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

UNITED STATES OF AMERICA PLAINTIFF, *v.* CHARLES C. ADAMS, M.D., CHARLES C. ADAMS, M.D., P.C., D/B/A FULL CIRCLE MEDICAL CENTER, AND PERSONAL INTEGRATIVE MEDICINE DEFENDANTS.	Civil Action No. No. 4:18-cv-191-HLM

UNITED STATES' BRIEF IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

NOW COMES the United States of America, by and through the undersigned Assistant United States Attorney, and the United States Attorney for the Northern District of Georgia, and files its Brief in Opposition To Defendants' Motion to Dismiss ("MTD") (Doc. 13).

INTRODUCTION AND SUMMARY OF THE ARGUMENT

The United States' FCA claims arise from fact that, although Medicare reimburses providers for the administration of the drug EDTA when used to treat patients suffering from lead poisoning, Medicare does not cover—and explicitly

excludes coverage for—EDTA when used as an alternative, or off-label therapy for other conditions. (Doc. 1, ¶¶109-117). The Complaint alleges that Defendants knowingly submitted false claims to Medicare for EDTA treatment that was excluded from coverage.

In their MTD, Defendants argue that the United States has failed to sufficiently allege two elements required to state a claim under the False Claims Act (the "FCA"): falsity and scienter. As discussed below, the United States has sufficiently alleged both elements.

Falsity. Referencing specific claims, the Complaint offers particularized allegations that Dr. Adams' EDTA claims were false for four distinct reasons. First, in the claims that they submitted to Medicare, Defendants falsely stated that Dr. Adams had diagnosed his patients with various forms of Heavy Metal Poisoning ("HMP"), despite evidence to the contrary (including Dr. Adams' own admissions and the underlying medical records). Second, the claims sought reimbursement for experimental EDTA therapy that was (and is) excluded from Medicare coverage by National Coverage Determination ("NCD") 20.22. Third, the claims sought reimbursement for off-label, non-FDA approved uses of EDTA, which are not covered by Medicare. Fourth, the claims falsely certified that the EDTA

treatments were medically necessary based on the patients' individual signs and symptoms.

In their MTD, Defendants fail to address the allegations that Defendants included false diagnoses on the claims that they submitted to Medicare. Instead, they attack the second and third theories of falsity as not constituting a sufficient basis for showing falsity, and they attack the fourth theory on the ground that a difference in medical opinions regarding the use of chelation therapy is an insufficient basis to show falsity.

However, contrary to Defendants' argument, courts can look to NCDs and CMS guidance to determine whether a claim for services is reasonable and necessary. *See e.g.*, *U.S. ex rel. Ryan v. Lederman*, No. 04-CV-2483, 2014 WL 1910096, at *3–7 (E.D.N.Y. May 13, 2014); *U.S. v. Mount Sinai Hospital*, 256 F.Supp.3d 443, 452-453 (S.D.N.Y, 2017). Similarly, medical judgments can, in fact, be "false or fraudulent as proscribed by the FCA[.]" *U.S. ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 742 (10th Cir. 2018), *see also U.S. v. Paulus*, 894 F.3d 267, 275 (6th Cir. 2018). Accordingly, all of Defendants' arguments regarding the element of falsity are unavailing.

Scienter. Defendants assert that the "Complaint does not adequately allege that Dr. Adams acted with the requisite scienter." (Doc. 13, p. 21) Although they

concede that scienter is not required to be pled with particularity, they contend that the Complaint's allegations that the claims were submitted with actual knowledge, reckless indifference or deliberate ignorance are "plainly insufficient." (Doc. 13, p. 22). In fact, the Eleventh Circuit has held that similar allegations were sufficient to allege scienter in a FCA. *See U.S. ex rel. Matheny v. Medco Sols., Inc.*, 671 F.3d 1217, 1224 (11th Cir. 2012).

At any rate, the Complaint does contain specific factual allegations showing that Defendants were, at minimum, recklessly indifferent regarding the falsity of the claims that they submitted. For example, the Complaint alleges that, in submitting false claims, "Defendants either had actual knowledge that, or acted in deliberate ignorance or reckless disregard of the falsity of the claims." (Doc. 1, ¶20.) Even though Defendants acknowledge that scienter can be satisfied by showing actual knowledge, deliberate ignorance or reckless indifference, they focus entirely on actual knowledge, to the exclusion of the other two bases for FCA scienter.

Finally, Defendants argue that the United States' payment by mistake and unjust enrichment claims are "derivative" of its allegedly deficient FCA claims and must accordingly be dismissed. However, the United States' common law claims are independent of the FCA claims, and have been adequately pled.

ARGUMENT

I. THE COMPLAINT ADEQUATELY PLEADS VIOLATIONS OF THE FALSE CLAIMS ACT UNDER 31 U.S.C. § 3729(a)(1)(A) & (B). (COUNTS I–II).

To state a claim under § 3729(a)(1)(A) of FCA, the Government must show the following: (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. *U.S. v. Lincare Holdings, Inc.*, 857 F.3d 1148, 1154 (11th Cir. 2017). Similarly, a § 3729(a)(1)(B) claim requires a showing 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.*

Here, Defendants argue that the United States has failed to adequately allege that the claims were false and that Defendants had the requisite scienter. As shown below, these arguments are without merit.

A. The Complaint Sufficiently Alleges That Defendants' Claims Were False.

1. Defendants' Claims Were False As They Contained False Diagnosis Codes.

The Complaint alleges that Defendants schemed to obtain reimbursements for alternative EDTA chelation therapy (which is *not* covered under Medicare) by submitting claims to CMS wherein they misrepresented—through the use of ICD-

9 Diagnostic Codes for HMP—that he administered EDTA to patients diagnosed with (and suffering from) various forms of HMP, such as lead poisoning.[1] (Doc. 1, ¶6-8.) The Complaint provides detailed examples of Dr. Adams utilizing ICD-9 Diagnostic Codes for HMP/lead poisoning on claims submitted to Medicare (*see* Doc. 1, ¶¶ 6-8, 160-162), and alleges that such claims are false as the patients had not been diagnosed with, or treated for, HMP/lead poisoning.[2] (*See, e.g.*, Doc. 1, ¶17-19) Indeed, Dr. Adams admitted that diagnoses codes associated with HMP should not have been utilized on his claims. (Doc. 1, ¶¶147-149). Defendants included the false diagnoses because they knew that Medicare would not reimburse for EDTA treatment unless it was used to treat HMP/lead poisoning. (Doc. 1, ¶14-18).

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[1] As noted in the Complaint, lead poisoning is the most commonly diagnosed form of HMP, and the majority of Dr. Adams' false claims are associated with ostensible cases of lead poisoning. Therefore, while the Government seeks to recover on all of Defendants' claims reflecting HMP diagnoses, its discussion largely centers on lead poisoning.

[2] The Complaint alleges in detail – and the medical records confirm – that (with reference to the medical consensus for diagnosing and treating HMP) the patients were not suffering from HMP, as they had not been exposed to potentially toxic heavy metals and had little (if any) of such metals in their blood. (Doc. 1, ¶¶ 6-8, 93-99, 133-136, 160-62, 174-185).

Due to the false diagnoses contained therein, Defendants' claims are false under the FCA. Under the FCA, a claim is straightforwardly false when "it involves an incorrect description of goods or services provided[.]" *U.S. v. Sci. Applications Int'l Corp.*, 626 F.3d 1257, 1266 (D.C. Cir. 2010); *U.S. ex rel. Gelbman v. City of New York*, No. 14-CV-771 (VSB), 2018 WL 4761575, at *5 (S.D.N.Y. Sept. 30, 2018) (same). Moreover, a physician's claims are "false" under the FCA when they contain "false diagnoses." *See U.S. v. Crumb*, No. 15-0655-WS-N, 2016 WL 4480690, at *11–14 (S.D. Ala. Aug. 24, 2016) (denying 12(b)(6) motion, court ruled government had adequately pled falsity in FCA Complaint by alleging that defendants' claims contained "falsified diagnoses"). [3]

Stated plainly, Defendants' claims are "factually" false as they misrepresent that EDTA was administered to treat patients diagnosed with, and suffering from, lead poisoning. *See, U.S. v. Rite Aid Corp.*, No. 2:12-cv-01699-KJM-EFB, 2018 WL 4214887, at *3 (E.D. Cal. Sept. 5, 2018) (Court found that use of false diagnosis codes

[3] In *Crumb*, the court explained that "a fair reading of these factual allegations is that Dr. Crumb knowingly falsified diagnoses of ST/GTD in hundreds of cases, then listed those false diagnoses on Form CMS-1500s that were submitted [to Medicare.] The Government relied on the false diagnosis codes[.] This is the Government's "false diagnosis" theory of liability[,] . . . [a]nd it is adequately pleaded in the Amended Complaint[.]" *Id.* at *14.

constituted the "making of 'explicit lies' in a claim for payment."); *U.S. ex rel. Ramsey-Ledesma v. Censeo Health, LLC*, No. 3:14-CV-00118-M, 2016 WL 5661644, at *5–7 (N.D. Tex. Sept. 30, 2016) (same.)

Revealingly, Defendants decline to address the Complaint's allegations regarding their use of false diagnosis codes. Indeed, these allegations, standing alone, satisfy the element of falsity with respect to *all* of the United States' FCA claims against Defendants.[4]

2. Defendants' Claims Were False Because They Sought Reimbursement For Experimental Chelation Therapy Excluded From Medicare Coverage By NCD 20.22.

Additionally, Defendants' claims were false as they sought reimbursement for experimental EDTA chelation therapy that was, and is, excluded from Medicare coverage by National Coverage Determination ("NCD") 20.22. NCDs are nationwide determinations as to what goods or services Medicare will cover. (*See, infra* p. 10-13) NCD 20.22 provides that "the use of EDTA as a chelating agent to treat atherosclerosis, arteriosclerosis, calcinosis or similar generalized

[4] Defendants' overarching *AseraCare*-based "medical judgment/objective falsehood" argument is completely inapplicable to the Complaint's allegations as to "falsified diagnoses." *See, e.g., Graves v. Plaza Med. Ctrs., Corp.*, 276 F. Supp. 3d. 1335, 1342 (S.D. Fla. 2017)

conditions not listed by the FDA as an approved use is not covered. Any such use of EDTA is considered experimental." (Doc. 1, ¶¶ 113–117) The only indicated use for EDTA on the FDA approved label—and hence the only use of EDTA chelation therapy that is covered under Medicare—is the treatment of lead poisoning. (Doc. 1, ¶¶ 113, 147–48)

The Complaint alleges that Defendants submitted claims for EDTA treatment for various conditions other than lead poisoning (Doc. 1, ¶¶ 113, 147–48), as Dr. Adams is a practitioner of integrative medicine, and administers EDTA as an "experimental" treatment for a variety of conditions, such as "chronic fatigue," "healthy aging," and "bone growth." (Doc. 1, ¶¶ 123-126) Indeed, the Complaint provides detailed examples of claims associated with Dr. Adams' "experimental" EDTA chelation therapy. (*See, e.g.,* Doc. 1, ¶¶ 166, 171-172). Consequently, these claims are false.

In their MTD, Defendants do not dispute the sufficiency of the Complaint's allegations regarding Dr. Adams (1) administering EDTA as an alternative therapy and (2) billing Medicare for such therapy,[5] but argue that NCDs are "not legally

[5] To the contrary, Defendants admit that they administered EDTA as an alternative therapy. (Doc. 13, p. 2.)

binding," but merely "interpretive rules," which cannot form the basis of an FCA claim. (Doc. 13, p. 19–21.) These assertions are incorrect.

a. NCDs are binding regulations that specify whether a particular treatment is covered under Medicare.

An NCD is a binding determination by the U.S. Department of Health and Human Services ("HHS") of "whether a particular item or service is covered nationally under Medicare." 42 C.F.R. § 405.1060. In describing HHS's authority to determine what services are covered under Medicare, the court in *Polukoff*, 895 F.3d 730, explained that:

> The Secretary of Health and Human Services decides "whether a particular medical service is 'reasonable and necessary' . . . by promulgating a generally applicable rule or by allowing individual adjudication." The former course involves a "national coverage determination" that announces "whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B). In the absence of a national coverage determination, local Medicare contractors may issue a "local coverage determination" that announces "whether or not a particular item or service is covered" by that contractor. *Id.* § 1395ff(f)(2)(B).

Id. at 735 (internal citations omitted).

Contrary to Defendants' contention that NCDs are mere "guidance" and "not legally binding," (Doc. 13, p.19–20) "NCDs are considered substantive rules,

which carry the force of law[,]" *Advanced Diabetes Treatment Ctrs., LLC v. Sebelius*, 2011 WL 13268857, at *4 (S.D. Fla. Apr. 7, 2011).[6]

b. Claims submitted in contravention of an NCD are false under the FCA.

Claims submitted to Medicare in contravention of an NCD are "legally false" under the FCA, and thus give rise to FCA liability. *See e.g.*, *U.S. ex rel. Ryan v. Lederman*, No. 04-CV-2483, 2014 WL 1910096, at *3–7 (E.D.N.Y. May 13, 2014) (Court found that claims for procedure excluded by an LCD were false under the FCA); *Sklar*, 273 F.Supp.3d at 895–99 ("LCDs are binding and may provide the basis for liability under the FCA."); *U.S. v. Kinetic Concepts, Inc.*, No. CV 08-01885-BRO, 2017 WL 2713730, at *8 (C.D. Cal. Mar. 6, 2017) ("[The] failure to comply with . . . LCDs may give rise to an FCA claim.")[7]

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[6] Defendants cite to numerous cases – *e.g.*, *Shalala v. Guernsey*, 115 S.Ct. 1232 (1995), *Cmty. Hosp. v. Thompson*, 323 F.3d 782 (9th Cir. 2003) – in support of the argument that NCDs are "interpretive rules," which are not binding. (Doc. 13, p. 20). However, none of these cases say anything about NCDs, which are legally binding rules that are – in fact – promulgated through formal rulemaking. *See, e.g.*, 42. U.S.C § 1395ff(f)(1)(B); *see also* 42 C.F.R. §§ 400.202, 405.1060

[7] *Lederman*, *Sklar* and *Kinetic* deal with *local* coverage determinations (LCDs) (which are only regional in scope and issued by Medicare contractors), but their holding – *e.g.*, that claims that violate LCDs are "false" – is plainly also applicable to NCDs (which are promulgated through HHS rulemaking and are national in scope). *(see supra* p.10-11)

In *Lederman*, the United States alleged an oncologist had violated the FCA by submitting claims for a procedure excluded from Medicare coverage by an LCD. *Id.* at *3. As Dr. Adams argues here, the defendant in *Lederman* argued that the LCD was "not controlling," only "guidance," and not a basis for liability under the FCA. *Id.* at *3–5. However, after reviewing the relevant statutory and regulatory text, the court in *Lederman* stated that "[t]he text gives no indication that particular LCDs are anything other than conclusive on the matters they address[,]" and rejected the argument that LCDs are simply "guidance" or "advisory" and not a basis for FCA liability. *Id.* at *4. The *Lederman* court further explained that "the government has proven as a matter of law that [defendant] submitted claims that were false because they were not covered by his Medicare Part B carrier." *Id.* at *6 (emphasis added).

In *Sklar*, the relators alleged that a podiatrist violated the FCA by submitting claims for procedures excluded from coverage by several LCDs. *Sklar*, 273 F.Supp.3d at 895–96. In response, the *Sklar* defendants argued that LCDs were "mere guidance—and not binding requirements—for doctors to use when rendering and claiming reimbursement for treatment." *Id.* at 896. In assessing this contention, the court in *Sklar* noted that:

> [T]he first issue we must address is whether LCDs are binding and enforceable on doctors who submit claims to Medicare and whether the submission of claims for reimbursement for treatment that is not reasonable and necessary under an applicable LCD can create liability under the FCA.

Id. The court in *Sklar* answered both questions in the affirmative, and ruled that "LCDs are binding and may provide the basis for a claim for submission of false claims under the FCA." *Id.* at 898. Defendants do not cite to any caselaw indicating that NCDs cannot serve as the basis for allegations of falsity. (*See*, Doc. 13, pg. 19-21).

As the preceding cases illustrate, by billing Medicare for experimental EDTA chelation explicitly excluded from coverage by NCD 20.22, Defendants submitted "false" claims under the FCA. Moreover, this theory of falsity, standing alone, is sufficient to establish falsity with respect to *all* of the United States' FCA claims.[8]

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[8] In view of NCD 20.22, Dr. Adams' overarching *AseraCare*-based contention, *e.g.*, that his claims "cannot" be false as the therapy was appropriate in his "medical judgment" is inapt. *Sklar*, 273 F.Supp.3d at 897 ("Because we conclude that LCDs are binding, we reject defendants' contention that the four treatments at issue are reimbursable simply because [defendant] considered them medically reasonable and necessary."); *see also Lederman*, 2014 WL 1910096, at *6.

3. Defendants' Claims Were False As They Sought Reimbursement For Off-Label Uses of EDTA.

Similarly, Defendants' claims are false as they sought reimbursement for non-FDA approved uses of EDTA, *i.e.*, uses that are outside of the indications listed on EDTA's FDA approved label, which states that EDTA is *only* indicated for lead poisoning. (Doc. 1, ¶113) Medicare only covers claims that are "reasonable and necessary." (Doc. 1, ¶57) Although the "reasonable and necessary" requirement is both statutory and regulatory, Medicare provides more detail regarding the "reasonable and necessary" requirements as it pertains to medications in the *Medicare Benefit Policy Manual*. Specifically, the manual states that Medicare does not cover the cost of drugs when utilized for off-label purposes, *absent* a finding by the local Medicare Administrative Contractor ("MAC") that a particular off-label use is medically accepted. (Doc. 1, ¶¶60-63).

Dr. Adams does not treat lead poisoning with EDTA (Doc. 1, ¶ 147-150), but a variety of other conditions not listed on EDTA's FDA label. (Doc. 1, ¶¶123-128, 164-173). However, the medical consensus is that chelation is only effecting in treating HMP. (Doc. 1, ¶¶ 74-76, 98, 106-109) Moreover, because the relevant MAC never found *any* off-label uses of EDTA to be medically accepted (Doc. 1, ¶¶60-63, 112-113), Defendants' claims for off-label uses of EDTA were false under

the FCA. *See, e.g., U.S. ex rel. Brown v. Celgene Corp*, No. CV 10-3165-GHK, 2014 WL 3605896, at *4 (C.D. Cal. July 10, 2014) (Court found that relator sufficiently pled falsity by alleging that "claims were false because they were for off-label uses that are not covered by Medicare[]").

Defendants do not contest the sufficiency of the United States' allegations concerning Dr. Adams' off-label uses of EDTA, but argue the Medicare manuals stating that off-label and/or experimental uses of drugs are not reimbursable are mere "sub-regulatory guidance," which are "not sufficient bases for FCA liability." (Doc. 13, p. 19–20.) Additionally, Defendants suggest that an internal DOJ memorandum (*i.e.*, the "Brand Memorandum") precludes DOJ attorneys from relying upon CMS and/or Medicare guidance documents when pursuing FCA claims. (Doc. 13, 20–12).

Defendants' assertion that Medicare interpretations of the "reasonable and necessary" statutory standard (*i.e.,* 42 U.S.C. § 1395y(a)(1)(A)) are irrelevant to FCA liability has been squarely rejected by numerous courts. *See, e.g., U.S. v. Mount Sinai Hospital*, 256 F.Supp.3d 443, 452-453 (S.D.N.Y, 2017) (Court noted that, "there have been numerous cases imposing FCA liability…based on violations of Medicare program manuals."); *In re Cardiac Devices Qui Tam Litig*., 221 F.R.D. 318,

349-354 (D. Conn. 2004) (Collecting cases illustrating that Medicare regulations inform whether a particular service is "reasonable and necessary.")

For instance, in *Polukoff*, 895 F.3d at 742–43 (Court overruled district court's decision that, *inter alia*, relator failed to plead falsity under the FCA). Indeed, after defining "reasonable and necessary" with reference to the *Medicare Program Integrity Manual* referenced in the Complaint (*see* Doc. 1, ¶58) (and which Defendants attempt to minimize in their MTD (*see* Doc. 13, 19–20)), the court in *Polukoff* explained that:

> For a claim to be reimbursable, it must meet the government's definition of "reasonable and necessary," as found in the Medicare Program Integrity Manual . . . . We thus hold that a doctor's certification to the government that a procedure is "reasonable and necessary" is "false" under the FCA if the procedure was not reasonable and necessary under the government's definition of that phrase.

Id. at 742–43.[9]

[9] Defendants cite to numerous cases – *e.g.*, *U.S. v. Aegis Therapies, Inc.,* 2015 WL 1541491 (Mar. 31, 2015, S.D. Ga.), *Cmty. Hosp. of Monterey Peninsula v. Thompson*, 323 F.3d 782, (9th Cir. 2003), *Shalala v. Guernsey*, 115 S.Ct. 1232 (1995) – to support the assertion that, Medicare manuals do not have "force of law" and are not "legally binding." (Doc. 13, p. 20). To clarify, the Government's FCA claims arise from Defendants' violation of the "reasonable and necessary" requirement set forth in 41 U.S.C § 1395y(a)(1)(A). However, consistent with the reasoning in *Mt. Sinai, In re Cardiac*, and *Polukoff*, the Government cites to the *Medicare Program Integrity Manual* to demonstrate that Defendants' claims are not "reasonable and

Finally, Defendants' invocation of an internal office memorandum (*i.e.*, the Brand Memorandum) is legally inapt. (Doc. 13, pgs. 20-21) Indeed, the Brand Memorandum itself stated that it: "is not intended to, does not, and may not be relied upon to, create any rights, substantive or procedural, enforceable at law by any party in any matter civil or criminal." In contrast to, *inter-alia*, statutes, regulations, and caselaw, internal office memos – such as the Brand Memo – do not constitute the type of legal authority that can be illustrative, persuasive or controlling in deciding the legal issues associated with the MTD.

4. Defendants' Claims Were False Due To Defendants' False Certifications That EDTA Was Medically Necessary.

Finally, the Complaint alleges that Defendants' claims were false due to Dr. Adams' false certifications that EDTA was medically necessary based on the patients' signs and symptoms. (*See, e.g.*, Doc. 1, ¶¶ 174-185).

In their MTD, Defendants attempt to mischaracterize the United States' claims as a "specious disagreement" or "difference of opinion" with Dr. Adams'

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necessary" as defined by Medicare. None of Defendants' cases state that Medicare manuals cannot be used in an FCA action to demonstrate that a particular service is not "reasonable and necessary." Indeed, in *Aegis*, the court noted that where, "statutes and regulations fail to give a precise standard…CMS provides that guidance." *Id.* at *6.

"clinical judgment about the use of chelation therapy, and his practice of alternative medicine." (Doc. 13, p. 2.) Next, Defendants—in reliance upon *AseraCare*, 176 F. Supp. 3d 1282 and *U.S. v. Vista Hospice Care, Inc.*, No. 3:07-cv-00604-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016)—contend that such "differences in medical opinion alone cannot prove falsity without further proof on an objective falsehood[:]"[10] (Doc. 13, p. 14)

> 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.

(Doc. 13, p. 15.) However, these contentions suffer from multiple problems.

a. A physician's medical opinion/judgment can be "false" under the FCA.

First of all, a physician's subjective medical opinions and/or judgments can, in fact, be "false" under the FCA. *See*, *e.g.*, *Polukoff*, 895 F.3d at 743 ("It is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA[.]"); *Paulus*, 894 F.3d at 275 (same). Citing to *AseraCare*, Defendants contend that,

[10] Similarly, Defendants cite to several cases in support of the proposition that "Expressions of opinion, scientific judgments or statements as to conclusions about which reasonable minds may disagree cannot be false." (*See* Doc. 13, p. 13 n.5)

absent an objective falsehood, a physician's medical opinion cannot be false under the FCA. Pursuant to this notion, a physician's medical opinion—*no matter how fanciful, unsupported, or fringe*—is immune from FCA liability. To the extent that *AseraCare* and its progeny support this proposition, these cases were wrongly decided, and should not be adopted by the Court. [11]

Indeed, in *Polukoff*, the Tenth Circuit reversed a district court's dismissal of an FCA complaint, which was predicated upon the notion that "opinions, medical judgments and conclusions about which reasonable minds may differ cannot be false for the purposes of an FCA claim." *Id.* at 739 (internal citations omitted). In rejecting this contention, the Tenth Circuit explained that "[i]t is possible for a medical judgment to be 'false or fraudulent' as proscribed by the FCA[,]" and "the

[11] To be sure, citing to *AseraCare*, several district courts have endorsed the notion that "contradiction based on clinical judgment or opinion alone cannot prove falsity under the FCA[.]" 176 F. Supp. 3d at 1286. However, other district courts have disagreed. *See, e.g.*, *U.S. v. Robinson*, No. 13-cv-27-GFVT, 2015 WL 1479396, at *5 (E.D. Ky. Ma. 31, 2015 ("[P]roof of an objective falsehood is not the only means of establishing an FCA claim."); *U.S. v. SavaSeniorCare, LLC*, No. 3:11-00821, 2016 WL 5395949, at *13 (M.D. Tenn. Sept. 27, 2016) ("[F]acts that rely upon clinical judgment are not . . . excluded from liability under the FCA.") (internal citations omitted). With respect to Courts of Appeals, the Tenth and Sixth Circuits have rejected *AseraCare's* "medical opinion/objective falsity" standard in *Polukoff* and *Paulus*, respectively, and *AseraCare* itself is currently on appeal. *See U.S. v. CGNSC Admin. Servs., LLC*, No. 16-13004 (11th Cir.) (argued Mar. 13, 2017.)

fact that an allegedly false statement constitutes the speaker's opinion does not disqualify it from forming the basis of FCA liability." *Id.* at 742.

Similarly, in *Paulus*, 894 F.3d at 275, the Sixth Circuit reviewed a district court's decision to acquit a healthcare fraud defendant on the grounds that the defendants' allegedly fraudulent conduct originated from "a subjective medical opinion, incapable or confirmation or contradiction[.]" *Id.* In vacating the order of acquittal, the Sixth Circuit in *Paulus* disagreed, and explained that "opinions are not, and have never been, completely insulated from scrutiny." *Id.*

b. The medical consensus is that the only clinically indicated use of EDTA is to treat lead poisoning.

Here, Defendants' certification that EDTA was administered as a medical necessary treatment runs contrary to the medical consensus, and is thus false. (Doc. 1, ¶¶174-185) As detailed in the Complaint, the medical consensus associated with chelation therapy specifies that it should only be administered to patients with BLLs in excess of 50/80 mcg/DL. (Doc. 1, ¶¶ 93-99.) Referencing specific claims, the Complaint alleges that Dr. Adams chelated patients that objectively did not have lead poisoning, *e.g.*, patients with miniscule amounts—if any—of lead in their blood, and thus were not clinically indicated for EDTA chelation therapy. (Doc. 1, ¶¶174-185)

Defendants' efforts to minimize the Complaint's well pled description of the medical consensus associated with HMP/lead poisoning is unavailing.[12] Indeed, in *Polukoff*, 895 F.3d at 743 the Court (citing to the *Medicare Program Integrity* Manual) – in rejecting the notion that a physician's opinion that a procedure was medically necessary was invariably insulated from FCA liability – the court noted that a procedure *may* be reasonable and necessary *if* "…furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition[.]" *Id.*

Moreover, the Complaint alleges that the medical consensus is that chelation therapy is only efficacious as a treatment for patients suffering from acute HMP, and has not been found to be efficacious or medically necessary to treat *any* of the conditions for which Dr. Adams administered EDTA as an alternative treatment. (*See, e.g.*, Doc. 1, ¶¶ 74-76, 93-99.)

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[12] Dr. Adams suggests that the Complaint's well pled description of the medical consensus regarding chelation has no "nexus" to him. (Doc. 13, p. 8) However, in determining whether a treatment is reasonable and necessary, the medical consensus regarding the particular treatment is a primary consideration. *See, e.g., McCue v. Secretary of HHS*, 2019 WL 150540, *4-6 (Jan. 4, 2019, D. Maine) (In evaluating whether a treatment was covered, court noted that the *Medicare Program Integrity Manual* required an assessment of whether the treatment was, "Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition.")

c. Defendants' arguments regarding medical necessity are inapt at the pleading stage.

Finally, irrespective of its merits (or lack thereof), Defendants' arguments regarding medical necessity are inapt at the motion to dismiss stage due to the necessity of making "factual determinations," and/or "weigh[ing] the evidence, which is inappropriate at this stage of the litigation." [13] *U.S. ex rel. Groat v. Boston Heart Diagnostics Corp.*, 255 F.Supp.3d 13, 27–29 (D.D.C. 2017) (Evaluating Rule 12(b)(6) motion, Court declined to entertain whether FCA claims constituted "contradiction based on clinical judgment or opinion alone," and found that FCA claim for unnecessary services had been pled); *see also U.S. v. Snap Diagnostics, LLC,* No. 1:14-cv-3988, 2018 WL 2689270, at *3-4 (N.D. Ill. June 5, 2018) (Disregarding "objective falsehood" and "medical necessity" arguments in 12(b)(6) motion, court explained that "[e]ach of these arguments ask the Court to make a factual determination at the motion to dismiss stage, which the Court cannot do."); *SavaSeniorCare*, 2016 WL 5395949, at *12 (Collecting cases echoing *AseraCare's*

[13] Indeed, in citing to *AseraCare* and its progeny (*see* Doc. 13, p. 12-19), Defendants ignore the fact that those opinions were rendered at summary judgment, not in the context of a motion to dismiss.

"objective falsity" standard, court observes such cases arise "*in the context of what must be proven, not pled*") (emphasis added).

B. The Complaint Adequately Alleges That Defendants Submitted False Claims With FCA Scienter.

According to Defendants, the United States' FCA claims should be dismissed because the "Complaint does not adequately allege that Dr. Adams acted with the requisite scienter."[14] (Doc. 13, p. 21). Although Defendants acknowledge that scienter under the FCA can be satisfied by showing either actual knowledge, reckless indifference or deliberate ignorance (Doc 13, p.22), they argue that the Complaint did not allege sufficient facts to show actual knowledge by Dr. Adams, without addressing the reckless indifference or deliberate ignorance standard at all. Similarly, although Defendants acknowledge that scienter can be alleged generally, they go on to argue that the allegations that Defendants

[14] Dr. Adams also contends that, because Medicare consistently paid his chelation claims, he lacked FCA "knowledge" that such claims were false. (Doc. 13, p. 2, 22). This notion is dubious as the Complaint (1) alleges that Dr. Adams "knowingly" utilized false diagnosis codes (and otherwise schemed) to obtain reimbursement for his claims (Doc. 1, ¶17), and also explains that (2) Medicare only paid the claims in reliance upon Dr. Adams' certifications that EDTA was medically necessity to treat HMP. (Doc. 1, ¶¶64–65, 157)

submitted the alleged false claims with actual knowledge, reckless indifference or deliberate ignorance are insufficient.

However, as shown below, the Complaint adequately alleges scienter under the FCA.

1. FCA Scienter Encompasses Actual Knowledge, Reckless Disregard, and Deliberate Indifference, And May Be Generally Alleged Under Rule 9(b).

The FCA defines "knowingly" to include not only "actual knowledge," but as also "deliberate ignorance" and "reckless disregard." *See* 31 U.S.C. § 3729(b); *see also, U.S. ex rel. Matheny v. Medco Sols., Inc.*, 671 F.3d 1217, 1224 n.11 (11th Cir. 2012) (same.) Defendants concede this point (*see* Doc. 13, p. 22), but then ignore the last two standards, and exclusively focus on whether the Government has alleged "actual knowledge."(*Id.*). Defendants fail to address the portions of the Complaint alleging reckless disregard and deliberate ignorance. For example, the Complaint specifies that, "[d]efendants tendered these false claims with 'knowledge'—as that term is defined in the FCA—of their falsity." (Doc. 1, ¶20; *see also* ¶¶ 189–91, 193, 197).

Moreover, Rule 9(b) explicitly states that "[m]alice, intent, knowledge and other conditions of the mind *may be alleged generally*." *See* Fed. R. Civ. Pro. 9(b) (emphasis added); *U.S. ex rel. Bibby v. Wells Fargo Bank, N.A.*, 906 F. Supp.2d 1288,

1295 (N.D. Ga. 2012) ("In contrast to the particularized standard a complainant must use in alleging the mechanics of the fraud, a complainant may plead the scienter portion of the fraud generally.").

The Eleventh Circuit has noted that, with respect to an FCA complaint, "[a]t the pleading stage, knowledge, and other conditions of a person's mind may be alleged generally." *Medco*, 671 F.3d at 1224 (Court overruled district court's decision that dismissal was warranted as FCA complaint did not adequately allege scienter); *see also Crumb*, 2016 WL 4480690, at *27–28 (Collecting cases indicating that "plaintiff need only plead scienter generally in an FCA case"). Indeed, in *Medco*, the Eleventh Circuit found that by alleging that the defendants had, "…willfully and knowingly devised a scheme to create false records[,]" the relators adequately pled FCA scienter under Rule 9(b). *Medco*, 671 F.3d at 1224.[15]

Once again, Defendants acknowledge that scienter is not required to be pled with particularity (Doc. 13, p. 21), but then argue that the Complaint's allegations

[15] Defendants cite to *U.S. v. Fulton County*, 2016 WL 4158392 (N.D. Ga. Aug. 5, 2016) in support of their argument that FCA scienter must be pled with particularity. (Doc. 13, 22-23). However, that case is distinguishable, as the Complaint's scienter allegations are much more robust than those in *Fulton County*. *See, infra*, pg. 26-28. Moreover, to the extent that *Fulton County* is in conflict with the Eleventh Circuit's clear position that FCA scienter can be generally alleged, it must be disregarded.

of intent are conclusory and lack particularized facts. *(Id.)* The Complaint's allegations satisfy the generalized pleading requirements for scienter; moreover, as shown below they also provide specific factual allegations supporting the existence of scienter.

2. The Complaint Sufficiently Alleges Scienter Under the FCA and Rule 9(b).

The Complaint easily satisfies the standards for pleading scienter under the FCA and Rule 9(b). The Complaint alleges that "Defendants either had actual knowledge of, or acted in deliberate ignorance or reckless disregard of, the falsity of the claims[,]" (Doc. 1, ¶20) and alleges that "Defendants knowingly, within the meaning of the FCA[,]" submitted false claims to the Government. (Doc. 1, ¶¶189–91, 193–94, 197). As recognized by the Eleventh Circuit in *Medco*, 671 F.3d at 1224, "[u]nder Rule 9(b)'s standards, these general allegations are sufficient."

However, the Complaint goes further, identifying facts showing that Defendants had actual knowledge that the claims were false or, at minimum, reckless disregarded the falsity of their claims. The Complaint alleges that Dr. Adams had actual knowledge of the dispositive NCD and Medicare policies (*see* Doc. 1, ¶¶ 17, 19–20, 45–47, 57–63, 155, 158, 168, 190, 193), as well as the medical

consensus regarding HMP/lead poisoning and chelation. (*See* Doc. 1, ¶¶ 20, 45–47, 147, 152–53, 158).

At minimum, Dr. Adams acted with "reckless disregard" and/or "deliberate indifference" to the medical consensus regarding the use of EDTA chelation as a treatment for HMP/lead poisoning. Similarly, at minimum, in submitting Medicare claims for his alternative EDTA therapy, Dr. Adams acted in "reckless disregard" and/or "deliberate indifference" to NCD 20.22 and the Medicare's off-label drug rule, which constitute the very "Medicare laws, regulations and program instructions" to which he agreed to adhere. (*See* Doc. 1, ¶¶ 44–47). As noted in *U.S. v. Mackby*, 261 F.3d 821, 828 (9th Cir. 2001):

> It was [defendant's] obligation to be familiar with the legal requirements for obtaining reimbursement from Medicare[.] His claim that he did not know of the Medicare requirements does not shield him from liability. By failing to inform himself of such requirements[,] . . . he acted in reckless disregard or deliberate ignorance of such requirements, either of which was sufficient to charge him with knowledge of the falsity of the claims in question.

Id. at 828.

Additionally, the Complaint alleges Dr. Adams knew that the claims for EDTA treatment that he submitted to Medicare were for patients who were not suffering from lead poisoning. (Doc. 1, ¶¶ 8, 17–18, 151–61). The Complaint alleges that Dr. Adams admitted he does not treat lead poisoning (Doc. 1, ¶¶ 147–

50), and that Dr. Adams knew that the patients did not have lead poisoning, as evidenced by their extremely low BLLs. (Doc. 1. ¶¶ 152–53, 181, 162(v), 166(iv), 171(v), 182(v), 183(v), 184(v)).

II. THE COMPLAINT ADEQUATELY PLEADS CLAIMS FOR PAYMENT BY MISTAKE OF FACT AND UNJUST ENRICHMENT (COUNTS III-IV).

Defendants argue that the United States' common-law claims should be dismissed as (1) the United States fails to specify whether the claims arise under federal or state common law, and because (2) they are "derivative," and "should be dismissed for the same reasons as the FCA claims upon which they are based.[16] (Doc. 13, p.30) Each of these assertions lack merit.

First, in *U.S. ex rel. Heesch v. Diagnostic Phys. Group, P.C.*, No. 11-0364-KD-B, 2014 WL 2155363, at *10 (S.D. Ala. May 22, 2014), the court rejected the argument the Government's failure to specify whether claims arose under federal or state common law warranted dismissal, and recognized that the Government's "rights arising under a nationwide federal program such as Medicare are governed by

[16] The Government notes that it has already refuted each of Defendants' attacks on the viability of its FCA claims, and incorporates those arguments herein, in the context of Defendants' challenges to the Government's federal common law claims, which are overwhelmingly derivative of their FCA arguments. *See, supra,* at pg. 5-28.

federal law, not state law." Defendants rely upon *U.S. ex rel. St. Joseph's Hosp. Inc. v. United Dist., Inc.*, 918 F. Supp. 2d 1306, 1316 (S.D. Ga. 2013), but in *St. Joseph's*, the court simply granted the Government leave to specify whether it was pursuing federal or state common law claims.

Second, Defendants' "derivative" argument lacks merit, as detailed by the court in *Crumb*, 2016 WL 4480690, at *17–18 (Rejecting "derivative" argument, court noted that "these common-law claims are independent of . . . and have distinct elements of proof from . . . the False Claims Act.") Indeed, pursuant to the federal common law doctrines of payment by mistake and unjust enrichment, "the United States has a longstanding power, independent of any statute, to recover monies that its agents have wrongfully, erroneously or illegally paid out[.]" *U.S. v. DeFelice*, 2015 WL 7018018, *3-4 (E.D. Ok. November 10, 2015).

The "payment by mistake" doctrine enables the United States to recover payments made under a material and erroneous belief that the payments were properly owed. *See U.S. v. Medica-Rents Co.*, 285 F.Supp.2d 742, 776 (N.D. Tex. 2003). Similarly, under the doctrine of "unjust enrichment," "a person is unjustly enriched if the retention of a benefit would be unjust[,]" and the United States can recover where: (1) it has a reasonable expectation of repayment, (2) the recipient

of the payment should expect to repay, and (3) society's expectations would be defeated by non-payment. *U.S. v. Rogan*, 459 F.Supp.2d 692, 728 (N.D. Ill. 2006).

The United States has pled *prima facie* claims for recovery under both doctrines. The Complaint alleges that Medicare paid Defendants' EDTA claims on the mistaken and material belief that Defendants' EDTA treatments were medically necessary to treat lead poisoning (and thus reimbursable under Medicare) (Doc. 1, ¶¶186-188, 201-207). In truth, Defendants schemed to obtain Medicare reimbursements by fraudulently masquerading – in claims submitted to CMS – their alternative EDTA therapies as treatments for patients suffering from lead poisoning. (Doc. 1, ¶¶6-20).

CONCLUSION

For the reasons identified and argued herein, the United States respectfully requests that Defendants' motion be DENIED.

Respectfully submitted,

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Certificate of Compliance

I hereby certify, pursuant to Local Rules 5.1 and 7.1D, that the foregoing brief has been prepared using Book Antiqua, 13 point font.

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Certificate of Service

The United States Attorney's Office served this document today by filing it using the Court's CM/ECF system, which automatically notifies the parties and counsel of record.

February 19, 2019

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