the conduct discussed above, the Defendants knowingly caused the submission of false claims and false statements material to false claims to be submitted to the Government.

Count One
False Claims Act
31 U.S.C. §§ 3729(a)(1)(A), (B), (C), & (G)

104. Relator realleges and incorporates by reference the allegations contained in paragraphs 1 through 103 above as though fully set forth herein.

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

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

107. By virtue of the acts described above, Defendants knowingly made or used, or caused to be made or used, false or fraudulent records or statements material to false or fraudulent claims for payment by the Government.

108. By virtue of the acts described above, Defendants knowingly caused its customers to conceal or improperly avoid or decrease an obligation to pay or transmit money or property to the Government;

109. By virtue of the acts described above, Defendants knowingly conspired with others to violate the FCA. Moreover, Defendant took substantial steps toward the completion of the goals of that conspiracy by the conduct alleged herein.

110. Relator cannot at this time identify all of the false claims for payment that were caused by Defendants; conduct. The false claims were presented by several separate entities. Relator does not have access to the records of all such false or fraudulent statements, records or claims.

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

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

113. Additionally, the United States is entitled to the maximum penalty for each and every violation arising from Defendants' unlawful conduct alleged herein.

PRAYER

WHEREFORE, *qui tam* Plaintiff-Relator Leighsa Wilson prays for judgment against the Defendants as follows:

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

2. 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 for each violation of 31 U.S.C. § 3729;

3. That Relator be awarded the maximum amount allowed pursuant to § 3730(d) of the False Claims Act.

4. That Relator be awarded all costs of this action, including attorneys' fees and expenses; and

5. That Relator recover such other relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Relator hereby demands a trial by jury.

Dated: December 4, 2017

s/ Regina Dunleavy Poserina

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