IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORIA
ROME DIVISION

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	**CIVIL ACTION**
	)	
v.	)	**No. 4:18-cv-191-HLM**
	)	
CHARLES C. ADAMS, M.D., CHARLES C. ADAMS, M.D., P.C., D/B/A/ FULL CIRCLE MEDICAL CENTER, AND PERSONAL INTEGRATIVE MEDICINE PLLC,	)	
	)	
Defendants.	)	
	)	

DEFENDANTS' MOTION TO DISMISS

Defendants Charles C. Adams, M.D., Charles C. Adams, M.D., P.C. d/b/a/ Full Circle Medical Center, and Personal Integrative Medicine PLLC (collectively "Dr. Adams" or "Defendants") by counsel, respectfully move the Court to dismiss the Complaint (Doc. 1) filed by the United States of America ("government") pursuant to Federal Rules of Civil Procedure 12(b) and 9(b). In support of this Motion to Dismiss, Defendants state as follows:

I. INTRODUCTION

The government filed this action against Dr. Adams seeking to recover damages and civil penalties for alleged violations of the False Claims Act, 31

U.S.C. §§ 3729-3733 (2009) ("FCA"), or alternatively, under the common law doctrines of payment by mistake and unjust enrichment. The government's theory of liability is based entirely on the premise that Dr. Adams' use of chelation therapy was not "reasonable and necessary," and therefore not subject to reimbursement by Medicare Part B. The government admits that Medicare reimbursed Dr. Adams for 4500 claims for chelation therapy between November 2008 and September 2015 (Compl. ¶1). Yet despite its repeated payment of these claims for over seven years, the government also alleges that Dr. Adams "knew" all of these claims were "false" claims, subjecting him to liability under the False Claims Act.

The complaint in this case represents little more than the government's specious disagreement, years later, with Dr. Adams' medical decision-making and clinical judgment about the use of chelation therapy, and his practice of alternative medicine generally.[1] Notably, however, the National Institutes of Health has

[1] Dr. Adams is a physician licensed to practice medicine in the State of Georgia, with a medical office in Ringgold, Georgia. (Compl. ¶23.) Yet the government apparently feels compelled to allege that "Dr. Adams is not board certified in internal medicine (or any other medical discipline or specialty) by the American Board of Medical Specialists," and refers to Dr. Adams' "board certification" from the American Board of Integrative and Holistic Medicine in quotations. (Compl. ¶¶26-27.) And the Complaint is replete with references to what the government describes as Dr. Adams' practice of "so-called 'alternative medicine.'" (Compl. *passim*.) There is no requirement for a doctor to be board certified and, in fact, most internal medicine doctors are not. There also is no allegation, nor could there be, that alternative treatments never are "reasonable and necessary." These

recognized that alternative medicine often is appropriate and effective, as it formed the National Center for Complementary and Alternative Medicine in 1992. *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3846961/. In 2013, the government estimated that over 100,000 Americans received chelation therapy every year. *Id*. The chelating agent used by Dr. Adams, Calcium Disodium Versentate or its generic equivalent edetate calcium disodium ("EDTA"), is FDA-approved for chelation therapy. *Id*. The government's effort to portray Dr. Adams' use of chelation therapy on these patients as "fringe medicine" or inappropriate, simply is incorrect. *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2922724/ ("Chelation therapy is the preferred medical treatment for reducing the toxic effects of metals").

The government fails to sufficiently allege that Dr. Adams *knowingly* submitted *false* claims in violation of the FCA. Moreover, the government does not allege any facts demonstrating that, if its FCA claims are dismissed, it would still be entitled to recover money from Dr. Adams under the common law doctrines of payment by mistake and unjust enrichment. Accordingly, the Complaint must be dismissed in its entirety.

II. BACKGROUND

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irrelevant and unnecessary allegations have no bearing on any claim in this case – and notably, the government reimbursed Dr. Adams' claims for this treatment for seven years without question.

The government claims that Dr. Adams violated the FCA by submitting allegedly false Medicare Part B claims seeking reimbursement for chelation therapy that was not "reasonable and necessary." (Compl. ¶¶1, 40.) The crux of the government's argument is that, "Medicare only covers items and services that are 'reasonable and necessary for the diagnosis or treatment of illness or injury.'" (Compl. ¶¶57.) Accordingly, this case rests on how and where the term "reasonable and necessary" is defined, and the extent to which any such definition can be used to impart liability under the FCA or under the common law for payment by mistake and unjust enrichment.

A. The Complaint Primarily Consists of General Allegations about Medicare and the "Medical Consensus" regarding Chelation Therapy.

The Complaint in this case, which exceeds 200 paragraphs and spans 61 pages, contains mostly general allegations and legal conclusions about the federal Medicare program and the government's alleged "medical consensus" regarding chelation therapy.

Medicare Basics. The Medicare program, enacted by 42 U.S.C. §1395 et seq., pays the costs of certain healthcare services upon a showing of entitlement. (Compl. ¶38.) The U.S. Department of Health and Human Services ("HHS") administers the Medicare Program through the Centers for Medicare and Medicaid Services ("CMS"). (Compl. ¶39.) To participate in the Medicare Program,

providers complete an Enrollment Application, titled CMS Form-8551. (Compl. ¶44.) Once enrolled, providers submit claims seeking reimbursement for services using CMS Form-1500. (Compl. ¶48-49.) The government argues that, when submitting claims on these forms, a provider certifies that the services rendered are "medically indicated and necessary for the health of the patient." (Compl. ¶¶48, 55.) Medicare Part B claims are administered by Medicare Administrative Contractors ("MACs") who act on behalf of CMS to process and pay Part B claims and perform administrative functions on a regional level. (Compl. ¶42.)

"Reasonable and Necessary" Services. According to the government, "Medicare only covers items and services that are 'reasonable and necessary for the diagnosis or treatment of illness or injury'" and "where use of the drug has been shown to be safe and effective." (Compl. ¶¶57, 60.) The government cites the CMS Medicare Program Integrity Manual to define "reasonable and necessary" as "not experimental or investigational." (Compl. ¶58.) The government then alleges that "safe and effective" drugs are those prescribed and used in accordance with FDA labeling.[2] (Compl. ¶61; *see also* ¶¶109-10.)

The "Medical Consensus" on Chelation Therapy. The government alleges that chelation therapy is a "rare treatment" that is only appropriate for patients suffering from "an uncommon condition called heavy metal poisoning (HMP)."

[2] This definition is from the Medicare Benefit Policy Manual, Chapter 15, §50.4.1, although the government does not provide a citation for its definition.

(Compl. ¶¶2, 66.) The government further alleges the "clear medical consensus" to be that chelation therapy is generally only indicated for "clinically confirmed" cases of HMP. (Compl. ¶74.) Over 50 paragraphs of the Complaint are used to describe this alleged "medical consensus" regarding chelation therapy, yet the government cites only a handful of articles and commentary from random sources in support of this "medical consensus," none of which are directly linked to this case.[3] Because the "medical consensus" allegedly is that chelation therapy is only indicated for HMP, the government contends that the use of chelation therapy to treat any condition other than HMP constitutes an alternative or experimental treatment. (Compl. ¶¶106-07.)

B. Few Factual Allegations Have a Nexus to Dr. Adams.

The Complaint contains few factual allegations about the medical consensus regarding chelation therapy that even arguably have a nexus to Dr. Adams.

Dr. Adams' Use of Chelation Therapy. The government alleges that Dr. Adams' use of chelation therapy is contrary to the "medical consensus and standard of care" alleged in the Complaint. (Compl. ¶130.) According to the

[3] In support of its argument, the government cites "one article," for which it does not provide the name of the author, article, publisher, date of publication, or any other identifying information as to the source (Compl. ¶80); a 2015 Minnesota Department of Health Bulletin (Compl. ¶81, ¶84 n.10); statements from the American College of Medical Toxicology ("ACMT"), a professional association (Compl. ¶¶70-73, 88, 91-92); a March 2007 article from the National Institutes of Health (Compl. ¶97); and Goldfranks Toxicological Emergencies (Compl. ¶102, n. 15).

government, Dr. Adams does not treat patients for HMP, which "medical consensus" deems the only condition that warrants chelation therapy. Rather, Dr. Adams treats patients for "excess body burden of heavy metals." (Compl. ¶147.) The government disagrees with, and in fact criticizes, Dr. Adams' treatment decisions, including his diagnostic testing methods and his administration of chelation therapy. (*See, e.g.*, Compl. ¶¶131 and n. 18, 134, 135 and n. 19, 138-39, 140.)

Dr. Adams' Alleged Knowledge. Despite devoting more than 50 paragraphs to describe the purported "medical consensus" about chelation therapy, the government simply concludes (with no allegations of fact) that Dr. Adams was aware of the "medical consensus" about chelation therapy and that he knew that Medicare would not cover his claims seeking reimbursement for chelation therapy.[4] The government appears to rely on certain Medicare form documents to demonstrate Dr. Adams' alleged knowledge, without any specific factual allegations that he was aware of the language on which it relies in this case. (*See, e.g.*, Compl. ¶¶45-47, 50, 117, 122, 152-153, 155, 158b.) The Complaint likewise fails to allege that Dr. Adams was aware of the supposed "medical consensus" alleged in the Complaint.

[4] Again, the government reimbursed these claims for over seven years without question.

III. LEGAL STANDARD

Federal Rule of Civil Procedure 12(b)(6) allows the Court to dismiss a complaint, or portions of a complaint, for "failure to state a claim upon which relief can be granted." *Hull v. Hull*, No. 4:14-CV-0162-HLM, 2014 WL 12703566, at *5 (N.D. Ga. Sept. 3, 2014) (Murphy, J.) (quoting Fed. R. Civ. P. 12(b)(6)). Although the Court must accept the factual allegations as true and construe those allegations in the light most favorable to the government, the Court is not required to accept the government's legal conclusions. *See id.* (citing *Chandler v. Sec'y of Fla. Dep't of Transp.*, 695 F.3d 1194, 1199 (11th Cir. 2012) (citing *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)); *Rivell v. Private Health Care Sys., Inc.*, 520 F.3d 1308, 1309 (11th Cir. 2008)). Moreover, the Court must reject "unwarranted deductions of fact or conclusions masquerading as facts." *Id.* (citing *Snow v. DirecTV, Inc.*, 450 F.3d 1314, 1321 (11th Cir. 2006) (internal quotation marks and citation omitted)).

The Court may dismiss a complaint if it does not plead "enough facts to state a claim to relief that is plausible on its face." *Id.* (citing *Chandler*, 695 F.3d at 1199 (internal quotation marks and citation omitted)). A complaint "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). Rather, the allegations "must be enough to raise a right to relief above the

speculative level on the assumption that all the allegations in the complaint are true (even if doubtful in fact)." *Id.* A claim is plausible on its face 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). A claim will not survive a motion to dismiss if it presents only the mere possibility that the defendant might have acted unlawfully. *Id.* The well-pleaded allegations of the complaint must move the claim "across the line from conceivable to plausible." *Hull*, 2014 WL 12703566, at *5 (quoting *Twombly*, 550 U.S. at 570).

In addition, FCA complaints also must meet the heightened pleading standard of Rule 9(b) and "state with particularity the circumstances constituting fraud or mistake." *United States v. Southerncare, Inc.*, No. CV410-124, 2015 WL 5278413, at *2 (S.D. Ga. Sept. 9, 2015). The complaint must provide the defendant with "enough information to formulate a defense to the charges." *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1313 n.24 (11th Cir. 2002). The complaint must plead not only the "who, what, where, when, and how of improper practices," but also the "who, what, where, when, and how of fraudulent submissions to the government." *Corsello v. Lincare, Inc.*, 428 F.3d 1008, 1014 (11th Cir. 2005).

IV. ARGUMENT

The Complaint in this case reads more like a 60-page criticism of Dr. Adams' medical judgment about the use of chelation therapy. There is no allegation that Dr. Adams knew of any alleged "medical consensus" regarding the use of chelation therapy – and his use of such therapy and the government's reimbursement of over seven years' worth of claims for such treatment, *inter alia*, belie any such knowledge. In sum, the government fails to allege *facts* showing that Dr. Adams *knowingly* submitted *false* claims in violation of the FCA, or that it would be entitled to recover money from Dr. Adams under the common law doctrines of payment by mistake and unjust enrichment. The Complaint must be dismissed in its entirety.

A. The Complaint Fails to Sufficiently Allege Dr. Adams Knowingly Submitted False Claims in Violation of the FCA.

Under the FCA, any person who "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval" or who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim" is liable to the United States. *See U.S. ex rel. Phalp v. Lincare Holdings*, 857 F.3d 1148, 1154-55 (11th Cir. 2017) (citing 31 U.S.C. § 3729(a)(1)(A)-(B)). As the United States Supreme Court recognized, "[t]he False Claims Act is not 'an all-purpose antifraud statute' . . . or a vehicle for punishing garden variety breaches of contract or regulatory violations." *Universal Health*

Servs., Inc. v. United States ex rel. Escobar, 136 S. Ct. 1989, 2003 (2016). Rather, liability under the FCA is reserved for those "who present or directly induce the submission of false or fraudulent claims" to the government. *Id.* at 1996.

The government asserts claims under 31 U.S.C. § 3729(a)(1)(A) and (B). (Compl., Counts I-II.) To establish a cause of action under § 3729(a)(1)(A), the government must prove three elements: "(1) a false or fraudulent claim, (2) which was presented, or caused to be presented, for payment or approval, (3) with the knowledge that the claim was false." *Phalp*, 857 F.3d at 1154. To prove a claim under § 3729(a)(1)(B), the government must show that: "(1) the defendant made (or caused to be made) a false statement, (2) the defendant knew it to be false, and (3) the statement was material to a false claim." *Id.*

The Complaint contains over 200 paragraphs and exceeds 60 pages, yet the FCA claim can be reduced to three basic allegations:

- Medicare only covers items and services that are "reasonable and necessary" for the diagnosis or treatment of illness or injury and where use of the drug has been shown to be safe and effective, which sub-regulatory guidance defines as "not experimental or investigational" and used in accordance with FDA labeling.
- According to "medical consensus" and the "standard of care," chelation therapy can only be used to treat HMP and Dr. Adams does not treat HMP.
- Dr. Adams knew that his claims for chelation therapy were not reimbursable according to the "medical consensus" and certain Medicare form documents.

To set forth an FCA claim, the government must sufficiently allege that Dr. Adams presented *false* information to the government and that he *knew* the information was false. The government fails to allege that Dr. Adams' claims for chelation therapy were false because its entire theory of falsity rests on (a) differences of medical opinion about chelation therapy that cannot be false and (b) sub-regulatory guidance that does not have the force of law. The government also fails to allege that Dr. Adams knew that his claims for chelation therapy were not reimbursable.

1. The Complaint does not adequately allege that Dr. Adams' claims for chelation therapy were false.

Eleventh Circuit case law is clear: "the submission of a false claim is the *sine qua non* of a False Claims Act violation." *Urquilla–Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1052 (11th Cir. 2015) (citations and internal quotations omitted). "Practices that may be improper, standing alone, are insufficient to show falsity without proof that specific claims were in fact false when submitted to Medicare." *Id.* at 1045 (*quoting Corsello v. Lincare,* Inc., 428 F.3d 1008, 1012 (11th Cir.2005)). The "fact that there may have been a violation of the laws governing Medicare ... is not enough, standing alone, to sustain a cause of action under the False Claims Act." *Phalp*, 857 F.3d at 1154. Indeed, "[t]he FCA requires '***proof of an objective falsehood***.'" *United States ex rel. Parato v. Unadilla Health Care Ctr. Inc.*, 787 F.Supp.2d 1329, 1339 (M.D. Ga. 2011) (emphasis added); *see also*

United States v. Aegis Therapies, No. CV–210–072, 2015 WL 1541491, at *12 (S.D. Ga. Mar. 31, 2015).

The government's theory of falsity is based entirely on the premise that Dr. Adams' use of chelation therapy was not "reasonable and necessary," and therefore not reimbursable under Medicare Part B. In other words, according to the government, a Medicare claim is false if it is not reimbursable. This, however, simply is not the law.

a. Differences in medical opinion do not constitute falsity under the FCA.

"A mere difference of opinion between physicians, without more, is not enough to show falsity." *United States v. AseraCare Inc.*, 176 F. Supp. 3d 1282, 1283 (N.D. Ala. 2016) ("Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false."). Indeed, "the prevailing view of courts is that 'contradiction based on clinical judgment or opinion alone cannot constitute falsity under the [False Claims Act] as a matter of law.'" *United States ex rel. Groat v. Boston Heart Diag. Corp.*, 255 F. Supp. 3d 13, 27-28 (D.D.C. 2017).[5] Differences in medical opinion "alone

[5] A*ccord, e.g., United States ex rel. Jones v. Brigham & Women's Hosp.*, 678 F.3d 72, 87 (1st Cir. 2012) ("We agree with the district court that [e]xpressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false." (citation and quotation marks omitted)); *United States ex rel. Hill v. University of Med. & Dentistry of N.J.*, 448 F. App'x 314, 316 (3d Cir. 2011) ("Because [e]xpressions of opinion, scientific

cannot prove falsity without further evidence of an objective falsehood." *AseraCare*, 176 F. Supp. 3d at 1283. The FCA "should not be used to call into question a health care provider's judgment regarding a specific course of treatment." *United States ex rel. Phillips v. Permian Residential Care Ctr.*, 386 F. Supp. 2d 879, 884 (W.D. Tex. 2005). In fact, "to demonstrate that the claims are 'known to be false' the Government must demonstrate that there were 'lies'—and not merely a scientific or technical dispute." *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1033 (D. Nev. 2006).

The *AseraCare* decision cited above directly addresses this issue.[6] The government accused AseraCare, a for-profit chain of hospice providers, of violating the FCA by submitting Medicare claims for patients who were not eligible for hospice care. *AseraCare*, 176 F. Supp. 3d at 1283. Central to the government's argument was AseraCare physicians' assessments of whether the Medicare patients had a prognosis of a life expectancy that was required for

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judgments or statements as to conclusions [about] which reasonable minds may differ cannot be false, FCA liability will not attach." (citation and quotation marks omitted)); *United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 983 (10th Cir. 2005) (citation omitted) ("Expressions of opinion, scientific judgments, or statements as to conclusions about which reasonable minds may differ cannot be false."); *United States ex rel. Riley v. St. Luke's Episcopal Hosp.*, 355 F.3d 370, 376 (5th Cir. 2004) (agreeing "in principle with the district court" that "expressions of opinion or scientific judgments about which reasonable minds may differ cannot be 'false.'" (citation omitted)).

[6] The government filed an appeal in United States Court of Appeals for the Eleventh Circuit, Case No. 16-3004.

hospice eligibility. *Id.* The court *sua sponte* considered and granted summary judgment at the close of the government's case-in-chief at trial. The government's only evidence of falsity was the expert testimony of a physician that, based on his review of sample patients' medical records, he would not have considered each patient to be terminally ill. *Id.* at 1285-86. As the government relied on "this difference of opinion alone," the court determined that the government failed to present any *objective* evidence of falsity. *Id.* at 1285. The court expressed "concern[] that allowing a mere difference of opinion among physicians alone to prove falsity would totally eradicate the clinical judgment required of certifying physicians." *Id.* The court held that "contradiction based on clinical judgment or opinion alone cannot constitute falsity under the FCA as a matter of law." *Id.* at 1286.

The court in *United States v. Vista Hospice Care, Inc.*, No. 3:07-cv-00604-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016), citing *AseraCare*, similarly refused to impose FCA liability based on the subjective clinical analysis of an expert regarding hospice eligibility. Indeed, the court found that "[b]ecause a physician must use his or her clinical judgment to determine hospice eligibility, an FCA claim about the exercise of that judgment must be predicated on the presence of an objectively verifiable fact at odds with the exercise of that judgment, not a matter of questioning subjective clinical analysis." *Id.* at *17. The relator argued

that the expert testimony, when coupled with the defendant's aggressive corporate policy of marketing, enrolling, and maintaining eligible patients, was sufficient evidence of falsity. *Id.* at *18. The court rejected that argument, finding that FCA liability did not arise in the absence of a causal link between the corporate policy and the allegedly false claims. *Id.* at *20.

The core issue is in this case is one of medical judgment. The government makes specific allegations about the clinical judgments underlying the decision to prescribe and administer chelation therapy per the "medical consensus" and the "standard of care," such as:

- chelation therapy is *only* indicated for HMP;
- providers must conduct a differential diagnosis of HMP;
- provoked urine tests, which the government alleges Dr. Adams used, are "unreliable and potentially dangerous" and should not be used to diagnose HMP;
- blood tests are the most reliable indicator of HMP and only sufficiently high results warrant chelation therapy;
- oral chelating agents are generally recommended;
- intravenous chelating agents like EDTA, which is what Dr. Adams used, should be reserved for incapacitated patients; and
- the use of chelation therapy to treat any condition other than HMP constitutes an "alternative" or "experimental" treatment.

(Compl. ¶¶74-105.) Each allegation centers on whether, why, and how a patient receives chelation therapy, which can only be determined based on the patient's individual needs according to the medical judgment of a licensed physician like Dr. Adams. At bottom, the government challenges Dr. Adams' clinical judgment that chelation therapy was an appropriate treatment for his patients and his decision to administer the chelating agent EDTA. That is precisely the type of "clinical judgment or opinion" that does not and cannot constitute falsity as a matter of law.[7]

As *AseraCare* and *Vista Hospice* make clear, the government must allege an *objective* falsehood to set forth a claim under the FCA. Here, the government simply alleges its own subjective opinion of the "medical consensus" and the "standard of care" for chelation therapy, whose supposed violation the government contends equals the knowing submission of false claims. In an FCA case like this one, where the alleged falsehood is rooted in medical judgment, the government must allege more than a subjective difference of opinion regarding the exercise of that judgment. The government's disagreement with and criticism of Dr. Adams'

[7] One court has found that allegations regarding medical judgment, when coupled with numerous other factual allegations not rooted in medical judgment, can be false so as to survive a motion to dismiss. *See United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F. Supp. 3d 730 (10th Cir. 2018) (holding "it is possible for medical judgment to be 'false or fraudulent' as proscribed by the FCA," focusing on specific factual allegations of objective falsity well-beyond the issue of the defendant's medical judgment).

medical opinion regarding the use of chelation therapy for his patients does not and cannot, without more, constitute objectively "false" claims.

Moreover, it is not sufficient for the government to simply cite "medical consensus" in support of its allegations of falsity without establishing a nexus to Dr. Adams. FCA claims must meet the heightened pleading requirements of Rule 9(b) and such vague allegations fall far short of the specificity the rule mandates. Despite the length of the Complaint, it does not state with particularity the circumstances constituting the fraud. The fraud in this case is rooted in the purported "medical consensus" about chelation therapy – but that "medical consensus" has no clear basis. The government cites a handful of publications from various sources with no connection to Dr. Adams. Although the Court is required to accept the factual allegations as true, the Court need not accept the government's conclusions or deductions "masquerading as facts." *Hull*, 2014 WL 12703566, at *5.

Equally important for purposes of this motion, Rule 9(b) also serves "to protect a defendant from harm to its goodwill or reputation." *U.S. ex rel. Stinson, Lyons, Gerlin & Bustamante, P.A. v. Blue Cross Blue Shield of Georgia, Inc.*, 755 F. Supp. 1040, 1053 (S.D. Ga.). The Complaint is replete with unnecessary and irrelevant allegations disparaging Dr. Adams, including that he practices "so-called 'alternative medicine" and that he is not board certified in Internal Medicine.

(Compl. ¶¶26, 27.) These disparaging allegations beget the "harm to reputation" that Rule 9(b) is intended to protect against. In the absence of any specific factual allegations regarding the government's claims of fraud based on "medical consensus" that permeate this case, the government should not be allowed to challenge Dr. Adams' medical judgment and qualifications and engage in discovery to bolster its position before trial.

b. Alleged violations of sub-regulatory guidance are not sufficient bases for FCA liability.

Central to the government's case is the definition of "reasonable and necessary." The term "reasonable and necessary" is not defined in the legislation enacting the Medicare program. Indeed, several courts have recognized that "[w]hat constitutes 'reasonable and necessary' services is not defined in the statute." *See, e.g., Aegis Therapies, Inc.*, 2015 WL 1541491, at *6 (citing 42 U.S.C. §1395y(a)). The government has failed to identify any binding law or regulation that prohibits Dr. Adams from submitting claims for chelation therapy.

Here, the government cites the CMS Medicare Program Integrity Manual to define "reasonable and necessary" as "not experimental or investigational." (Compl. ¶58.) The government also relies on a 2003 National Coverage Determination (NCD), which characterizes the use of EDTA as a chelating agent to treat atherosclerosis and calcinosis as "experimental" and not reimbursable. (Compl. ¶¶114-15.) Medicare manuals and coverage determinations are

interpretive rules – they do not have "the force and effect of law" and are not legally binding. *See, e.g.*, *Shalala v. Guernsey Mem'l Hosp.*, 115 S. Ct. 1232, 1239 (1995) (Medicare Provider Reimbursement Manual ("PRM") is an interpretative rule that "do[es] not have the force and effect of law"); *Cmty. Hosp. of Monterey Peninsula v. Thompson*, 323 F.3d 782, 791 (9th Cir. 2003) ("Pronouncements in manuals like the PRM . . . do not have the force of law"); *Mile High Therapy Ctrs. Inc, v. Bowen*, 735 F. Supp. 984, 986 (D. Colo. 1988) ("Agency manuals, guidelines and memoranda are interpretive rules not subject to the APA."). Dr. Adams should not be subject to FCA liability and the attendant severe penalties for an alleged failure to follow sub-regulatory guidance that is not legally binding, especially "in light of the quasi-criminal nature of FCA violations." *Atkins*, 470 F.3d at 1360.

Moreover, the Department of Justice's ("DOJ") internal policies specifically direct DOJ attorneys to refrain from filing civil cases based on sub-regulatory guidance. On January 25, 2018, then-Associate Attorney General Rachel Brand issued a memorandum titled "Limiting Use of Agency Guidance Documents in Affirmative Civil Enforcement Cases" ("Brand Memo").[8] The Brand Memo instructs DOJ litigators not to use guidance documents as the basis for liability in

[8] *Available at* https://www.justice.gov/file/1028756/download (last visited Oct. 24, 2018).

civil enforcement actions because the practice evades the notice-and-comment rulemaking process. Although the Brand Memo is an internal guideline, it supports the argument that FCA cases based on an alleged failure to comply with the "reasonable and necessary" standard, precisely the type of case at issue here, are inappropriate.[9]

2. The Complaint does not adequately allege that Dr. Adams acted with the requisite scienter.

The government must sufficiently allege that the defendant acted "knowingly," which the FCA defines as either "actual knowledge of the information," "deliberate ignorance of the truth or falsity of the information," or "reckless disregard of the truth or falsity of the information." *See* 31 U.S.C. § 3729(b)(1)(A). Although, unlike the other elements of an FCA claim, scienter is not required to be pled with particularity, conclusory allegations of scienter, such as those presented by the government in this case, are insufficient. *United States v.*

[9] Defendants acknowledge that some courts have permitted FCA cases based on alleged violations of agency guidance to proceed beyond the motion to dismiss stage. On appeal, the Tenth Circuit held that the claims could be "false" under the FCA if the heart procedure at issue was "not reasonable and necessary under the government's definition of the phrase" in the Medicare Program Integrity Manual. *Polukoff*, 895 F. Supp. 3d at 743. *See also United States v. Kinetic Concepts, Inc.*, No. CV 08-01885-BRO, 2017 WL 2713730, at *8 (C.D. Cal. Mar. 6, 2017) (permitting case to proceed based on misuse of a modifier billing code in violation of LCD). Defendants respectfully argue that these cases were wrongly decided, and this court should decline to follow them.

Fulton Cty., Georgia, No. 1:14-CV-4071-WSD, 2016 WL 4158392, at *11 (N.D. Ga. Aug. 5, 2016).

Here, the government simply tracks the language of the FCA, alleging that Dr. Adams submitted the alleged false claims with actual knowledge, or was recklessly indifferent or deliberately ignorant to the falsity of his claims. (Compl. ¶189.) That conclusory language is plainly insufficient. The government's main contention appears to be that Dr. Adams had actual knowledge that his claims for chelation therapy were false. (Compl. ¶¶190-91.) "'Actual knowledge' requires 'subjective' awareness of the falsity of the claim, record, or statement." *Graves v. Plaza Med. Ctrs., Corp.*, 276 F. Supp. 3d 1335, 1343 (S.D. Fl. 2017) (citations omitted). The government presents no allegations that show a subjective awareness by Dr. Adams that Medicare would not reimburse his claims for chelation therapy – in fact, such subjective awareness is refuted by the government reimbursing such claims for over seven years without question. The Complaint, therefore, fails to allege scienter under the FCA.

Certification Statements. The government alleges that Dr. Adams, by completing standard Medicare forms, certified that his treatments were medically necessary for the health of the patient. (Compl. ¶¶45-47 (Dr. Adams signed provider enrollment Form-8551); Compl. ¶150 (Dr. Adams submitted CMS 1500 forms seeking reimbursement for chelation therapy).) These general allegations

based on form language do not in any way demonstrate that Dr. Adams was subjectively aware of the specific Medicare guidance on which the government relies, such as the definition of "reasonable and necessary," nor does it show awareness of any specific guidance regarding chelation therapy. Every single Medicare-enrolled physician is required to sign these standard forms; merely signing these forms, therefore, cannot constitute "knowledge."

Policy Statements. The government alleges, without any factual basis whatsoever, that Dr. Adams knew his use of chelation therapy to treat conditions other than HMP was experimental and excluded from Medicare coverage by NCD 20.22. (Compl. ¶158b.) The government fails to allege any facts demonstrating that Dr. Adams received or knew of the 2003 NCD at any time from November 2008 to September 2015, the period at issue in the Complaint. The government makes similar allegations that Dr. Adams knew of the policy statements of "private insurers" regarding "experimental" chelation therapy because, "upon information and belief," the statements "were mailed" to Dr. Adams. (Compl. ¶122.) "[W]here allegations are based on information and belief, the complaint must set forth a factual basis for such belief." *U.S. ex rel. Phillips v. Permian Residential Care Ctr.*, 386 F. Supp. 2d 879, 883 (W.D. Tex. 2005) (citation omitted). The government cites no facts in support of its "belief" that Dr. Adams was mailed – let alone received or read – the coverage determinations listed in the Complaint.

Consent Form. The sole allegation that arguably directly relates to Dr. Adams appears in a footnote reciting language in a consent form. The government alleges that Dr. Adams required his patients to sign a consent form stating that chelation therapy "may be considered experimental . . . by Medicare," and that the patient would be responsible for payment of services performed should Medicare refuse coverage. (Compl. ¶117, n.16.) This consent form does not demonstrate that Dr. Adams knew that Medicare would not cover chelation therapy. The consent form demonstrates, at most, that Dr. Adams employed the standard business practice of informing his patients that they are responsible for the cost of their treatment if the third-party payer does not remit payment. The Eleventh Circuit dismissed an FCA case where the relators relied on "general allegations of [the defendant's] 'standard operating procedure[s],' 'standard business practice[s],' and the 'course of … operations,'" none of which "hardly established" that the defendant "ask[ed] the [g]overnment to pay amounts it did not owe." *Carrell v. AIDS Healthcare Found., Inc.*, 898 F.3d 1267, 1278 (11th Cir. 2018). The same is true here, where the government has not alleged any facts demonstrating that Dr. Adams submitted claims for chelation therapy that he knew Medicare would not cover.

Medical Consensus. The remaining allegations that touch upon scienter assume that Dr. Adams was aware of the government's unspecified "medical

consensus" about chelation therapy. (Compl. ¶¶20, 189-91.) For example, the government simply concludes, without any factual support, that Dr. Adams knew EDTA chelation was for patients with significantly heightened blood lead levels and that chelation therapy is not covered by Medicare. (Compl. ¶¶152, 153, 155.) The government does not allege that Dr. Adams knew about any of the publications or other sources that support the "medical consensus" as set forth in the Complaint, even after obtaining tens of thousands of pages of documents from Dr. Adams as part of its pre-filing investigation. These conclusory allegations do not demonstrate that Dr. Adams was subjectively aware that his claims for chelation therapy were false.

The government's FCA claims fail to state a claim upon which relief can be granted and must be dismissed. The government is required to present plausible factual allegations that Dr. Adams *knowingly* submitted *false* claims, which it does not do. The government's case is rooted in medical judgment that cannot render a Medicare claim false without additional evidence of an objective falsity. The government's case also relies heavily on a definition of "reasonable and necessary" that is not defined in the Medicare legislation and that the DOJ itself deems an insufficient basis on which to bring an FCA case. And the government fails to plausibly plead knowledge by Dr. Adams.

B. The Claims for Payment by Mistake of Fact and Unjust Enrichment Also Must Fail.

In the event that its FCA claims fail, the government asserts alternative claims against Dr. Adams for payment by mistake (Count III) and unjust enrichment (Count IV). These common law causes of action are based on the same factual allegations as the FCA claims, *i.e.* Dr. Adams submitted claims for chelation therapy that were not reasonable and necessary, and the government should be able to recoup related federal funds from Dr. Adams. (*See* Compl. ¶¶201-03; ¶¶204-07.) It is not clear from the Complaint whether the government pleads its claims for payment by mistake and unjust enrichment under federal common law or Georgia state law. For that reason alone, Counts III and IV should be dismissed for failure to state a claim. *U.S. ex rel. St. Joseph's Hosp., Inc. v. United Distributors, Inc.*, 918 F. Supp. 2d 1306, 1316 (S.D. Ga. 2013) ("Because it is unclear from the Complaint whether the Government's claims of unjust enrichment and payment by mistake were pled under federal common or Georgia state law, the United Defendants' motion to dismiss as to Counts Four and Five are granted."). Even if it had identified the source of these claims, the government fails to state a claim under either theory and both counts should be dismissed.

Some district courts have held that common law claims for payment by mistake and unjust enrichment "involve rights of the United States under a nationwide federal program," and therefore are governed by federal common law

and not state law. *United States v. Halifax Hosp. Med. Ctr.*, No. 6:09-CV-1002-ORL-31, 2013 WL 6017329, at *7 (M.D. Fla. Nov. 13, 2013) (citing *United States v. Kimbell Foods, Inc.*, 440 U.S. 715, 726 (1979); *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366–67 (1943)). Other district courts have analyzed these claims in FCA cases under state law. *See, e.g.*, *United States ex rel. Reeves v. Mercer Transp. Co., Inc.*, 253 F. Supp. 3d 1242, 1255 (M.D. Ga. 2017).

1. The Complaint does not set forth a claim for payment by mistake of fact.

To set forth a claim for payment by mistake under federal common law, the government must allege sufficient facts to "show that it made payments 'under an erroneous belief which was material to the decision to pay.'" *Halifax*, 2013 WL 6017329, at *7 (quoting *United States v. Mead*, 426 F.2d 118, 124 (9th Cir. 1970)). To recover for payment by mistake of fact under Georgia law, a party "must prove that its payment was not voluntarily made because certain material facts were not known at the time of payment, or because a valid reason existed for its failure to determine the truth." *Applebury v. Teachers' Retirement System of Georgia*, 620 S.E. 2d 452, 453 (Ga. App. 2005). Even when money is paid under a mistake of fact, "it can not [sic] be recovered unless the circumstances are such that the person to whom it was paid can not [sic] in good conscience retain it." *Time Ins. Co. v. Fulton-DeKalb Hosp. Auth.*, 438 S.E.2d 149, 151 (Ga. App. 1993) (citation omitted).

The government alleges that it "ma[de] payments of certain sums of money in the mistaken belief that the Defendants' claims involved chelation therapy that was medically necessary to treat patients suffering from lead poisoning or another form of heavy metal poisoning." (Compl. ¶202.) The only alleged "mistake" set forth in the Complaint is the government's purported mistaken belief that the chelation therapy at issue was "reasonable and necessary," a term that is not defined in the law and that lies at the heart of all of the government's claims against Dr. Adams in this case. Dr. Adams provided chelation therapy to his patients per his independent medical judgment. And the sole challenge to his entitlement to retain money paid for his services is a mistake based on an undefined "medical consensus" with no link to Dr. Adams and a term whose ascribed meaning is not legally binding. This is not the type of "mistake" for which the government can argue that Dr. Adams should not "in good conscience" retain the payments made for medical treatment rendered.

2. The Complaint does not set forth a claim for unjust enrichment.

A claim for unjust enrichment under federal common law arises when "(1) the government had a reasonable expectation of payment; (2) the defendant should reasonably have expected to pay, or (3) 'society's reasonable expectations of person and property would be defeated by nonpayment.'" *Halifax*, 2013 WL 6017329, at *7 (citing *United States v. Rogan*, 459 F.Supp.2d 692, 728 (N.D. Ill.

2006)). To recover for a claim for unjust enrichment under Georgia law, the government to prove: "(1) a benefit has been conferred, (2) compensation has not been given for receipt of the benefit, and (3) the failure to so compensate would be unjust." *Clark v. Aaron's, Inc.*, 914 F. Supp. 2d 1301, 1309 (N.D. Ga. 2012).

The government's claim for unjust enrichment alleges that "Defendants received [] federal monies to which they are not entitled" because: (1) Defendants violated 42 U.S.C. §1395a(a)(1)(A) by billing claims for services that were not "reasonable or necessary," and (2) Defendants billed Medicare for "experimental" or "alternative" uses of EDTA that were not for FDA-approved indications and thus were not reimbursable. (Compl. ¶206.) These arguments are specific to the Medicare program, and cannot be divorced from the statutes and other documents on which they are based. The government cannot be allowed to force a failed FCA claim to become an unjust enrichment claim based on allegations that exist only in the FCA context. Moreover, the government does not allege that Dr. Adams failed to provide the services at issue to the patient. Because Dr. Adams treated the patients according to his medical judgment and submitted claims for services that were actually rendered, there can be no argument that he should have expected to pay the money back or that retention of the payment for his services is unjust.

Although there are conceivable situations where the government could seek the return of federal funds because of a mistake of fact or unjust enrichment that do

not rise to the level of fraud proscribed by the FCA, this is no such case. These claims are rooted in the government's disapproval of Dr. Adams' medical judgment and hinge on the meaning of "reasonable and necessary," which can only be considered in the context of the Medicare program and, by extension, the FCA. These claims should be dismissed for the same reasons as the FCA claims on which they are based. *See, e.g., United States v. Aegis Therapies, Inc.*, No. CV 210-072, 2015 WL 1541491, at *14 (S.D. Ga. Mar. 31, 2015) (granting summary judgment for similar claims as "derivative" of the FCA).

V. CONCLUSION

Accordingly, for all the foregoing reasons, the Complaint should be dismissed in its entirety.

CERTIFICATION OF FONT SIZE

The foregoing was prepared in Times New Roman, 14-point font, approved by the Court in Local Rule 5.1 (B).

Date: November 28, 2018

Defendants Charles C. Adams, M.D., Charles C. Adams, M.D., P.C. d/b/a/ Full Circle Medical Center, and Personal Integrative Medicine PLLC

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CERTIFICATE OF SERVICE

I hereby certify that on November 28, 2018, I electronically filed the foregoing Defendants' Motion to Dismiss with the Clerk of Court using the CM/ECF system, which will automatically send e-mail notification of such filing to the following attorneys of record:

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