**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF GEORGIA**
**ATLANTA DIVISION**

United States of America,

Plaintiff,

Case No. 1:19-cv-3510-MLB

v.

Robert A. Burkich, M.D. and
Preventive Medicine Anti-Aging &
Chelation, Inc.,

Defendants.

_____/

## OPINION & ORDER

Robert A. Burkich, M.D. frequently administers a drug called edetate calcium disodium ("EDTA") to patients at his medical practice, Preventive Medicine Anti-Aging & Chelation, Inc. The drug helps remove heavy metals from the human body as part of a treatment called "chelation." Medicare covers EDTA chelation only if the patient has lead poisoning. But Dr. Burkich repeatedly billed Medicare for EDTA chelation even when his patients did not have lead poisoning. So the United States sued him and his medical practice for violating the False

Claims Act ("FCA"), for unjust enrichment, and for payment by mistake of fact.

The United States now moves for summary judgment on the FCA claims. (Dkt. 117.) Defendants move for summary judgment on all claims. (Dkt. 116.) And the United States moves to exclude Defendants' experts under *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993). (Dkts. 114; 115.) The Court denies the summary judgment motions and grants the United States's *Daubert* motions.[1]

## I. Standard of Review

### A. Daubert

"Expert testimony may be admitted into evidence if: (1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand

[1] The United States also moves to file a sur-reply in opposition to Defendants' motion for summary judgment. (Dkt. 143.) "[T]he Court has discretion to allow a surreply." *Morris v. Johnson*, 2019 WL 2360886, at *5 (N.D. Fla. May 3, 2019). The Court exercises that discretion here and considers the sur-reply.

the evidence or to determine a fact in issue." *City of Tuscaloosa v. Harcros Chemicals, Inc.*, 158 F.3d 548, 562 (11th Cir. 1998). "The party offering the expert has the burden of satisfying each of these three elements by a preponderance of the evidence." *Rink v. Cheminova, Inc.*, 400 F.3d 1286, 1292 (11th Cir. 2005). The district court must conduct a "rigorous inquiry" into each element to "ensure that speculative, unreliable expert testimony does not reach the jury under the mantle of reliability that accompanies the appellation 'expert testimony.'" *Id.* at 1291. Ultimately, "the admission or exclusion of expert testimony is a matter within the sound discretion of the trial judge." *McDowell v. Brown*, 392 F.3d 1283, 1294 (11th Cir. 2004).

**B. Summary Judgment**

Summary judgment is appropriate when "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material if "it might affect the outcome of the suit under the governing law." *W. Grp. Nurseries, Inc. v. Ergas*, 167 F.3d 1354, 1360 (11th Cir. 1999). A factual dispute is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* at

1361. "Upon discovering a genuine material dispute, the court must deny summary judgment and proceed to trial" because "[i]t is not the court's role to weigh conflicting evidence or to make credibility determinations." *A.L. by & through D.L. v. Walt Disney Parks & Resorts US, Inc.*, 900 F.3d 1270, 1289 (11th Cir. 2018); *Mize v. Jefferson City Bd. of Educ.*, 93 F.3d 739, 742 (11th Cir. 1996).

## II. The United States's Daubert Motions

### A. Dr. Douglas L. Nelson

Defendants have retained Dr. Douglas L. Nelson to offer expert testimony about the medical necessity of the EDTA chelation for which Dr. Burkich billed Medicare. The United States moves to exclude this testimony on the grounds Dr. Nelson is unqualified, his methodology is unreliable, and his opinions are misleading. The Court agrees that Dr. Nelson's methodology is unreliable. So the United States's motion is granted.

Dr. Nelson is a Doctor of Osteopathic Medicine. (Dkt. 107-33 at 3.) He runs an "alternative medicine practice" in Florida. (Dkt. 102 at 27.) He has chelated several patients, including with EDTA. (*Id.* at 22–23.) But he does not hold any chelation "credentials." (*Id.* at 23.) And he has

taken only a few courses on the subject. (*Id.* at 21.) Most of his chelation knowledge comes from "mentors" and "life experience." (*Id.* at 21–22.)

Dr. Nelson has submitted a two-page expert report. (Dkt. 107-33.) In it, he opines that Defendants' EDTA chelation was "medically necessary and reasonable" because (1) Dr. Burkich "used an extensive patient questionnaire," "performed a physical examination," and "relied on an extensive differential diagnosis process"; (2) Dr. Burkich "utilized calcium EDTA provoked urine heavy metal lab tests," which is "the current gold standard" for assessing toxicity in the human body; (3) patients had "clear signs and symptoms of heavy metal toxicity"; (4) "[t]here are no safe and acceptable levels of heavy metal toxicity in the human body"; (5) Dr. Burkich used "intravenous EDTA chelation to treat patients," which is "state of the art" care; and (6) "there were no reported safety issues nor adverse outcomes." (*Id.* at 1–2.)

These opinions are inadmissible because Defendants have not shown they are "properly grounded, well-reasoned, . . . not speculative," and "supported by appropriate validation." *United States v. Frazier*, 387 F.3d 1244, 1261–62 (11th Cir. 2004). Dr. Nelson's report is only two pages long. It includes no citations. (Dkt. 102 at 48.) And it says little-

to-nothing about the basis for his conclusions. It does say Dr. Nelson formed his opinions after reviewing Defendants' patient files. But Dr. Nelson admitted at his deposition that he reviewed only "five or six" such files and did not read even those files in their entirety. (*Id.* at 15–16.) Moreover, he never explained which pages he reviewed, why, or what analysis he applied to those pages. He could not even identify any articles or treatises he considered in preparing his report. He "just sort of reviewed documents on ACAM and the ICIM sites just to refresh [his] memory [and] get those synapses livened up again and recall what [he had] experienced and tried to remember." (*Id.* at 47.)[2]

Dr. Nelson has not shown "whether he performed any [meaningful] analysis," what that analysis was, "whether his opinions were subject to any verification or peer review," or "how his experience specifically informed his opinions." *Webb v. Carnival Corp.*, 321 F.R.D. 420, 430 (S.D.

[2] ACAM is the American College for Advancement in Medicine. ICIM is the International College of Integrative Medicine. Both organizations focus on "alternative" medicine "beyond what the current conventional system offers." (Dkts. 107-43; 107-44; 107-45; 107-46.) Notably, in 1998, ACAM "agreed to settle Federal Trade Commission charges that it made unsubstantiated and false advertising claims that non-surgical, EDTA 'chelation therapy' is effective in treating atherosclerosis, and that the effectiveness of the therapy has been proven by scientific studies." (Dkt. 107-8 at 1.)

Fla. 2017). He simply offers "conclusory" assertions "[un]tethered to any supporting materials or sources." *Id.* That is not enough. The Court's "gatekeeping function requires more than simply taking the expert's word for it." *Frazier*, 387 F.3d at 1261. Defendants have not met their burden to show "the reasoning or methodology underlying [Dr. Nelson's] testimony is . . . valid" and "properly can be applied to the facts in issue." *Daubert*, 509 U.S. at 592–93. So Dr. Nelson's opinions are excluded.[3]

**B. Dr. Dana B. Barr**

Defendants have also retained Dr. Dana B. Barr to offer expert testimony in this case. The United States claims Dr. Barr is not qualified to opine on "the diagnosis or treatment of patients." (Dkt. 115 at 9.) The Court agrees.

Dr. Barr is a professor at the Emory University Rollins School of Public Health. (Dkt. 107-34 at 6.) She specializes in exposure science, environmental chemistry, and environmental epidemiology. (*Id.* at 1.) Although she is not a medical doctor, she has submitted a two-page

[3] The Court also has grave concerns about Dr. Nelson's qualifications to serve as an expert at all. (*See* Dkts. 114 at 5–10; 126 at 3–7.) But the Court need not explore those concerns given the unreliability of his opinions.

expert report in which she purports to evaluate "Dr. Burkich's patient care." (*Id.* at 2.) She claims (1) Dr. Burkich provided "an inordinate amount of constructive care [to his] patients to alleviate metal toxicity"; (2) this care—which included EDTA chelation—was "appropriate," "medically necessary," "comparable to that given regularly to patients exhibiting metal-toxicity symptoms," and "appeared to help relieve many of the symptoms"; (3) she "would have recommended a similar approach to alleviate such symptoms"; and (4) the symptoms involved were "consistent with heavy metal or metalloid toxicity." (Dkt. 107-34 at 2–3.)

Dr. Barr is not qualified to offer any of these opinions. She is an environmental health professor, not a physician. She has never attended medical school, taken courses in medicine, worked as a healthcare provider, "treated a patient for anything," "done any work or studies in a clinical context," reviewed the accuracy of a medical diagnosis, or assessed whether a physician "acted within the standard of care." (Dkt. 101 at 19–21, 24–25, 59, 61.) Indeed, she does not "work with patients" at all and does not even know what a medical file is supposed to include. (*Id.* at 26–27, 39–40.) Instead, she does "more research work . . . trying to understand how exposures to certain chemicals or agents are related

to adverse health outcomes." (*Id.* at 27.) This macro-level work in environmental health does not qualify her to diagnose or treat specific patients on the ground. Only physicians can do that. (*See id.* at 39 ("I couldn't have ordered [chelation therapy]."), 52–53 ("Treatment decisions including chelation should be made in consultation with a *physician*." (emphasis added)); O.C.G.A. § 43-34-22(a) (only licensed medical professionals can engage in diagnosis or treatment). She is missing years of additional education and/or training. Defendants have not shown Dr. Barr should be allowed to testify as an expert about something she is not qualified to do herself. *See In re Vioxx Prod. Liab. Litig.*, 401 F. Supp. 2d 565, 586–87 (E.D. La. 2005) (professor of pharmacoepidemiology could testify that "Vioxx accelerates atherosclerosis" but, because he was "not a medical doctor," he "lack[ed] . . . the necessary training to testify as to what doctors should have done").

Defendants note Dr. Barr is "working with a physician at Grady Hospital right now on lead toxicity in gunshot patients." (Dkt. 101 at 23.) But, in this role, she simply views and interprets "measurements of lead in the lab"—and then presents her work to a physician "for *her* [the

physician] to evaluate." (*Id.* at 23–24 (emphasis added).) Moreover, this lab experience is not really relevant to her opinions here because she admits she did not review any "laboratory data on [the] levels of metals" in Defendants' patients. (*Id.* at 40.)

Dr. Barr certainly has impressive credentials. But she is "seeking to testify outside the scope of [her] academic and professional specialty." *Moore v. Intuitive Surgical, Inc.*, 995 F.3d 839, 853 n.12 (11th Cir. 2021). She is not qualified to do that. So her testimony is excluded. *See Trilink Saw Chain, LLC v. Blount, Inc.*, 583 F. Supp. 2d 1293, 1304 (N.D. Ga. 2008) ("[An expert] must stay within the reasonable confines of his subject area. Thus, many courts have excluded testimony when they determine that the witness is testifying to an area outside of—but related to—his expertise."). That is, Dr. Barr cannot "opine[] on the quality of the treatments the defendants gave to their patients and whether the defendants complied with the standard of care." (Dkt. 115 at 1.) This includes, but is not limited to, the four specific opinions listed above. Those opinions are excluded.[4]

[4] Dr. Barr's expert report also includes opinions about "lead exposure, toxicokinetics, and toxicity" more generally. (Dkt. 107-34 at 1–2.) The

## III. Defendants' Motion for Summary Judgment

### A. FCA Claims

In Count 1 of the complaint, the United States claims Defendants falsely billed Medicare for EDTA chelation in violation of 31 U.S.C. 3729(a)(1)(A). (Dkt. 10 ¶ 245.) Count 2 claims Defendants violated 31 U.S.C. 3729(a)(1)(B) by making "false records and statements" in connection with their Medicare bills for EDTA chelation. (*Id.* ¶¶ 250–251.) Defendants move for summary judgment on both counts. They say the claims are time-barred and the United States cannot show Defendants' Medicare submissions were false or material. (Dkt. 116-1 at 11–13, 17–23.) The Court disagrees.

#### 1. Statute of Limitations

An FCA action "may not be brought . . . more than 3 years after the date when facts material to the right of action are known or reasonably should have been known by the official of the United States charged with responsibility to act in the circumstances." 31 U.S.C. § 3731(b)(2). Citing this rule, Defendants claim the United States knew the material facts in

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United States has not moved to exclude these opinions. (Dkt. 115 at 3, 9.) So the Court declines to address their admissibility at this juncture.

this case no later than September 3, 2015; thus "the government had to file suit against Dr. Burkich . . . on or before September 3, 2018"; the United States did not file suit until August 2, 2019; so this action is untimely by almost a year. (Dkt. 116-1 at 13.) But this line of reasoning ignores a key fact: Defendants agreed to toll the statute of limitations for *more than a year* (396 days). (Dkts. 129-1; 129-2.) This allowed the United States to file suit any time before October 2019. The United States sued Defendants in August 2019, months before that deadline. So this action is timely. *See, e.g.*, *U.S. Sec. & Exch. Comm'n v. Revolutionary Concepts, Inc.*, 2022 WL 386085, at *5 (11th Cir. Feb. 9, 2022) ("[A] statute of limitations . . . can be tolled, and so [defendant's] tolling agreement made [the SEC's] complaint timely."); *United States v. Sulzbach*, 2010 WL 1531492, at *7 (S.D. Fla. Apr. 16, 2010) (giving effect to "tolling agreements between the parties" in an FCA case).

Defendants counter that the tolling agreements—there were two of them—somehow "expired" before the United States filed its complaint. (Dkt. 141 at 8.) The Court disagrees. The first tolling agreement says "the period of time between and including December 1, 2017 and June 30, 2018 shall be excluded when determining whether any civil or

administrative claims are time-barred by statute of limitations." (Dkt. 129-1 at 1.) The second agreement is identical except that it excludes "the period of time between and including July 1, 2018 and December 31, 2018." (Dkt. 129-2 at 1.) Defendants' theory is that "each agreement expired at the end of its term," presumably June 30, 2018 and December 31, 2018. (Dkt. 141 at 8.) But this makes no sense. The agreements do not say the "excluded" time is somehow included again once the tolling periods end. Nor is that how tolling agreements usually work. Tolling agreements simply *pause* the statute of limitations "until some later event permits the statute to continue running." *Colonial Bancgroup Inc. v. PricewaterhouseCoopers LLP*, 2016 WL 9687003, at *3 (M.D. Ala. July 29, 2016); *see Artis v. D.C.*, 138 S. Ct. 594, 601 (2018) ("Ordinarily, 'tolled' . . . means that the limitations period is suspended (stops running) . . . , then starts running again when the tolling period ends, picking up where it left off."). The Court sees no reason to depart from that principle here. It is strange for Defendants to say the agreements "expired." The documents do not set some time period during which the United States was permitted to file suit such that they could expire. They simply say a

period of time is excluded from any consideration of the statute of limitations, whenever that calculation might be done.

This is not a close call. Defendants signed two tolling agreements that categorically "excluded" 13 months from the FCA's statute of limitations. So, even assuming the 3-year limitations period started running in September 2015 (as Defendants contend), the United States timely filed suit less than 4 years later in August 2019.[5]

**2. Falsity**

The United States brings its FCA claims under Sections 3729(a)(1)(A) and 3729(a)(1)(B). Section 3729(a)(1)(A) makes it unlawful to "knowingly present[], or cause[] to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Section 3729(a)(1)(B) imposes liability on anyone who "knowingly makes, uses, or causes to be made or used, a false record or statement material to a

[5] Defendants' reply brief claims the limitations period may have begun as early as 2008. (Dkt. 141 at 8–9.) The Court declines to consider this argument because Defendants did not raise it in their opening brief. *See United States v. Coy*, 19 F.3d 629, 632 n.7 (11th Cir. 1994) ("Arguments raised for the first time in a reply brief are not properly before a reviewing court."). But, even considering the argument, it fails on the merits for the reasons stated in the United States's sur-reply. (*See* Dkt. 143-1 at 4–9.)

false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B). "Both provisions require a false claim." *United States ex rel. Cimino v. Int'l Bus. Machines Corp.*, 3 F.4th 412, 424 (D.C. Cir. 2021) (Rao, J. concurring); *see Klusmeier v. Bell Constructors, Inc.*, 469 F. App'x 718, 721 n.5 (11th Cir. 2012) ("[A] false or fraudulent claim or statement . . . is a requirement of both [provisions]."). "Medicare claims may be false if they claim reimbursement for services or costs that either are not reimbursable or were not rendered as claimed." *United States v. R&F Properties of Lake Cnty., Inc.*, 433 F.3d 1349, 1356 (11th Cir. 2005).

The United States says Defendants' reimbursement claims for EDTA chelation were false for four reasons. (*See* Dkt. 117-1 at 14–23; 134 at 12, 15.) First, Dr. Burkich submitted diagnostic codes associated with lead poisoning and heavy metal poisoning when, in truth, none of his patients had those conditions. Second, under Medicare's "off-label" rule, Medicare only covers EDTA chelation for FDA-approved indications; the FDA has approved EDTA chelation solely as a treatment for lead poisoning and lead encephalopathy; none of Defendants' patients had lead poisoning or lead encephalopathy; so Defendants' chelation of those patients was not reimbursable. Third, Defendants' use of EDTA

chelation for non-FDA-approved purposes violated Medicare National Coverage Determination 20.22, which says "[t]he use of EDTA as a chelating agent to treat . . . [a] generalized condition not listed by the FDA as an approved use is not covered." (Dkt. 107-10.) Fourth, Medicare only covers treatments that are "medically necessary," and Defendants' EDTA chelation treatments were not medically necessary.

A reasonable jury could find for the United States on all four theories. Starting with the first, Dr. Leland Garrett (a Medicare claims processor) has submitted an affidavit saying Defendants' Medicare claims included diagnostic codes for "lead poisoning" and "heavy metal poisoning." (Dkt. 109 ¶¶ 9–14.) This is problematic because there is substantial evidence that Defendants' patients had neither condition. For example, Dr. Travis D. Olives (a physician and medical toxicologist) has submitted an expert report concluding "the patients chelated by Dr. Burkich were not suffering from: 1) lead poisoning [or] 2) other heavy metal poisoning." (Dkt. 131-1 at 47.) And, when the United States asked Defendants (via interrogatories) whether they had diagnosed anyone with lead poisoning or heavy metal poisoning, Defendants responded only that they had diagnosed patients with "heavy metal toxicity, *as defined*

*by Defendants*." (Dkt. 107-31 at 2–4 (emphasis added).) Dr. Burkich later clarified that his definition of heavy metal toxicity is something less than heavy metal poisoning, that "the only condition [he was] treating [in 2000–2015] was heavy metal toxicity," that "none of [his] patients was diagnosed solely with . . . lead poisoning," and that he does not recall diagnosing anyone with lead poisoning. (Dkts. 97 at 164; 98 at 83, 239–240, 243.) Given this weighty evidence, a jury could conclude Defendants used false diagnostic codes on their Medicare claims.

Moving to the second and third theories, Stephen Quindoza (a Medicare fraud investigator) has submitted an expert report about Medicare's "off-label" rule. He says the rule means Medicare only covers EDTA chelation for FDA-approved indications. (Dkt. 133-1 at 9.) Medicare National Coverage Determination 20.22 includes the same coverage restriction. (Dkt. 107-10.) It is undisputed that the FDA has approved EDTA chelation solely for lead poisoning and lead encephalopathy (a severe form of lead poisoning). (*See* Dkts. 107-5 at 2; 135 ¶ 12.) So Defendants' EDTA chelation treatments were not reimbursable unless they were specifically for those conditions. Defendants admit their patients did *not* have lead encephalopathy. (Dkt.

135 ¶ 76.) And, as explained above, there is substantial evidence Defendants' patients did not have lead poisoning either. So a jury could conclude Defendants billed Medicare for EDTA chelation that was not reimbursable. *See R&F Properties*, 433 F.3d at 1356 ("Medicare claims may be false if they claim reimbursement for services or costs that . . . are not reimbursable.").

Finally, it is undisputed that "Medicare does not cover items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury." (Dkt. 135 ¶ 28.) Several authoritative sources say EDTA chelation is warranted only to treat lead poisoning in patients with seriously elevated levels of lead in their blood. (*See* Dkt. 118 ¶¶ 19–25, 70.) This puts Defendants in a tough spot because, again, there is substantial evidence their patients did *not* have lead poisoning or high blood lead levels. Dr. Olives said so based on his review of Defendants' patient files. (Dkt. 131-1 at 47–48.) Dr. Burkich testified that he typically did not do blood tests and instead based his diagnoses on urine tests. (Dkts. 97 at 137–138; 118 ¶ 65.) One of Defendants' medical billers testified to the same effect. (Dkt. 100 at 25–26.) Defendants' discovery responses—supplemented by Dr. Burkich's

deposition testimony—suggest none of Defendants' patients had lead poisoning. (Dkts. 97 at 164; 98 at 83, 239–240, 243; 107-31 at 2–4.) And Dr. Olives has squarely opined that "[t]he chelation with calcium disodium EDTA that Dr. Burkich administered to his patients was unwarranted and medically unnecessary." (Dkt. 131-1 at 5.) Given this evidence, a jury could conclude Defendants billed Medicare for unnecessary EDTA chelation that was not reimbursable. And, as explained above, that conclusion would mean Defendants' claims were false.

Defendants offer a few counterarguments, but none are persuasive. (*See* Dkts. 116-1 at 17–20; 141 at 10–14.) For example, Defendants tout their own experts and criticize the United States's experts. But the Court has now excluded the bulk of Defendants' expert evidence, leaving only a few general opinions—essentially background opinions—from Dr. Barr that do not even arguably compel summary judgment. And Defendants have not moved to exclude the United States's experts, so the alleged weaknesses in their opinions are matters for the jury to consider (absent a timely filed *Daubert* motion). (*See, e.g.,* Dkt. 145-1 at 13 n.5 (Judge Ross dismissing defendants' criticisms of a United States expert at

summary judgment, because defendants did not move to exclude the expert).) Defendants also claim their certification of medical necessity could not have been false because it reflected a subjective clinical opinion rather than an objective fact. But that is simply not the law. *See United States v. Adams*, 371 F. Supp. 3d 1195, 1211 (N.D. Ga. 2019) ("[A] physician's subjective medical opinions or judgments can be false for purposes of the FCA."); *United States ex rel. Dildine v. Pandya*, 389 F. Supp. 3d 1214, 1220 (N.D. Ga. 2019) ("[A]llowing physicians to avoid allegations of fraud by simply subjectively asserting the services were medically necessary cannot be the standard for determining falsity."); (Dkt. 145-1 at 9–14 (Judge Ross discussing this issue)). On the contrary, Medicare determines medical necessity based on "accepted standards of medical practice." (Dkt. 118 ¶ 29.) Most courts do as well. *See, e.g.*, *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1117–19 (9th Cir. 2020); *United States ex rel. Polukoff v. St. Mark's Hosp.*, 895 F.3d 730, 743 (10th Cir. 2018).[6] And, even assuming

[6] The Eleventh Circuit's decision in *United States v. AseraCare, Inc.*, 938 F.3d 1278 (11th Cir. 2019) is not to the contrary. (*See* Dkt. 145-1 at 9–14 (Judge Ross making this point)); *see also Winter*, 953 F.3d at 1119 (noting *AseraCare* both "identified circumstances in which a medical opinion

Defendants were right that their characterization of medical necessity controls, this would knock out only *one* of the United States's falsity theories (the fourth); the other three theories would remain. (*See* Dkt. 145-1 at 14 n.6 (Judge Ross declining to address all the government's falsity theories at summary judgment because at least one of those theories was viable).)

The bottom line is that a jury must decide whether Defendants' Medicare submissions were false. The Court cannot resolve that issue in Defendants' favor on summary judgment.

**3. Materiality**

A Medicare misrepresentation does not violate the FCA unless it was "material to the Government's payment decision." *Universal Health Servs., Inc. v. United States*, 579 U.S. 176, 192 (2016). A misrepresentation is material if it has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4). "While no single factor is dispositive, some factors that are relevant to the materiality analysis include: (1) whether the

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would be false" and "recognized that [an] 'objective falsehood' requirement [does] not necessarily apply to a physician's certification of medical necessity").

requirement is a condition of the government's payment, (2) whether the misrepresentations went to the essence of the bargain with the government, and (3) to the extent the government had actual knowledge of the misrepresentations, the effect on the government's behavior." *United States ex rel. v. Mortg. Invs. Corp.*, 987 F.3d 1340, 1347 (11th Cir. 2021).

Defendants' Medicare claims were allegedly false because they requested reimbursement for chelating patients who did not have lead poisoning or sufficiently high blood lead levels. Dr. Garrett—who processes Medicare claims in Georgia—has submitted an affidavit explaining what Medicare would have done had it known the truth about Defendants' treatments. (Dkt. 109.) He says Defendants' claims "would have been denied" because "reimbursement of such claims would be in contravention of (1) [Medicare] National Coverage Determinations (NCDs) 20.21 and/or 20.22; (2) [Medicare's] coverage prohibition on experimental uses of a drug; (3) [Medicare's] coverage prohibition for uses of a drug that go beyond those indicated on the drug's FDA approved label; and (4) [Medicare's] policy to only reimburse for services that are reasonable and necessary." (*Id.* ¶ 22; *see also id.* ¶¶ 19–21.) He also says

Medicare would have investigated Defendants for fraud. (*Id.* ¶¶ 23–24.) Indeed, "Medicare has taken action against other health care providers who billed for non-covered chelation therapy." (Dkt. 133-1 at 11.) All of this suggests Defendants' misrepresentations were material.

Defendants counter that Dr. Garrett's opinions are speculative because he did not work for Medicare when Defendants submitted their claims and thus "could not have been . . . aware" of those claims in real time. (Dkt. 116-1 at 22–23.) But, again, Defendants have not moved to exclude Dr. Garrett's opinions. So any quibbles they have with his opinions are for a jury to resolve (absent a timely filed *Daubert* motion). Moreover, Defendants' criticism misunderstands the role of an expert. "[E]xperts are allowed to testify in hypothetical terms." *M & N Materials, Inc. v. Town of Gurley, Alabama*, 2015 WL 12830451, at *4 (N.D. Ala. Oct. 5, 2015). They are not limited to "firsthand knowledge or observation." *Daubert*, 509 U.S. at 592. So Dr. Garrett need not have handled or known about Defendants' claims when they were first submitted in order to opine on them now. "[T]he Court rejects Defendants' argument that the United States provided no evidence of materiality simply because Dr. Garrett did not work for [Medicare] at the

time the alleged false claims were submitted." (Dkt. 145-1 at 17 (Judge Ross case).)

Defendants also say their false claims cannot be material because the United States discovered the truth about those claims in September 2015 but continued paying them anyway. (Dkts. 116-1 at 22; 130 at 20.) The Court again disagrees. All that happened in September 2015 was a relator filed suit against Dr. Burkich. (*Id.*) This may have tipped the United States off to *alleged* wrongdoing, but it did not give them knowledge of *actual* wrongdoing. So there are limits to what it tells us about materiality here. *See Mortg. Invs. Corp.*, 987 F.3d at 1347 (noting the government's conduct after acquiring "actual knowledge of the misrepresentations" is what counts); *United States ex rel. Escobar v. Universal Health Servs., Inc.*, 842 F.3d 103, 112 (1st Cir. 2016) ("[M]ere awareness of allegations concerning noncompliance with regulations is different from knowledge of actual noncompliance."). Moreover, less than a year after the relator's complaint, Medicare initiated a special "pre-payment review process for [Defendants'] claims" in order to "reduce fraud, waste, and abuse in the Medicare program." (Dkt. 129-4 at 1.)

Presumably Medicare would not have done this unless it cared about the alleged falsity of Defendants' claims.

The United States's response to the relator's complaint does not preclude a finding of materiality here. Nor do Defendants' criticisms of Dr. Garrett. A jury must decide whether Defendants' allegedly false submissions were material.[7]

**B. Common Law Claims**

Count 3 asserts a claim for "payment by mistake of fact" on the theory that "Defendants have caused the United States to make payment 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 [heavy metal poisoning]/lead poisoning." (Dkt. 10 ¶ 256.) Count 4 asserts an unjust enrichment claim on the theory that Defendants "received . . . federal monies to which they are not entitled"

[7] Defendants' reply brief argues the United States may have been on notice of Defendants' false claims as early as 2008. (Dkt. 141 at 14–15.) But, again, "[a]rguments raised for the first time in a reply brief are not properly before a reviewing court." *United States v. Coy*, 19 F.3d at 632 n.7. And, even considering the argument, it fails on the merits for the reasons explained in the United States's sur-reply. (Dkt. 143-1 at 4–9.) Indeed, just a few months ago, Judge Ross rejected a virtually identical argument in an analogous case. (Dkt. 145-1 at 17–20.)

by billing Medicare for non-reimbursable services. (*Id.* ¶ 260.) Defendants move for summary judgment on both counts. They say the claims are time-barred and meritless as a matter of law. The Court disagrees.

### 1. Statute of Limitations

Defendants argue the United States's common law claims are untimely under the FCA's 3-year statute of limitations. (Dkt. 116-1 at 13–16.) But Defendants are wrong. The FCA's limitations rule does not govern claims for unjust enrichment or payment by mistake of fact. Those claims are instead subject to a 6-year period under 28 U.S.C. § 2415. *See United States v. Kaman Precision Prod., Inc.*, 2010 WL 11626636, at *7 (M.D. Fla. Apr. 19, 2010) ("[A] claim for unjust enrichment is . . . governed by § 2415(a)'s six year statute of limitations."); *United States ex rel. Borges v. Doctor's Care Med. Ctr., Inc.*, 2007 WL 9702639, at *18 (S.D. Fla. Jan. 29, 2007) ("The six-year statute of limitations also applies to claims for payment by mistake of fact.").[8]

[8] *See also Fed. Deposit Ins. Corp. v. Bank One, Waukesha*, 881 F.2d 390, 393 (7th Cir. 1989) ("[T]he United States may choose the six-year period in unjust enrichment cases."); *United States v. Intrados/Int'l Mgmt. Grp.*,

Moreover, the 6-year period does not begin until "facts material to the right of action" are known or reasonably could have been known "by an official of the United States charged with responsibility to act in the circumstances." 28 U.S.C. § 2416(c). The United States's common law claims are timely under these rules because, although the United States allegedly was on notice of the material facts in this case by September 2015, it filed suit less than 4 years later on August 2019—well within the required 6 years. (*See* Dkt. 116-1 at 15.)

Defendants cite no caselaw in support of their position, even though the statute of limitations is an affirmative defense on which they bear the burden of proof. *See Smith v. Duff & Phelps, Inc.*, 5 F.3d 488, 492 n.9 (11th Cir. 1993). They do cite 31 U.S.C. § 3731(c). (Dkt. 116-1 at 14–15.) But, as the United States points out, that provision is inapplicable on its face. (Dkt. 134 at 8.) It simply makes the United States's complaint "relate back" to the filing date of the relator's complaint in cases where the United States intervenes as a plaintiff. 31 U.S.C. § 3731(c). That rule is irrelevant here because the United States did not intervene in this

265 F. Supp. 2d 1, 13 (D.D.C. 2002) ("[T]he payment-by-mistake claim is . . . subject to the six-year limitations period under section 2415(a).").

case; it filed suit itself. Defendants note that a relator filed a similar complaint against Dr. Burkich in 2015. (Dkt. 134-1 ¶ 1.) But the United States never intervened in that case either. (*Id.* ¶ 11.) And the case was dismissed a year later. (*Id.*) Moreover, even if the United States's complaint did "relate back" to the relator's complaint, it is hard to see how that would help Defendants. It would effectively change the filing date of this case from 2019 to 2015, which would presumably *reduce* the risk of any timeliness issues.

Frankly, the Court does not know why Defendants latched onto Section 3731(c). It does not apply here. And, even if it did, it would hurt—not help—the Defendants. The limitations period is 6 years (not 3 years) based on 28 U.S.C. § 2415 (not the FCA). So, to the extent Defendants contend otherwise, they have not shown the United States's common law claims are untimely.

**2. Payment by Mistake of Fact**

"A claim for payment under mistake of fact requires the government to show that payment occurred pursuant to an erroneous belief which was material to the decision to pay." *Doctor's Care*, 2007 WL 9702639, at *18. Defendants say the materiality element is missing here

for the same reasons it is missing from the United States's FCA claims. (Dkts. 116-1 at 22–23; 141 at 15–16.) But the Court has already rejected Defendants' FCA materiality arguments. So those arguments fail here as well. Given the totality of the evidence, the United States could prevail at trial on its claim for payment by mistake of fact. *See Adams*, 371 F. Supp. 3d at 1218 (declining to dismiss a claim for mistaken payment in a similar EDTA chelation case).

**3. Unjust Enrichment**

"Unjust enrichment applies in situations where there is no legal contract, but where the person sought to be charged is in possession of funds which in good conscience and justice should not be retained, but should be delivered to the rightful owner." *Adams*, 371 F. Supp. 3d at 1216–17. Defendants say there was no unjust enrichment here because their Medicare claims were not false. (Dkt. 141 at 17.) But the Court has already concluded a jury must decide the falsity question. So Defendants' argument is a nonstarter. Defendants also attack the opinions of Michael J. Petron, the United States's damages expert. (Dkts. 116-1 at 23; 141 at 17–19.) But Defendants do not move to exclude Mr. Petron. And their criticisms are not persuasive. Moreover, even if Defendants' criticisms

were valid, they would principally impact damages, not liability. They certainly would not defeat the United States's claim as a matter of law. There is enough evidence here to send the United States's unjust enrichment claim to a jury. *See Adams*, 371 F. Supp. 3d at 1217 (declining to dismiss an unjust enrichment claim in a similar EDTA chelation case).

### C. Conclusion

Defendants have not shown the United States's claims are time-barred or meritless as a matter of law. So the Court denies Defendants' motion for summary judgment.

## IV. The United States's Motion for Summary Judgment

The United States also moves for summary judgment on its FCA claims. The Court denies the United States's motion because, even assuming Defendants submitted materially false Medicare claims, a jury could find they did not do so with the requisite scienter.

### A. Legal Standard

"Under the FCA, a person acts with the requisite scienter when []he 'knowingly' submits a false claim, which the FCA defines as either 'actual knowledge,' 'deliberate ignorance,' or 'reckless disregard.'" *Olhausen v.*

*Arriva Med., LLC*, 2022 WL 1203023, at *2 (11th Cir. Apr. 22, 2022). Reckless disregard is "an aggravated form of gross negligence." *Urquilla-Diaz v. Kaplan Univ.*, 780 F.3d 1039, 1057 (11th Cir. 2015). It "capture[s] the ostrich type situation where an individual has buried his head in the sand and failed to make simple inquiries which would alert him that false claims are being submitted." *Id.* at 1058. Deliberate indifference "plainly demands even more culpability than that needed to constitute reckless disregard." *Id.* at 1058 n.15. And "[a]ctual knowledge requires subjective awareness of the falsity of the claim." *Graves v. Plaza Med. Centers, Corp.*, 281 F. Supp. 3d 1260, 1266 (S.D. Fla. 2017). None of these definitions impose "a burdensome obligation on government contractors"; just "a limited duty to inquire." *Urquilla-Diaz*, 780 F.3d at 1058.

"The scienter requirement in FCA actions is rigorous and must be strictly enforced." *Ruckh v. Salus Rehab., LLC*, 963 F.3d 1089, 1108 (11th Cir. 2020). It ensures liability does not reach "honest mistakes," "simple negligence," or "claims . . . based on reasonable but erroneous interpretations of a defendant's legal obligations." *Olhausen*, 2022 WL 1203023, at *2; *Urquilla-Diaz*, 780 F.3d at 1057. Whether a defendant acted with scienter is "necessarily a fact-intensive inquiry," often

depends "heavily on credibility," and is "rarely appropriate for summary judgment."[9] "[T]he government therefore faces a difficult task at the summary judgment stage." *U.S. ex rel. Ryan v. Lederman*, 2014 WL 1910096, at *7 (E.D.N.Y. May 13, 2014); *see United States v. Taber Extrusions, LP*, 341 F.3d 843, 846 (8th Cir. 2003) ("Particularly when the issue turns on the defendant's intent or scienter, summary judgment for the plaintiff is inappropriate.").

**B. Analysis**[10]

The United States claims Dr. Burkich acted with scienter as a matter of law because he "failed to educate himself concerning the Medicare rules and requirements applicable to his EDTA claims." (Dkt. 117-1 at 24.) The Court disagrees. Dr. Burkich may have known little about the Medicare rules himself. But he testified repeatedly that he relied on billing and coding specialists to ensure he complied with those

[9] *United States v. Quicken Loans Inc.*, 239 F. Supp. 3d 1014, 1025 (E.D. Mich. 2017); *United States ex rel. Raggio v. Jacintoport Int'l, LLC*, 2013 WL 12321941, at *7 (D.D.C. Dec. 23, 2013).

[10] The parties appear to assume Defendant Preventive Medicine's scienter depends solely on Dr. Burkich's scienter. So the Court takes the same approach in this Order.

rules.[11] He said he only started billing Medicare for his chelation treatments because a "certified biller and coder" named Cheryl Sweeney told him to do so. (Dkts. 97 at 196–197; 98 at 102; *see id.* at 97, 123–124.) He said she told him "chelation therapy is covered for patients with heavy metal toxicity from a provocative urine test," and that she was doing similar billing for another medical provider. (Dkts. 97 at 41, 222, 231–232; 98 at 127–129.) He said she never retracted this advice (as far as he was aware), that he would have stopped billing Medicare had she done so, and that he only learned the advice was wrong sometime in 2015–2017. (Dkts. 97 at 41, 210–211; 98 at 134–138, 154–155, 181.) He said Ms. Sweeney reviewed his patient files, was "very aware of . . . what [he was] treating patients for," knew his chelation treatments were based on

[11] (*See, e.g.*, Dkts. 97 at 34 ("I don't do billing. I have someone who is an expert [who] is hired to look at this and say okay, yes or no to that."), 37 ("whether or not insurance gets billed" is a decision "I leave . . . to my billing person"); 98 at 94 ("When it comes to what are the standards, in terms of reimbursement, that's what I rely on my billing people to do."), 120–121 ("I relied on the billing people."), 123 ("I trusted [my billing specialists], that they were on top of [Medicare's chelation rules] and they were viewing that and researching all that and making sure everything was up to par."), 178 ("I am trusting the people around me to [determine] this is a covered service, this is not a covered service."), 233 ("I do just the medicine. I just see patients. . . . I delegate [insurance coverage issues] to the people who this is their specialty.").

urine tests, and continued billing for them anyway. (Dkt. 97 at 209, 222, 229; 98 at 127.) He said he believed his treatments were covered as a result. (Dkt. 98 at 124.)

The United States points to *United States v. Mackby*, 261 F.3d 821 (9th Cir. 2001), where the Ninth Circuit found the managing director of a health clinic was reckless for "failing to inform himself of [Medicare] requirements." *Id.* at 828. But the court reached that conclusion (on clear-error review) after a three-day trial, not at the summary judgment stage. And, although the court identified a general duty to "be familiar with the legal requirements for obtaining reimbursement," the court did not consider the extent to which a doctor can delegate that duty to specialists or otherwise comply with that duty by relying on specialists. *Id.* at 828. To deem reckless any Medicare doctor who does not himself know every Medicare rule would impose exactly the kind of "burdensome obligation" on providers that the Eleventh Circuit has eschewed. *Urquilla-Diaz*, 780 F.3d at 1058. Medicare providers can "rel[y] upon the work of [their] subordinates" without "independently and specifically verifying" compliance unless that reliance "amount[s] to gross negligence under the circumstances." *Urquilla-Diaz*, 780 F.3d at 1061–62. Whether

Dr. Burkich's reliance "amounted to gross negligence under the circumstances" here is a fact-intensive inquiry best left to a jury.

The United States notes Dr. Burkich—not his billing team—was responsible for "diagnosing patients and selecting what treatments to provide." (Dkt. 142 at 14.) And that is obviously true. But the diagnoses and treatments are not really the problem here. It is whether and how those diagnoses and treatments were *billed to Medicare* that counts. And Dr. Burkich's testimony could not be clearer that he relied on billing specialists to make those decisions. The United States insists Dr. Burkich chose which diagnostic codes to include on his Medicare claims. (*Id.*) But Dr. Burkich testified otherwise. (Dkts. 97 at 222–225; 98 at 78, 140–141, 277 ("I am not the coder."), 280.) He said he "delegate[d] that to somebody else" because he knows nothing about coding. (Dkts. 97 at 224; 98 at 156, 280.) A jury could believe him.

The United States claims Dr. Burkich "received and ignored numerous proverbial red-flags," including some from the very billing specialists on whom he purportedly relied. (Dkts. 117-1 at 24; 142 at 14.) But none of these "red flags" compel a finding of scienter. For example, the United States cites a 2011 letter from Cheryl Sweeney to unnamed

"providers" about the need for blood testing rather than urine testing. (Dkt. 107-14.) But Dr. Burkich testified he never saw or read the letter. (Dkt. 97 at 202–211.) So it says little about his intent. Ms. Sweeney also sent Dr. Burkich an email saying "it is very clear that you must move away from edta." (Dkt. 107-18.) Dr. Burkich said he has no memory of this email either. (Dkt. 98 at 173.) And he testified that, if he had read it, he would simply have understood it to mean "there are less and less third-party payers that are covering chelation therapy"—not that his Medicare claims were false. (*Id.* at 175.) A 2013 email from Ms. Sweeney is similarly inconclusive because it notes only that she was "encouraging providers"—not requiring Dr. Burkich specifically—"to have blood labs showing heavy metals on file." (Dkt. 107-19 at 1.) Dr. Burkich also claims he never saw the email. (Dkt. 98 at 178–181.)

In 2012, another billing specialist (Lea Kapherr) emailed Dr. Burkich a Blue Cross Blue Shield policy on chelation therapy, a UnitedHealthcare policy on chelation therapy, a Medicare coverage determination for chelation therapy in Florida, and a few related materials. (Dkt. 107-16.) The documents noted urine testing was unreliable, blood testing was required, and chelation therapy was not

covered for "alternative medicine uses." But most of these materials were prepared by private insurers or entities other than Georgia Medicare. And Dr. Burkich testified he does not recall seeing any of the documents, his staff knew emails and letters were not how to get his attention, and he would expect billing personnel to tell him directly if Medicare did not cover his EDTA chelation treatments, particularly since they were similarly direct when they told him to *start* billing Medicare for those treatments several years earlier. (Dkts. 97 at 228; 98 at 135–137, 165–169.)

In 2012, Blue Cross Blue Shield also sent Dr. Burkich a letter saying it would not cover his chelation treatments because Defendants' documentation failed to show the treatments were necessary or appropriate. (Dkt. 107-15 at 3–4.) The letter went on to say "[c]helation therapy is considered alternative medicine under Medicare Guidelines and not covered by Medicare." (*Id.* at 4.) This is certainly probative of scienter but, again, at the summary judgment stage, the Court cannot say it is dispositive. Dr. Burkich testified that *Blue Cross Blue Shield's* position did not prompt him to question *Medicare's* coverage because "[t]hey're two different entities" and he "didn't have any reason to believe

that Medicare was doing things the same way Blue Cross Blue Shield was." (Dkt. 98 at 146–147; *see id.* at 154 ("[T]his is Blue Cross Blue Shield, what does this have to do with Medicare?").) That explanation makes at least some sense. Moreover, Dr. Burkich does not remember reading the letter's language about Medicare. (*Id.* at 154.) And he testified that, if he had read it, he would have given it to his billing specialists and asked them to "get clarification" and ensure he was doing things "properly." (*Id.* at 154–155.) He testified further that, "[i]f there was something that we were doing wrong and I was made aware of it, we would have stopped doing it." (*Id.* at 134.) A jury could believe him. Indeed, Dr. Burkich testified he stopped billing Blue Cross Blue Shield and Medicare for EDTA chelation once he learned his own administration of that treatment was not reimbursable. (*See* Dkts. 97 at 41, 206, 215–216, 233–234; 98 at 137–138, 141, 145–147; *see also* Dkt. 107-16 at 1.)[12]

To be clear, none of these "red flags" are good news for Defendants. The United States's case is strong. Dr. Burkich's repeated claim that he did not read materials saying or suggesting he could not do what he was

[12] Notably, as Dr. Burkich pointed out in his deposition, the Blue Cross Blue Shield statement about Medicare is incorrect. (Dkt. 98 at 153–154.) Medicare does in fact cover chelation therapy under some circumstances.

doing may be weak. Whether to grant summary judgment for the United States is a close call. But, on balance, after considering the record in its entirety, the Court believes a jury should decide whether Defendants acted with scienter. Dr. Burkich says he relied on billing and coding specialists to ensure he was Medicare-compliant. He says one of those specialists explicitly told him he could bill Medicare for his chelation treatments. And, although various people sent him documents in *some* degree of tension with that advice, he says he does not recall seeing or reading most of these documents. He also says no one flatly told him Medicare did not cover his chelation treatments. On the contrary, he says his team of billing/coding specialists knew exactly what he was doing and continued to bill for it. A reasonable jury could believe him, weigh the evidence, and conclude his conduct fell below the recklessness required for liability under the FCA. That may be an unlikely outcome. But it is possible. So the Court denies the United States's motion for summary judgment.

## V. Conclusion

The Court **GRANTS** the United States's Motion to Exclude Expert Opinions of Douglas L. Nelson (Dkt, 114), Motion to Exclude Witness

Dana Barr (Dkt. 115), and Motion to File Surreply (Dkt. 143). The Court **DENIES** the United States's Motion for Summary Judgment (Dkt. 117) and Defendants' Motion for Summary Judgment (Dkt. 116).

The Court **ORDERS** the parties to meet and confer in a serious, good faith effort to resolve this case within the next 30 days. At least some of these discussions must be in person. If the parties are interested in mediation—with a magistrate judge or a private mediator—they should notify the Court within the next 30 days. The Court is open to staying this action if the parties believe doing so would facilitate settlement discussions.

**SO ORDERED** this 14th day of September, 2022.

MICHAEL L. BROWN
UNITED STATES DISTRICT JUDGE