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.	)	
	)	

REPLY IN SUPPORT OF 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, submit this Reply in support of Defendants' Motion to Dismiss (Doc. No. 13) to address certain erroneous arguments raised in the government's Opposition to Defendants' Motion to Dismiss (Doc. No. 23, hereinafter "Gov. Opp.") regarding falsity and knowledge under the False Claims Act, 31 U.S.C. §§ 3729-3733 (2009) (FCA).

The Government Did Not Adequately Plead Falsity Under the FCA

The government argues that the claims at issue are false because (1) the International Classification of Diseases, Ninth Revision (ICD-9) codes that Dr. Adams used to bill chelation therapy are only used to bill "heavy metal poisoning," and (2) National Coverage Determination (NCD) 20.22 is binding authority prohibiting the chelation therapy claims at issue in this case. Neither of these arguments warrant denying Dr. Adams' motion to dismiss.

ICD-9 Codes. According to the government, Dr. Adams billed chelation therapy using ICD-9 codes "associated with" heavy metal poisoning. The codes are:

- 9848 Toxic Effect Lead Compounds NEC (Not Elsewhere Classifiable);
- 9840 Toxic Effect Inorganic Lead Compound; and
- 9851 Toxic Effect Arsenic.

(Compl. ¶ 6.) The government argues that billing under these codes is "'factually' false" because the codes represent that the patient was diagnosed with or suffering from lead poisoning. (Gov. Opp. at 7.) But none of these codes includes the term "lead poisoning," and the government does not allege with particularity how, if at all, these codes are *only* used to bill for lead poisoning. The code language generally refers to "toxic effect," with no additional information. Such vague

allegations of falsity are not enough, especially when combined with equally vague allegations as to medical consensus and medical judgment that appear throughout the Complaint.

NCDs. The government argues that NCDs are legally binding, relying on 42 C.F.R. § 405.1060. (Gov. Opp. At 10.) The regulation sets forth the "general rule" that "[a]n NCD is binding on fiscal intermediaries, carriers, QIOs, QICs, ALJs and attorney adjudicators, and the [Medicare Appeals] Council." 42 C.F.R. § 405.1060(a)(4).[1] The regulation means only that NCDs are binding on administrators and adjudicators *within* the Medicare system. Nothing in the regulation, which specifically enumerates those bound by its terms, indicates that it is binding on providers or on this court. Nothing in *Advanced Diabetes Treatment Centers, LLC v. Sebelius*, 2011 WL 13268857, No. 09-61698, *4 (S.D. Fla. Apr. 7, 2011), cited by the government, changes the limited scope of the regulation because the court recognized that "NCDs are binding at all stages of the *agency's review process*." (emphasis added) (addressing denial of coverage for services). This case is not an internal Medicare review; therefore, the rules governing such internal proceedings do not constitute binding authority in this court.

[1] The abbreviated terms are defined at 42 C.F.R. § 405.902.

Medical Judgment. The government urges this Court to outright reject *United States v. AseraCare, Inc.*, 176 F. Supp. 3d 1282 (N.D. Ala. 2016), which is persuasive authority from a district court within this circuit, and with it the "several district courts [that] have endorsed" its holding. (Gov. Opp. at 19 and n.11.) None of the contrary authority from jurisdictions outside of this circuit warrants any such rejection. *Aseracare* makes clear that the government cannot impose on Dr. Adams civil and quasi-criminal liability under the FCA for exercising his medical judgement. In fact, there is more support for the holding in *Aseracare* than for the government's position, as several other circuit and district courts have recognized that expressions of opinion or conclusions about which reasonable minds may differ cannot be false and declined to impose FCA liability in the absence of other alleged falsity.[2] The government's use of more than 50 paragraphs of the

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[2] *See, 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 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. 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)); *United States v. Vista Hospice Care, Inc.*, No. 3:07-cv-00604-M, 2016 WL 3449833 (N.D. Tex. June 20, 2016); *United*

Complaint to describe the alleged "medical consensus" regarding chelation therapy underscores the need for the holding in *Aseracare*.

The Government's Scienter Allegations Are Inadequate

The government fails to adequately allege scienter. The government cannot simply state that Dr. Adams acted with deliberate ignorance or reckless disregard under the FCA. Rather, the government must plead *facts* to support such allegations. As Judge Duffey explained: "Although specific intent to defraud is not required, 31 U.S.C. § 3729(b)(1)(B), and knowledge need not be pled with particularity, Fed. R. Civ. P. 9(b), ***the scienter requirement is 'rigorous.'***" *United States v. Fulton Cty., Georgia*, No. 1:14-CV-4071-WSD, 2016 WL 4158392, at *11 (N.D. Ga. Aug. 5, 2016) (citation omitted). Contrary to the government's arguments, Judge Duffey's holding in *Fulton County* is not "in conflict" with the law that scienter may be alleged generally. (Gov. Opp. at 25 n.15.)

As Judge Duffey made clear in *Fulton County*, the government cannot simply parrot the language in the statute without also providing supporting factual allegations. "[F]ormulaic recitation[s] of the elements of a ... claim ... are conclusory and not entitled to be assumed true." *Ashcroft v. Iqbal*, 556 U.S. 662, 681 (2009). Nor is it enough for the government to simply allege that Dr. Adams

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States ex rel. Phillips v. Permian Residential Care Ctr., 386 F. Supp. 2d 879, 884 (W.D. Tex. 2005).

said or did something that is not true; "[k]nowledge is not shown by simply saying...that Defendants are saying something that is not true." *Fulton Cty.*, 2016 WL 4158392, at *11 (citation omitted). Such allegations are insufficient to meet the "rigorous" requirement, and therefore fail to adequately plead scienter.

In this case, as discussed in more detail in Defendants' original brief, the government fails to allege facts to support scienter (*i.e.*, that Defendants knew or should have known about the NCDs that are cited in the government's Complaint). Without these well-pleaded facts, the government's Complaint simply fails to state a claim upon which relief can be granted.

The Complaint Must Be Dismissed in its Entirety

As set forth in Defendants' Motion to Dismiss and this Reply, the government fails to sufficiently allege that Dr. Adams *knowingly* submitted *false* claims in violation of the FCA. First, the government does not sufficiently allege that any of the claims Dr. Adams submitted were objectively false, which is required to impose FCA liability. Whether the chelation therapy at issue was reasonable and necessary for Dr. Adams' patients is a question of medical judgment and cannot be "false" under the FCA as a matter of law. Second, the government fails to sufficiently allege that Dr. Adams acted with the requisite *mens rea*. Finally, the government does not allege sufficient facts such 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, Defendants respectfully request that this Court grant the motion and dismiss the Complaint in its entirety.

Date: March 5, 2019

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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CERTIFICATION OF FONT SIZE

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

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CERTIFICATE OF SERVICE

I hereby certify that on March 5, 2019, I electronically filed the foregoing Reply in Support of 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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