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**UNITED STATES EX REL. ESTATE OF ROBERT CUNNINGHAM, Plaintiff,
Appellant, v. MILLENNIUM LABORATORIES OF CALIFORNIA, INC.,
Defendant, Appellee.**

No. 12-1258

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

2013 U.S. App. LEXIS 7398

April 12, 2013, Decided**PRIOR HISTORY:** [*1]

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS. Hon. Joseph L. Tauro, U.S. District Judge. *United States ex rel. Estate of Cunningham v. Millennium Labs.*, 841 F. Supp. 2d 523, 2012 U.S. Dist. LEXIS 10347 (D. Mass., 2012)

DISPOSITION: Affirmed in Part, Vacated in Part, and Remanded.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff, the estate of the relator, brought a federal *False Claims Act* (FCA) suit alleging that defendant corporation encouraged physicians to bill the government multiple times for single drug tests and to perform excessive, medically unnecessary original and confirmation tests. The United States District Court for the District of Massachusetts dismissed the complaint for lack of subject matter jurisdiction. The relator appealed.

OVERVIEW: The relator argued that the district court erred when it found that the corporation's California complaint had publicly disclosed all of the allegations made in the relator's complaint. The court found that the district court was correct in finding that all requirements of the public disclosure bar were met as to the relator's FCA claim based on the allegations concerning multiple billing for single test kits because the allegations in both the federal and California suits detailed a scheme involving multiple billing or individual billing for the unbundled components for a single test. The relator's

FCA claim based on its allegations of improper confirmation testing was also barred since the information was both publicly disclosed and was substantially similar to information provided in the corporation's California suit. Finally, the relator's factual allegations pertaining to excessive testing without medical necessity may not have been subject to the FCA's public disclosure bar because neither the corporation's California complaint nor the e-mails attached thereto mentioned this kind of excessively frequent testing as part of the corporation's fraudulent scheme.

OUTCOME: The district court's order was affirmed with respect to the dismissal of two of the claims. The district court's order was vacated with respect to the dismissal of the claim concerning excessively frequent testing. The excessive testing claim was remanded to the district court for its consideration of whether the relator alleged sufficient facts to survive dismissal under *Fed. R. Civ. P. 12(b)(6)* and *9(b)*.

CORE TERMS: billing, testing, public disclosure, confirmation, e-mail, sheet, disclosure, fraudulent, laboratory, kit, patient's, encouraged, matter jurisdiction, publicly, account executives, excessive, screening, screen, lab, fraudulent scheme, billed, substantially similar, jurisdictionally, jurisdictional, pertaining, amend, conspiracy, clinic, medically, incorrect

LexisNexis(R) Headnotes*Civil Procedure > Jurisdiction > General Overview*

[HN1]Jurisdiction is determined based on whether it existed at the time the plaintiff filed the original complaint.

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > General Overview

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Defects of Form

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Motions to Dismiss

Civil Procedure > Pleading & Practice > Pleadings > Rule Application & Interpretation

[HN2]Ordinarily, the issue of stating multiple claims in a single count is dealt with as a "shotgun" pleading, or a pleading that fails to identify claims with sufficient clarity to enable a defendant to frame a responsive pleading. Under *Fed. R. Civ. P. 10(b)*, a party must state each claim founded on a separate transaction or occurrence in a separate count or defense if doing so would promote clarity. However, a pleading deficiency is usually addressed by motion for a more definite statement pursuant to *Fed. R. Civ. P. 12(e)*, and unless none of the multiple claims alleged in a single count assert a ground for subject matter jurisdiction, the "shotgun" nature of the pleading on its own cannot serve as a basis for granting a motion to dismiss pursuant to *Fed. R. Civ. P. 12(b)(1)*.

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > General Overview

Civil Procedure > Pleading & Practice > Defenses, Demurrers & Objections > Motions to Dismiss

Civil Procedure > Appeals > Standards of Review > De Novo Review

[HN3]An appellate court reviews de novo a district court's dismissal of a complaint for lack of subject matter jurisdiction. Jurisdiction is determined based on whether it existed at the time the plaintiff filed the original complaint.

Labor & Employment Law > Employer Liability > False Claims Act > Coverage & Definitions > Jurisdictional Bar

[HN4]See 31 U.S.C.S. § 3730(e)(4)(A).

Labor & Employment Law > Employer Liability > False Claims Act > Coverage & Definitions > Jurisdictional Bar

Labor & Employment Law > Employer Liability > False Claims Act > Coverage & Definitions > Original Source

[HN5]For the *False Claims Act* (FCA) public disclosure bar to apply, each of three elements must be met: (1) a public disclosure of the allegations or transactions in a relator's complaint must have occurred; (2) said disclosure must have occurred in the manner which is specified in the FCA; and (3) the relator's suit must be based upon those publicly disclosed allegations or transactions. If those elements have been met, then a court may only exercise jurisdiction over the suit if the relator falls within the "original source" exception.

Labor & Employment Law > Employer Liability > False Claims Act > Coverage & Definitions > Jurisdictional Bar

[HN6]In the context of the *False Claims Act* public disclosure bar, a prior public disclosure may occur through any public document available on the docket in a civil hearing. To be a disclosure of fraud, a disclosure must either contain a direct allegation of fraud or allow for a proper inference of fraud by revealing a misrepresented state of facts in conjunction with a true state of facts. In assessing whether a given later-filed suit is based upon publicly disclosed allegations, a court looks to whether those allegations are substantially similar to said allegations. The court does this by comparing the substance of the prior disclosures with the substance of a relator's complaint.

Civil Procedure > Jurisdiction > Subject Matter Jurisdiction > General Overview

[HN7]A court must determine whether it has subject matter jurisdiction over an action based on the original complaint filed.

Labor & Employment Law > Employer Liability > False Claims Act > Coverage & Definitions > Jurisdictional Bar

[HN8]In the context of the *False Claims Act* public disclosure bar and whether a given later-filed suit is based upon publicly disclosed allegations, a court does not determine whether information in a subsequently filed action is based upon a prior filing in terms of whether the former is parasitic to the latter. Rather, the court compares the respective substance of the prior disclosures with a relator's complaint and determine if they are substantially similar.

Evidence > Procedural Considerations > Burdens of Proof > Preponderance of Evidence

Labor & Employment Law > Employer Liability > False Claims Act > Coverage & Definitions > Original Source

[HN9]An "original source," as defined by former 31 U.S.C.S. § 3730(e)(4)(B), is 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 the section which is based on the information. § 3730(e)(4)(B). Knowledge is direct if it is as marked by absence of an intervening agency, instrumentality, or influence: immediate. Knowledge is not direct if it is based on research into public records, review of publicly disclosed materials, or some combination of these techniques. Knowledge is independent if it did not depend on the public disclosure or if it merely constitutes a use of an individual's unique expertise or training to conclude that the material elements already in the public domain constitute a false claim. The relator as the proponent of federal jurisdiction bears the burden of proving its existence by a preponderance of the evidence.

Civil Procedure > Appeals > Reviewability > Preservation for Review

[HN10]If any principle is settled in the First Circuit, it is that, absent the most extraordinary circumstances, legal theories not raised squarely in the lower court cannot be broached for the first time on appeal.

Labor & Employment Law > Employer Liability > False Claims Act > Coverage & Definitions > Original Source

[HN11]In the context of former 31 U.S.C.S. § 3730(e)(4)(B), knowledge that is based on research into public records, review of publicly disclosed materials, or some combination of these techniques is not direct.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

Civil Procedure > Appeals > Standards of Review > Abuse of Discretion

[HN12]An appellate court reviews a district court's denial of leave to amend a complaint for abuse of discretion.

Civil Procedure > Pleading & Practice > Pleadings > Amended Pleadings > Leave of Court

Civil Procedure > Pleading & Practice > Pleadings >

Heightened Pleading Requirements > General Overview

[HN13]For deficiencies under *Fed. R. Civ. P. 9(b)*, leave to amend is often given, at least for plausible claims.

Civil Procedure > Appeals > Reviewability > Preservation for Review

[HN14]It is a general rule that a federal appellate court does not consider an issue not passed upon below.

COUNSEL: John Roddy, with whom Elizabeth Ryan, Bailey & Glasser LLP, Robert A. Griffith, Dana P. Petrillo, and Gargiulo/Rudnick, LLP, was on brief for appellant.

Catherine E. Stetson, with whom Jessica L. Ellsworth, David M. Ginn, and Hogan Lovells US LLP, were on brief for appellee.

JUDGES: Before Torruella, Howard and Thompson, Circuit Judges.

OPINION BY: TORRUELLA

OPINION

TORRUELLA, Circuit Judge. This is an appeal from a dismissal of a federal *False Claims Act* ("FCA") complaint on grounds that it was jurisdictionally barred by the FCA's public disclosure provision. The Appellant, the Estate of Robert Cunningham ("Relator"),¹ brought an FCA suit against Millennium Laboratories of California ("Millennium") and John Doe physicians (collectively, "Appellees"), alleging that Millennium encouraged physicians to bill the government multiple times for single drug tests and to perform excessive, medically unnecessary original and confirmation tests.

1 Robert Cunningham passed away on December 5, 2010. After his death, the Estate of Robert Cunningham was substituted [*2] as Relator.

Prior to the filing of said complaint, Millennium had filed a suit against Relator's employer, Calloway Laboratories ("Calloway"), in California state court ("California suit"), attaching e-mails from Calloway employees to third parties suggesting fraudulent activity in Millennium's billing practices. The district court found this prior disclosure to constitute a jurisdictional bar to Relator's suit, dismissing his complaint. This appeal

followed.

Since we find error in the district court's dismissal of all of Relator's claims when only some of them had been disclosed by way of being substantially similar to the information contained in Millennium's prior California suit, we affirm in part and vacate in part the district court's dismissal, remanding for the district court's consideration of whether Relator's remaining FCA claim was sufficiently pled under *Fed. R. Civ. P. 12(b)(6)* and *9(b)*.

I. Background

A. Factual Background

[HN1]Jurisdiction is determined based on whether it existed at the time the plaintiff filed the original complaint, *Sallen v. Corinthians Licenciamentos LTDA*, 273 F.3d 14, 23 (1st Cir. 2001), so we provide the factual background as alleged in Relator's original [*3] complaint. Since we ultimately find that said facts were integrated in Relator's amended complaint, we only distinguish between the two complaints when there are noted differences as to the language and count number of their respective allegations.²

2 While it is true that the original complaint contained four separate FCA counts and the amended complaint contains only one, the number of counts is not determinative of either the number of FCA claims alleged or of the factual allegations underlying those claims. [HN2]Ordinarily, the issue of stating multiple claims in a single count is dealt with as a "shotgun" pleading, or a pleading that fails to identify claims with sufficient clarity to enable a defendant to frame a responsive pleading. Under *Fed. R. Civ. P. 10(b)*, a party must state "each claim founded on a separate transaction or occurrence . . . in a separate count or defense" if doing so would promote clarity. However, a pleading deficiency is usually addressed by motion for a more definite statement pursuant to *Fed. R. Civ. P. 12(e)*, and unless none of the multiple claims alleged in a single count assert a ground for subject matter jurisdiction, the "shotgun" nature of the pleading [*4] on its own cannot serve as a basis for granting a motion to dismiss pursuant to *Fed. R. Civ. P. 12(b)(1)*. See, e.g., *Ledford v. Peeples*, 605 F.3d 871, 892 (11th

Cir. 2010), vacated on other grounds, 657 F.3d 1263 (11th Cir. 2011) ("When faced with a complaint [that lumps multiple claims together in one count, and] in which the counts incorporate by reference all previous allegations and counts, the district court must cull through the allegations, identify the claims, and, as to each claim identified, select the allegations that appear to be germane to the claim. This task can be avoided if the defendant moves the court for a more definite statement or if the court, acting on its own initiative, orders a repleader."); *Kuehl v. FDIC*, 8 F.3d 905, 908 (1st Cir. 1994) ("Our federal rules promote the disposition of claims on the merits rather than on the basis of technicalities, and courts should be reluctant to impose a dismissal with prejudice for a rules violation that is neither persistent nor vexatious, particularly without some review of the merits.") (citing *Foman v. Davis*, 371 U.S. 178, 181-182, 83 S. Ct. 227, 9 L. Ed. 2d 222-82 (1962)). Therefore, for the purposes of our review, we focus on the factual allegations [*5] and the legal claims pled based on said allegations, not the number of counts listed in the amended complaint.

As relevant here, Millennium developed a urine drug-testing program for physicians to monitor the medications of chronic pain patients and to assess patients' compliance with prescribed medication regimes. The testing method begins as point-of-care testing in a doctor's office and uses various chemically-treated test strips ("units") inserted into a single cup filled with the patient's urine ("specimen") (collectively, the "test kit").

Robert Cunningham, now deceased, worked as a compliance officer for Calloway, a competitor of Millennium's, in 2007 and 2008. It was during his employment at Calloway that Cunningham learned of the allegedly improper billing practices at issue in his qui tam complaint against Millennium and the unnamed physicians. Cunningham labeled Millennium's alleged fraudulent practices, collectively, as "Millennium's Physician Billing Model" in his original complaint. The overall scheme is alleged to involve different components, but as a general matter, is

designed to 1) encourage physicians to perform and order medically excessive and unnecessary testing, [*6] thereby

significantly increasing the revenues of the John Doe [physician] defendants at the expense of the government and private health insurance programs, and 2) by increasing the John Doe [physician] defendants' revenues, significantly increase Millennium's revenues and market share, enabling Millennium to profit from the billing for reflex screenings and confirmations.

The complaint states that, unlike other laboratories "which profit from the tests ordered by a physician with no payment to the physician," Millennium's model allows a physician "to substantially increase his or her revenue based upon the laboratory tests ordered." The complaint then proceeds to break down the various aspects of the larger scheme, which involves alleged fraudulent activity related to multiple billing for single test kits, excessive testing without medical necessity, and improper confirmation testing.

First, Millennium is alleged to have billed multiple times for the testing of a single test kit. Specifically, the original complaint alleges that Millennium encouraged doctors "to use a multi-class qualitative drug screen which uses a single specimen, and to bill the government and private insurance programs [*7] multiple units for the single testing event devices" ("Aspect 1"). Millennium then encouraged doctors "to improperly bill the government under CPT codes 80101, 80101QW, and/or other pathology and laboratory codes," resulting in federal monies lost as a result of "laboratory services which were not performed as claimed or were inflated." Millennium did this by informing physicians that, rather than bill one unit of 80101QW for each test kit, the physician should bill "as many units as there are panels in the test kit." (emphasis added). Further, Millennium gave physicians a document, entitled "Gross Revenue by Insurance Category for Multi-Clin 11 Panel Test Kit," which suggested that "each physician can bill at least 9 units per kit," despite the fact that all nine units are tested "in a single testing event." Relator alleges fraud in that payment because use of CPT code 80101QW "would only be proper if it was billed in one unit. . . . Rather, at Millennium's encouragement and in conspiracy with Millennium, the John Doe [physician] defendants . . . have billed Federal programs and other health insurance programs multiple units of 80101QW per patient per day."

Second, Relator claims that [*8] Millennium directed and encouraged physicians to test excessively, more than was reasonable or medically necessary ("Aspect 2"). Specifically, the original complaint alleges that Millennium

represents to the physician that by simply ordering one (1) test per day and billing Medicare at the rate of \$19.24 per panel for nine (9) units, the physician can earn \$173.18 per day Millennium also informs the physician that if she or he were to order twenty (20) tests per day and bill Medicare at the rate of \$16.67 per panel for nine (9) units, the earnings would be \$3,463.20 per day. . . .

Thus, as distinct from the first set of allegations, the second set of allegations does not involve billing more than one time for a single unit, but rather involves the unnecessary frequency with which physicians were encouraged to use and bill entire test kits. These allegations also include charges that Millennium informed physicians that, if they were to order twenty tests per day, they could earn \$8,640.00 per day based on "the standard indemnity, auto insurance, and [w]orkmen's compensation policies at the reasonable and customary rate of \$80.00 per panel for nine (9) units." These amounts are [*9] also reflected in the "Gross Revenue by Insurance Category for Multi-Clin 11 Panel Test Kit" document, which also breaks down the potential revenues a physician can earn by ordering between one and twenty tests per day. The complaint states that Millennium thus "encourages the physician to order more testing than that physician would have prior to engaging in Millennium's point[-] of[-]care model, and increases Millennium's market share by drawing other physicians to the practice with the hope and promise of greater revenues." It further alleges that the physician defendants did order "significantly more testing for their patients since entering the conspiracy than they did prior to participating in the conspiracy with Millennium. This would include . . . the initial screens conducted by" the physician defendants. The alleged fraud consists of Millennium's promotion of said billing model and physician defendants' misrepresentation of "the medical necessity of the tests performed."

Third and finally, the complaint alleges fraudulent activity related to confirmation testing of initial screen

tests ("Aspect 3"). After performing an initial qualitative test, physicians at the point of care [*10] may confirm the results of those tests by another method. The complaint claims that Millennium encouraged physicians to order more testing than they would have otherwise not only with respect to the initial tests, but with the confirmation tests as well. The fraud that the complaint alleges is that Millennium "knowingly encouraged the [physician] defendants . . . to misrepresent the medical necessity of confirmation testing. Defendants knew that these practices and procedures resulted in fraudulent claims to the federal government through the Medicare, Medicaid, and other federally funded programs."³

3 The amended complaint states the same facts detailed above as to Aspects 2 and 3, although it omits separate FCA counts charging Millennium and the physician defendants with the underlying facts pertaining to Aspects 2 and 3. The amended complaint does, however, incorporate those facts by reference in the single FCA count brought.

Prior to the Relator's filing of the instant suit, Millennium filed a complaint in its own right against Calloway and unnamed John Does, inclusive, in the Superior Court of California, alleging, inter alia, defamation and intentional interference with contractual [*11] relations. Millennium's complaint alleged that two Calloway account executives sent e-mails to individuals and a Millennium customer describing Millennium's practice of billing insurance companies and the government twice for the same service, and claiming that that practice could put both Millennium and physicians at risk of "potential legal exposure" or "potential insurance fraud." Since the e-mails attached to the California complaint were both the factual basis for the claims alleged in the complaint, as well as basis for the district court's jurisdictional determination regarding prior public disclosure, we will describe the facts alleged therein in detail. We only list facts that are relevant for the public disclosure bar as it governs Relator's complaint.

The first e-mail attached to the California complaint is from a Calloway account executive, Greg Williams, to Michael Schatman, Ph.D., of Pacific Northwest University Health Sciences in Yakima, Washington, and Marty Schultz. Williams expresses his shock that their clinic chose a lab for services "that allow[] the clinic to generate revenue by billing for the drug screens. There is a very un-reputable lab going around, called [*12]

Millennium, that is offering this revenue generating scenario. I hope this is not the lab you all have bought into." Williams goes on to describe the "severe pitfalls" of the physician billing scheme utilized by Millennium, stating that: (1) "there are . . . patients and insurances being billed twice for the same service"; and (2) the "in-house screens that clinics are billing the 80101 code for should be bundled, but clinics are 'un-bundling' each metabolite screened for on the cup or test strip." Williams suggests that these practices are unlawful, unethical, and the basis for an office being audited.⁴

4 While Williams' e-mail mentions confirmation testing, it does not do so in reference to Millennium. Rather, Williams distinguishes Millennium's point-of-care drug screens from the kind of testing that occurs at "confirmation labs like Calloway." Williams argues that such confirmation labs "are becoming so prevalent in the market place because the medical community recognizes the only information of value in this day and age comes from the results of a confirmed specimen." If anything, then, Williams' e-mail, Exhibit A to Millennium's California complaint, distances Millennium from [*13] direct involvement with any confirmation tests.

The second e-mail was also sent by a Calloway account executive, Stephen Schur, but was sent to a Millennium customer. Schur's e-mail consisted of a two-sentence introduction to an attached question-and-answer information sheet ("Q & A Sheet I"). The introduction indicates that the attached sheet "should clear things up" and invites further contact should the customer have any questions. Q & A Sheet I in its own right appears to be a guide drafted for physicians as a means to clarify the value of Calloway's urine-testing services. The Sheet distinguishes between Calloway's own model and the competing point-of-care "physician screening model." It does not mention Millennium by name, but states that "[s]ome laboratories" that promote the "physician screening model" "are sure to attract the attention of regulatory authorities" for unlawful billing practices. These include "suggesting that a physician can bill multiple units of CPT Code 80101, sometimes with a 'QW' modifier, for qualitative tests performed by a physician's office using one of a variety of drug testing kits on the market." Q & A Sheet I then claims that the Center for Medicare [*14] and Medicaid Services ("CMS") "does not authorize the billing of multiple units

of 80101; i.e. -- they are considered a single test for billing." It further asserts that state Medicaid manuals require that, "when a test kit with multiple drug test cards is used, the provider should bill for a single instance of 80101 with a 'QW' modifier, not multiple." Secondly, the Q & A Sheet provides the following question and answer about confirmation testing by labs promoting the "physician screening model":

The lab promoting the "Physician Screening Model" does confirmation testing so at least the issue of detecting specific drugs within a drug class is handled. Right?

Possibly. It appears some of these labs are performing and billing for so-called "confirming EIA analysis." This is considered double-billing by CMS because your Point-of-Care-Testing is also "EIA" (Enzyme Immunoassay) testing and regulations specifically prohibit one EIA test confirming another EIA test. The physician needs to order only confirmation tests performed by GC/MS or LC/MS/MS.

The third e-mail attached to the California complaint was also sent by Stephen Schur to Teresa Tinc of Pain Diagnosis, and contained another Q & [*15] A Sheet ("Q & A Sheet II"). The body of Schur's e-mail described the attached Q & A Sheet more fully, identifying the information contained therein as "info that is pertinent to a physician billing model like Millennium's. . . . a model that is potentially fraudulent." The first question on Q & A Sheet II involves whether a physician who "perform[s] a drug screen with a Point-of-Care device" may "bill the patient's insurance for drug screening." The response states that, while "[s]ome laboratories promote a 'Physician Screening Model' suggesting that a physician can bill multiple units of CPT Code 80101, sometimes with a 'QW' modifier. . . . This is incorrect and possibly abusive." It states the same reasons for challenging the practice as stated in Q & A Sheet I -- CMS not authorizing the billing of multiple units when they should be considered as a single test and also referencing state Medicaid manuals prohibiting the practice. Q & A Sheet II also copies exactly the language of Q & A Sheet I regarding confirmation testing under the "Physician Screening Model" described therein.

B. Procedural History

Cunningham filed his original complaint in this action five days after Millennium [*16] filed the California suit, on December 29, 2009. On February 25, 2011, his Estate filed an amended complaint. Millennium moved to dismiss that complaint on three grounds: the FCA's public disclosure bar deprived the court of subject matter jurisdiction; in the alternative, Relator failed to state a claim upon which relief could be granted under *Fed. R. Civ. P. 12(b)(6)*; and, lastly, he failed to plead fraud with the requisite particularity under *Fed. R. Civ. P. 9(b)*.

The district court granted Millennium's motion, dismissing Relator's complaint with prejudice on grounds that it lacked subject matter jurisdiction under the FCA's public disclosure bar.

II. Discussion

A. The FCA's Public Disclosure Bar

In challenging the district court's dismissal order, Relator argues that the court erred when it found that Millennium's California complaint had publicly disclosed all of the allegations made in Relator's own complaint. Even if the multiple billing allegations described as Aspect 1 were disclosed in the California suit, Relator claims, Millennium's complaint did not state facts relating to Aspects 2 and 3 of the fraudulent billing practices that Relator's complaint exposes, namely, excessive [*17] testing and excessive confirmation testing of negative results.

Further, Relator contends that mere rumors of improper billing stated in Calloway's account executives' e-mails are insufficient to constitute a "public disclosure" of Millennium's fraudulent conduct and it does not put the government on notice of fraud as required under the statute and this Circuit's case law. What is exposed, Relator claims, is a sanitized, innocuous version of Millennium's business model, not the details of the fraudulent conduct. Relator also asserts that the allegations in his complaint were not "based upon" Millennium's California complaint since: (1) Aspects 2 and 3 are only discussed in Relator's complaint and are not mentioned in the California complaint; and (2) Relator did not learn of the multiple billing fraud of Aspect 1 from the California complaint. Relator argues in the alternative that, if the court finds that the information

contained in the instant complaint was publicly disclosed in the California suit, the court should assert jurisdiction under the "original source" exception as Cunningham was an original source who acquired all of his information through his own investigation, without [*18] an intervening agency.

Finally, Relator states that it was error for the district court to dismiss the complaint with prejudice, without granting leave to amend, because the dismissal was based on a "mistakenly abridged reading" of the complaint, and on remand, Relator should be allowed to file a second amended complaint given the "well-known, liberal standards for amendment." Upon amendment, Relator promises to provide more of Millennium's marketing materials, e-mails, and laboratory testing forms demonstrating Millennium's intent that physicians profit from billing for a multiplicity of results derived from a single urine test, and that Millennium and the defendant physicians both profit from performing as many tests as possible regardless of medical necessity, in violation of the FCA.

[HN3]This Court reviews de novo the district court's dismissal of a complaint for lack of subject matter jurisdiction. *Abdel-Aleem v. OPK Biotech LLC*, 665 F.3d 38, 41 (1st Cir. 2012). Jurisdiction is determined based on whether it existed at the time the plaintiff filed the original complaint. *Sallen*, 273 F.3d at 23.

Pursuant to the FCA, 31 U.S.C. § 3730(e)(4)(A) (2006),

[HN4][n]o court shall have jurisdiction over [*19] an action . . . based upon the public disclosure of allegations or transactions in a . . . civil . . . hearing . . . , unless the action is brought by the Attorney General or the person bringing the action is an original source of the information.⁵

[HN5]For the public disclosure bar to apply, each of three elements must be met: (1) a public disclosure of the allegations or transactions in a relator's complaint must have occurred; (2) said disclosure must have occurred in the manner which is specified in the FCA; and (3) the relator's suit must be "based upon" those publicly disclosed allegations or transactions. *United States, ex rel. Duxbury v. Ortho Biotech Prods., L.P.*, 579 F.3d 13,

21 (1st Cir. 2009) (quotations and citation omitted). If those elements have been met, then a court may only exercise jurisdiction over the suit if the relator falls within the "original source" exception. *Id.*

5 In 2010, Congress amended the public disclosure provision of the FCA and explicitly narrowed the jurisdictional bar to disclosures in federal rather than federal and state cases or hearings. 31 U.S.C. § 3730(e)(4)(A) (2010). Since Relator's complaint was filed prior to amendment, his complaint could [*20] be properly barred on the basis of a public disclosure of information in a state court proceeding.

[HN6]A prior public disclosure may occur through any public document available on the docket in a civil hearing. See *United States ex rel. Poteet v. Bahler Med., Inc.*, 619 F.3d 104, 111 (1st Cir. 2010). To be a disclosure "of fraud," a disclosure must either contain a direct allegation of fraud or allow for a proper inference of fraud by revealing a misrepresented state of facts in conjunction with a true state of facts. *Id.* at 110. In assessing whether a given later-filed suit is "based upon" publicly disclosed allegations, we look to whether those allegations are "substantially similar" to said allegations. *United States ex rel. Ondis v. City of Woonsocket*, 587 F.3d 49, 57 (1st Cir. 2009). We do this by comparing the substance of the prior disclosures with the substance of a relator's complaint. *Poteet*, 619 F.3d at 114.

As a preliminary matter, we must address the issue of which complaint -- Relator's original or amended complaint -- we are comparing to Millennium's California complaint for the purposes of the public disclosure bar. The record is not entirely clear which complaint was reviewed [*21] below for the purposes of the public disclosure bar. The district court first cited to the proper rule -- that [HN7]a court must determine whether it has subject matter jurisdiction over an action based on the original complaint filed -- but then only considered its subject matter jurisdiction over the allegations made in Count One of the original complaint, summarily stating in footnote 59 that, since Relator's other three counts "do not appear in the First Amended Complaint," they "thus have no bearing on this motion to dismiss." The district court then went on to say that, even if the additional three claims were not barred by the public disclosure bar, "they do not provide Relator with the ability to amend the complaint to include a claim that was jurisdictionally

barred at the time Cunningham filed the original Complaint." After making this statement in a footnote, the district court did not analyze whether the claims made in the three separate counts in the original complaint were either: (1) integrated into the amended complaint in its factual section or under the single FCA count; or (2) barred by the FCA's public disclosure provision as a result of having been disclosed in Millennium's [*22] California suit.

The district court erred in the first instance when it did not consider all FCA counts of the original complaint in determining whether or not said complaint was jurisdictionally barred by prior public disclosure. It also erred when it failed to meticulously compare Relator's allegations in both the original and amended complaint regarding excessive and confirmatory testing with the information contained in Millennium's California complaint and attached e-mails. Specifically, in reciting the relevant "substantially similar" facts shared by Millennium's California complaint and Relator's complaint, the district court only cited to the California complaint's attached e-mails detailing the multiple billing fraudulent scheme, or, as the district court described the scheme, "a plan that billed insurance agencies and the federal government multiple times for the same test." A detailed comparison, however, reveals that, while the district court was correct that Millennium's California complaint discussed the purportedly fraudulent activity associated with Millennium's multiple billing practices, it failed to assess whether Relator's excessive and confirmatory testing allegations [*23] contained in Counts 2 and 3 of the original complaint, and retained in paragraphs 1, 5, 16, 18, 22 and 23 of the amended complaint, were also disclosed in the California suit. Therefore, while we agree with the district court that Aspect 1 of Relator's fraud allegations was disclosed in the California suit, we must also address the prior disclosure of Aspects 2 and 3 as alleged in the original complaint and retained in the amended complaint. Perusing both Relator's complaints and the California complaint, we find that Aspect 3 of Relator's FCA allegations was also disclosed in the California suit, but Aspect 2 was not.

1. Aspects 1 and 3 of the Alleged Scheme

We first discuss the multiple billing allegations and our reasons for affirming the district court's dismissal of the Relator's complaint as barred by the FCA's public

disclosure provision. Relator appears to concede that the multiple billing scheme alleged as Aspect 1 of its FCA claim was disclosed in the California complaint, stating that that complaint was "limited to th [e] discrete issue of multiple billing," and the district court's holding in dismissing the complaint was "wrong because the California Complaint is devoid of [*24] the other two aspects of the fraud -- excessively frequent testing, and the automatic confirmation of negative results." (emphasis added). However, for the sake of thoroughness, we briefly review the reasons the public disclosure bar applies to Aspect 1 as alleged in Relator's complaint.

Relator is incorrect and misguided in suggesting that Aspect 1 was not "publicly disclosed" in the California suit "as fraud" because the allegations made in that case consisted of "mere rumors." Since Relator does not contest that a disclosure of information on a civil docket may constitute "public disclosure" for the purposes of the FCA, we construe Relator's challenge to be directed at the extent to which Millennium's complaint made a direct or properly inferable public disclosure of fraud. Yet, the California complaint and attached e-mails could not have been more explicit that the information the Calloway account executives were spreading about Millennium's billing practices concerned allegations that they involved and encouraged unlawful and unethical misrepresentations to the government and private insurers about billing for multiple tests when in fact only a single unit was tested. As cited [*25] supra, in the first e-mail attached, Williams states the following about Millennium's billing practices:

First, there are the patients and insurances being billed twice for the same service. Medicaid and Medicare frown upon being billed twice for the same thing. . . . Second, these in-house screens that clinic are billing the 80101 code for should be bundled, but clinic are "un-bundling" each metabolite screened for on the cup or test strip and again Medicaid and Medicare frowns upon that.

The third e-mail attached to the California complaint states that "participating in any plan to increase revenues by billing excessive or incorrect codes violates a number of federal and state statutes," and that Millennium's billing model involving billing for each test strip rather

than the single testing event puts physicians "at risk for potential insurance fraud."

Even assuming these statements did not constitute direct allegations of fraud, the e-mails compare Millennium's version of the facts associated with its billing practices⁶ with the "true" state of those facts as claimed by Calloway account executives. Specifically, the e-mails say that, while Millennium represents that "physicians can [*26] bill multiple units of 80101 . . . for qualitative tests[,] . . . [CMS] does not authorize the billing of multiple units of 80101: i.e.--they are considered a single test for billing." Therefore, the district court did not err in finding that the disclosure constituted a disclosure of fraud.

6 Relator concedes as much in his opening brief in stating that "the California Complaint artfully describes only those aspects of Millennium's billing practices that are arguably legitimate."

While we share Relator's concern that a person or entity committing fraud against the government could theoretically shield itself from a qui tam action through preemptively filing its own action, thus creating a sanitized public disclosure while barring a future whistleblower action, the Supreme Court has been clear that self-disclosure can bar such suit under the FCA, and it has further characterized concerns about insulation from FCA liability as unwarranted in most cases. *Schindler Elevator Corp. v. United States ex rel. Kirk*, 131 S. Ct. 1885, 1895, 179 L. Ed. 2d 825 (2011) (dismissing as "pure speculation" concerns that potential defendants may insulate themselves from FCA liability by making FOIA requests); *Graham Cnty. Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 559 U.S. 280, 130 S. Ct. 1396, 1410, 176 L. Ed. 2d 225 (2010) [*27] (stating that careful disclosure of potential fraud would not immunize a fraudulent actor "from FCA liability in an action brought by the United States" because it still tips off the Attorney General; furthermore, Congress "carefully preserved the rights of the most deserving qui tam plaintiffs: those whistle-blowers who qualify as original sources") (quotations and citations omitted).

Finally, Relator is incorrect in suggesting that his suit is not "based upon" the allegations contained in the California suit as to Aspect 1. Relator misconstrues what this court has understood the terms "based upon" to mean in the context of FCA liability. [HN8]We do not, as

Relator suggests, determine whether information in a subsequently filed action is "based upon" a prior filing in terms of whether the former is "parasitic" to the latter. Rather, we compare the respective substance of the prior disclosures with a relator's complaint and determine if they are "substantially similar." *Ondis*, 587 F.3d at 57. As just discussed, the allegations in both suits detail a scheme involving multiple billing or individual billing for the "unbundled" components for a single test under CPT codes 80101 and 80101QW. [*28] We thus find that, as to Aspect 1, the district court was not incorrect in finding that all requirements of the public disclosure bar were met, and it properly found that it lacked subject matter jurisdiction as to Relator's FCA claim based on the Aspect 1 allegations.

Relator's FCA claim based on its allegations as to Aspect 3 of Millennium's purportedly fraudulent scheme is also barred since Aspect 3 was both publicly disclosed and was "substantially similar" to information provided in Millennium's California suit. The facts alleged pertaining to Millennium's confirmation testing scheme in Relator's complaint were as follows: (1) since the start of the company in 2007, Millennium used and promoted the Physician Billing Model designed to, inter alia, "increase [the physician] defendants' revenues, [and] significantly increase Millennium's revenues and market share, enabling Millennium to profit from the billing for . . . confirmations"; (2) the physician defendants ordered "significantly more testing for their patients since entering the conspiracy than they did prior to participating in the conspiracy with Millennium," and this included "confirmatory tests ordered by the [physician] [*29] defendants"; and (3) in conspiracy with the physician defendants, Millennium "knowingly encouraged" them "to misrepresent the medical necessity of confirmation testing."⁷

7 The original and amended complaints state the same facts as pertaining to Aspect 3.

The California complaint states that Millennium's business strategy included physicians sending drug tests and results "to an independent laboratory, such as Millennium, for confirmation testing and additional testing for drugs not tested with the point[-]of[-] care device," and further states that "the laboratory only bills for any confirmation tests and additional testing that is necessary." This statement in Millennium's complaint is counterposed with statements made in Calloway account

executives' e-mails regarding confirmation testing and billing. As cited supra, Calloway account executives forwarded Q & A Sheets warning of the potential fraud surrounding billing for confirmation tests. Specifically, they warned that billing practices like Millennium's may be "considered double-billing by CMS because your Point-of-Care-Testing is also 'EIA' (Enzyme Immunoassay) testing and regulations specifically prohibit one EIA test confirming [*30] another EIA test. The physician needs to order only confirmation tests performed by GC/MS or LC/MS/ MS."

Thus, the allegations in Relator's complaint and the California suit both concern fraudulent billing of confirmation tests when such tests were purportedly unnecessary, and they further link that practice with Millennium's billing model which benefits Millennium and the physician defendants. Since these allegations are "substantially similar," Relator's FCA claim as based in Aspect 3 of Millennium's fraudulent scheme is jurisdictionally barred.

Further, the claims arising from Aspects 1 and 3 in Relator's complaint cannot be saved by Relator's belated assertion that he was the "original source" of the information concerning Millennium's alleged fraud. [HN9]An "original source," as defined by statute at the time Relator's original complaint was filed, is "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)(B) (2009).

Knowledge is "direct" if it is as "marked by absence [*31] of an intervening agency, instrumentality, or influence: immediate." *Ondis*, 587 F.3d at 59 (citation omitted). Knowledge is not direct if it is "based on research into public records, review of publicly disclosed materials, or some combination of these techniques." *Id.* Knowledge is "independent" if it did not depend on the public disclosure or if it merely constitutes a use of an individual's "unique expertise or training to conclude that the material elements already in the public domain constitute a false claim." *Id.* at 59-60. The relator as the proponent of federal jurisdiction bears the burden of proving its existence by a preponderance of the evidence. *Id.* at 54.

Relator raises his original source argument for the

first time on appeal. He contends that he had direct and independent knowledge of the information at issue because he undertook an independent investigation into Millennium's activities by reviewing Millennium's Physician Billing Model and other documents as well as speaking to a number of people about Millennium's practices during his tenure at Calloway. Specifically, he claims that he reviewed "complaints from the sales force, interviews with lead industry personnel, [*32] actions he observed, documents he obtained, and information he gleaned independently." Relator further claims that even information he gleaned from public sources, including the California complaint, should be exempted from the public disclosure bar because he "discovered and synthesized that information."

However, because Relator never raised his original source argument before the district court, it is waived. *Warren Freedendfeld Assocs. v. McTigue*, 531 F.3d 38, 48 (1st Cir. 2008) ([HN10]"If any principle is settled in this circuit, it is that, absent the most extraordinary circumstances, legal theories not raised squarely in the lower court cannot be broached for the first time on appeal.") (quoting *Teamsters, Chauffeurs, Warehousemen and Helpers Union, Local No. 59 v. Superline Transp. Co. et al.*, 953 F.2d 17, 21 (1st Cir. 1992)).⁸ In any event, while Relator claims in a conclusory manner that he conducted an independent investigation of Millennium's fraudulent practices, he fails to show how the knowledge he obtained was "direct." Specifically, the sources he lists for obtaining the information -- Calloway's sales force and lead industry personnel -- are third parties, and Relator makes [*33] no argument to meet his burden in showing that the information gleaned from those sources is "marked by the absence of an intervening agency, instrumentality, or influence." See *Ondis*, 587 F.3d 59. Further, our case law is clear that [HN11]"[k]nowledge that is based on research into public records, review of publicly disclosed materials, or some combination of these techniques is not direct." *Id.* To the extent that Relator asks this court to join other circuits in holding that discovery and synthesis of information from different public sources during the course of an independent investigation can result in original sourcing, we decline to do so. This, because of the scant and vague evidentiary basis upon which Relator makes his claims both as to Aspects 1 and 3 of the alleged fraud and as to the nature of his purported "independent investigation" beyond interviews with Calloway's sales force and leading industry personnel. See, e.g., *Kennard v. Comstock*

Resources, Inc., 363 F.3d 1039 (10th Cir. 2004); *United States v. Bank of Farmington*, 166 F.3d 853, 864 (7th Cir. 1999); *United States ex rel. Barajas v. Northrop Corp.*, 5 F.3d 407, 410 (9th Cir. 1993); see also *United States ex rel. Yannacopolous v. Gen. Dynamics*, 315 F. Supp. 2d 939, 953-54 (N.D. Ill. 2004).

8 In [*34] Relator's reply brief on appeal, he argues that he raised the original source argument in his sur-reply to Millennium's motion to dismiss before the district court. However, the cited page numbers of the sur-reply brief only include Relator's argument that his case was not "based upon" the allegations contained in Millennium's California complaint. Original source doctrine is in fact referenced, but only in Relator's explication of the arguments raised in *United States ex rel. Hutcheson v. Blackstone Med., Inc.*, 694 F. Supp. 2d 48, 59 (1st Cir. 2010), not in relation to his own case. Instead of arguing that the original source exception applied to retain subject matter jurisdiction, Relator claimed that one of the elements required for the public disclosure bar to apply -- the requirement that the allegations be "based upon" the prior disclosure -- was not met in his case:

The Relator in this case specifically states in the Amended Complaint that his allegations are based upon his experience in the urine drug testing industry, not the allegations in the California defamation action. . . . Here, Plaintiff/Relator's suit is most certainly not derived from Defendant's California Complaint. [*35] Under the *Hutcheson I & II* analysis, which is currently the law within the First Circuit, the Amended Complaint cannot be 'based upon' the California Complaint. Jurisdiction exists over this case under the 1986 version of the FCA, and Defendant's Motion to Dismiss must be denied.

While it appears that Relator may have confused the "based upon" analysis with some aspects of the original source doctrine, it nevertheless remains true that Relator never presented to the district court briefing, argumentation, or allegations to support his claims that he was an original source of information on Millennium's fraudulent billing scheme, and thus the district court was never able

to evaluate what the basis for such an exception to the public disclosure bar could consist of in this case. This was also the district court's own understanding in its memorandum dismissing Relator's complaint: "[t]he Relator does not even attempt to argue that it fits into the original source exception to the bar."

Finally, [HN12]we review a district court's denial of leave to amend a complaint for abuse of discretion. *Aponte-Torres v. University of Puerto Rico*, 445 F.3d 50, 58 (1st Cir. 2006). There was no such abuse here [*36] with respect to denying Relator leave to amend his complaint as to Aspects 1 and 3. Assuming Relator's request in his sur-reply brief and at oral argument constituted a "sufficient request" to amend pursuant to *Fed. R. Civ. P. 15(a)*, see *Rost*, 507 F.3d at 734, our comparison of the information disclosed in Relator's complaint and Millennium's California complaint, and Relator's failure to indicate any additional facts in its briefing as to Aspects 1 and 3 beyond the information disclosed in the California complaint, leaves us to conclude that the jurisdictional defect with respect to those FCA claims is incurable.

We thus affirm the district court's dismissal with prejudice of Relator's complaint as to the FCA claim based on Aspect 1 of Millennium's purported fraudulent scheme. Aspect 3 of that scheme is also jurisdictionally barred.

2. Aspect 2 of the Fraudulent Scheme

As stated supra, Relator's complaint alleges that one component of Millennium's fraudulent billing scheme included directing and encouraging the physician defendants to test excessively in a manner that was not medically necessary,

represent[ing] to the physician that by simply ordering one (1) test per day and billing [*37] Medicare at the rate of \$19.24 per panel for nine (9) units, the physician can earn \$173.18 per day Millennium also informs the physician that if she or her were to order twenty (20) tests per day and bill Medicare at the rate of \$16.67 per panel for nine (9) unites, the earnings would be \$3,463.20 per day. . . .

The allegations thus involve testing patients with an

unnecessary frequency while incentivizing that testing through providing revenue sheets that break down the gross revenues a physician could earn by ordering multiple tests rather than one test per day.

Neither Millennium's California complaint nor the e-mails attached thereto mention this kind of excessively frequent testing as part of Millennium's fraudulent scheme. The first e-mail from Williams only references allegations pertaining to Aspect 1 of Relator's complaint, and the other two e-mails and attached Q & A Sheets reference facts pertaining only to Aspects 1 and 3 of Millennium's billing practices.

However, while Relator's factual allegations pertaining to Aspect 2 of Millennium's model may not be subject to the FCA's public disclosure bar, Relator must still sufficiently plead the fraud associated with those [*38] allegations to survive dismissal under *Fed. R. Civ. P. 12(b)(6)* and *9(b)*. While Millennium's motion to dismiss Relator's complaint included alternative grounds to dismiss the complaint pursuant to *Rules 12(b)(6)* and *9(b)*, the district court never reached those questions since it dismissed the complaint on jurisdictional grounds. The parties did not fully brief those issues on appeal.⁹ [HN13] For deficiencies under *Fed. R. Civ. P. 9(b)*, leave to amend is often given, at least for plausible claims. *N. Am. Catholic Educ. Programming Found., Inc. v. Cardinale*, 567 F.3d 8, 16 (1st Cir. 2009). Accordingly, we vacate the order dismissing Relator's complaint as to Relator's Aspect 2 allegations and remand to allow the district court to consider whether Relator's complaint should be dismissed under *Rules 12(b)(6)* and *9(b)*. *Singleton v. Wulff*, 428 U.S. 106, 120, 96 S. Ct. 2868, 49 L. Ed. 2d 826 (1976) ([HN14]"It is a general rule . . . that a federal appellate court does not consider an

issue not passed upon below.").

9 Millennium mentions pleading deficiencies as to Relator's allegations of medically unnecessary testing under *Rule 9(b)* in its opposition brief, but that argument was cursorily incorporated into its broader argument that Relator's [*39] amended complaint only alleged a single theory of fraud in the FCA count that remained following amendment from the original complaint. Relator, for his part, limited his briefing to the district court's jurisdictional grounds for dismissing his complaint.

III. Conclusion

We conclude that the district court did not err in dismissing Relator's complaint as jurisdictionally barred as to Aspects 1 and 3 of Millennium's alleged fraudulent scheme, and we therefore **affirm** dismissal as to those claims. However, we **vacate** the district court's order dismissing with prejudice Aspect 2 of Relator's FCA claim, **remanding** said claim to the district court for its consideration of whether Relator alleged sufficient facts to survive dismissal under *Fed. R. Civ. P. 12(b)(6)* and *9(b)*. The district court may award Plaintiff-Appellant the costs of the appeal in the event that Plaintiff-Appellant ultimately prevails on the merits of the remaining FCA claim. Plaintiff-Appellant may then seek costs taxed in the district court under *Fed. R. App. P. 39(e)*. See, e.g., *L-3 Communs. Corp. v. OSI Sys.*, 607 F.3d 24 (2d Cir. 2010).

Affirmed in Part, Vacated in Part, and Remanded.