United States of America et al v. Miraca Life Sciences, Inc. et al Doc. 56

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF OHIO

United States of America,
and the States of California
and North Carolina, ex rel.
Girishwar Sharma

Plaintiff/Relator,

-vs-

Miraca Life Sciences, Inc.,
***et al*.,**

Defendants

Case No. 1:15cv2355

JUDGE PAMELA A. BARKER

MEMORANDUM OPINION AND ORDER

Currently pending are the Motions to Dismiss of Defendants Miraca Holdings, Inc., Miraca Life Sciences, Inc., and Metroplex Pathology Associates. (Doc. Nos. 47, 48.) For the following reasons, Defendants' Motions are GRANTED.

I. Procedural History

On November 17, 2015, Plaintiff/Relator Girishwar Sharma (hereinafter "Relator") filed a Complaint in this Court, on behalf of himself and the United States of America and the States of California and North Carolina, against Defendants Miraca Life Sciences, Inc., Metroplex Pathology Associates, and Miraca Holdings, Inc., for alleged violations of the Federal False Claims Act, 31 U.S.C. § 3729 *et seq*. and the California and North Carolina False Claims Act Statutes, Cal. Gov't Code Section 12650, *et seq.* and N.C. Gen. Stat. Section 1-605, *et seq*., respectively. (Doc. No. 1.)

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Pursuant to 31 U.S.C. § 3730(b), the Complaint was filed under seal to allow the United States the opportunity to determine whether it wished to intervene.[1]

On February 7, 2019, after receiving several extensions of time to make its intervention decision, the United States filed a Notice informing the Court that it had elected not to intervene in the instant action. (Doc. No. 15.) Several days later, on February 12, 2019, then-assigned District Judge Dan Polster issued an Order unsealing the Complaint and ordering that it be served upon the Defendants. (Doc. No. 16.)

On June 27, 2019, this matter was re-assigned to the undersigned pursuant to General Order 2019-13. On July 18, 2019, the States of California and North Carolina filed a Notice of their Intention to Decline Intervention. (Doc. No. 31.)

On September 11, 2019, Defendants Miraca Life Sciences, Inc. and Metroplex Pathology Associates filed a Motion to Dismiss for Failure to State a Claim. (Doc. No. 39.) Relator thereafter filed a First Amended Complaint raising the same federal and state False Claims Act ("FCA") claims against Defendants. (Doc. No. 40.)

Defendants Miraca Life Sciences, Inc. and Metroplex Pathology Associates then filed a Motion to Dismiss the First Amended Complaint on October 23, 2019. (Doc. No. 47.) On that same date, Defendant Miraca Holdings, Inc. filed its own Motion to Dismiss for both lack of personal

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[1] The FCA allows a private individual to bring a lawsuit alleging FCA violations on behalf of the government, which is known as a *qui tam* action. *See United States ex rel. Bledsoe v. Community Health Systems, Inc. ("Bledsoe I"),* 342 F.3d 634, 640 (6th Cir. 2003). *See also* 31 U.S.C. § 3730. The private individual bringing the *qui tam* suit, known as a relator, must first serve the complaint upon the government, where the complaint then remains under seal for at least sixty days. *See* 31 U.S.C § 3730(b)(2). During this time period, the government may elect to intervene. *Id*. If the government does not intervene in the action, the relator may proceed with the action. *See* 31 U.S.C. § 3730(b)(4)(B), (c)(3). If the relator successfully recovers funds for the government in pursuing the *qui tam* action, he or she may be entitled to up to 25–30% of the proceeds recovered. *See* 31 U.S.C. § 3730(d)(2).

jurisdiction and failure to state a claim upon which relief may be granted. (Doc. No. 48.) Relator filed Briefs in Opposition on December 4, 2019, to which Defendants responded. (Doc. Nos. 51, 52, 53, 54.)

II. Factual Allegations

The First Amended Complaint sets forth the following factual allegations. Relator Girishwar Sharma, M.D., graduated from medical school in India in July 1993. (Doc. No. 40 at ¶ 6.) He subsequently moved to the United States and, in 2004, completed a residency in pathology at University Hospitals in Cleveland, Ohio. (*Id.*) Relator is not and has never been licensed to practice medicine in Ohio or any other State. (*Id.*)

In July 2005, Relator was hired by Onco Diagnostics Laboratory, Inc. ("Onco") to perform preliminary interpretations of surgical pathology specimens which would then be re-read by a licensed pathologist. (*Id.*) In January 2010, Onco was purchased by Predictive Biosciences, Inc. ("Predictive"). (*Id.*) From January 2010 until January 2013, Relator was employed by Predictive as a pathologist associate. (*Id.*)

During the time period that he was employed by Predictive, Relator alleges that he was directed to "interpret [pathology] studies and sign them out under licensed pathologists' names, even though it was Relator who was reading and interpreting the studies as an unlicensed pathologist." (*Id*. at ¶¶ 53, 67.) Specifically, Relator alleges as follows:

> 67. Once Onco Diagnostics was acquired by Predictive profitability and turnaround time became a corporate priority. To facilitate those goals, James Groves, Vice President of Operations at Predictive and Senior Management from Boston, instructed Dr. Sharma to perform urine cytology interpretations and sign them out under the name of a licensed pathologist. Emails directing that this be done were sent by both Groves and others in management. Rather than providing a screening, Relator was now providing the definitive read though he was not licensed to do so. This course of conduct continued from January 2010 to January 2013 during which as many as

> 35,000 to 50,000 [fn omitted] urine cytology studies were signed out by Dr. Sharma under another pathologist's name. These urine cytology studies were assigned a CPT code of 88112 for which Medicare was paid, it is estimated, between $100.07 and $105.02 per study.
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> 68. By virtue of these fraudulent billings, Medicare paid Predictive somewhere between $3,500,000 and $5,250,000 for fraudulently billed and presented claims between January 2010 and January 2013 for urine cytology studies reviewed and signed out by an unlicensed pathologist under a licensed pathologist's name. The civil penalties associated with these fraudulent billings according to 31 USC §3729 as updated by 28 CFR §85.3(a)(9) is between $192,000,000 and $550,000,000 [footnote omitted].

(*Id*. at ¶¶ 67, 68.)[2] Notably, Relator acknowledges some "uncertainty" regarding how many studies (or which specific studies) were presented to Medicare, stating "Relator's estimates in this First Amended Complaint as to the number of studies performed are gross numbers that do not take into account whether the studies were paid for by Medicare or by another payor. Those studies paid for by another payor will need to be deducted from these estimates." (*Id*. at p. 18, fn 2.)

Relator also alleges a second category of allegedly fraudulent billings as follows. Relator alleges that the States of California, North Carolina, South Carolina and Utah have each promulgated regulations providing that only a physician licensed in those respective states is permitted to examine any pathology samples taken from a patient in those states. (*Id*. at ¶¶ 75-78.) Relator alleges that Predictive was aware of these laws but directed Relator and other unlicensed pathologists to interpret and sign out pathology studies under the properly licensed pathologists from those States. (*Id.* at ¶¶

[2] Relator also alleges that, during this time period, Predictive instructed him to "assess and sign out tissue biopsy results and urine molecular studies under the name of other pathologists who were licensed." (*Id*. at ¶ 72.)

80A, 80B.) This occurred even when these properly licensed pathologists were on vacation, unavailable, or no longer employed by Predictive.[3] (*Id*. at ¶¶ 93, 94, 95, 98, 100, 101, 102, 105, 106.)

Lastly, Relator alleges that Predictive implemented a fraudulent scheme whereby pathologists were directed to sign out on computer-generated test results relating to urine molecular studies without ever examining the underlying data. Specifically, Relator alleges as follows:

> 113. From 2011 to January 2013 Predictive was providing testing for bladder cancer with their proprietary bladder cancer assay known as CertNDx. CertNDx was a noninvasive molecular diagnostic test which was promoted by Predictive as having the ability to detect bladder and upper urinary tract cancers by detecting mutations in the Fibroblast Growth Factor Receptor 3 gene ("FGFR3") found in cells in urine samples. These tests were conducted by technologists employed by Predictive and the results were then sent to Predictive's pathologists. The pathologists were instructed to sign off on these results, often at night, after being provided with an email list of cases to sign out without ever being provided with the underlying data upon which the results were based.
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> 114. When a CertNDx study was performed upon a urine sample a report would be created by Defendant's molecular lab. The pathologists who would ultimately sign out the molecular reports had no significant involvement in the operations of the molecular lab and had no supervisory role over the lab. The pathologists would simply be sent a list of the final reports. Although the pathologists were provided by Defendants with access to the actual reports they were provided with no meaningful images of the cells being reported upon in the reports. Additionally, they were not involved in any fashion in the diagnostic workup. As such, they were in possession of none of the underlying data which formed the basis for the report's conclusions. The pathologists were instructed by email directive to sign out the reports though they had no basis upon which to determine if the reports were accurate and complete. The pathologists, sight unseen, would then sign these studies out in batches electronically. The only care that the pathologists would take would be to make sure that those studies involving patients from states with a requirement that the interpreting pathologist be licensed in that state were signed out using the name of a pathologist so licensed.

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[3] Specifically, Relator alleges that, from January 2010 to January 2012: (1) "thousands of prostate cases were knowingly and fraudulently signed out under the names of" Dr. Kevin Cooper, Dr. Young Sin Park, and Dr James Bentley; and (2) approximately 1,500 G.I. and urinary bladder biopsy cases and 5000 urine cytology cases from North Carolina, South Carolina, California and Utah were fraudulently signed out under the names of Drs. Cooper, Park and Bentley. (*Id*. at ¶¶ 98, 100, 101.) From January 2012 to January 2013, Relator alleges that approximately 1,500 prostate cases, 500 G.I. and urinary bladder biopsy cases, and 1,500 urine cytology cases were fraudulently signed out under the names of Drs. Cooper, Park and Bentley. (*Id*. at ¶¶ 102, 105, 106.) Relator further alleges that these cases were "fraudulently presented and billed to Medicare." (*Id*.)

(*Id*. at ¶¶ 113, 114.) Relator further alleges that Predictive employed the same practice with respect to its UroVysion Bladder Cancer Detection Test. (*Id.* at ¶¶ 119-123.) He alleges that this practice resulted in the submission of false and fraudulent claims under the FCA because, although the CertNDx and UroVysion studies were performed by laboratory scientists or technicians (and not physicians), "they were signed out by physicians and were billed to Medicare as a physician performed interpretation though they were not interpreted by physicians."[4] (*Id.* at ¶¶ 116, 124.)

In January 2013, the Anatomic Pathology Division of Predictive was acquired by Defendant Miraca Life Sciences, Inc. ("MLS").[5] (*Id.* at ¶¶ 6, 129.) Relator acknowledges that he "does not know whether the transaction whereby [MLS] acquired [Predictive] was a merger, a reorganization, a sale of stock, a sale of assets or some other type of transaction." (*Id.* at ¶ 129.) However, Relator alleges, "on information and belief," that the acquisition was one "where [MLS] took over the corporate entity which was previously known as Predictive Biosciences, Inc." (*Id*. at ¶ 130.) In the alternative, Relator alleges that "the acquisition was one in which Miraca acquired assets from Predictive." (*Id.* at ¶ 131.)

According to Relator, Defendant MLS (which is headquartered in Irving, Texas) "specializes in the development and commercialization of anatomic pathology services" and also offers general surgery pathology services. (*Id*. at ¶ 7.) Defendant MLS is a wholly owned subsidiary of Defendant Miraca Holdings, Inc. ("MHI"), which is a Japanese corporation organized under Japanese law. (*Id*.

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[4] Relator alleges that, from 2010 to 2013, approximately 15,000 CertNDx studies and approximately 6000 UroVysion tests were performed by Predictive, signed out using this fraudulent practice, and billed to Medicare. (*Id*. at ¶¶ 118, 127.)

[5] Relator alleges that Predictive subsequently went out of business on May 30, 2013. (*Id.* at ¶¶ 129, 136.)

at ¶¶ 7, 10.) Defendant Metroplex Pathology Associates ("Metroplex") is wholly owned by Defendant MLS. (*Id.* at ¶ 9.) Relator alleges, "on information and belief," that "some or all of the billings of [MLS] to Medicare were made through Metroplex." (*Id.*)

Relator was employed by Defendant MLS as an unlicensed pathologist from January 2013 until May 2014.[6] (*Id.* at ¶ 6.) He alleges that, when it acquired Predictive, Defendant MLS was "fully aware of the fraudulent practices of Predictive . . ., having undertaken a thorough due diligence inspection of the facilities, systems and procedures of Predictive prior to consummating the acquisition." (*Id.* at ¶ 133.) More specifically, Relator alleges that:

> 133. *** During that due diligence review, which went on for a week prior to the finalization of the acquisition, [MLS] became aware of Predictive's procedures whereby unlicensed and unqualified and unregistered pathologists were interpreting studies and signing them out under licensed and qualified pathologists' names. They also, at that time, became aware of how pathologists unlicensed in North Carolina, South Carolina, California and Utah were signing out cases from those states under the names of pathologists who were so licensed. They also, at that time, became aware of how pathologists were signing out molecular studies without ever seeing the slides, images or cells which formed the base of the interpretations which they simply rubber stamped with their signatures.

(*Id.* at ¶ 133.)

Relator further alleges that "not only did [MLS] become aware of those practices before they acquired the Anatomic Pathology Division of Predictive, they also, by direction from management, continued those practices after the acquisition until at least such time as Dr. Sharma left." (*Id.* at ¶ 134.) Specifically, Relator alleges as follows:

> 69. As of January 1, 2013, the Anatomic Pathology Division of Predictive Biosciences was acquired by Miraca. James D. Bentley, M.D. functioned as the Medical Director for Miraca. Dr. Rajal B. Shah, M.D. functioned as the Director of Urologic Pathology

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[6] Relator alleges that, when it acquired Predictive, MLS also hired a number of other Predictive employees (including Dr. Park and Dr. Bentley), and continued to service at least five of Predictive's customers. (*Id.* at ¶¶ 131G, 131H, 132.)

> for Miraca. Dr. Richard H. Lash, M.D. functioned as the Chief Medical Officer for Miraca.
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> 70. Upon the direction of Dr. Shah, Dr. Bentley was instructed to continue the scheme whereby Dr. Sharma, though unlicensed to practice medicine in Ohio or in any other state, would perform the urine cytology interpretations which would then be used by urologists to determine a course of further management for patients suspected of having urinary tract cancer or other significant conditions. At about 2-3 months into the acquisition of the Predictive lab by Miraca, Dr. Bentley, then functioning as Medical Director of the lab for Miraca, advised Relator that Dr. Shah (Director Urologic Pathology for Miraca) had instructed him to have Relator, though unlicensed, do virtually all of the urine cytology work. In practice, this worked out to Dr. Sharma doing approximately ninety percent (90%). This course of conduct continued through at least May 2014 during which time 15,000 to 18,000 urine cytology studies would be assigned a CPT code of 88112 and billed and presented to Medicare by Miraca. ***
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> 71. By virtue of these fraudulent billings which Miraca knowingly presented to Medicare, Medicare paid somewhere between $800,000 and $1,700,000 to Miraca for fraudulently billed services between January 2013 and at least May 2014 for urine cytology studies assessed and signed out by an unlicensed pathologist under a licensed pathologist's name. The civil penalties associated with these fraudulent billings according to 31 USC §3729 as updated by 28 CFR 85.3(a)(9) are between $74,250,000 and $178,200,000.

(*Id.* at ¶¶ 70, 71.) Relator further alleges, although Dr. Cooper was no longer employed by Predictive and/or MLS as of January 1, 2013, Defendant MLS directed its pathologists to fraudulently sign out approximately 400 prostrate cases, 300 G.I. and urinary bladder biopsy cases, and 1000 urine cytology cases from North Carolina, South Carolina, and California under Dr. Cooper's name, between January 2013 and July 2013. (*Id.* at ¶¶ 88, 91, 92.) In addition, Relator alleges that, between January 2013 and May 2014, Defendant MLS directed its pathologists to fraudulently sign out approximately 400 prostrate cases, 200 G.I. and urinary bladder biopsy cases, and 1,500 urine cytology cases under the names of Drs. Park and Bentley. (*Id.* at ¶¶ 107, 109, 110.) Relator alleges that these cases were billed and presented to Medicare by Defendant MLS in violation of the federal FCA and analogous state law provisions.

Lastly, Relator alleges that "approximately 4,000 UroVysion 4 probe studies were performed by [MLS] from January 2013 through May 2014 that were fraudulently signed out and billed and presented to Medicare for a total of between $3,500,00 and $3,800,000 in fraudulent claims," resulting in potential civil penalties of between $22,000,000 and $44,000,000. (*Id.* at ¶ 128.)

In support of these allegations, Relator attaches 29 exhibits to his First Amended Complaint, consisting of approximately 200 pages. (Doc. Nos. 40-1 through 40-29.) The majority of these exhibits are emails that appear to identify specific cases and/or studies (identified by a partially-redacted patient number) for Relator's signatures. (*Id.*) Several of these emails contain instructions to sign out the cases/studies under the names of various licensed physicians, including Drs. Bentley, Park, and Cooper. *See e.g.*, Doc. Nos. 40-1 through 40-5, 40-26, 40-27. Other emails appear to identify batches of CertNDx and UroVysion results for electronic sign off, allegedly without providing the underlying data for review. *See, e.g.,* Doc. Nos. 40-28, 40-29. The majority of the attached exhibits relate to the time period when Relator was employed by Predictive.

The First Amended Complaint alleges that Defendant MLS is liable, not only for its own fraudulent Medicare claims, but also for the fraudulent claims of Predictive under the federal Successor Liability Doctrine because (1) MLS had notice of Predictive's fraudulent practices before the acquisition; and (2) there is a substantial continuity in the operation of the business before and after the sale. (Doc. No. 40 at ¶¶ 129-136.) Relator further alleges that Defendant MHI is liable for the conduct of Defendant MLS because MLS's fraudulent acts inured to the benefit of MHI, thus allowing a piercing of the corporate veil. (*Id.* at ¶ 137.)

III. Standard of Review

Under Fed. R. Civ. P. 12(b)(6), the Court accepts the plaintiff's factual allegations as true and construes the Complaint in the light most favorable to the plaintiff. *See Gunasekara v. Irwin*, 551 F.3d 461, 466 (6th Cir. 2009). In order to survive a motion to dismiss under this Rule, "a complaint must contain (1) 'enough facts to state a claim to relief that is plausible,' (2) more than 'formulaic recitation of a cause of action's elements,' and (3) allegations that suggest a 'right to relief above a speculative level.'" *Tackett v. M & G Polymers, USA, LLC*, 561 F.3d 478, 488 (6th Cir. 2009) (quoting in part *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555–556 (2007)).

The measure of a Rule 12(b)(6) challenge — whether the Complaint raises a right to relief above the speculative level — "does not 'require heightened fact pleading of specifics, but only enough facts to state a claim to relief that is plausible on its face.'" *Bassett v. National Collegiate Athletic Ass'n.*, 528 F.3d 426, 430 (6th Cir.2008) (quoting in part *Twombly*, 550 U.S. at 555–556). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Deciding whether a complaint states a claim for relief that is plausible is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Id.* at 679.

In addition, "[c]omplaints alleging FCA violations must comply with Rule 9(b)'s requirement that fraud be pled with particularity because 'defendants accused of defrauding the federal government have the same protections as defendants sued for fraud in other contexts.'" *Chesbrough v. VPA, P.C.*, 655 F.3d 461, 466 (6th Cir. 2011) (quoting *Yuhasz v. Brush Wellman, Inc.*, 341 F.3d 559, 563 (6th Cir. 2003)). *See also United States ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905, 914 (6th Cir. 2017). To plead fraud with particularity under Rule 9(b), a plaintiff must

allege (1) the time, place, and content of the alleged misrepresentation; (2) the fraudulent scheme; (3) the defendant's fraudulent intent; and (4) the resulting injury. *See Chesbrough*, 655 F.3d at 467; *United States ex rel. Bledsoe v. Cmty. Health Sys. Inc.*, ("*Bledsoe II*"), 501 F.3d 493, 504 (6th Cir. 2007). "In the *qui tam* context, 'the Court must construe the complaint in the light most favorable to the plaintiff, accept all factual allegations as true, and determine whether the complaint contains enough facts to state a claim to relief that is plausible on its face.'" *United States ex rel. SNAPP, Inc. v. Ford Motor Co.*, 532 F.3d 496, 502 (6th Cir. 2008) (quoting *Bledsoe II*, 501 F.3d at 502). *See also Ibanez*, 874 F.3d at 914.

IV. Analysis

A. Motion to Dismiss of Defendants Miraca Life Sciences, Inc. and Metroplex Pathology Associates (Doc. No. 47)

In the First Amended Complaint, Relator alleges that Predictive and Defendant MLS knowingly participated in a fraudulent scheme which caused false claims to be submitted to Medicare. As discussed above, this alleged fraudulent scheme consists of three components. First, Relator alleges that Predictive and MLS fraudulently billed Medicare for urine cytology studies that were interpreted by unlicensed pathologists but signed out under the names of licensed pathologists.[7] (Doc. No. 40 at ¶¶ 2, 67-74.) Second, Relator alleges that Predictive and MLS fraudulently billed Medicare for urine cytology studies, G.I. and urinary bladder biopsies, and prostate biopsies that were signed out by various pathologists under the names of pathologists who no longer worked at MLS or Predictive, were on vacation, or were otherwise unavailable but were licensed in California, North

[7] Relator alleges that this conduct violates 42 C.F.R. §§ 410.32(d), 493.1273(b) and (d), 493.1449(b) and (l), 493.1274(e)(3), as well as corresponding state requirements. (*Id.* at ¶ 2.)

Carolina, South Carolina, and/or Utah, in order to circumvent those states' licensing requirements.[8] (*Id.* at ¶¶ 3, 81-111). Finally, Relator alleges that Predictive and MLS fraudulently billed Medicare for CertNDx and UroVysion urine molecular studies under circumstances where the pathologist never reviewed the underlying data and/or results and, in some instances, when the pathologist that signed off on the studies was not licensed to practice medicine in Ohio or any other state.[9] (*Id.* at ¶¶ 4, 113-128.)

By virtue of this fraudulent scheme, Relator alleges that Defendants (1) knowingly presented or caused to be presented, false or fraudulent claims to the United States Government for payment or approval, in violation of 31 U.S.C. § 3729(a)(1)(A); (2) knowingly made, or used, false or fraudulent records and statements, and/or omitted material facts, to induce the U.S. Government to approve and pay such false and fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(B); and (3) conspired to present false or fraudulent claims for payment or approval, or caused to be made or used, fraudulent records and statements to induce the U.S. Government to approve and pay such false or fraudulent claims, in violation of 31 U.S.C. § 3729(a)(1)(C). (*Id.* at ¶¶ 141-144.) Relator also alleges violations of analogous statutes under the California and North Carolina False Claims Acts. (*Id.* at ¶¶ 146-156.)

Defendants MLS and Metroplex assert that the First Amended Complaint should be dismissed for two reasons. (Doc. No. 47.) First, these Defendants argue that Relator fails to allege facts sufficient to sustain his claim that MLS is liable for the alleged pre-2013 conduct of Predictive under principles of successor liability. (*Id.* at pp. 4-13.) Second, Defendants assert that Relator fails to set

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[8] Relator alleges that this conduct violates 42 C.F.R. §§ 410.20, 410.32, 411.15(k)(1), 493.1274(e)(3), and 493.1273(d). (*Id.* at ¶ 3.)

[9] Relator alleges that this conduct violates 42 C.F.R. § 411.15(k)(1) and Chapter X of the National Correct Coding Initiative Policy Manual for Medicare Services. (*Id.* at ¶ 4.)

forth sufficient factual allegations to meet Rule 9(b)'s heightened pleading standard for FCA claims because Relator fails to allege a single example of a false claim that was actually submitted to Medicare for payment. (*Id.* at pp. 13-25.)

As it is dispositive, the Court will first address Defendants' argument that the First Amended Complaint fails to set forth sufficient factual allegations to meet the heightened pleading standard for FCA claims set forth under Rule 9(b) and Sixth Circuit law.

1. Failure to Plead Presentment with Particularity—Section 3929(a)(1)(A)

Defendants MLS and Metroplex argue that the First Amended Complaint should be dismissed because Relator "fails to allege a single example of an individual false claim that was actually submitted to the government, as strictly required by the Sixth Circuit under Rule 9(b) in FCA cases." (Doc. No. 47-1 at p. 14.) Defendants further assert that "what little the Relator does plead lacks the particularity required under Rule 9(b)." (*Id.* at p. 15.) Specifically, Defendants maintain that Relator fails to sufficiently allege any facts demonstrating that MLS actually submitted, and that Medicare actually paid, any false claims. (*Id.* at p. 16.) Defendants also argue that Relator fails to sufficiently allege the nature of the services for which reimbursement was sought, noting numerous instances in the First Amended Complaint wherein Relator hypothesizes regarding the services that were presented to Medicare for payment.[10] (*Id.* at p. 17.) In addition, Defendants maintain that Relator fails to clearly allege who actually submitted the alleged false claims for payment and, in particular, fails to make any specific factual allegations regarding Metroplex's alleged role in the billing process.

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[10] For example, Defendants highlight Paragraph 88 of the First Amended Complaint, in which Relator alleges that "[i]f less than 10 core biopsies were submitted for a patient, each would have been coded as CPT Code 88305 . . . If one assumes that each patient has 12 cores submitted on his behalf, 400 studies would have been processed." (Doc. No. 40 at ¶ 88.)

(*Id.* at p. 18.) Lastly, Defendants assert that Relator fails to sufficiently plead key facts regarding the underlying fraudulent scheme, including specific factual allegations regarding the identities of the participants in, and the Defendants' alleged knowledge of, the alleged scheme. (*Id.* at pp. 20-21.)

Relator argues that "the allegations in [the] 160-paragraph, 59-page First Amended Complaint plus 29 exhibits are sufficiently particular to satisfy the requirements of Rules 9(b) and 8(a)." (Doc. No. 51 at p. 19.) Relator "acknowledges that he cannot identify the individual claims that were submitted to Medicare, as he did not work in MLS's accounting or billing departments and thus, is in no position to know which individual claims were actually submitted to Medicare for payment." (*Id.* at p. 20.) However, he argues that the factual allegations set forth in the First Amended Complaint are nonetheless sufficient because he has "alleged specific internal facts grounded in personal knowledge that strongly support the submission of claims to the government and receipt of payment." (*Id.* at p. 21.) Relator further argues that the First Amended Complaint sufficiently alleges (1) the types of claims submitted to Medicare (e.g., urine cytology studies, CertNDx and UroVysion molecular studies, prostate biopsies, etc.); (2) the specific individuals involved (e.g, Rajal Shah, Richard Lash, James Groves and Frank Basile); (3) the dates and numbers of the claims; and (4) Defendants' knowledge of the submission of fraudulent claims. (*Id.* at pp. 22-25.) Lastly, Relator argues that "it would be premature to dismiss a defendant on the face of the pleadings prior to discovery" and requests that, if the Court finds the First Amended Complaint to be insufficient, it should grant Relator leave to amend. (*Id.* at p. 25, fn13.)

In response, Defendants acknowledge that the Sixth Circuit has recognized a "personal knowledge" exception to the requirement that a relator identify a representative false claim that was actually submitted to the government. (Doc. No. 54 at p. 12.) Defendants assert, however, that this

exception applies only in "limited circumstances" where a relator alleges that he has "specific personal knowledge that relates directly to billing practices, supporting a strong inference that a claim was submitted." (*Id*. quoting *Ibanez*, 874 F.3d at 915). Defendants maintain that the factual allegations in the First Amended Complaint do not satisfy this exception because Relator never alleges that he has any personal knowledge regarding Defendants' billing practices and, in fact, "actually admits in his opposition that he 'is in no position to know which individual claims were actually submitted to Medicare for payment.'" (*Id*. at p. 13.) Defendants further assert that the First Amended Complaint otherwise fails to meet the requirements of Rule 9(b) regarding the time, place, and content of the alleged fraudulent scheme. (*Id*. at pp. 13-19.) Lastly, Defendants argue that leave to amend should be denied given the passage of time and the fact that Relator already had an opportunity to amend in response to Defendants' first Motion to Dismiss. (*Id.* at p. 20.)

Section 3729(a)(1)(A) of the FCA prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). "A claim under § 3729(a)(1)(A) 'requires proof that the alleged false or fraudulent claim was 'presented' to the government.'" *Ibanez*, 874 F.3d at 914 (quoting *United States ex rel. Marlar v. BWXT Y-12, LLC*, 525 F.3d 439, 445 (6th Cir. 2008)). *See also United States ex rel. Prather v. Brookdale Senior Living Communities*, 838 F.3d 750, 768 (6th Cir. 2016). At the pleading stage, the Sixth Circuit has interpreted this requirement stringently: "[W]here a relator alleges a 'complex and far-reaching fraudulent scheme,' in violation of § 3729(a)(1), it is insufficient to simply plead the scheme; he must also identify a representative false claim that was actually submitted to the government." *Chesbrough,* 655 F.3d at 470 (quoting *Bledsoe II*, 501 F.3d at 510). "Although the relator does not need to identify *every* false claim submitted for payment, he must identify with specificity

'characteristic examples that are illustrative of the class of all claims covered by the fraudulent scheme.'" *Chesbrough*, 655 F.3d at 470 (quoting *Bledsoe II,* 501 F.3d at 511) (emphasis in original). Thus, "where a relator pleads a complex and far-reaching fraudulent scheme with particularity, and provides examples of specific false claims submitted to the government pursuant to that scheme, a relator may proceed to discovery on the entire fraudulent scheme." *Bledsoe II*, 501 F.3d at 510.

Here, Relator acknowledges that "he cannot identify the individual claims that were submitted to Medicare, as he did not work in MLS's accounting or billing departments and thus, is in no position to know which individual claims were actually submitted to Medicare for payment." (Doc. No. 51 at p. 20.) However, he argues that the factual allegations in the First Amended Complaint are sufficient to satisfy Rule 9(b) under the "relaxed" standard that has been applied by the Sixth Circuit where a relator has "specific personal knowledge" that justifies a "strong inference" that a false claim was submitted to Medicare.[11] (*Id*. at p. 21.)

Relator is correct that the Sixth Circuit has recognized a narrow exception to the requirement that a relator specifically identify a representative false claim that was actually submitted to the government. *See Prather*, 838 F.3d at 769. This exception applies when a relator "pleads facts that create a 'strong inference' based on the relator's detailed firsthand knowledge of the defendant's billing practices, that the defendant actually submitted false claims to the government for payment." *United States ex rel. Hockenberry v. OhioHealth Corp*., 2017 WL 4315016 at * 2 (6th Cir. Apr. 14,

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[11] The Court rejects Relator's argument that, by failing to address the "personal knowledge" exception in their Motion to Dismiss, Defendants "waived" the argument that Relator's allegations are insufficient to show "specific personal knowledge" supporting the inference that false claims were submitted by Defendants. (Doc. No. 51 at p. 20.) In their Motion, Defendants clearly raised the argument that Relator failed to plead the FCA presentment requirement with particularity under the general standard articulated by the Sixth Circuit. Defendants were not also required to address the "specific personal knowledge" exception to that general standard unless and until Relator raised it in his Brief in Opposition. After Relator did so, Defendants challenged the applicability of that exception in their Reply Brief. Under these circumstances, the Court rejects Relator's waiver argument.

2017) (quoting *Prather,* 838 F.3d at 769-772.) *See also United States ex rel. Holloway v. Heartland Hospice, Inc*., 386 F.Supp.3d 884, 901 (N.D. Ohio 2019); *United States ex rel. Petkovic v. Foundations Health Solutions, Inc.*, 2019 WL 251556 at * 3 (N.D. Ohio Jan. 17, 2019). As the Sixth Circuit has explained:

> This could include personal knowledge that claims were submitted by Defendants for payment or other personal knowledge of billing practices or contracts with the government, as well as personal knowledge that was based either on working in the defendants' billing departments, or on discussions with employees directly responsible for submitting claims to the government.

Prather, 838 F.3d at 769 (internal quotations and citations omitted).

Notably, "[p]ersonal knowledge of the allegedly fraudulent *scheme* is not enough to warrant application of the relaxed standard." *Petkovic*, 2019 WL 251556 at *4 (emphasis added) (citing *United States ex rel. Eberhard v. Physicians Choice Lab. Servs., LLC*, 642 Fed. Appx 547, 552-53 (6th Cir. 2016)). Rather, a relator must also show knowledge of "submission of specific fraudulent claims." *Eberhard*, 642 Fed. Appx at 552 (citing *Chesbrough, supra*, 655 F.3d 461). This is so because "[t]he FCA attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the claim for payment." *Id.* (quoting *Sanderson v. HCA-The Healthcare* Co., 447 F.3d 873, 878 (6th Cir. 2006)) (emphasis supplied).

This so-called "relaxed" standard is an extremely narrow exception that has been applied only one time by the Sixth Circuit, in *United States ex rel. Prather v. Brookdale Senior Living*, 838 F.3d 750 (6th Cir. 2016). In *Prather*, the relator's job required her to review the company's Medicare claims documentation to ensure compliance with state and federal insurance guidelines. *Prather,* 838 F.3d at 770. Prather alleged that this review "directly related to Defendants' efforts to bill [] claims to Medicare" and that she "worked with employees in Brookdale's billing office." *Id.* at 757. After

her review, Prather alleged that she would deliver the claims documents to the billing department, whose job it was to submit the claims for payment. *Id*. Additionally, Prather identified four patients for whom the defendants submitted requests for anticipated and final payment and, for each patient, specified: the services received, the start and end dates of service, the date of the allegedly fraudulent certification, the dates defendants requested payment, and the amounts paid or billed. *Id*. at 758-59. She also provided spreadsheets listing over 1,200 claims that she alleged were fraudulent and, for each such claim, identified the patient, certification period, servicing network, and servicing community. *Id*. at 759.

The Sixth Circuit found that these factual allegations, taken together, were sufficient to establish with particularity that the defendant "submitted a claim for payment," as they described when, where, and how the defendant submitted the claim. *Id*. at 770-772. The court explained:

> These allegations must also be viewed in context. Prather was hired to work on the Held Claims Project—a project devoted to working through a backlog of Medicare claims—and her responsibilities were focused on reviewing the documentation for those Medicare claims, in anticipation of them being submitted to Medicare. Prather also received confirmation that the final claims that she reviewed were submitted for payment. She and other employees received an email from Diana Sharp—an Innovative Senior Care employee who "headed up the group of temporary employees" hired for the Held Claims Project- "gleefully reporting: '[we] have processed and released over 10,000 claims since 2/7!!" And "[d]efendants issued weekly reports, called the 'Home Health Held Claims Report,' that showed how many claims were being held and how many claims had been released for billing to Medicare."
>
> Even though Prather was reviewing final claims for submission, her knowledge of their submission and documentation supports a strong inference that requests for anticipated payment were submitted for each patient whose final claim Prather reviewed. This is because the entire held-claims project existed to avoid the "looming financial crisis" created by those held claims, which was a product of the fact that if those claims were not submitted for final payment, the defendants would have faced the recoupment of anticipated payments that had been made regarding the same episode of care, see 42 C.F.R. § 409.43(c)(2). **Prather's detailed knowledge of the billing and treatment documentation related to the submission of requests for final payment, combined with her specific allegations regarding requests for**

> **anticipated payment, also creates a strong connection between the requests for anticipated payment and the requests for final payment.** Prather further alleged that requests for anticipated payment were submitted. Accepting all of these allegations as true, we cannot deny the strong inference that the specific documentation that Prather reviewed related to patients for whom requests for anticipated payment had been submitted to the government for payment.

Id. at 770 (emphasis added) (internal citations omitted).

The Court finds that *Prather* is distinguishable from the instant case. Unlike the relator in *Prather*, Relator herein does not allege any personal knowledge regarding the billing practices and/or claims submission processes of either Predictive, MLS, or Metroplex. Nor does Relator allege that he has any personal knowledge based on interactions he had with individuals working in Predictive's and/or the Defendants' billing or claims departments. To the contrary, Relator expressly states, in his Brief in Opposition, that he "is in no position to know which individual claims were actually submitted to Medicare for payment." (Doc. No. 51 at p. 20.) In addition, in the First Amended Complaint, Relator again indicates a lack of information regarding Defendants' billing practices, noting that "estimates in this First Amended Complaint as to the number of studies performed are gross numbers that do not take into account *whether the studies were paid for by Medicare or by another payor*." (Doc. No. 40 at p. 18, fn. 2) (emphasis added). Under the circumstances presented, the Court finds that Relator's allegations are insufficient to "create a 'strong inference' based on the relator's detailed firsthand knowledge of the defendant's billing practices, that the defendant actually submitted false claims to the government for payment." *Hockenberry*, 2017 WL 4315016 at * 2 (quoting *Prather,* 838 F.3d at 769-772.)

Relator appears to argue that declaratory statements in the First Amended Complaints that Defendants "billed Medicare for services covered by Medicare" and submitted "false and/or fraudulent statements and claims to Medicare for reimbursement" are sufficient to satisfy this

"relaxed" standard. (Doc. No. 51 at pp. 20-21.) The Court disagrees. Under the Sixth Circuit authority noted above, simply alleging that Defendants presented false and fraudulent claims to Medicare is not sufficient. Rather, Relator must set forth sufficient allegations demonstrating the factual basis for these statements; i.e. factual allegations that demonstrate that Relator has personal knowledge justifying a "strong inference" that Defendants actually submitted claims to the government for payment. *See, e.g, Hockenberry*, 2017 WL 4315016 at * 2 (exception applies when a relator "pleads *facts* that create a strong inference that based on relator's detailed firsthand knowledge of the defendant's billing practices, that the defendant actually submitted false claims to the government for payment.") (emphasis added). Relator fails to do so. Indeed, although Relator pleads numerous facts showing his firsthand knowledge of the alleged underlying fraudulent scheme, he does not direct this Court's attention to any factual allegations in the First Amended Complaint that demonstrate that he possesses any firsthand knowledge relevant to the Defendants' billing practices or otherwise suggesting that Defendants actually submitted false claims to the government for payment. This is fatal to Relator's Section 3729(a)(1)(A) claim.[12]

The exhibits attached to the First Amended Complaint do not cure this deficiency. As discussed above, these exhibits consist primarily of emails from various individuals at Predictive

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[12] The Court also rejects Relator's suggestion that the sheer volume of alleged pathology studies pled in the First Amended Complaint, combined with the allegation that payments from Medicare account for half of Defendants' sales, is sufficient to create a strong inference that Defendants submitted false claims to the government for payment. (Doc. No. 51 at pp. 20-21.) The Court disagrees. As the Sixth Circuit has explained, "Rule 9(b) does not permit a False Claims Act plaintiff merely to describe a private scheme in detail but then to allege simply . . . that claims requesting illegal payments must have been submitted, were likely submitted, or should have been submitted." *Sanderson*, 447 F.3d at 877. *See also Eberhard*, 642 Fed. Appx. at 551. Rather, the Sixth Circuit has strictly required that, to adequately plead a claim under the FCA, a relator must either (1) specifically identify a representative false claim that was actually submitted to the government, or (2) plead facts creating a strong inference "based on the relator's detailed firsthand knowledge of the defendant's billing practices" that defendants actually submitted false claims to the government for payment. *Hockenberry*, 2017 WL 4315016 at * 2. As discussed at length above, here, Relator has failed to meet either of these standards.

and/or Defendant MLS to Relator that appear to direct him to sign out on pathology studies under the names of licensed physicians. For example, Exhibit 1 to the First Amended Complaint is an email dated July 24, 2012 from Kelly Hauck to Relator which provides as follows:

> Hi Dr. Sharma,
>
> I have two more UroVysion cases for you to sign out tonight:
>
> PC12-0586-**
> PC12-0587-**
>
> They are both Dr. Bentley cases so please sign-out under his name.
>
> Thanks,
> Kelly

(Doc. No. 40-1.) *See also,* Doc. No. 40-2 through 40-5. Other exhibits consist of emails that forward tables of CertNDx or UroVysion results to Relator (and sometimes others) and appear to contain the following information: (1) sample ID number, (2) test result (i.e., negative, positive, intermediate, sample insufficient, cannot be determined, etc.), (3) the State in which the patient resides; and, occasionally, (4) a specific doctor. *See, e.g*, Doc. No. 40-28.

The Court finds that these exhibits are not sufficient to satisfy the Sixth Circuit's "relaxed" standard under Rule 9(b). While these exhibits may be relevant to the Defendants' alleged fraudulent *scheme*, Relator does not explain how any of the specific emails attached to the First Amended Complaint contain any information relating to Defendants' *billing practices*. Indeed, upon the Court's own review, none of these exhibits appear to contain any information suggesting that any of the specific cases or studies referenced therein were actually submitted to Medicare. *See, e.g., Holloway*, 386 F.Supp.3d at 902 (finding patient list submitted by relator was not sufficient to warrant application of "relaxed" standard because "the list does not describe claims for payment. It gives

information about the patients listed but omits information in the *Prather* four-patient sample, such as the amounts billed and/or paid, the Medicaid or Medicare certification dates, and the specific services provided.")

In light of the above, the Court declines to apply the "relaxed" standard to Relator's claims under Section 3729(a)(1)(A). As discussed above, the relaxed standard exception is "extremely narrow." *Petkovic*, 2019 WL 251556 at * 5. It has been applied by the Sixth Circuit only once, in *Prather, supra*, which is distinguishable from the instant case for the reasons discussed above. Moreover, both the Sixth Circuit and district courts within this Circuit have refused to apply the "relaxed" standard under circumstances similar to those presented herein. *See e.g., United States ex rel. Crockett v. Complete Fitness Rehabilitation*, 721 Fed. Appx. 451, 458 (6th Cir. 2018) ("By contrast, Crockett specifically disavows any knowledge of how Complete Rehab charged Bortz or how Bortz submitted bills to the federal government, and several intermediaries existed between the behavior Crockett observed and the submissions of claims to the government. Therefore, Crockett lacks the very knowledge that Prather used to justify an exception to Rule 9—and for that reason, she cannot invoke the relaxed standard."); *Ibanez*, 874 F.3d at 915 ("Here, relators do not allege this type of personal knowledge. Relators were sales representatives of BMS and, unlike the relator in *Prather*, did not directly engage with claims whatsoever."); *Petkovic*, 2019 WL 251556 at * 6-10 (refusing to apply relaxed standard where relators "have not alleged any personal knowledge of FHS' billing-related procedures").[13]

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[13] The cases cited by Relator to the contrary are either not applicable or distinguishable. Specifically, Relator's reliance on *U.S. ex rel. Groat v. Boston Heart Diagnostics*, 255 F.Supp.3d 13 (D.D.C. 2017), *amended on recons*., 296 F.Supp.3d 155 (D.D.C. 2017) and *U.S. ex rel. Heath v. AT&T, Inc*., 791 F.3d 112 (D.C. Cir. 2015) is misplaced because neither of those cases are from the Sixth Circuit or apply Sixth Circuit law. Relator's reliance on *U.S. ex rel. Daugherty v. Bostwick*, 2012 WL 6593804 (S.D. Ohio Dec. 18, 2012), *U.S. ex rel. McDonough v. Symphony Diagnostic Services, Inc.*, 2012 WL

For all the reasons set forth above, the Court finds that application of the relaxed standard is not appropriate here. Moreover, Relator acknowledges that he cannot identify a single allegedly false claim submitted to the government for payment. Accordingly, the Court finds that Relator has failed to adequately allege a violation of 31 U.S.C. § 3729(a)(1)(A).

2. Sections 3729(a)(1)(B) and (C)

Relator also alleges claims under 31 U.S.C. §§ 3729(a)(1)(B) and (C). Section 3729(a)(1)(B) prohibits "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). Section 3729(a)(1)(C) imposes liability on anyone who "conspires to commit a violation of" the FCA's other prohibitions. 31 U.S.C. § 3729(a)(1)(C).

Defendants MLS and Metroplex move to dismiss Relator's claims under these Sections on the grounds that Relator failed to plead these claims with particularity as required under Rule 9(b). (Doc. No. 47.) For the following reasons, the Court agrees.

Although the Supreme Court in *Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 671 (2008) held that "presentation" of a false statement or record to the government is not an element of a false records claim under § 3729(a)(1)(B), the Sixth Circuit has since clarified that this does not "relieve [a relator] of the need to plead a connection between the alleged fraud and an actual claim made to the government." *Chesbrough*, 655 F.3d at 472-73 (emphasis added). *See also Ibanez*,

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628515 (S.D. Ohio Feb. 27, 2012) and *U.S. ex rel. Lane v. Murfreesboro Dermatology Clinic, PLC,* 2010 WL 1926131 (E.D. Tenn. May 12, 2010) is also misplaced. These district court decisions are from 2010 and 2012, prior to the Sixth Circuit's reported decisions in *Prather* and *Ibanez* which emphasized the narrow nature of the "relaxed" standard and limited it to situations where the relator had specific personal knowledge of the defendants' billing practices. Moreover, *Lane* is distinguishable because, in that case, the "plaintiff asserted that she and her co-workers personally implemented the billing practices described by submitting actual claims to Medicare." *Lane,* 2010 WL 1926131 at * 4. Likewise, *McDonough* is distinguishable because, there, the relator alleged specific conversations with specific employees of defendant (including its CEO) regarding defendant's Medicare billing practices. *McDonough*, 2012 WL 628515 at * 9.

874 F.3d at 916. "The alleged connection must be evident." *Ibanez*, 874 F3d at 916 (citing *Allison Engine Co.*, 553 U.S. at 671–72). Otherwise, "a cause of action under the FCA for fraud directed at private entities would threaten to transform the FCA into an all-purpose antifraud statute." *Allison Engine Co*., 553 U.S. at 672.

Here, Relator's claim fails because, although Relator alleges that Defendants made false or fraudulent statements as part of their allegedly fraudulent scheme, there are no allegations connecting these statements to any claim that was actually made to the government. Accordingly, and for all the reasons discussed in connection with Relator's Section 3729(a)(1)(A) claim, Relator fails to adequately plead a 31 U.S.C. § 3729(a)(1)(B) claim because he fails to allege a link between a false statement and the Government's decision to pay or approve a false claim. *See Chesbrough*, 655 F.3d at 473. *See also United States ex rel. Dennis v. Health Mgmt. Assocs., Inc*., 2013 WL 146048 at *17 (M.D. Tenn. Jan. 14, 2013) (finding that the failure to identify a false or fraudulent claim with particularity subjects a claim to dismissal under Section 3729(a)(1)(B)).

Relator also fails to state a claim under Section 3719(a)(1)(C). That Section prohibits FCA conspiracies, requiring a relator to plead facts showing that there was a plan or agreement "to commit a violation of" one or more of the FCA subsections. *See* 31 U.S.C. § 3729(a)(1)(C). To meet this requirement, "it is not enough for relators to show there was an agreement that made it *likely* there would be a violation of the FCA; they must show an agreement was made *in order to* violate the FCA." *Ibanez*, 874 F.3d at 917 (emphasis in original). In addition, the Sixth Circuit has held that "[a]n FCA conspiracy claim requires a 'request or demand' intended to be paid by the government." *United States ex rel. Crockett v. Complete Fitness Rehabilitation*, 721 Fed. Appx 451, 459 (6th Cir. 2018).

Here, as discussed *supra*, Relator has identified no such specific request or demand and has specifically disavowed any personal knowledge of either Predictive or MLS' billing practices. As with Relator's other FCA fraud claims, there is no specific identification of a particular claim improperly made to the government by virtue of Defendants' alleged conspiracy. *See, e.g., United States ex rel Winkler v. BAE Systems, Inc*., 957 F.Supp.2d 856, 876 (E.D. Mich. 2013) ("Winkler's failure to sufficiently plead a violation of § 3729(a)(1)(A) or (B) necessitates a finding of a failure to plead a conspiracy to violate those sections under § 3729(a)(1)(C).") Further, Relator's conspiracy claim fails for the additional reason that he has failed to sufficiently plead the existence of an agreement by or between the Defendants that was made in order to violate the FCA. *See Ibanez*, 874 F.3d at 917.

Accordingly, the Court finds that Relator has failed to state a claim under 31 U.S.C. §§ 3729(a)(1)(B) and (C).[14]

3. State Law Claims

The First Amended Complaint also pleads state law claims for violations of the California False Claims Act, Cal. Gov't Code Section 12650*, et seq*., and the North Carolina False Claims Act,

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[14] In his Brief in Opposition, Relator suggests, in a footnote, that he has asserted a claim under 31 U.S.C. § 3729(a)(1)(G), which prohibits "knowingly mak[ing], us[ing], or caus[ing] to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government, or knowingly conceal[ing] or knowingly and improperly avoid[ing] or decreas[ing] an obligation to pay or transmit money or property to the Government." As Defendants correctly note, however, no such claim is actually pled in the First Amended Complaint. *See* Doc. No. 40 at pp. 54-55. The Court does note that Section XII of the First Amended Complaint makes passing reference to 31 U.S.C. 3729(a)(1)(E), which imposes liability on anyone who "is authorized to make or deliver a document certifying receipt of property used, or to be used, by the Government and, intending to defraud the Government, makes or delivers the receipt without completely knowing that the information on the receipt is true." *See* Doc. No. 40 at pp. 54-55. However, while referencing this section, the First Amended Complaint does not contain any allegations (factual or legal) that appear to state a claim under this section. Relator has not directed this Court's attention to any factual allegations relating to a "document certifying receipt of property used . . . by the Government." Indeed, the word "receipt" does not appear a single time in the First Amended Complaint. Accordingly, the Court finds that (1) the First Amended Complaint does not assert a claim under 31 U.S.C. § 3729(a)(1)(G); and (2) Relator has failed to state a claim under 31 U.S.C. § 3729(a)(1)(E).

N.C. Gen. Statute Section 1-605, *et seq*. (Doc. No. 40 at ¶¶ 146-156.) Specifically, Relator alleges that Defendants knowingly submitted and/or caused the submission of false claims when they knowingly and wrongfully billed Medi-Cal and the North Carolina Medicaid System for (1) pathology services performed by an unlicensed pathologist; (2) pathology services that were performed by physicians who were not licensed to practice in the States of California or North Carolina; and (3) molecular testing services and readings that were never viewed or interpreted by any licensed physician. (*Id.*)

Defendants MLS and Metroplex move for dismissal of these claims on the grounds that Relator "alleges no particular facts relating to claims made to or paid by Medi-Cal or North Carolina at all." (Doc. No. 47-1 at p. 23.) Relator does not address this argument in his Brief in Opposition. (Doc. No. 51.)

Defendants' Motion to Dismiss Relator's state-law claims is granted. Relator does not direct this Court's attention to any factual allegations in the First Amended Complaint relating to any claims for pathology and/or molecular testing services that were made to or paid by either Medi-Cal or the North Carolina Medicaid System. Accordingly, and in light of the lack of any meaningful argument to the contrary,[15] Relator's state law claims against these Defendants are subject to dismissal.

4. Request to Amend

[15]In a footnote, Relator states that "to the extent [he] did not address an issue [in his Brief in Opposition], it is not a concession but a reflection of the limited space and relative merits of such arguments." (Doc. No. 51 at fn 13.) Regardless of whether Relator intended to concede the issues which he did not address, the fact remains that he failed to address Defendant's arguments regarding his state law claims, despite having been granted leave to exceed the page limitations. Relator's opportunity to argue the merits was in his Brief in Opposition. To the extent he failed to address certain arguments and issues raised by Defendants in their Motion to Dismiss, the Court deems those issues unopposed.

Finally, Relator argues, summarily and in a footnote, "if *arguendo* some allegation was insufficient, the Court should grant plaintiff leave to amend the complaint, rather than granting defendants' motion to dismiss." (Doc. No. 51 at p. 25, fn 13.) Relator offers no further argument in support of this request nor does he attach a proposed Second Amended Complaint to his Brief in Opposition. Defendants oppose Relator's request for leave to amend. (Doc. No. 54 at pp. 19-20.)

Relator's request is denied. Although Rule 15 provides that leave to amend should be freely granted where justice so requires, the Sixth Circuit recently noted (in a FCA case) that "[w]here parties have fully argued the merits of a 12(b)(6) motion to dismiss and the district court has duly considered those arguments and issued an opinion resolving the motion, it is a stretch to say justice requires granting leave to cure the complaint's deficiencies as identified in adversarial pleadings and the district court's order—even where the initial order turned on a failure to meet Rule 9(b)'s particularity requirements." *Ibanez*, 874 F3d at fn 2. *See also SNAPP, Inc*., 532 F.3d at 510–11 (noting that "*Bledsoe II* should not be taken to imply that the district court must grant Relator leave to file an amended complaint") (Suhrheinrich, J., concurring).

In the instant case, Relator already amended his Complaint once after having the opportunity to review and consider the arguments raised in Defendant MLS' and Metroplex's first Motion to Dismiss. Notably, in that Motion to Dismiss, Defendants MLS and Metroplex expressly raised the argument that Relator's allegations (including his allegations regarding presentment) failed to satisfy the heightened pleadings requirements of Rule 9(b). (Doc. No. 39 at pp. 16-20.) Relator offers no meaningful argument why he should be provided yet another opportunity to amend, nearly four years after this case was filed. Relator's request for leave to amend his First Amended Complaint is, therefore, denied.

Accordingly, and for all the reasons set forth above, Defendants MLS' and Metroplex's Motion to Dismiss (Doc. No. 47) is GRANTED.

B. Motion to Dismiss of Defendant Miraca Holdings, Inc. (Doc. No. 48)

In the First Amended Complaint, Relator alleges that Defendant Miraca Holdings, Inc., a Japanese corporation, is the parent corporation of Defendant MLS. (Doc. No. 40 at ¶¶ 7, 10.) Relator alleges generally that "[u]nder corporate law principles, a parent company's corporate veil may be pierced and the shareholder held liable for the subsidiary corporation's conduct when, inter alia, the corporate form would otherwise be misused to accomplish certain wrongful purposes, most notably fraud, on the shareholder's behalf." (*Id.* at ¶ 10.) Relator then alleges as follows:

> 137. The false claims that Miraca made upon the United States constituted a fraud which inured to the benefit of Miraca Holdings thus allowing a piercing of the corporate veil rendering Miraca Holdings liable. Additionally, to the extent that Miraca Holdings directly participated in the false and fraudulent billing described herein, it is directly liable.

(*Id.* at ¶ 137.)

Defendant Miraca Holdings, Inc. ("MHI") argues that the First Amended Complaint should be dismissed for several reasons. (Doc. No. 48.) First, Defendant MHI argues that the First Amended Complaint should be dismissed for lack of either general or specific personal jurisdiction. (*Id.*) Next, Defendant MHI asserts that the First Amended Complaint should be dismissed for failure to state a claim because "Relator does not allege that Miraca Holdings engaged in any conduct *itself* and he proffers no facts to support his conclusory assertion that Miraca Holdings can be held liable for the alleged conduct of its former subsidiary." (*Id.*) Lastly, like Defendants MLS and Metroplex, Defendant MHI asserts that Relator's FCA claims should be dismissed under the heightened

pleadings standards set forth in Rule 9(b) because he "does not allege even a single example of a false claim actually submitted to Medicare." (*Id.*)

Relator does not direct this Court's attention to any allegations in the First Amended Complaint that Defendant MHI itself (1) participated in the alleged fraudulent scheme; or (2) knowingly presented, or caused to be presented, false or fraudulent claims and/or statements to the government for payment or approval. To the contrary, the only allegations in the First Amended Complaint against Defendant MHI are derivative of the allegations against its subsidiary, Defendant MLS. [16]

Having dismissed all of Relator's claims against Defendants MLS and Metroplex for failure to state a claim under Rules 9(b) and 12(b)(6), the Court finds that the claims against MHI are also necessarily subject to dismissal.

Accordingly, Defendant MHI's Motion to Dismiss (Doc. No. 48) is GRANTED.

V. Conclusion

For all the reasons set forth above, Defendants' Motions to Dismiss (Doc. Nos. 47, 48) are GRANTED.

IT IS SO ORDERED.

s/Pamela A. Barker
PAMELA A. BARKER
U. S. DISTRICT JUDGE

Date: July 14, 2020

[16] Relator's allegation that "to the extent that Miraca Holdings directly participated in the false and fraudulent billing described herein, it is directly liable," is entirely speculative and not sufficient to plead that Defendant MHI itself engaged in any fraudulent conduct. Nor are Relator's general references to "defendants" throughout the First Amended Complaint sufficient to plead fraudulent conduct on the part of Defendant MHI. As the Sixth Circuit has explained, "[a] complaint 'may not rely upon blanket references to acts or omissions by all of the 'defendants,' for each defendant named in the complaint is entitled to be apprised of the circumstances surrounding the fraudulent conduct with which he individually stands charged.'" *Bledsoe I*, 342 F.3d at 643 (quoting *Benoay v. Decker*, 517 F.Supp. 490, 493 (E.D. Mich, 1981)).