UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA *ex rel.* REY C. PATRIARCA,	:	
Plaintiff,	:	**MEMORANDUM DECISION AND ORDER**
- against -	:	
SIEMENS HEALTHCARE DIAGNOSTICS, INC., BAYER DIAGNOSTICS CORPORATION,	:	11 Civ. 00181 (BMC)
Defendants.	:	

COGAN, District Judge.

Plaintiff Rey C. Patriarca ("Relator") brought this action on behalf of the United States against Siemens Healthcare Diagnostics, Inc. and Bayer Diagnostics Corporation (collectively, "Siemens") to recover damages under the False Claims Act ("FCA") for alleged fraudulent conduct from February 2006 through December 2010 (the "Relevant Time Period"). Relator claims that Siemens marketed a test to measure the levels of a certain hormone knowing that the test was flawed, and that countless medical professionals ordered treatments for patients on the basis of the test's inaccurate results. Through Medicare, the United States reimbursed many of these treatments. In response, Siemens argues that the discrepancies about which Relator complains were, in fact, widely known and, in any event, did not undermine the test. Siemens has moved to dismiss Relator's complaint, and for the reasons discussed below, Siemen's motion is granted.

BACKGROUND

I. PTH Testing and Parties

Patients with Chronic Kidney Disease ("CKD") may have high levels of parathyroid hormone ("PTH"), which can lead to bone disease. More than 26 million Americans suffer from CKD. Vitamin D analogs are used to treat high levels of PTH, but overdosing of these analogs can lead to serious health consequences. Accurate diagnosis of PTH levels is therefore critical. Doctors may also order parathyroidectomies in serious cases when PTH levels exceed a certain threshold.[1] Many patients receive care at kidney dialysis centers, and Medicare covers 75% of those patients who do.

At the time he filed the complaint, Relator worked as a District Manager for Scantibodies Clinical Laboratories, Inc. ("Scantibodies"), and was responsible for selling and marketing Scantibodies products to dialysis centers and nephrologists' office. Siemens is a major healthcare company, and in 2006 it purchased assets from Bayer Diagnostics Corporation. One of those assets, the "Siemens Test,"[2] is used to measure PTH levels.

The Siemens Test is what is known as a "Second Generation" PTH test. Second Generation Tests measure both the whole PTH molecule ("1-84" PTH) and large fragments of the molecule ("7-84" PTH). On the other hand, "Third Generation Tests" are designed to report only the level of whole PTH molecules and omit the fragments. For this reason, Second Generation Tests report PTH levels roughly twice that of Third Generation Tests.

[1] The parathyroid glands are four, pea-sized glands located in the neck that release PTH.

[2] The full name of the test is the "ADVIA Centaur Intact PTH Assay."

II. History of PTH Testing

In 1987, Nichols Diagnostics ("Nichols") produced a PTH test (the "IRMA Test") that was performed manually and required a several-hour long incubation period. The test was approved by the FDA and became the industry standard.

Five years later, Nichols produced a new, automated test, with a reduced incubation period of just 37 minutes. The new test was "aligned" with the IRMA Test, which means that its PTH measurements were consistent with the earlier test's results. Nicholas continued to launch improved tests (together, these subsequent tests are "the Nichols Tests"). The overwhelming majority of dialysis centers in the United States used Nichols Tests by the early 2000s.

By this point, many other companies, including Siemens, produced PTH tests that were purportedly aligned with the IRMA test. In 2002, Bayer sought FDA approval for two PTH tests. Bayer represented that the first, the ACS 180 Test, was 98.5% correlated to the IRMA Test (the only difference between the two was that the ACS 180 Test was automated, and the IRMA test was manual), and that the Siemens test was 99.4% correlated to the ACS 180 Test. Accordingly, Bayer argued, the Siemens test was, through the principle of transference, sufficiently correlated to the IRMA Test to warrant a "substantial equivalence" determination by the FDA.[3] The FDA agreed, and approved the Siemens test that year.

To determine substantial equivalence, the FDA looks to whether the new device has the "same technological characteristics" as the predicate device, and "does not raise different questions of safety and effectiveness." Such a finding does not necessarily mean that the two devices are the same or return identical results. For its FDA application, Siemens submitted data

[3] The FDA relied on transference when approving the Siemens Test.

showing that the Siemens Test was correlated to the ACS 180 Test, which itself was correlated to the IRMA Test, which means that the results from the three tests have a predictable relationship. This is distinct from finding that the tests yield the same results; in fact, they did not, and Siemens did not represent that they did.

Later versions of the Nichols Tests "drifted" upward, consistently overstating patient's PTH levels, leading to medically unnecessary prescriptions and surgeries. After a *qui tam* action relating to the tests' inaccuracy and a settlement, Nichols withdrew its tests from the market around 2005. The suit was brought by Relator's employer at Scantibodies, Tom Cantor. Competitors – including Siemens – stepped into the space left by the withdrawn Nichols Tests, and aggressively marketed their tests across the country.

III. Siemens Test Drift

In his complaint, Relator alleges that by early 2006 – concurrently with it becoming the dominant PTH test in the United States – the Siemens Test had materially "drifted" from the IRMA test.[4]

Relator bases his allegation primarily on roughly 20 separate "parallel" experiments he conducted between 2006 and 2010. In a parallel experiment, different PTH tests are used to analyze the same patient sample. Relator compared the Siemens Test to the PTH test developed by his own company, the "Scantibodies Test," which is a Third Generation Test.[5] Relator alleges that during the Relevant Time Period, Scantibodies conducted a bi-weekly experiment to confirm that its test remained aligned with the IRMA Test. On average, Relator alleges that the

[4] Between filing his complaint and his opposition to Siemens' motion to dismiss, Relator appears to have changed his argument somewhat. In the latter, Relator asserts that his "claims do not depend on [] proving 'drift,'" but instead describe that the Siemens Test became misaligned with the IRMA Test between February 2006 through 2010.

[5] Relator states that the FDA approved the Scantibodies Test in or about 2000, and that the FDA found that the test was "substantially equivalent" to the IRMA test.

Siemens Test measured a 42% higher amount of PTH than did the Scantibodies Test, and he concluded by transference that the Siemens test was measuring PTH 42% higher than the IRMA test.

Relator also claims that in May and June of 2010, Rubin Dialysis Center ("Rubin"), a dialysis center that sent its blood samples Spectra Laboratories, Inc. ("Spectra"), noticed higher than expected PTH levels. Spectra used the Siemens Test. Rubin then sent samples out to both Spectra and hospitals not using the Siemens Test, and discovered that the Siemens Test generated results indicating higher PTH levels.

Relator similarly describes that in the mid-2000s, Renal Care Group, Inc. ("RCG") (a dialysis chain) used the "Roche Test," which was allegedly "well-aligned with the IRMA Test." In 2006, RCG was acquired by a company that used Spectra for its lab work – and, as discussed above, Spectra used the Siemens Test. Accordingly, former RCG patients were transferred from the Roche Test to the Siemens Test, and their doctors began seeing higher than expected PTH results. Relator claims that Spectra conducted a parallel analysis of the Siemens and Roche tests in 2006, and found that the Siemens Test measured patients' PTH levels 22% higher than the Roche Test. In 2010, Spectra conducted an internal investigation to determine if its laboratory practices played any role in the apparent upward drift of PTH levels. Spectra found that its machinery was working properly.

IV. KDOQI Guidelines

In the early 2000s, doctors and scientists worked with the National Kidney Foundation to develop clinical practice guidelines to manage CKD. The Kidney Disease Outcomes Quality Initiative ("KDOQI") guidelines were published in 2003, and one of its stated purposes was to inform nephrologists about PTH testing. The guidelines were based on studies involving the

IRMA Test. Relator alleges that because of that basis, if a PTH test deviates from the IRMA Test, a doctor making medical decisions in light of the guidelines will be misguided.

Relator claims that during the Relevant Time Period, "the great majority of nephrologists . . . followed the KDOQI Guidelines," which recommended that they prescribe Vitamin D injections in response to PTH levels above a certain point, and that they order parathyroidectomies in response to PTH levels beyond a higher point. Relator points to statements by Dr. Stephen Z. Fadem, a practicing nephrologist, who claims that providers closely relied on the KDOQI PTH Guidelines in making treatment decisions. He also claims that after the Nichols Tests were removed from the market, the Siemens Test was extensively used, and that most clinicians never considered that the test had migrated upward from the IRMA Test. Dr. Fadem states that, "[i]f the [PTH] test fits the clinical picture, it is accepted as a valid measure, with trust placed on the laboratory to assure the machines are properly calibrated and the methodology is correct."

The KDOQI Guidelines also state that they "are not intended to define a standard of care, and should not be construed as one." And, as discussed above, the guidelines point out that Second Generation Tests (such as the Siemens Test) yield absolute results that are roughly double those of Third Generation Tests (such as the Scantibodies Test). Furthermore, the guidelines indicate that PTH levels are one of several data points that clinicians should consider when deciding a patient's course of treatment.

In 2010, the NKF updated its recommendations. It noted the wide "variability within and across" PTH tests, and acknowledged "analytic problems with PTH measurement." Accordingly, it recommended that therapeutic decisions should be based on trends, and not a

single test result. The NKF recommended the use of Second Generation Tests over Third Generation Tests.

V. Public Disclosures

In 2006, "a large group of renowned European scientists," studied fifteen commercially available PTH tests, including the Siemens Test, compared them to the IRMA Test, and published their findings (the "2006 Souberbielle Study"). The study made several points relevant to the instant case. First, the levels of PTH at which the KDOQI guidelines recommended specific courses of patient treatment could not be followed without knowing *which* PTH test was used, because the scientists found that the values yielded by Second Generation Tests varied widely. Second, the study found that most Second Generation Tests – including the Siemens Test – were predicative of PTH levels because they were "highly correlated" with the IRMA Test. Third, the study held that clinicians should monitor a patient's PTH levels over a series of tests, as opposed to making clinical decisions on the basis of a single finding. Fourth, the study showed that *neither* the Siemens nor the Scantibodies test yielded the same results as the IRMA Test. Furthermore, the study showed that a differential of up to 35% existed between the Siemens and Scantibodies tests.

In 2009, the authors of the 2006 Souberbielle Study published a follow-up study (the "2009 Souberbielle Study"). The authors noted that all PTH tests remained correlated with each other, but yielded different absolute results. Accordingly, they wrote that strict adherence to the KDOQI guidelines could lead to "potentially different therapeutic options." However, the report found no need to switch from Second Generation Tests to Third Generation Tests. The 2009 Souberbielle Study also disclosed that the Siemens Test was yielding absolute results that were

43% higher than the Scantibodies Test, only one percentage point off of what Relator alleges he discovered through his parallels.

A 2007 article published by Dr. Fadem noted that 1) the KDOQI guidelines were based on the IRMA Test; 2) the absolute results obtained from various PTH tests varied from those of the IRMA Test; and 3) the 2006 Souberbielle Study documented this variability. Based on these observations, Fadem recommended that nephrologists "use a single laboratory for results and look at trends in PTH as opposed to single values."

A 2009 study published by Cantor (Relator's former boss who brought a successful *qui tam* action against Nichols) disclosed the results of parallel testing of various PTH tests. In the study, Cantor concluded that the Siemens Test generated results that were on average 36% higher than the Scantibodies Test. This is nearly the same differential as that disclosed in the 2006 Souberbielle Study.

VI. Impact

Relator argues that the upward drift he observed in the Siemens Test caused physicians to prescribe "hundreds of millions of dollars of medically unnecessary Vitamin D, and to conduct untold numbers of medically unnecessary parathyroidectomies." Crucially for Relator's argument, during the Relevant Time Period, Medicare covered the cost of treatment for patients with CKD. Therefore, Medicare paid for a portion of the cost of the Siemens Test, prescribed Vitamin D and its analogs, and for surgeries related to elevated PTH levels.

Relator's complaint includes statements by several doctors who describe that they relied on results provided to them by labs using the Siemens Test in deciding upon a course of treatment for their patients. The doctors state that they acted consistent with the KDOQI Guidelines, and therefore typically prescribed Vitamin D or ordered parathyroidectomies for

patients whose PTH levels hit the relevant levels provided in the guidelines. The doctors also state that had they received test results indicating lower (and, Relator implies, more accurate) PTH levels, they would have ordered a different, lesser course of treatment, which would have involved fewer Medicare payments.

VII. Siemens' Knowledge

Relator alleges that he shared the results of his parallel experiments with Cantor, the owner of Scantibodies, who was very concerned. After seeing the results, in early 2007, Cantor went to Siemens' headquarters to present slides detailing Relator's experiments. At that time, Relator had compiled evidence from more than ten parallels, which, on average, allegedly showed that the Siemens Test was measuring PTH 51% higher than the IRMA Test. Cantor told Relator that Siemens officials responded with words to the effect of "our customers like the PTH values our test provides."

For the next several years, Relator continued to share the results of his parallels with Cantor. In 2010, Cantor sought to persuade Spectra that it should stop using the Siemens Test because of its alleged upward drift. Cantor described how the allegedly inflated PTH levels recorded by the Siemens Test was leading to a nationwide problem of overdosing Vitamin D. In response, Spectra agreed to jointly conduct a parallel comparing the Scantibodies and the Siemens tests. Spectra conducted a PTH analysis on 250 patient samples using the Siemens Test, while Scantibodies used the Scantibodies Test on the same samples. After the results were analyzed, Cantor wrote to Spectra stating that the Siemens Test "is over estimating total PTH by 45% on patient samples."

During the Relevant Time Period, Siemens conducted studies regarding the accuracy of its test, including by comparing each new lot of the Siemens Test against previous lots.

However, Relator alleges that Siemens manipulated the results of these studies so as to continue selling non-conforming lots. As an example, Relator contends that when transitioning Spectra from lot 140 of the Siemens Test to lot 143, Siemens represented to Spectra that lot 143 was sufficiently correlated to lot 140. However, Relator states that in 2009 Spectra conducted its own analysis of lots 140 and 143 and found a difference outside of the range that Siemens had specified as acceptable. When Spectra notified Siemens of the discrepancy, and informed Siemens that Spectra was considering rejecting lot 143, Siemens acknowledged that if the results were accurate, lot 143 should be recalled or rejected.

Relator alleges that Siemens' Director of Quality Control proposed a two-pronged solution to the discrepancy: first, Siemens would "move" its "internal calibrator" so that lot 143 would stay within Siemens' internal specifications; second, he advised that Spectra should compare lot 143 not against lot 140, but against a different lot that would keep the discrepancy within specification. Spectra agreed, and after satisfactory testing, accepted lot 143 as within specifications.

VIII. False Statements

Relator also alleges that Siemens made a number of false statements in the Siemens Test's Instructions for Use ("IFU"), on its website, in "Customer Bulletins" issued when the Siemens Test was altered, in customer meetings (i.e., with Spectra), and in its product labeling.

As to statements in the IFU, Relator alleges that Siemens communicated that its test was sufficiently reliable to make a quantitative assessment of PTH in a patient sample adequate for "diagnostic" purposes. As to statements on its website, Relator alleges that Siemens stated that its test was "standardized against the gold standard IRMA method." As to statements in its Customer Bulletins, Relator points to Siemens' claim in a June 2010 bulletin that the use of a

new antibody pool to develop the Siemens Test did not result in any changes in the test's performance characteristics. Furthermore, Relator claim that Siemens' failure to disclose to its customers the test's alleged upward shift was an omission in violation of its legal obligations. Similarly, Relator contends that in its meetings with customers, including Spectra, Siemens never disclosed the alleged upward shift in PTH readings. Finally, Relator argues that the Siemens' Test's labeling never disclosed an upward shift in PTH readings, but, in fact, disclosed a downward shift in 2008.

IX. Claims

In summary, Relator argues that 1) the Siemens Test was initially aligned with the IRMA Test, and remained aligned through roughly 2005, as demonstrated by the 2006 Souberbielle Study; 2) after that, the Siemens test shifted upward from the IRMA Test by approximately 40%, as demonstrated by his parallel testing; 3) Siemens knew of this upward shift through its internal testing, Cantor's meeting, and the Spectra incident; 4) despite the upward shift, Siemens continued to manufacture and sell millions of Siemens Tests; and 5) had the Siemens Test's upward shift been acknowledged, the FDA would have recalled the test and Medicare would not have paid for medically unnecessary courses of treatment ordered based on its findings.

Accordingly, Relator brings claims under the FCA under a number of theories: a lack of medical necessity (insofar as Siemens caused laboratories to submit false claims for defective testing, and caused dialysis centers and physicians to prescribe medically unnecessary courses of treatment); provision of defective and/or non-conforming goods (because the government believed it was paying for a PTH test that worked consistent with the device's FDA approval, while Siemens knew that the device was defective and/or materially nonconforming to its FDA approval); and the interstate transport and sale of misbranded devices (as FDA labels for

Siemens Tests did not inform users (laboratories and physicians) that the devices measured PTH more than 40% higher than actual PTH). Relator also pleads conspiracy, although the conspiracy count in his complaint contains no details. In his opposition brief, Relator states that it "rests largely on Siemens' manipulation of the testing and calibration of Lot 143 of the Siemens Test, and its communications with a customer regarding the same."

DISCUSSION

"The [FCA] imposes liability on any person who 'knowingly presents . . . a false or fraudulent claim for payment or approval,' 'to an officer or employee of the United States." Kellogg Brown & Root Servs., Inc. v. U.S., ex rel. Carter, 135 S. Ct. 1970, 1973 (2015) (internal quotations and citations omitted). "The FCA defines a 'claim' as any request or demand . . . for money or property that is presented, directly or indirectly, to the United States." United States ex rel. Chorches for Bankr. Estate of Fabula v. Am. Med. Response, Inc. ("Fabula"), 865 F.3d 71, 81 (2d Cir. 2017) (internal quotations and alterations omitted). The FCA "may be enforced not just through litigation brought by the Government itself, but also through civil *qui tam* actions that are filed by private parties, called relators, in the name of the Government." Id. (internal quotations omitted).

I. Public Disclosure Bar

A. *2010 Amendment*

Claims under the FCA are subject to a public disclosure bar that prohibits a relator from bringing a claim for conduct that has already been made public. The bar is intended to discourage "opportunistic plaintiffs who have no significant information to contribute of their own." Graham Cty. Soil & Water Conservation Dist. v. U.S. ex rel. Wilson, 559 U.S. 280, 294 (2010); see also U.S. ex rel. Doe v. John Doe Corp., 960 F.2d 318, 319 (2d Cir. 1992)

(discussing "the potential for parasitic lawsuits by those who learn of the fraud through public channels and seek remuneration although they contributed nothing to the exposure of the fraud.").

The statute providing for the public disclosure bar was amended in 2010. For a complaint based primarily on pre-2010 conduct, the bar is jurisdictional, and serves as a basis for dismissal under Federal Rule of Civil Procedure 12(b)(1). See Fabula, 865 F.3d at 80. Following the 2010 amendment, the public disclosure bar operates on conduct that occurred after 2010 as a basis for dismissal under Rule 12(b)(6). Id.

"Since the amendment does not mention retroactivity and effects a substantive change in the law, the conduct alleged in [a relator's] complaint must be assessed under the law that existed when the conduct took place." United States ex rel. Amico v. Deutsche Bank AG, No. 15 CIV. 9551, 2017 WL 2266988, at *4 n. 4 (S.D.N.Y. May 8, 2017) (citing Hughes Aircraft Co. v. U.S. ex rel. Schumer, 520 U.S. 939, 946 (1997)). Accordingly, "the pre-2010 version of the public disclosure bar applie[s] to any conduct that occurred prior to the amendment and that the post-2010 version applie[s] to any conduct that occurred after the effective date of the 2010 amendment." United States v. Catholic Health Sys. of Long Island Inc., No. 12-CV-4425, 2017 WL 1239589, at *10 (E.D.N.Y. Mar. 31, 2017). Every Court of Appeals to address the issue has so held, either in a precedential or non-precedential decision. See United States ex rel. Saldivar v. Fresenius Med. Care Holdings, Inc., 841 F.3d 927, 933, n.1 (11th Cir. 2016); United States ex rel. Bloedow v. Planned Parenthood of the Great Nw. Inc, 654 F. App'x 335, n.1 (9th Cir. 2016); United States ex rel Gage v. Davis S.R. Aviation, L.L.C., 658 F. App'x 194, 197, n. 1 (5th Cir. 2016); U.S. ex rel. Ziebell v. Fox Valley Workforce Dev. Bd., Inc., 806 F.3d 946, 951-52 (7th Cir. 2015); U.S. ex rel. Antoon v. Cleveland Clinic Found., 788 F.3d 605, 614-15 (6th Cir.

2015); U.S. ex rel. Judd v. Quest Diagnostics Inc., 638 F. App'x 162, 165 (3d Cir. 2015); U.S. ex rel. May v. Purdue Pharma L.P., 737 F.3d 908, 915 (4th Cir. 2013).

Because the Relevant Time Period here covers claims submitted through December 31, 2010, the bar could serve as a basis for dismissal under Rule 12(b)(1) for claims submitted before March, 2010 (the data of amendment) and as a basis for dismissal under Rule 12(b)(6) for claims submitted after. See Id. at *10.

Under both the pre and post amendment versions of the FCA, courts analyzing the applicability of the public disclosure bar apply a two-step approach. See U.S. ex rel. Kester v. Novartis Pharm. Corp., 43 F. Supp. 3d 332, 346 (S.D.N.Y. 2014). At the first step, courts look to whether the substance of a relator's claim had been disclosed prior to the filing of his suit. At the second step, courts look to whether, if such disclosures had been made, the relator can be considered an "original source." Id. If so, the relator may proceed with his complaint.

B. *Step 1: Public Disclosures*

1. *Standard*

"Prior to the 2010 amendment, the bar applied where a *qui tam* action was *'based upon* the public disclosure of allegations or transactions.'" Id. (citing 31 U.S.C. § 3730(e)(4)(A) (2006)) (emphasis in original). "The Second Circuit follows the majority view and has repeatedly held that the relator's claim is 'based upon' the public disclosure if the allegations in the complaint are 'substantially similar' to the publicly disclosed information." United States v. Dialysis Clinic, Inc., No. 5:09-CV-00710, 2011 WL 167246, at *6 (N.D.N.Y. Jan. 19, 2011); see Leveski v. ITT Educ. Servs., Inc., 719 F.3d 818, 828 (7th Cir. 2013) ("we have previously interpreted the phrase 'based upon [a] public disclosure' to mean 'substantially similar to

publicly disclosed allegations,' in accordance with virtually every other circuit that has interpreted this phrase."); John Doe Corp., 960 F.2d at 324.

The 2010 amendment generally conformed the statutory language to the majority judicial interpretation of the pre-amendment language: the new language articulated the inquiry as whether "*substantially the same* allegations or transactions as alleged in the action or claim were publicly disclosed." Novartis Pharm. Corp., 43 F. Supp. 3d at 346 (citing 31 U.S.C. § 3730(e)(4)(A) (2010)) (emphasis in original). Therefore, "under both the pre- and post-2010 versions of the statute, courts assess whether the allegations in a *qui tam* complaint are 'substantially the same' as or 'substantially similar' to the allegations of fraud contained in the public disclosures in question." Id. (citing Ping Chen ex rel. U.S. v. EMSL Analytical, Inc., 966 F. Supp. 2d 282, 298 (S.D.N.Y. 2013)). Accordingly, the "general case law pertaining to the public disclosure bar would still be applicable to this Court regardless of if it was decided before or after the [2010 amendment]." EMSL Analytical, Inc., 966 F. Supp. 2d at 298, n.11 (internal citations and quotations omitted).

The Second Circuit has applied a broad view of the public disclosure bar. The Circuit does not require that the relator base all of his allegations on previously disclosed public information for the bar to come into effect. See U.S. ex rel. Kirk v. Schindler Elevator Corp., 437 F. App'x 13, 17 (2d Cir. 2011) ("We have previously interpreted this phrase to mean that the public disclosure bar applies to claims "based *in any part* upon publicly disclosed allegations or transactions."); U.S. ex rel. Kreindler & Kreindler v. United Techs. Corp., 985 F.2d 1148, 1158 (2d Cir. 1993) ("[T]he statute applies to a "*qui tam* action . . . based in any part upon publicly disclosed allegations or transactions."). Earlier disclosures will bar a relator's claim if they were "sufficient to set the government squarely upon the trail of the alleged fraud." EMSL Analytical,

Inc., 966 F. Supp. 2d at 298 (internal quotations omitted). The bar is triggered if "material elements" of the fraud have been publicly disclosed, and does not require that the alleged fraud, itself, have been disclosed. See U.S. ex rel. Rosner v. WB/Stellar IP Owner, L.L.C., 739 F. Supp. 2d 396, 405 (S.D.N.Y. 2010); see also Monaghan v. Henry Phipps Plaza W., Inc., 531 F. App'x 127, 130 (2d Cir. 2013).

Furthermore, "[m]erely providing more specific details about what happened does not negate substantial similarity." United States ex rel. Oliver v. Philip Morris USA Inc., 826 F.3d 466, 472 (D.C. Cir. 2016) (internal quotations omitted). A relator likewise does not overcome the bar by simply decoding or translating publicly available complex or technical information into a digestible form. See U.S. ex rel. Springfield Terminal Ry. Co. v. Quinn, 14 F.3d 645, 655 (D.C. Cir. 1994) ("Similarly, there may be situations in which all of the critical elements of fraud have been publicly disclosed, but in a form not accessible to most people, *i.e.*, engineering blueprints on file with a public agency. Expertise in the field of engineering would not in itself give a *qui tam* plaintiff the basis for suit when all the material elements of fraud are publicly available, though not readily comprehensible to nonexperts.").

The FCA provides a list of sources that count as "public disclosures." See 31 U.S.C. § 3730(4)(A). The list includes "the news media." Id. Guided by the precept that information is in the public domain where it is accessible by those not a party to the fraud, see John Doe Corp., 960 F.2d at 322, courts routinely interpret the "news media" to include disclosure in scientific and scholarly journals. See U.S. ex rel. Alcohol Found., Inc. v. Kalmanovitz Charitable Found., Inc., 186 F. Supp. 2d 458, 463 (S.D.N.Y.) ("the ordinary meaning of the statutory term 'news media,' would encompass the publication of information in scholarly or scientific periodicals."); see also, Novartis Pharm. Corp., 43 F. Supp. 3d at 346 (the public disclosure bar encompasses

"disclosures directed to smaller or professionally specialized reader bases." (internal quotations omitted)); U.S. ex rel. Rosner v. WB/Stellar IP Owner, L.L.C., 739 F. Supp. 2d 396, 402 (S.D.N.Y. 2010) ("Public disclosure occurs even if the information is not 'widely disseminated . . . '").

2. *Application*

As noted above, Relator seems to have changed the focus of his argument from the unsealing of his Amended Complaint to his opposition to Siemens' motion to dismiss. Originally, Relator claimed that the Siemens Test drifted out of alignment with the IRMA Test between 2005 and 2006. However, in a footnote in opposition to the motion to dismiss, Relator asserts that his "claims do not depend on [] proving 'drift.'" Instead, Relator's revised theory turns on his assertion that "starting on or before February 2006 through 2010, the Siemens Test was misaligned with the Nichols Test by a positive bias averaging over 40%."[6]

Relator reached this conclusion by conducting a series of parallel experiments, which measured the relation between the Siemens Test and the Scantibodies Test. Based on his assertion that the Scantibodies Test was consistently correlated to the IRMA Test, Relator inferred from the Siemens Test's deviation from the Scantibodies Test that the former also deviated from the IRMA Test, with which Siemens represented its test had a steady relationship.

Siemens argues that nearly the exact average differential figure between the Siemens and Scantibodies test at which Relator arrived over the course of his studies was disclosed in the public record. It also claims that the fact of significant differentials between PTH tests was

[6] Of course, at some point a "drift" or change must have occurred under Relator's theory of original alignment and subsequent misalignment.

widely known.[7] First, Siemens points to a number of studies released before Relator filed his complaint that show deviation between the Siemens Test and the Scantibodies Test within a narrow range around Relator's own findings. Second, Siemens points to publically available findings urging practitioners to incorporate the fact of different readings across and within studies. The results of these public disclosures compel the application of the bar against Relator's claims.

i. *The Differential Between the Siemens and Scantibodies Tests was Publically Disclosed*

First, Siemens points to the 2006 Souberbielle Study, which compared how 14 different commercially available tests detected PTH levels against three different concentration levels measured by the IRMA Test. The Siemens and Scantibodies tests were both included in the study.

When measuring the three concentration levels, the Siemens and Scantibodies tests deviated from each other's results by 25%, 31%, and 35% – close to the 42% average deviation between the two detected by Relator's parallels. The 2006 Souberbielle Study also showed that the Scantibodies and Siemens tests had a -14.5% and 9.5% deviation from the IRMA Test, respectively. In other words, neither test captured the same absolute values as the IRMA Test.

Relator responds to the 2006 Souberbielle Study in three ways: first, he makes several points about the study's methodology, with the presumed aim of distinguishing its findings from

[7] Because the public disclosure bar operates jurisdictionally on conduct before March, 2010, the Court can look to materials outside of the pleadings to satisfy itself that jurisdiction is proper when considering Relator's pre-amendment claims. See J.S. ex rel. N.S. v. Attica Cent. Sch., 386 F.3d 107, 110 (2d Cir. 2004). Therefore, the Court can take into account the studies that Siemens references in its briefs. For conduct after March 2010, the bar operates as a grounds for dismissal for failure to state a claim. The 2006 Souberbielle Study and the KDOQI guidelines are both cited and discussed in Relator's complaint. These documents are sufficiently important to the complaint so that they can be considered incorporated by reference, and therefore, the Court can consider them on a 12(b)(6) motion. See DiFolco v. MSNBC Cable L.L.C., 622 F.3d 104, 111 (2d Cir. 2010). For the reasons discussed below, those studies, alone, constitute a sufficient basis to apply the public disclosure bar.

those he arrived at; second, he claims that unlike his studies, it represents only a snapshot of a single period, and accordingly has no bearing on his claim that the Siemens Test later departed from a baseline; and third, he argues that the rough correspondence (9.5% deviation) between the Siemens and IRMA tests indicates the significance of the Siemens' test alleged later deviation.

Relator's methodological points are unconvincing. His purpose is plainly to try and set apart the 2006 findings from his own. To do so, he emphasizes the nature of the blood samples tested, the labs that tested them, and the use of blood serum as opposed to blood plasma (which was used in Relator's parallels). But before Siemens offered the study's findings as justification for imposition of the public disclosure bar, Relator *himself* cited approvingly to the study in his complaint, describing it as "an extensive scientific study [] undertaken by a large group of renowned European scientists." Furthermore, Relator does not contend that to the extent any of these distinctions are actually technically significant, they existed solely as to any one of the PTH tests studied; instead, it appears that they would apply in equal measure to all of the compared tests. The key takeaway from the study for purposes of public disclosure bar analysis is that the percentage deviation Relator claims to have discovered between the Siemens and Scantibodies test was earlier announced. There is no reason to believe that any of the methodological distinctions Relator highlighted between the 2006 Souberbielle Study and his own parallels affected the relation between the Siemens and Scantibodies tests, as opposed to the absolute levels of PTH that each detected.

Next, Relator argues that the study's presentation of just a snapshot of the relationship between the Siemens and Scantibodies tests does not publically disclose his claim of later change. However, regardless of whether Relator relies on the theory in his complaint or in opposition to the motion, the 2006 Souberbielle Study is problematic for him, because in 2006,

before any drift or arrival at a final misalignment, the Siemens Test was shown to correspond to the Scantibodies Test with nearly the exact differential that he claims it *later* arrived at. In other words, the circumstance he claims to have discovered was, in fact, disclosed nearly half a decade earlier.

Relator's final argument against the study – that it discloses close correspondence before 2006 between the Siemens and IRMA Tests against the former's later deviation – is immaterial. As described above, Relator's parallels were not a direct comparison of the Siemens and IRMA tests. Instead, they measured the Siemens and Scantibodies tests against each other, and generated results of the differential between the two. Relator did not calculate what differential between the Siemens Test and the IRMA Test would follow from the differential measured in his parallels between the Siemens and the Scantibodies tests. Therefore, the 42% differential Relator alleges he discovered between the Siemens and Scantibodies tests has only an indirect and undisclosed relationship to the 9.5% bias between the Siemens and the IRMA tests disclosed in the 2006 Souberbielle Study.

Second, Siemens points to a 2009 update to the Souberbielle Study, which reported that the Siemens Test yielded results that were 43% higher than the Scantibodies Test – one percentage off from what Relator claims to have uncovered. Relator levels a series of arguments against the validity and relevance of this study, none of which have any purchase against the inescapable fact that it discloses virtually the same results at which he claims to have uniquely arrived.[8]

[8] It is worth noting that Relator concedes that although the "study authors sought to determine a 'correction factor' for commercially available assays which were misaligned with the Nichols Test . . . they did not recommend a correction factor for the Siemens Test." In other words, the authors found that as of the publication of the study in 2009, the Siemens Test remained well-aligned with the IRMA Test.

Relator claims that the 2009 study used data from 2005, presumably to imply that the results do not bear on his allegation of the Siemens Test's drift or later misalignment against the IRMA Test. But this is not so; the study expressly says that its results are based on data collected in 2008. Relator also argues that the "confidence intervals" (which function akin to margins of errors in public polls) for the Siemens and Scantibodies test results render the reported 43% differential between the two tests illusory. But every study – including Relator's parallels[9] – will yield results with margins of errors, and their presence here does not diminish the significance of results nearly identical to those derived by Relator.

Relator next focuses on the methodology of the 2009 Souberbielle Study (as he did with the 2006 version), attempting to distinguish it from his own tests. He points out, for example, that the authors "amassed [results] from untold numbers of dialysis centers across 19 geographical regions in France." Relator contends that there exist relevant differences between general patient profiles in France and America, but he puts forth no reason to suspect that the relative, as opposed to absolute, yields of the Siemens and Scantibodies tests would be any different when testing American samples. As with his methodological efforts against the 2006 Souberbielle Study, Relator's points here do nothing to change the fact that the 2009 study disclosed nearly same differential between the Siemens and Scantibodies tests at which he arrived.

Siemens also points to a 2009 study conducted by Tom Cantor (Relator's employer), and others. The study disclosed that as of 2009, the Siemens and Scantibodies tests had a percentage differential of 36%.

[9] Notably, Relator does not appear to have included any margin of error or confidence intervals for *his* parallels.

Relator's response to the study is disingenuous: he claims that "the differential between the Siemens Test and the [Scantibodies Test] does not disclose the differential between the Siemens Test and the [IRMA] Test." But, as noted above, Relator did not do that either. Siemens correctly notes in its reply brief, "the Cantor study did *exactly* what [Relator's] complaint did two years later: it analyzed and disclosed the differential between the Siemens Test and the Scantibodies Test . . ." (emphasis in original). Relator also argues that the article does not count as a public disclosure because it was published in a journal with an annual subscription fee. This argument has no traction: as described above, courts regularly hold that scholarly works published in small-circulation journals qualify as public disclosures.

As he did with the Souberbielle studies, Relator disputes the Cantor study's methodology, and attempts to distinguish it from his own analysis. But just like his arguments against those studies, he makes no showing that the relative performance of the Siemens and Scantibodies tests would be altered with different variables or inputs; in other words, he does not show that the 36% break between the two would be any different. Instead, he only makes some arguments that would, if viable, indicate that the two tests might yield different absolute values under different conditions.

The 2006 and 2009 Souberbielle studies and the 2009 Cantor Study inescapably disclose the key information at the heart of Relator's complaint – that the Siemens and Scantibodies test yielded PTH results with a roughly 42% differential from each other.[10] Relator's attempts to challenge the validity of these studies, question their relevance, and distinguish his own parallels

[10] The Court notes that three of Relator's parallels were generated after the latest study (the 2009 Cantor study). These parallels yielded unremarkable results that fell in line with those produced by the earlier parallels, and Relator cannot credibly claim that anything distinct was provided in these last tests. These later tests yield results that are "substantially the same" as what had been publically disclosed prior to the filing of Relator's complaint.

are unavailing. At the end of the day, he cannot get around the fact that what he claims to have discovered was soundly public knowledge for years before he brought this action.

ii. *Differences Between PTH Tests Were Widely Known and Practitioners Were Told to Adjust Their Procedures Accordingly*

The above described studies are independently fatal to Relator's claims under the public disclosure bar because they show that nearly the exact differential between the Siemens and Scantibodies tests that Relator arrived at was publically available for years. Those studies, and others, also contain further disclosures that implicitly and explicitly disclosed the fact of a differential between PTH tests, generally. These conclusions further undermine Relator's contention to have contributed findings not already announced.

First, the KDOQI guidelines established in 2003 that second-generation PTH tests, including the Siemens Test, yield results roughly twice as high as those produced by third-generation tests, including the Scantibodies Test. This finding was repeated in the 2006 Souberbielle Study, which noted, "the [KDOQI] guidelines acknowledge that the third-generation PTH assays provide lower values than the second-generation [] assays." The 2009 Souberbielle Study confirmed this again: "the third-generation assays give lower values than the second-generation assays . . ." In light of these repeated findings, divergence between the Siemens and Scantibodies tests could have hardly come as a surprise.

Second, differences in measurements between tests were so well-known (and potentially medically significant) that numerous studies recommended that practitioners use a single test over time. For instance, the 2006 Souberbielle study noted, "[w]e demonstrate here that the [KDOQI] recommended limits are not applicable independently of the knowledge of the PTH assay used," and "it cannot be excluded that the decision to recommend parathyroidectomy in CKD patients may be influenced by this inter-method variability." The same study went on to

note that "the different second-generation ('intact') PTH assays recognize synthetic 7-84 PTH with various degrees of cross-reactivity as reported previously with some assays . . ." It concluded by stating, "we show important inter-method variation in PTH results. As a consequence, the therapeutic decision based on unique cutoff levels such as those recommended in [KDOQI] guidelines may depend on the PTH assay used."

Similarly, the Cantor study noted that "[t]he demonstrated differences in absolute numbers between the iPTH assays highlight that the type of assay must be considered when therapeutic decisions are made based on serum iPTH results." Even Dr. Fadem, who contributed to Relator's complaint, published a 2007 article advising the use of "a single laboratory for results" and urging doctors to "look at trends in PTH as opposed to single values."

Taken together, these conclusions clearly show that the general fact of divergence across PTH tests was public knowledge, and that practitioners had been encouraged for years in professional studies to adjust their treatment plans accordingly. This further erodes Relator's claim to have provided any novel information.

In sum, before Relator filed his complaint, 1) variation between PTH tests was widely known; 2) physicians were advised to adjust their course of treatment accordingly; 3) Second Generation tests, such as the Siemens Test, were known to yield higher absolute results than Third Generation tests, such as the Scantibodies Test; and 4) the average difference between the Siemens and Scantibodies tests had been published in several studies. Relator's lack of medical necessity, provision of defective and/or nonconforming goods, and interstate transport and sale of misbranded devices theories all fail because information critical to Relator's allegation of a differential between the Siemens and Scantibodies tests (and, *arguendo*, through transference,

the IRMA Test) – which necessarily undergirds the three theories – was squarely publically disclosed.

C. *Step 2: Original Source*

1. *Standard*

As noted above, a relator's claim will not be dismissed if he can establish that despite earlier public disclosures, he qualifies as an "original source." Under the pre-amendment version of the FCA, an original source was defined as "an individual who has direct and independent knowledge of the information on which the allegations are based and has voluntarily provided the information to the Government before filing an action under this section which is based on the information." 31 U.S.C § 3730(e)(4)(A) (2006). Under the 2010 version, and as relevant here, an "original source" is defined as an individual who "has knowledge that is independent of and materially adds to the publicly disclosed allegations or transactions, and who has voluntarily provided the information to the Government before filing an action under this section." 31 U.S.C. § 3730(e)(4)(A) (2010).

Although the pre- and post-amendment standards for determining if earlier available information counts as a public disclosure are functionally the same, the 2010 amendment effects a change in the rigorousness of the "original source" requirement. The Second Circuit has not yet decided which definition should apply when a relator's allegations include pre and post 2010 conduct. See United States ex rel Coyne v. Amgen, Inc., 229 F. Supp. 3d 159, 171 (E.D.N.Y.), report and recommendation adopted United States ex rel. Coyne v. Amgen, Inc., 243 F. Supp. 3d 295 (E.D.N.Y. 2017), aff'd, Coyne v. Amgen, Inc., No. 17-1522-CV, 2017 WL 6459267 (2d Cir. Dec. 18, 2017) (summary order). However, because, as discussed below,

Relator is not an original source under even the more generous post-amendment statute, the Court need not decide which version should apply.

Other Circuits have addressed this issue, and in so doing, have made clear that the task is not an easy one. For instance, the First Circuit has held that a relator only qualifies as an original source if his "new information is sufficiently significant or essential so as to fall into the narrow category of information that materially adds to what has already been revealed through public disclosures." United States ex rel. Winkelman v. CVS Caremark Corp., 827 F.3d 201, 211 (1st Cir. 2016). Accordingly, "a relator who merely adds detail or color to previously disclosed elements of an alleged scheme is not materially adding to the public disclosures." Id. The Eighth Circuit declined to hold that a relator was an original source when the "key facts" to his claims were "already thoroughly revealed," making it impossible to "say his knowledge (even if gained early and independently) materially contributes anything of import to the public knowledge about the alleged fraud." U.S. ex rel. Paulos v. Stryker Corp., 762 F.3d 688, 694 (8th Cir. 2014). The D.C. Circuit noted that with the 2010 amendment, Congress changed the FCA "to provide incentives to *only* those relators whose information adds value." U.S. ex rel. Davis v. D.C., 679 F.3d 832, 839 (D.C. Cir. 2012) (emphasis added). Particularly relevant to this suit is the notion that, "[j]ust as combining publicly available information with specialized expertise is not sufficient to overcome the first step of the public disclosure bar, neither does conducting an analysis based on such expertise qualify a relator as an original source." United States ex rel. JDJ & Assocs. LLP v. Natixis, No. 15-CV-5427, 2017 WL 4357797, at *11 (S.D.N.Y. Sept. 29, 2017). Instead, "a relator must bring more than expertise or a novel analysis to the table in order to avoid the public disclosure bar." Id.

2. *Application*

Here, Relator is clearly not an original source; his work is neither independent of nor contributes materially to that which was already available.

First, as described above, over the course of years, the Siemens and Scantibodies tests had been repeatedly compared to each other in a number of published studies. Relator's descriptions of his personal involvement in and thoroughness of his parallels notwithstanding, he makes no plausible allegation that his approach was significantly "independent" of these previously conducted studies. Second, his parallels produced results that did not materially depart from those arrived at earlier by others. His findings are not "sufficiently or qualitatively different from the core information" already publicly disclosed. Amgen, Inc., 229 F. Supp. 3d at 173.

The fact that Relator has made allegations of fraud does not convert his parallel results – which largely track with information that had been publicly available – into knowledge independent of and materially additive to that which was already disclosed. Accordingly, the original source exception is inapplicable, and the public disclosure bar comes into effect.

II. Relator's Conspiracy Claim

Although sparsely plead, it appears that Relator bases his conspiracy claim on his description of Siemens' apparent effort to get one lot of its test to align with a previous lot. Relator alleges that Siemens improperly adjusted various test parameters in order to represent the tests as coinciding, and that as a result, tens of thousands of false claims were submitted to the Government.

Relator argues that the public disclosure bar does not reach this count of his complaint, but he misunderstands the reach of that rule: as described above, it does not come into effect only if a relator's particular allegations were matters of public record, but rather works to block *qui tam* claims based in any part on publically available information sufficient to put the Government on notice that it was being defrauded. Accordingly, insofar as the gist of this allegation is to show that the Siemens Test deviated from the IRMA Test (through Relator's comparisons with the Scantibodies Test), it is barred.

However, to the extent that Relator intends his conspiracy charge to stand on its own, it is dismissed for failure to state a claim. A plaintiff's complaint must "contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" Ashcroft v. Iqbal, 556 U.S. 662, at 678 (2009) (citing Bell Atl. Corp. v. Twombly, 550 U.S. 544, 547, 127 S. Ct. 1955 (2007)). "A claim has facial plausibility when the pleaded factual content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. (citation omitted). Therefore, the "plausibility standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully." Id. (citation omitted).

Here, Relator has alleged conduct that is every bit as consistent with a description of Siemens innocently and routinely working to carry out presumably frequent adjustments of its tests' parameters as it is with unlawful conduct. Especially in light of the variability *within* PTH tests described above, Relator has simply not nudged his allegations over the line to plausibility.

CONCLUSION

Defendants' motion to dismiss is granted. The Clerk is directed to enter judgment, dismissing the complaint.

SO ORDERED.

Digitally signed by Brian M. Cogan

U.S.D.J.

Dated: Brooklyn, New York
March 14, 2018