J. Devlan Geddes
Henry J. K. Tesar
GOETZ, GEDDES & GARDNER, P.C.
35 North Grand Ave.
P.O. Box 6580
Bozeman, MT 59771-6580
Ph: 406-587-0618
Fax: 406-587-5144
Email: devlan@goetzlawfirm.com
htesar@goetzlawfirm.com

Joseph E. H. Atkinson, Esq. (*pro hac vice*)
Dale G. Mullen, Esq. (*pro hac vice*)
Michael H. Brady, Esq. (*pro hac vice*)
Michelle E. Hoffer, Esq. (*pro hac vice*)
WHITEFORD, TAYLOR & PRESTON L.L.P.
1021 E. Cary Street, Suite 2001
Richmond, Virginia 23219
Ph: 804-807-7385
Email: jeatkinson@whitefordlaw.com
dmullen@whitefordlaw.com
mbrady@whitefordlaw.com
mhoffer@whitefordlaw.com

Attorneys for Defendant

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA,
HELENA DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. THOMAS C. WEINER, Defendant.	Case No. CV-24-58-H-TJC **DEFENDANT THOMAS C. WEINER'S MEMORANDUM OF LAW IN SUPPORT OF MOTION TO DISMISS**

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

INTRODUCTION

Although replete with acronyms and bureaucratic jargon, the Complaint lacks specific, plain and plausible allegations of fact that lead to the legal conclusion that Dr. Weiner knowingly sponsored specific false certifications to procure government payments. Even assuming the validity of the Government's theories, the Complaint has not alleged facts showing they apply here, and so fails.

To expand: the claims based on the E&M (evaluation and management) coding of office visits, Compl. ¶¶ 75–86, whether based on failure to provide "significant different or separately identifiable" service or that it was a medical necessity, lack the requisite particularity for both falsity and scienter under the False Claims Act ("**FCA**") (Counts 1 and Count 2). The claims asserting medically unnecessary testing of oncology patients, Compl. ¶¶ 87–90, suffer from the same defect. Finally, the claims premised on prescriptions, Compl. ¶¶ 91–96, do not allege lack of medical necessity or "legitimate medical purpose," whether under the FCA or the Controlled Substances Act ("**CSA**"), 21 U.S.C. §§ 829, 842 (Counts 3 and 4), or scienter. Knowing falsity, including lack of medical necessity or legitimate medical purpose, must be plead plausibly, with particularity, and as to Dr. Weiner's subjective beliefs under both the FCA and CSA. *See United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 749 (2023) (FCA); *Ruan v. United States*, 597 U.S.

450, 465 (2022) (CSA). Failing that, the unjust enrichment claim (Count 5) fails too.

STANDARD OF REVIEW & ELEMENTS REQUIRED

The Complaint's claims must be dismissed if their elements are not plausibly, and particularly, alleged in satisfaction of Federal Rules of Civil Procedure 9(b) and 12(b)(6). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." But "[w]here a complaint pleads facts that are merely consistent with a defendant's liability, it stops short of the line between possibility and plausibility of entitlement to relief." *Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009) (internal quotations omitted). Thus, courts "begin by taking note of the elements a plaintiff must plead to state a claim" under their asserted theory. *Id.* at 675. Before showing, there must be telling for the Complaint to survive a Rule 12(b)(6) motion.

What must be told? "A claim under the False Claims Act," which covers Counts 1 and 2, requires pleading "(1) a false statement or fraudulent course of conduct, (2) made with the scienter, (3) that was material, causing (4) the government to pay out money . . . ." *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890, 899 (9th Cir. 2017) (internal citation omitted); *Godecke v. Kinetic Concepts, Inc.*, 937 F.3d 1201, 1208 (9th Cir. 2019) ("A Rule 12(b)(6) dismissal

'can be based on the lack of a cognizable legal theory or the absence of sufficient facts alleged under a cognizable legal theory.'" (quoting *Balistreri v. Pacifica Police Dep't*, 901 F.2d 696, 699 (9th Cir. 1990))).

What must be factually pled? "A complaint must plead sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face" as to each of these elements. *Godecke*, 937 F.3d at 1208 (internal quotations omitted). "A claim under the FCA must not only be plausible, Fed. R. Civ. P. 8(a), but pled with particularity under Rule 9(b)." *Id*. Rule 9(b) requires that such "allegations of fraud . . . be specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001). Thus, "[t]he party must allege the 'who, what, when, where, and how' of the misconduct." *Godecke*, 937 F.3d at 1208 (internal citations omitted).

Here, the Government has "the burden to prove *each* false claim," having chosen to bring "a fraud case that depends on whether medical care or the coding of a medical condition was appropriate, and fraud will have to be proved on a claim-by-claim basis based on the patient's actual medical condition and actual medical care." *United States ex rel. Conroy v. Select Med. Corp.*, 307 F. Supp. 3d 896, 905–06 (S.D. Ind. 2018). As such, it has the burden to plead the same, or at the very least

"allege the particular details of a scheme to submit false claims paired with reliable indicia that lead to a strong inference that claims were actually submitted." *United States v. United Healthcare Ins. Co.*, 848 F.3d 1161, 1180 (9th Cir. 2016). As *Kearns* explained, this requires "*more* than the neutral facts necessary to identify the transaction," not less. 567 F.3d at 1124 (emphasis in original). That means "the pleading must state 'enough fact[s] to raise a reasonable expectation that discovery will reveal evidence of [the misconduct alleged]." *Cafasso, U.S. ex rel. v. Gen. Dynamics C4 Sys., Inc.*, 637 F.3d 1047, 1055 (9th Cir. 2011) (internal quotations omitted).

Turning to the claims found in Counts 3 and 4 under 21 U.S.C. §§ 829 and 842, as interpreted by 21 C.F.R. § 1306.04(a), the Government must plead plausibly that regulation's requirement—that a prescription issued by an individual practitioner, like Dr. Weiner, be issued for a legitimate medical purpose—has been violated. In other words, that each prescription was not issued "for a legitimate medical purpose" given "the patient's actual condition and actual medical care." Under Supreme Court precedent, this requires the Government to plead Dr. Weiner's subjective knowledge that the prescription was not "issued for a legitimate medical purpose." The Supreme Court expressly rejected the "objective standard," which would make Dr. Weiner's alleged liability depend upon "the mental state of a

hypothetical 'reasonable' doctor, not on the mental state of the defendant himself . . . ." *Ruan*, 597 U.S. at 465.

STATEMENT OF FACTS

Dr. Thomas C. Weiner, a Montana-licensed physician, board-certified in oncology and hematology, was the chief medical oncologist—in fact the only medical oncologist physician—at St. Peter's Health Cancer Care in Helena, Montana ("**St. Peter's**") during the period in question. Compl. ¶¶ 2, 6, 55. For nearly 25 years, Dr. Weiner served cancer patients in the Helena, Montana community from the cancer treatment center ("**Cancer Treatment Center**") within St. Peter's. Compl. ¶ 55, 56. A prodigious worker, his absence to attend to personal matters obliged St. Peter's to contract with two to three medical providers. Compl. ¶ 55. As the only medical oncologist physician at St. Peter's, Dr. Weiner saw between fifty and seventy patients a day at the Cancer Treatment Center, far more than your average oncologist. Compl. ¶¶ 56, 58. As a result, he earned more than other physicians at St. Peter's. Compl. ¶ 59.

After nearly 25 years of service, and without a finding of wrongdoing, Dr. Weiner was suspended, and ultimately terminated, by St. Peter's "because of potential errors made . . . in treating numerous cancer patients." Compl. ¶ 60. Now, four years later, the Government brings this suit for an indeterminate number of alleged regulatory violations—"double-billing," inadequate documentation, excess

visits, and unnecessary testing and prescriptions—allegedly occurring over a forty-month period, August 2018 through December 2020, during which Dr. Weiner is estimated to have conducted over 40,000 oncology appointments. *See* Compl. ¶ 56.

Despite threatening Dr. Weiner with complete professional and personal ruin, the Government has not deigned to show its work. The Complaint identifies no dates of service, particular visits, prescriptions issued or testing done, patients served, or medical histories considered, except a few conclusory lines about two prescription regimens for two anonymous patients. Compl. ¶¶ 94–95. Being short on facts, the Complaint is long on characterizations and conclusions. *See, e.g.*, Compl. ¶¶ 76, 84 ("double-billing"), ¶¶ 85, 86 ("unnecessary" visits), ¶¶ 87, 88, 89, 90 ("unnecessary" testing and treatment), ¶¶ 91, 92, 93, 96 ("unnecessary" prescriptions). To avoid having nothing to say, the Government treats us not to facts, but to a plethora of vague pronouns, such as "certain," "the medical records," "the rules and regulations," "standard medical practice," "inappropriate types of cancer and clinical scenarios," and "non-standard regimens." Rather than defining the terms or specifying the facts or standards, the Complaint offers only non-specific characterizations, such as "most," "at least in part," "significantly different," "medically appropriate," "medically appropriate and justifiable," "separately identifiable," "typically," "many," "properly document[]," "falsified," "unnecessary," "routinely," "simply not," and "frequently." *See, e.g.*, Compl. ¶ 77,

78, 85, 86, 87, 88, 89, 90, 91, 92, & 93. The Complaint presupposes that the falsity of a medical record, the lack of medical need for an office visit, test or treatment, or the medical illegitimacy of hundreds of prescriptions involving nearly a dozen patients can be adequately plead as a conclusion, in a fact-free vacuum. Not so.

ARGUMENT

I. The Complaint Fails to Allege Sufficient Facts to Substantiate That False Claims Were Submitted or That Dr. Weiner Knew That Any Claims Were "False," or That His Prescriptions Lacked a "Legitimate Medical Purpose," at the Time They Were Made.

The "two essential elements of an FCA violation are (1) the falsity of the claim and (2) the defendant's knowledge of the claim's falsity." *Schutte*, 598 U.S. at 747. The Complaint's allegations fail to plausibly and particularly support either element.

Regarding falsity, the Complaint asserts a "false certification theory" under the FCA under which the Government must allege "the who, what, when, where, and how of the misconduct charged, including what is false or misleading about a statement, and why it is false." *United Healthcare*, 848 F.3d at 1180 (internal citations and quotations omitted). "Broad allegations that include no particularized supporting detail do not suffice." *Id.*

While "a false certification of medical necessity can give rise to FCA liability," *Winter ex rel. United States v. Gardens Reg'l Hosp. & Med. Ctr., Inc.*, 953 F.3d 1108, 1118 (9th Cir. 2020), as can false certifications of compliance with other statutory, regulatory, or contractual requirements, the Complaint did not allege with

any particularity what was false or misleading about the particular certifications or what made them false. Certainly, there were no factual allegations supporting the notion that Dr. Weiner believed certifications, including of medical necessity, to be false. *See Vatan v. QTC Med. Servs., Inc.*, 812 F. App'x 485, 487 (9th Cir. 2020) (noting that "a physician's medical opinion can be considered 'false' within the meaning of the False Claims Act under some circumstances, such as where the opinion is not honestly held by the doctor."). Taking the certifications in turn:

Medical Necessity & Legitimate Medical Purpose

We are told that Dr. "Weiner routinely scheduled patients for office visits in between cycles of chemotherapy treatment, which was not standard medical practice and was not medically necessary." Compl. ¶ 86. We are also told that Dr. "Weiner used serum tumor marker testing . . . more than was medically appropriate or necessary." Compl. ¶ 87. Similarly, it is alleged that Dr. "Weiner used . . . (PET) scans more than was medically necessary." Compl. ¶ 88. The Complaint also faulted Dr. Weiner for prescribing a particular cancer drug to some unknown number of patients "for years longer than was medically necessary." Compl. ¶ 89. Dr. Weiner is alleged to have "routinely used non-standard chemotherapy regimens" that "were not medically necessary, as they did not improve patient outcomes." Compl. ¶ 90.

Turning to the alleged lack of "legitimate medical purpose" for issuance of certain prescriptions for controlled substances under the CSA, we are told simply

that Dr. Weiner prescribed controlled substances "to treat patients after they no longer needed treatment" because those patients were "cancer-free" and, in doing so, "failed to" comply with "standard opioid guidelines." Compl. ¶ 91, 92. The Government's theory, that Dr. Weiner issued somewhere between 234 and 316 prescriptions for controlled substances to a mere eleven patients (of the many hundreds or even thousands he saw) so he could increase his compensation marginally makes little sense. Compl. ¶ 91, 96.

In all cases, we are told almost nothing more about patient history, medical condition, medical standards, or medical outcomes. The Complaint does not deny that all the patients had medical conditions requiring treatment, that some form of medical treatment was medically necessary, that Dr. Weiner did not provide them medical treatment, that such treatment was not efficacious, the conditions under which the given medical treatment may be medically necessary, or that such conditions did not exist. At best, the Complaint asserted a condition existed, a treatment was provided, and that the treatment was not medically necessary. A more conclusory and less particularized set of allegations about medical necessity are hard to imagine.

Perhaps the deficiency may be seen more clearly in contrast. In *Winter*, the Ninth Circuit found that a complaint had "plausibly allege[d] false certifications of medical necessity," 953 F.3d at 119. The Ninth Circuit reached that conclusion by

juxtaposing the complaint before it with one "that identifies a general sort of fraudulent conduct but specifies no particular circumstances of any discrete fraudulent statement." *Id.* at 1120 (internal quotations omitted). Unlike that case or the Complaint, the complaint in *Winter* "identifie[d] sixty-five allegedly false claims in great detail, listing the date of admission, the admitting physician, the patient's chief complaint and diagnosis, and the amount billed to Medicare. The complaint alleges that each admission failed to satisfy the hospital's own admissions criteria," violating its contract, and that such criteria "represent the consensus of medical professionals' opinions," meaning that "a failure to satisfy the criteria also means that the admission went against the medical consensus." *Id.* at 1120 (internal quotations omitted). There is no reason to believe that the Government lacks access to the pertinent data. In fact, the Complaint makes clear that the Government has simply decided to withhold additional information until what it believes to be "the proper time." Compl. ¶ 94 & n.1. Until then, Dr. Weiner must shadowbox.

E&M Coding & Documentation

The other theory of falsity is that the code for evaluation and management visits with Dr. Weiner was improperly used in conjunction with other medical care when Dr. Weiner allegedly provided no "significantly different or separately identifiable services from the tests or infusions" the patient was also receiving, or that such services, at least, were not properly documented. Compl. ¶¶ 76–78. The

Complaint does not deny that such visit occurred, identify the source of the alleged separate service or documentation requirements (stating only that it "was against the rules and regulations of the corresponding government health care program"), or give any detail about the alleged deficiency in either the service provided or the documentation maintained, much less identify even a single such visit or instance of improper documentation. Neither this Court nor Dr. Weiner are supplied with any facts at all about "the who, what, when, where, and how of the misconduct charged, including what is false or misleading about a statement, and why it is false."

At best, we are told that an "outside consultant" conducted an "audit" by February 2018 and found "that over 90% of Weiner's sampled E&M code billing was not justified by themedical (sic) records." Compl. ¶ 79. But we are told nothing about the audit, including about the sampling process or the period sampled, how the medical records failed to justify the billing, or even that the same deficiency (whatever it is) was present in any documentation during the period in question, which post-dates the audit by many months. "This type of allegation, which identifies a general sort of fraudulent conduct but specifies no particular circumstances of any discrete fraudulent statement, is precisely what Rule 9(b) aims to preclude" by requiring particularity. *Cafaso*, 637 F.3d at 1057. "Without these details, the [C]omplaint does not supply reasonable indicia that false claims were

actually submitted," just a theory under which they could have been. *United Healthcare*, 848 F.3d at 1182 (internal quotations omitted).

Knowledge of Falsity Not Sufficiently Alleged

Even if the Complaint's allegations are deemed sufficient to establish falsity, that is not enough. "What matters for an FCA case is whether the defendant knew the claim was false." *Schutte*, 598 U.S. at 743. "For a certified statement to be 'false' under the Act, it must be an intentional, palpable lie. Innocent mistakes, mere negligent misrepresentations and differences in interpretations are not false certifications under the Act." *U.S. ex rel. Hopper v. Anton*, 91 F.3d 1261, 1267 (9th Cir. 1996) (internal citation omitted). "The FCA's scienter element refers to respondents' knowledge and subjective beliefs—not to what an objectively reasonable person may have known or believed," and cares about "what the defendant knew when presenting the claim," and "what the defendant thought when submitting the false claim—not what the defendant may have thought" or known "*after* submitting it." *Schutte*, 598 U.S. at 749, 752. The same rule applies to Counts 3 and 4, raising claims under CSA with respect to certain prescriptions. The Government must plead and prove that Dr. Weiner did not "subjectively believe[his] conduct was in accord with the appropriate standard of care." *Ruan*, 56 F.4th at 1298, *cert. denied sub nom. Xiulu Ruan & John Patrick Couch v. United States*, 144 S. Ct. 377 (2023). The Supreme Court has stood by the rule that the Government

must "prove that a doctor knowingly or intentionally acted" to prescribe controlled substances that lacked a "legitimate medical purpose," rejecting the argument that this "will allow bad-apple doctors to escape liability by claiming idiosyncratic views about their prescribing authority." *Ruan*, 597 U.S. at 466. The same interpretation of the CSA applies to this civil case. *See Leocal v. Ashcroft*, 543 U.S. 1, 11 n.8 (2004).

The Supreme Court's cases teach that there must be "'strict enforcement of the [False Claims] Act's . . . scienter requirements'" as it the primary means by which "'concerns about fair notice and open-ended liability can be effectively addressed.'" *Winter*, 953 F.3d at 1117 (quoting *Universal Health Services*, 579 U.S. at 192). As the Supreme Court noted, the FCA's scienter "requirements are rigorous." *Universal Health Services*, 579 U.S. at 192. As such, "[t]o plead a claim for express false certification, a complaint must allege facts from which it may reasonably be inferred that the defendant submitted a claim for payment to the government in which it expressly certified that it had complied with a specific law or provision of the contract with which [he] knew [he] had not complied." *McElligott v. McKesson Corp.*, No. 21-15477, 2022 WL 728903, at *1 (9th Cir. Mar. 10, 2022); *United States v. Corinthian Colleges*, 655 F.3d 984, 997 (9th Cir. 2011) (to satisfy scienter, complaint must "clearly allege sufficient facts to support an inference or render plausible that" defendant "acted while knowing that its" actions were contrary to law).

Such allegations of fact are wanting here. Dr. Weiner's alleged knowledge of the supposed falsity is asserted in conclusory fashion. Compl. ¶¶ 2, 3, 86, 87, 88, 89, 98(a)–(g), 101(a)–(g). The only facts cited to substantiate awareness of falsity of any of the claims presented at his behest for the period between August 26, 2018 and December 31, 2020, Compl. ¶ 76, are as follows:

- Dr. Weiner saw many patients and spent a small amount of time with each patient, Compl. ¶¶ 57, 58, 85, 86

- that on or before February 2018 an "outside consultant conducted an audit which identified that that over 90% of Weiner's sampled E&M code billing was not justified by themedical (sic) records," and that he was apprised of the findings and what "he needed to add to the medical record to make these visits billable," Compl. ¶ 79, and "that this issue persisted into August of 2018," Compl. ¶ 80

- that Dr. Weiner was exasperated by St. Peter's failure to bill certain codes, and took steps to address the document issue identified by the consultant on or about August 13, 2018, by adding more information to the documentation and creating a prompt for Dr. Weiner to add justification for E&M code billing, Compl. ¶¶ 79–83

- that Dr. "Weiner routinely scheduled patients for office visits in between cycles of chemotherapy treatment," Compl. ¶ 86

- that Dr. "Weiner ordered and billed for tumor marker testing for at least one patient with early-stage breast cancer and another with lung cancer," and that this testing "could have been harmful to the patient and potentially led to further unnecessary medical treatment," Compl. ¶ 87

- that Dr. Weiner waited for insurance approval for a PET scan rather than use a lower level of imaging, Compl. ¶ 88

- that, "in several instances," Dr. Weiner "continued Rituximab treatment for 10 years or more after the patient's cancer was removed or in remission," Compl. ¶ 89

- that Dr. "Weiner routinely used non-standard chemotherapy regimens that had more frequent administrative schedules." Compl. ¶ 90
- that Dr. Weiner prescribed controlled substances "to patients who had been cancer-free, sometimes for years," including one patient who "was not treated for active cancer since at least 2014" and "had documented issues with alcoholism and had shown other addictive behaviors," Compl. ¶¶ 91, 94, and that Dr. Weiner prescribed opioids to another person whose cancer had been in remission for some years but did not "mention his prescribing" them in his medical records for that patient covering "August 19, 2019 through the end of 2020," Compl. ¶ 95.

While it is asserted in conclusory fashion that these billing codes were applied, treatments and tests were provided, and prescriptions were issued in contravention of standard medical practices or guidelines, or were not medically necessary or issued for a legitimate medical purpose, these facts do not evince Dr. Weiner's awareness that any of these medical services were not medically appropriate or properly billable and billed. Nothing is alleged about those practices, standards, or guidelines, or about Dr. Weiner's knowledge of them. Even those few facts alleged to show awareness, such as the February 2018 audit of E&M billing codes, ***pre-date by many months the period in question*** and are not paired with an allegation that relates those findings to the period in question, the alleged false claims complained of, or Dr. Weiner's knowledge of those claims. *See Schutte*, 598 U.S. at 749, 752 (noting that the relevant point is "what the defendant knew *when presenting the*

claim") (emphasis added). In sum, these allegations simply seek to show a lack of medical necessity or other falsity. They offer no evidence that Dr. Weiner was aware of that fact. But under the FCA and the CSA, "it is the defendant's subjective intent that matters," not the mere fact (or theory) of falsity. *Ruan*, 56 F.4th at 1297.

Moreover, the Complaint lacks sufficient allegations to support a plausible interpretation of the alleged billing, treatment, and prescription practices as misconduct. Instead, the allegations appear to be "innocent mistakes, mere negligent misrepresentations, and differences in interpretations," which "are not false certifications under the Act" because they do not demonstrate knowing misconduct. *Hopper*, 91 F.3d at 1267. The Complaint does allege the marginal benefit to Dr. Weiner of any such over-billing or treatment or the magnitude of the allegedly false claims, either in dollar value, or the "error rate" associated with his practice. Those few hard numerical clues provided by the Complaint, somewhere between 234 and 316 instances of alleged improper controlled substances prescriptions to eleven patients over sixteen months, a period in which he is supposed to have seen some 15,000 plus patients, suggests that Dr. Weiner's "conduct, applying to only a small percentage of all claims was, at worst, inadvertent, which does not trigger FCA liability." *United States v. Prabhu*, 442 F. Supp. 2d 1008, 1034 (D. Nev. 2006); *see id.* at 1034–35 (collecting cases holding that "an allegedly low error rate (even if true) reflects inadvertence or honest mistake, which does not trigger FCA liability.").

Thus, Counts 1 through 4 should be dismissed because the Complaint did not allege facts from which it may reasonably be inferred that Dr. Weiner certified for payment the provision of medical services and controlled substances knowing that these acts violated the law.

II. The Complaint Has Failed to Plead Facts Plausibly Showing That Dr. Weiner Knew Any Such Non-Compliance Was Material to the Government's Payment Decision.

Materiality too is an essential element of proving an FCA claim premised upon an alleged "misrepresentation about compliance with a statutory, regulatory, or contractual requirement." Put simply, that misrepresentation "must be material to the Government's payment decision in order to be actionable under the False Claims Act." *Universal Health Services*, 579 U.S. at 192. Like the requirement of scienter, the requirement of materiality is "rigorous," and must be "strict[ly] enforce[d]." *Id.* The question, for every claim that is allegedly actionable, is "whether the defendant knowingly violated a requirement that the defendant knows is material to the Government's payment decision." *Id.* at 181.

As stated by the Ninth Circuit, "It is not enough to allege regulatory violations; rather, the false claim or statement must be the *sine qua non* of receipt of state funding." *Campie*, 862 F.3d at 899 (internal quotations and citations omitted); *see Hopper*, 91 F.3d at 1266 ("Violations of laws, rules, or regulations alone do not create a cause of action under the FCA. It is the false *certification* of compliance

which creates liability when certification is a prerequisite to obtaining a government benefit."(Emphasis in original)).

The Supreme Court in 2016 took on the question of materiality, and made clear that, "The materiality standard is demanding. . . . A misrepresentation cannot be deemed material merely because the Government designates compliance with a particular statutory, regulatory, or contractual requirement as a condition of payment. Nor is it sufficient for a finding of materiality that the Government would have the option to decline to pay if it knew of the defendant's noncompliance. Materiality, in addition, cannot be found where noncompliance is minor or insubstantial." *Universal Health Services*, 579 U.S. at 194. The facts sufficient to establish materiality are not merely a matter of proof, but also of pleading. In *Universal Health Services*, the Supreme Court went out of its way to "reject [the] assertion that materiality is too fact intensive for courts to dismiss False Claims Act cases on a motion to dismiss or at summary judgment," and to reaffirm that "False Claims Act plaintiffs must also plead their claims with plausibility and particularity under Federal Rules of Civil Procedure 8 and 9(b) by, for instance, pleading facts to support allegations of materiality." *Id.* at 195 n.6.

What facts bear on materiality? As the Supreme Court explained, various facts are relevant and so should be pled to make out a plausible claim. On the one hand you have that the Government has "expressly identif[ied compliance with] a

provision [alleged breached] as a condition of payment" of a particular claim, a fact that is "not automatically dispositive." *Id.* at 194. To the same effect, "that the defendant knows that the Government consistently refuses to pay claims in the mine run of cases based on noncompliance with the particular statutory, regulatory, or contractual requirement." *Id.* at 195. Weighing strongly against materiality would be the fact that "the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated" or that the Government "regularly pays a particular type of claim in full despite actual knowledge that certain requirements were violated, and has signaled no change in position . . . ." *Id.*

The factual bases necessary to plausibly infer materiality have not been alleged. Although the Complaint makes repeated references to medical necessity and the general obligation of legal and regulatory compliance, including (in some instances) to the same being a condition of reimbursement, *see generally* Compl. ¶¶ 19, 21, 22, 26, 27, 28, 31, 33, 34, 37, 39, 72, 73, this is "not automatically dispositive" and little else is alleged bearing on materiality.

As a first order matter, the Complaint generally fails to specify particular acts of noncompliance or to tether them to any "particular statutory, regulatory, or contractual requirement." Where non-compliance is alleged, it is generally with respect to the obligation of medical necessity, and then tied only to categories, not to particular claims, prescriptions, tests, treatments or patients. The other category

of alleged violation of any statutory, regulatory, or contractual requirement involved the E&M code billing, and the alleged lack of "significant, separately identifiable service" or "proper document[ation] in the patient's medical records" of the service provided. (The details of these rules and the alleged failures are unspoken, suggesting that the Government does not want to confess that "those rules are ambiguous," meaning that "there cannot be any FCA liability as a matter of law." *Prabhu*, 442 F. Supp. 2d at 1034.)

By avoiding any particularity at all, the "complaint does not allege that compliance with" these alleged requirements are expressly "designated as a condition of payment," *McElligott*, 2022 WL 728903, at *2, but only vaguely alleges that these actions or omissions were "against the rules and regulations of the corresponding government health care program." Compl. ¶ 78. There is not even a "conclusory allegation" that had the Government known of these violations, it would not have paid the claims, allegations which themselves have been found "insufficient under Rule 9(b)." *Ebeid v. Lungwitz*, 616 F.3d 993, 1000 (9th Cir. 2010).

"[N]or does it allege other facts from which it could reasonably be inferred that the [G]overnment deemed noncompliance with" the alleged significant, separately identifiable service or proper documentation requirements (wherever they are found and whatever they say) to be "relevant to its decision to pay." *McElligott*, 2022 WL 728903, at *2.

In any event, one will search in vain for an allegation that Dr. Weiner "knows that the Government consistently refuses to pay claims" that lack such "significant, separately identifiable service," "proper document[ation]" or of questionable medical necessity. The closest the Complaint gets to this issue is an allegation about "an audit which identified that over 90% of Weiner's sampled E&M code billing was not justified by themedical (sic) records," Compl. ¶ 79, although there is no allegation as to the basis for the finding, that Dr. Weiner was aware of it, or that the issues audited sometime around February of 2018 were the same concerns raised in the Complaint, which cover August 2018 through the end of 2020.

Absent too is any allegation, conclusory or otherwise, that the Government does not pay such claims "in full despite its actual knowledge that certain requirements were violated." In fact, the Complaint implies that Dr. Weiner engaged in the same practices for years, even decades, and was regularly paid without objection on all such claims. *See* Compl. ¶¶ 55, 56, 59, 79, 89, 94, 95. There is no allegation one way or the other regarding the Government's knowledge about any requirements being violated. The Complaint is also devoid of allegations that allow one to decide whether the "noncompliance is minor or insubstantial" with respect to any individual claim for payment, about which almost nothing is alleged. *Universal Health Services*, 579 U.S. at 194.

In short, "nothing in the [C]omplaint gives rise to a reasonable inference that" Dr. Weiner knew that any particular regulatory violation that has been alleged "was material to the [G]overnment's decision to pay for medical [services] that [Dr. Weiner] actually delivered," in the manner and with the documentation by which he delivered them. *McElligott*, 2022 WL 728903, at *2. Accordingly, Counts 1 and 2 should be dismissed. *See, e.g.*, *id.* (affirming dismissal without leave to amend for failure "to allege materiality," among other FCA requirements).

III. Because the FCA and CSA Claims Fail, So Too Does the Unjust Enrichment Claim.

Finally, Count 5 derives from Counts 1 through 4, and rests upon the exact same factual allegations. Compl. ¶ 110. If Dr. Weiner did not obtain the benefits gained through participation in the referenced government programs by submission of false claims, but rather by arduous and honest application of specialized medical knowledge to restore and preserve the health of those facing potentially terminal illness, including the poorest members of our society, what the Supreme Court has recognized to be "socially beneficial conduct" even in the ordinary case, *Ruan*, 597 U.S. at 459, there is nothing whatever unjust about such enrichment. Accordingly, that Count falls if Counts 1, 2, 3 and 4 do. *See, e.g.*, *United States v. Peters*, No. 2:24-CV-00287 WBS CKD, 2024 WL 3378034, at *6 (E.D. Cal. July 11, 2024) (dismissing unjust enrichment claim premised on an FCA claim that "the government has failed to plead . . . with particularity"); *Prabhu*, 442 F. Supp. 2d at

1035 (concluding that having granted summary judgment on the FCA claims, it must also grant judgment on the unjust enrichment claim lest the "Court's ruling . . . be internally inconsistent"); *but see, e.g.*, *United States v. Anderson*, 271 F. Supp. 3d 950, 959 (M.D. Tenn. 2017) (holding that, "[t]o the extent Defendants were not entitled to those payments, the Government has sufficiently asserted . . . an unjust enrichment claim").

CONCLUSION

The Government seeks to impose ruinous financial penalties on Dr. Weiner for individual medical decisions made with respect to specific patients with documented medical conditions. Yet, years later and despite asserting fraud claims and urging myriad regulatory requirements, the Complaint omits mention of nearly all details relevant to whether the visits, tests, treatments and prescriptions issued by Dr. Weiner were medically necessary, including reference to any particular Medicare standards that govern those determinations. In doing so, the Complaint seeks to shift to Dr. Weiner the burden of disproving that none of tens of thousands of unspecified medical decisions, made years ago, were medically inappropriate or otherwise a regulatory violation. That is not how fraud claims must be pled.

The Complaint as pled denies Dr. Weiner adequate notice to allow him to defend these charges, which are by their nature individualized to each particular claim, not to any general policy, and threaten him with untold (and apparently still

uncalculated, Compl. ¶¶ 96, 102, 105, 106, Request for Relief), professional and personal loss. The Complaint thus suffers from not only technical deficiency, but also violates the "principal purposes" of Rule 9: notice to permit the defendant to respond and mount a defense and to prevent "false or unsubstantiated charges" to be used as a pretext for punishing, through legal process, an unpopular person. *United Healthcare Ins. Co*., 848 F.3d at 1180 (9th Cir. 2016).

For all these reasons, those to be urged in Dr. Weiner's Reply Brief, and those that may be argued orally, all Counts of the Complaint should be dismissed.

DATED this 15th day of November, 2024.

By*: /s/ Michelle E. Hoffer*
Joseph E. H. Atkinson, Esq. (*pro hac vice*)
Dale G. Mullen, Esq. (*pro hac vice*)
Michael H. Brady, Esq. (*pro hac vice*)
Michelle E. Hoffer, Esq. (*pro hac vice*)
WHITEFORD, TAYLOR & PRESTON L.L.P.

By: */s/ J. Devlan Geddes*
J. Devlan Geddes
Henry J. K. Tesar
GOETZ, GEDDES & GARDNER, P.C.

Attorneys for Defendant

CERTIFICATE OF COMPLIANCE

Attorneys for Defendant hereby certify that the foregoing principal brief, including the accompanying motion to dismiss, does not exceed 6,500 words, as required by Local Rule 7.1(c) & (d).