UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK
BUFFALO DIVISION

UNITED STATES OF AMERICA ex rel. DEBORAH CONRAD, Plaintiff/Relator, v. ROCHESTER REGIONAL HEALTH and UNITED MEMORIAL MEDICAL CENTER, Defendants.	Case No. 1:23-cv-00438-JLS

DEFENDANTS ROCHESTER REGIONAL HEALTH AND UNITED MEMORIAL MEDICAL CENTER'S MOTION TO DISMISS RELATOR'S AMENDED COMPLAINT WITH PREJUDICE AND MEMORANDUM OF LAW IN SUPPORT

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Rochester Regional Health and United Memorial Medical Center (collectively, "RRH") move under Federal Rules of Civil Procedure 12(b)(6) and 9(b) to dismiss all of Relator Deborah Conrad's claims against RRH as set forth in the Amended Complaint (Dkt. 34).

I. INTRODUCTION

In this non-intervened qui tam, Relator is on her second bite at the apple. Following the Court's dismissal of the first Complaint at a bench hearing in August 2024, Relator promised she could file an Amended Complaint that satisfied her pleading burden to particularly allege a fraudulent scheme that resulted in specific false claims/certifications made to the government. Despite attaching four redacted COVID-19 vaccine cards and adding considerable conclusory arguments and assertions to her Amended Complaint that do not materially change any of the previously asserted factual allegations, Relator has not lived up to her promise. In fact, the Amended Complaint adds no new particularized pleadings sufficient to allege violations of the False Claims Act ("FCA"). So, for the following reasons, the Amended Complaint should be dismissed with prejudice:

First, Relator's false certification theories do not state viable claims under the FCA because Relator has not shown an underlying contractual breach or non-compliance with a statutory requirement specific to vaccination providers administering COVID-19 vaccines under the CDC's COVID-19 Vaccination Program.

Second, the allegations in the Amended Complaint do not allege fraud with the required particularity under Rule 9(b); moreover, Relator has not pled facts sufficient to plead fraud under *Chorches*' alternative pleading standard.

Third, Relator cannot establish RRH acted with the required scienter under the FCA.

Fourth, Relator cannot establish a reverse false claim by alleging the same conduct forming the basis of a traditional false claim.

Fifth, the intra-corporate conspiracy doctrine bars Relator's conspiracy claim, and Relator has pled no facts to support an FCA conspiracy claim.

Finally, Relator's retaliation claims fail because she did not engage in protected activity and was not terminated *because of* asserted whistleblowing.

II. BACKGROUND

The gist of Relator's fraud theory against RRH remains the same. Relator contends that RRH knowingly submitted false claims/certifications to the government when seeking payment for vaccine administration claims submitted under the CDC COVID-19 Vaccination Program Provider Agreement ("Vaccination Provider Agreement" or "Agreement"). Relator, a physician's assistant who worked with patients admitted to a RRH hospital, claims many of her patients (and those of her colleagues) presented with adverse events for which RRH assumed obligations to report such events to the Vaccine Adverse Event Reporting System ("VAERS").[1] She contends RRH failed to submit VAERS reports, suppressed her and other hospital staff from reporting to VAERS, and failed to educate hospital staff on VAERS reporting obligations. Based on these asserted failures, she contends that RRH breached contractual provisions of the Vaccination Provider Agreement and various statutes ostensibly imposing COVID-19 vaccine reporting obligations and, as a result, falsely certified compliance to the government when seeking payment for vaccine injections in violation of the FCA.

Despite Relator's promise that, through an amendment, she could cure many of the pleading deficiencies this Court identified at the August 20, 2024 hearing on RRH's Motion to

[1] The VAERS guidance for reporting adverse events from COVID-19 vaccines administered under an emergency use authorization is attached as Exhibit A to the Peacock Declaration.

Dismiss, Relator's Amended Complaint includes few new factual details. RRH has identified the following new factual allegations:

1. The Amended Complaint introduces four redacted COVID-19 vaccination record cards for individuals M.D., N.M, D.A., and C.M. Dkt. 34 ¶ 91; Dkt. 34-26.
2. Relator knew, from public sources, that constituent elements of RRH's hospital network provided vaccines to the public. Dkt. 34 ¶¶ 42–43.
3. Relator had access to a hospital patient's vaccination records through the New York State Immunization Information System (NYSIIS) and through patients' medical charts in RRH's EPIC system. *Id.* ¶ 53.
4. Relator alleges the identities and job titles of several employees—none of whom are alleged to have worked at a vaccine clinic—who she claims were prevented from submitting VAERS reports. *Id.* ¶ 93.

Notwithstanding the new exhibit and these new allegations, Relator does not plead any other non-conclusory facts to show why she, as a physician's assistant who never worked in a vaccine clinic, possesses sufficient knowledge about RRH's activities as a vaccine provider under the Vaccination Provider Agreement on which to base a FCA case against RRH. As discussed below, Relator's Amended Complaint is meritless and should be dismissed with prejudice.

III. LEGAL STANDARDS

Under Rule 12(b)(6), "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). "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." *Id*. (citing *Twombly*, 550 U.S. at 556). While the Court is required to accept as true the complaint's factual

allegations, drawing all reasonable inferences in favor of the plaintiff, mere labels, conclusions, "formulaic recitation[s] of the elements[,]" "naked assertion[s] devoid of further factual enhancement[,]" and "[t]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Id*. at 678 (internal quotation marks and citation omitted). After disregarding the conclusory allegations, the petition must contain sufficient well-pleaded factual allegations to "nudge[] [plaintiff's] claims . . . across the line from conceivable to plausible." *Id*. at 680–81 (internal quotation marks and citation omitted).

Under Rule 9(b), the plaintiff must "state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). In the Second Circuit, this requires the complaint's allegations to "(1) specify the statements that the plaintiff contends were fraudulent, (2) identify the speaker, (3) state where and when the statements were made, and (4) explain why the statements were fraudulent." *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 81 (2d Cir. 2017) (citations omitted). Rule 9(b)'s particularity requirement furthers important policy goals, including giving a defendant fair notice of fraud allegations and protecting a defendant's reputation from baseless, unsupported accusations of fraud. *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 25 (2d Cir. 2016). The Second Circuit "rigorously enforces these salutary purposes of Rule 9(b)." *Id*. (quoting *Ross v. Bolton*, 904 F.2d 819, 823 (2d Cir. 1990)).

IV. ARGUMENTS AND AUTHORITIES

A. Relator's False Certification Theories Do Not Assert Viable FCA Claims.

As a matter of law, Relator has not asserted a viable path to impose FCA liability on RRH under the Amended Complaint's false certification theories. The Amended Complaint alleges that (1) the Vaccination Provider Agreement, (2) the National Childhood Vaccine Injury Act ("Vaccine Injury Act"), 42 U.S.C. § 300aa-1 *et seq*, and (3) the emergency use authorization provisions of the Food, Drug and Cosmetic Act, 21 U.S.C. § 360bbb-3 ("EUA Statute"), all impose various

COVID-19 adverse event reporting obligations on RRH, and by violating these provisions but certifying to the contrary when seeking payment, RRH violated the FCA. *See* Dkt. 34 ¶¶ 19–41. Yet each of these theories of liability are flawed and necessarily fail to sufficiently plead false certifications of compliance with contractual or statutory requirements. Accordingly, all Relator's FCA claims premised on false certifications should be dismissed.

1. **The Vaccination Provider Agreement.**

   a. The CDC COVID-19 Vaccination Program Provider Agreement only applies to a vaccine provider's "handling" of COVID-19 vaccines.

Under the clear terms of the Vaccination Provider Agreement, the vaccine provider's Chief Medical Officer ("CMO") and Chief Executive Officer ("CEO") are required to make the following attestation when enrolling in the Vaccination Provider Agreement:

> "By signing this form, I certify that all relevant officers, directors, employees, and agents of [Vaccine Provider] ***involved in handling COVID-19 Vaccine*** understand and will comply with the agreement requirements listed above and that the information provided in sections A and B is true."
>
> Dkt. 34 ¶ 41; Dkt. 34-24, at 3 (emphasis added).

Relator does not allege details about any RRH employee "involved in handling COVID-19 Vaccine" and therefore has not alleged facts that could give rise to a breach of the obligations in the Vaccination Provider Agreement (and therefore a subsequent false certification). Nor could she. After all, Relator identifies herself as a "Physician Assistant" and "Director of Advanced Practice Providers (APPs)" whose responsibilities were limited to providing care in "inpatient and ambulatory settings." Dkt. 34 ¶¶ 49–50. Her duties also "included the evaluation, diagnoses, and treatment of *hospital admissions*[.]" *Id.* ¶ 49 (emphasis added). Quite simply, Relator oversaw the care of inpatient hospital admissions at UMMC, one of the facilities within RRH's network of care

centers. She did not work at a RRH vaccine clinic,[2] and she does not allege any conduct whatsoever—let alone any misconduct—by any RRH personnel involved in the handling and administering of vaccines. Functioning in her role as a bedside hospitalist, Relator is not a COVID-19 vaccine provider. The same is true for her hospital-based colleagues whose VAERS reporting decisions she attempted to influence—they are not alleged to be vaccine providers. Accordingly, her claims based on false certifications arising from so-called breaches of the Vaccination Provider Agreement fail as a matter of law because her alleged experience fails to provide a basis upon which she could allege misconduct by those "involved in handling COVID-19 vaccine."

b. Other provisions in the Vaccination Provider Agreement demonstrate its limited scope of obligations.

Additionally, other provisions of the Vaccination Provider Agreement impose more limited obligations than what would be required to sustain Relator's false certification theories. The Vaccination Provider Agreement describes obligations relating to the safe storage, handling, and administration of the vaccine, which underscore that the obligations must be geographically and temporally proximate to the administered dose:

- Provider must identify the "Number of affiliated vaccination locations covered by this Agreement." Dkt. 34-24, at 1 (Organization Identification).
- Each individual Organization vaccination location must adhere to the requirements listed in Section A. *Id.*, at 5 (Section B).
- Provider must report "Vaccine-Administration Data" to "the relevant state, local, or territorial public health authority" *within 24 hours* of administering a vaccine. Dkt. 34-24, at 2, ¶ 2 (emphasis added).
- Provider must "*store and handle* COVID-19 Vaccine under proper conditions[.]" *Id*. at 2, ¶ 7(a) (emphasis added).

[2] Relator alleges in conclusory fashion that she had personal knowledge of vaccines administered in RRH's vaccine clinics, but she has offered no facts to support these conclusory allegations. *See* Dkt. 34 ¶ 42–43.

- Provider must "monitor vaccine-storage-unit temperatures at all times[.]" *Id.* at 2, ¶ 7(b).
- Provider must "monitor and comply with COVID-19 Vaccine expiration dates[.]" *Id.* at 2, ¶ 7(c).
- Provider "must report the number of doses of COVID-19 Vaccine . . . that were unused, spoiled, expired, or wasted[.]" *Id.* at 3, ¶ 8.
- Provider "must report moderate and severe adverse events *following* vaccination to [VAERS]." *Id.* at 3, ¶ 10 (emphasis added).
- Provider "must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient[.]" *Id.* at 3, ¶ 11.

RRH's COVID-19 Vaccine Clinic Playbook reinforces that these obligations exist in temporal proximity to the administration of the vaccine. Under a section titled "Post Administration Monitoring/Adverse Event Reporting," the Playbook recommended monitoring vaccine recipients for 15 minutes following their injections. Dkt 34-25, at 5. Further, the Playbook referenced the Vaccination Provider Agreement and stated only that "COVID-19 *vaccination providers* are required to report [qualifying adverse events] . . . to VAERS . . . [.]" *Id.* (emphasis added).

The Vaccination Provider Agreement also showcases that its obligations are tied geographically to the site of vaccine administrations. Section B of the Agreement states that "[e]ach individual Organization vaccination location must adhere to the requirements listed in Section A." *Id.* Section B also requires the Organization to provide the address of the "location where COVID-19 Vaccine will be administered[.]" *Id.* In sum, the information requested by the CDC in the Agreement touches only those "involved in handling" the vaccine, and so those obligations are necessarily tied to locations where that "handling" occurs.

The Vaccination Provider Agreement further demonstrates that compliance would be judged based on each administered dose of the COVID-19 vaccine. Dkt 34-24, at 3

("Reimbursement for *administering COVID-19 Vaccine* is not available under any federal healthcare program if Organization fails to comply with these requirements *with respect to the administered COVID-19 vaccine*.") and ("Each time Organization submits a reimbursement claim for *COVID-19 Vaccine administration* to any federal healthcare program, Organization expressly certifies that it has complied with these requirements *with respect to that administered dose*.") (emphases added).

Based on these provisions, Relator's theory of falsity—*i.e.*, that submitted claims contained false certifications of compliance with the obligations in the Vaccination Provider Agreement—is legally untenable. Relator does not allege that any patients who received a vaccination from RRH experienced a qualifying adverse event *at the vaccination site*. At best, she offers examples only of a few "patients *treated* by [RRH] for [alleged] post vaccination adverse events." *Id.* ¶ 91 (emphasis added). And although Relator does not allege when RRH treated these patients, the fact they allegedly became hospital patients some indeterminate time after vaccination demonstrates, through their new hospital admission, the creation of a separate episode of care that is temporally and geographically removed from the vaccine clinic (and any corresponding COVID-19 adverse event reporting obligations tied to vaccine administration).

The terms of the Vaccination Provider Agreement are therefore necessarily tied to the administration of the vaccine (after all, it is a "Vaccination Program *Provider* Agreement"). Yet Relator's allegations would stretch a vaccine provider's obligations temporally and geographically beyond common-sense limits and impose those obligations upon a vaccine-providing organization with affiliated hospitals that routinely admitted patients for a whole variety of reasons, many of which are unrelated to the patient's previous receipt of a COVID-19 vaccine. In other words, Relator's theory would create liability where a large healthcare system provides vaccines to the

public in one sector of its business and treats admitted patients in another sector of its business by imposing vaccine handling or vaccine administration obligations onto care providers treating patients admitted to the hospital. The terms of the Vaccination Provider Agreement neither contemplate nor impose these sorts of attenuated obligations.

Because the clear terms of the Vaccination Provider Agreement do not support extending a vaccine provider's VAERS reporting obligations to vaccinated patients who are admitted to the hospital some indeterminate later time, Relator's theory of false certifications based on non-compliance with the Vaccination Provider Agreement fails.

2. The Vaccine Injury Act.

Relator cannot allege that any false certifications were submitted to the government in connection with administering COVID-19 vaccines based on asserted non-compliance with the Vaccine Injury Act. First, the Vaccination Provider Agreement neither incorporates the Vaccine Injury Act nor its vaccine-related reporting obligations. The Agreement incorporates and contains cross-references and footnotes to other legal sources and guidance, but the Vaccine Injury Act is not one of them.

Second, even assuming the Vaccination Provider Agreement incorporated the reporting obligations under the Vaccine Injury Act, the Act does not apply to COVID-19 vaccines. The Vaccine Injury Act imposes statutory vaccine reporting obligations only on "health care providers" and "vaccine manufacturers" with respect to vaccines listed on the Vaccine Injury Table. 42 U.S.C. §§ 300aa-25(b), 300aa-33(1). COVID-19 vaccines are not listed on the Vaccine Injury Table. 42 C.F.R. § 100.3. Nor were they during 2021 when Relator worked at RRH and alleged COVID-19 vaccine adverse event reporting failures. In fact, in January 2021 and April 2021—just as the COVID-19 vaccine was becoming available to many Americans—the Department of Health and Human Services ("HHS") promulgated Final Rules revising the Vaccine Injury Table, and these

table revisions did not include COVID-19 vaccines. 86 FED. REG. 6249 (January 21, 2021 Final Rule); 86 FED. REG. 21209 (April 22, 2021 Final Rule). Since COVID-19 vaccines were never listed on the Vaccine Injury Table, the Vaccine Injury Act's adverse event reporting obligations do not apply, and Relator cannot link up a statutory violation of that Act to a false certification made under the Vaccination Provider Agreement. Hence, all claims based on alleged false certifications of compliance with the Vaccine Injury Act must fail.

3. The EUA Statute.

Under the EUA Statute, the HHS Secretary can authorize unapproved drugs, devices, or biological products for use in an emergency following a declaration that a qualifying emergency exists. 21 U.S.C. § 360bbb-3(a)–(b). When authorizing an unapproved product for emergency use, the HHS Secretary must establish conditions on the emergency authorization as may be necessary or appropriate to protect public health. *Id.* § 360bbb-3(e)(1). In December 2020 and February 2021, the FDA wielded this authority on behalf of HHS to issue EUAs for COVID-19 vaccines (*i.e.*, Pfizer, ModernaTX, and Janssen). *See* 86 FED. REG. 5200, 5202, 5211; 86 FED. REG. 28608, 28619.[3] And when approving these vaccines, the EUAs imposed conditions ("EUA Conditions") on the emergency use specific to "vaccination providers."[4] 86 FED. REG. at 5204, 5213; 86 FED. REG. at 28621. Here, Relator seemingly contends RRH submitted false certifications based on

[3] Under the EUA Statute, the HHS Secretary is required to publish EUAs in the Federal Register. 21 U.S.C. § 360bbb-3(h)(1).

[4] The EUA letters define "vaccination provider" as referring to "the facility, organization, or healthcare provider licensed or otherwise authorized by the emergency response stakeholder (e.g. non-physician healthcare professionals, such as nurses and pharmacists pursuant to state law under a standing order issued by the state health officer) to administer or provide vaccination services in accordance with the applicable emergency response stakeholder's official COVID-19 vaccination and emergency response plan(s) and who is enrolled in the CDC COVID-19 Vaccination Program."

asserted non-compliance with the EUA Conditions. *See* Dkt. 34 ¶¶ 25–38. But this liability theory fails too.

The Vaccination Provider Agreement and EUA Conditions mutually reinforce the same set of obligations. Just as the Vaccination Provider Agreement demands compliance with "all applicable requirements as set forth by the U.S. Food and Drug Administration, including but not limited to requirements in any EUA that covers COVID-19 Vaccine" (Dkt. 34-24, at 3, ¶ 12), the EUA Conditions likewise require "vaccination providers" to "comply with the terms and training required by CDC's COVID-19 Vaccination Program." 86 FED. REG. at 5208, 5218; 86 FED. REG. at 28626. Because each legal framework requires compliance with the other, since Relator fails to allege that RRH submitted false certifications of compliance with the Vaccination Provider Agreement, she necessarily fails to show the same with respect to the EUA Conditions.

In the same vein, the EUA Conditions also define "vaccination provider" as an entity that is (a) licensed by state law to administer or provide vaccination services, and (b) who is enrolled in the CDC's COVID-19 Vaccination Program (*i.e.*, a signatory to the Vaccination Provider Agreement). 86 FED. REG. at 5204, 5213; 86 FED. REG. at 28621. If a necessary precondition of being a "vaccination provider" under the EUA Conditions requires the "vaccination provider" to be subject to the Vaccination Provider Agreement, then—just like under the Agreement, which demands certifications of compliance only for those "involved in handling COVID-19 vaccine"—any certifications of compliance as to the EUA Conditions would be similarly limited to those involved in handling the vaccine.

Other EUA Conditions further undermine Relator's theory that care providers for inpatient admissions must report COVID-19 adverse events to VAERS. The EUA Conditions state directly that the obligation to report to VAERS belongs to the "[v]accination providers *administering* the

[Pfizer, ModernaTX, or Janssen] COVID-19 Vaccine" and only requires them to report to VAERS an adverse event "of which they become aware." 86 FED. REG. at 5208, 5218; 86 FED. REG. at 28626 (emphasis added). By tying the VAERS reporting obligation only to those who *administer* the vaccine, the EUA Conditions' COVID-19 adverse event reporting obligations are perfectly consistent with the Vaccination Provider Agreement, which imposes a contractual obligation on those involved in *handling* COVID-19 vaccine. Moreover, imposing a reporting obligation on only those who *administer* a vaccine is narrower than on those who *handle* a vaccine because anyone who administers a vaccine necessarily handles it while someone who handles a vaccine (*i.e.*, the person charged with its storage or maintaining its proper temperature) does not necessarily administer it. Nevertheless, since Relator does not allege conduct by a person "handling" or "administering" a COVID-19 vaccine and failing to report to VAERS, Relator cannot allege that RRH submitted false certifications of compliance with the EUA Conditions when seeking payment for administering vaccines under the Vaccination Provider Agreement.

As a matter of law, the contractual and statutory underpinnings of Relator's false certification theories cannot be extended—geographically or temporally—beyond the vaccination location or other situs where RRH employees are "involved in handling COVID-19" vaccine. Accordingly, her FCA claims premised on false certifications must be dismissed.

B. The Amended Complaint Does Not Satisfy Rule 9(b).

Relator has not alleged particularized details of the submission of false claims, provided specific examples to support her systemic fraud theory, or otherwise shown that the rigidity of Rule 9(b) should not be applied to, and therefore bar, her Amended Complaint. Rule 9(b) demands allegations of the who, what, when, where, and how of the alleged fraud. *United States ex rel. Pepe v. Fresenius Med. Care Holdings*, No. 14-CV-03505 (LDH) (ST), 2024 WL 4635236, at *4 (E.D.N.Y. Oct. 31, 2024). Yet, for the reasons discussed below, Relator fails to meet this standard.

1. **Relator alleges nothing about specific claims submitted, dates claims were submitted, the content of the claims, or the purportedly false representations made therein.**

Courts frequently dismiss FCA complaints when the relator fails to provide specifics (*i.e.*, the who, what, when, where, and how) of the submission of false claims. *See, e.g.*, *Conte v. Kingston NH Operations, LLC*, 585 F. Supp. 3d 218, 238 (N.D.N.Y. 2022) ("Plaintiff has failed to allege facts plausibly suggesting that Defendant had submitted any Medicaid or Medicare claims that were false or fraudulent[.]"); *Ameti ex rel. United States v. Sikorsky Aircraft Corp.*, No. 3:14-cv-1223 (VLB), 2017 WL 2636037, at *6 (D. Conn. June 19, 2017) ("[Relator] does not identify any particular false claim submitted to the Government, who made the false claim or when the false claim was allegedly made.").

To satisfy this standard, Relator's Amended Complaint should have explained in detail: (1) the content of COVID-19 vaccine reimbursement claims made by RRH to the government such as claim numbers, vaccine recipient information, the dates the vaccines were administered, etc., (2) the specific dates RRH submitted these claims to the government, (3) who at RRH submitted these claims, and (4) what content within the claims rendered them false or fraudulent. *Cf. Ameti*, 2017 WL 2636037 at *6 ("[Relator] could have included (but did not) the dates of the claims, the content of the bills, the identification numbers, the charged amount, particular goods or services billed, and the length of time between the fraudulent practices and submitted bills."); *see also United States ex rel. Duhaine v. Apple Health Care Inc.*, No. 3:19-CV-00963 (KAD), 2022 WL 3226631, at *6 (D. Conn. Aug. 10, 2022) ("Plaintiff's Amended Complaint . . . does not identify any specific claims for Medicare reimbursement—to include the date of any such claim, the content of the forms or bills submitted, identification numbers, the amount billed to the Government, the particular services for which the Government was billed, the patients or individuals involved in

the billing, or the length of time between the alleged non-reimbursable treatment of Medicare patients and the submission of claims for their care.").

Although there is no "mandatory checklist" setting forth criteria that must be shown in an FCA complaint, a relator "who provides 'zero details identifying particular false claims and instead concludes fraudulent bills must have been submitted . . . [a]t best . . . alleges a course of conduct or scheme which he assumes culminated with the submission of claims.'" *United States ex rel. Pilat v. Amedisys, Inc.*, No. 17-CV-136 (JLS), 2023 WL 2481144, at *4 (W.D.N.Y. Mar. 13, 2023) (quoting *Ameti*, 2017 WL 2636037 at *6), *aff'd in part, vacated in part, reversed in part, on other grounds, by United States ex rel. Pilat v. Amedisys, Inc.*, No. 23-566, 2024 WL 177990 (2d Cir. Jan. 17, 2024). Allegations describing the fraudulent scheme to submit false claims, on their own, are not sufficient "unless they are linked to allegations, stated with particularity, of the actual false claims submitted to the government that constitute the essential element of an FCA qui tam action." *United States ex rel. Mooney v. Americare, Inc.*, No. 06-CV-1806 (FB) (VVP), 2013 WL 1346022, at *3 (E.D.N.Y. Mar. 29, 2013) (quoting *United States ex. rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004)).

Relator's Amended Complaint fails to provide any details surrounding the submission of claims (let alone *false* claims) following a vaccine recipient's receipt of a COVID-19 vaccine from a RRH vaccine clinic. None of the example patients referenced in the Amended Complaint satisfy the level of particularity required by Rule 9(b):

F.H: Relator alleges F.H. was a RRH patient who died and had received a vaccine from RRH. Dkt. 34 ¶ 81. However, she does not allege when or how F.H died, when he received his vaccine from RRH, whether or when any vaccine reimbursement claim was submitted to the

government, the contents of that claim, what representations it made, or even whether RRH submitted the reimbursement claim before learning that F.H. had died.

S.C.: Relator alleges S.C. was a RRH patient who died within 48 hours of receiving a COVID-19 vaccine. *Id.* ¶ 87. Like F.H., Relator does not allege any of the *who, what, when, where, or how* details of the submission of any claim for S.C.'s vaccination, but even more problematic, Relator does not allege that S.C. obtained a COVID-19 vaccine from a RRH vaccine clinic. *See id.* Therefore, it is wholly implausible to assume that RRH would have submitted a vaccine reimbursement claim to the government absent additional allegations connecting S.C.'s vaccine administration to a RRH vaccine clinic.

E.F., **S.B.**, and **J.F.**: Relator alleges E.F., S.B., and J.F. were patients admitted to RRH for treatment. *Id.* ¶ 91. But once again, Relator not only fails to allege details concerning the submission of any claims following these patients' COVID-19 vaccinations, but she also admits she does not actually know if these patients even received vaccines from a RRH vaccine clinic. *Id.*

M.D., **N.M.**, **D.A.**, and **C.M.**: Relator alleges the redacted Vaccination Record Cards attached as Exhibit 26 to the Amended Complaint correspond to these individuals. *Id.* While these Vaccination Record Cards provide the dates on which these vaccine recipients received COVID-19 vaccines and the vaccine clinic location,[5] Relator alleges no details about the submission of reimbursement claims associated with these vaccine recipients. Moreover, Relator alleges no facts explaining how she obtained these vaccine records, facts to support an inference that these vaccine recipients became patients of RRH, facts to support her opinion that these individuals experienced

[5] The first, second, and fourth Vaccination Record Cards attached as Exhibit 26 to the Amended Complaint identify "UMMC" as the vaccine clinic location. The third however appears to list the University of Rochester Hospital System as the vaccine clinic location. *See* Dkt. 34-26.

an adverse vaccine reaction, or dates when these patients were admitted to any hospital (RRH or otherwise).

Relator also provides a table of 170 individuals for whom she claims no VAERS reports were submitted. *Id.* ¶ 92. But Relator does not even allege whether these individuals received vaccinations or, if vaccinated, where they received vaccinations. Even if she contends these individuals were RRH patients (which the Amended Complaint does not make clear), failing to allege that these patients received a RRH vaccine necessarily dooms these claims because there is no supporting allegation to suggest that RRH would have submitted a vaccine reimbursement claim.

In sum, Relator has alleged no particularized details of the submission of a claim for any alleged RRH-vaccinated individual. Instead, she offers her own theory of a fraudulent scheme but fails to link those allegations back up to the submission of any claims as a result of the asserted fraud scheme. *See Pepe*, 2024 WL 4635236, at *5 ("[A]bsent from the 105-page complaint are any facts connecting the alleged conduct to 'specific claims [that] were indeed submitted' to the government.") (quoting *Chorches*, 865 F.3d at 93); *Mooney*, 2013 WL 1346022, at *4 ("The greatest detail relates to Izlicht's role in the scheme, but even those allegations are vague and unconnected to specific claims."). And to the extent Relator contends the alleged fraud scheme was systemic and led to the widespread submission of false claims, she must plead representative examples "with a high level of particularity." *Pepe*, 2024 WL 4635236, at *5. These allegations must not be conclusory and must support an inference that the alleged fraud truly was widespread. *Id.* Relator's Amended Complaint fails to do so.

2. <u>Relator has failed to plead particularized details of any false certification</u>.

Relator has also not alleged any particularized details that would support proceeding under either an express or implied false certification theory. Relator has only alleged that RRH entered

into the Vaccination Provider Agreement, which contains several conditions or program requirements concerning the subsequent submission of claims, such as that each time a claim is submitted, RRH certifies those involved in handling the vaccine have complied with the terms and conditions of the Vaccination Provider Agreement. Dkt. 34 ¶¶ 40–41. But while Relator focuses only on the language in the Agreement (which as discussed above fails as a matter of law to support her false certification theory), she also fails to particularly allege any false certifications subsequently made to the government under the Agreement.

In *Escobar*, the Supreme Court held an implied false certification theory of liability can be viable when two conditions are present: "First, the claim does not merely request payment, but also makes specific representations about the goods or services provided; and second, the defendant's failure to disclose noncompliance with material statutory, regulatory, or contractual requirements makes those representations misleading half-truths." *Univ. Health Servs. v. United States ex rel. Escobar*, 579 U.S. 176, 190 (2016).

Relator does not allege what "specific representations" were made in any claims submitted by RRH about the vaccine administration services provided. As explained above, Relator does not allege any details concerning a claim RRH may have submitted, nor does she allege she ever saw the contents of a claim. Accordingly, Relator is in no position to identify any "specific representations" those claims contained. Instead, she falls back on alleging that RRH signed a copy of the Vaccination Provider Agreement, (Dkt. 34 ¶ 6(c)), which embodies certain program requirements she alleges RRH did not honor. But nothing in these allegations explain the "specific representations" in the submitted claims, as opposed to the requirements RRH agreed to when enrolling in the CDC's Vaccination Provider Agreement. Yet *Escobar* and subsequent cases focus on "specific representations" made in the *claims* themselves. *See Escobar*, 579 U.S. at 189 ("[B]y

submitting claims for payment using payment codes that corresponded to specific counseling services, Universal Health represented that it had provided individual therapy, family therapy, preventive medication counseling, and other types of treatment."); *United States ex rel. Jackson v. Ventavia Rsch. Grp., LLC*, 667 F. Supp. 3d 332, 355 (E.D. Tex. 2023) (holding Relator failed to plead implied false certification where she failed to identify "specific representations" about "Pfizer's vaccine, or compliance with protocols or regulations, in those invoices" that were submitted to DoD for payment); *United States ex rel. Lacey v. Visiting Nurse Serv. of N.Y.*, No. 14-cv-5739 (AJN), 2017 WL 5515860, at *8 (S.D.N.Y. Sept. 26, 2017) (concluding relator sufficiently alleged "specific representations" under *Escobar* where relator alleged claims contained "specific codes designated by CMS" such as "Type of Bill Code," "Revenue Code," and "Treatment Authorization Code"). Relator has not alleged the claims themselves contain any "specific representation" about the COVID-19 vaccine administration services provided. Accordingly, the Amended Complaint does not provide a basis to proceed under *Escobar*'s implied false certification parameters.

Similarly, an express false certification arises when "a claimant explicitly represents that he or she has complied with a contractual condition, but in fact has not complied." *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 104 n.7 (2d Cir. 2021). Under this theory, Relator must "plead an actual certification that was either (1) signed by the defendant or (2) caused to be signed because of the false claims alleged in the complaint." *United States ex rel. Gelbman v. City of New York*, No. 14-CV-771 (VSB), 2018 WL 4761575, at *7 (S.D.N.Y. Sept. 30, 2018), *aff'd by* 790 F. App'x 244 (2d Cir. 2019). Relator has not pled any examples of actual certifications signed by RRH that were submitted to the government, and she therefore cannot satisfy the pleading requirements to proceed on an express false certification theory.

Finally, Relator's false certification theories are plead indiscriminately and without tailoring specific factual allegations to support either theory. *See* Dkt 34 ¶ 105–106. This alone supports dismissal. *See, e.g.*, *Gelbman*, 2018 WL 4761575, at *6 ("This lack of clarity [in distinguishing between express and implied certification theories] alone is a basis to dismiss the legally false claims."); *United States ex rel. Corporate Compliance Assocs. v. New York Soc'y for the Relief of the Ruptured & Crippled, Maintaining the Hosp. for Special Surgery*, No. 07 Civ. 292 (PKC), 2014 WL 3905742, at *17 (S.D.N.Y. Aug. 7, 2014) (stating a complaint that does not distinguish between express and implied certification theories but alleges them both fails to state a claim based on false legal certifications).

3. Relator has failed to plead particularized details of any fraudulent inducement.

Relator's fraudulent inducement allegations are wholly conclusory and should not be assumed true. *See* Dkt. 34 ¶ 107. To proceed on this theory, Relator must allege that a defendant made a knowingly false representation for the purpose of inducing the government to enter a contract, which it did relying upon the representation, and that contract led to the submission of claims tainted by the initial false representation. *See United States v. Strock*, 982 F.3d 51, 60–61 (2d Cir. 2020); *United States ex rel. Kolchinsky v. Moody's Corp.*, No. 12cv1399, 2018 WL 1322183, at *5 (S.D.N.Y. Mar. 13, 2018); *Lacey*, 2017 WL 5515860, at *6. Relator has not plausibly alleged any facts describing representations that RRH made to the CDC to induce its entrance into the Vaccination Provider Agreement. Thus, any claims based on this theory should be dismissed.

4. Relator fails to show the materiality of any allegedly false claim or statement.

Relator has also failed to plead sufficient facts that any submitted false claim or certification was *material*. "A misrepresentation about compliance with a statutory, regulatory, or contractual requirement must be material to the Government's payment decision in order to be

actionable under the False Claims Act." *Escobar*, 579 U.S. at 192. This materiality element is "rigorous" and "demanding." *Id.* at 181, 194. When evaluating materiality, three factors are considered: (1) whether the requirement is an express condition of payment; (2) the government's response to noncompliance with the requirement; and (3) whether the noncompliance was minor or insubstantial. *See Strock*, 982 F.3d at 59–65. Relator fails to satisfy materiality under these factors, as her Amended Complaint does not allege an answer to the question: in connection with paying vaccine administration claims, does the government consider it material to its vaccination payment decision if a *hospital* (as opposed to a vaccine clinic) fails to report adverse events observed in an admitted patient when that patient previously received a COVID-19 vaccine and later shows up to the hospital.

The Amended Complaint shows that the government did not consider Relator's allegations material. In fact, Relator notified the government of her allegations on numerous occasions through 2021 and yet it did nothing. She contacted the FDA, CDC, and New York State Department of Health. Dkt. 34 ¶¶ 59–61. Notably, the "CDC did not respond[,]" the FDA referred her to her state's DNV or joint commission, and the New York State Department of Health did not provide her any "satisfactory answers." *Id.* Undeterred, she even retained a law firm, Siri Glimstad, to send letters directly to HHS (Secretary Xavier Becerra), FDA (Dr. Peter Marks and Dr. Janet Woodcock), and CDC (Dr. Rochelle P. Walenksy and Dr. Tom Shimabukuro) outlining her VAERS underreporting allegations. *Id.* ¶ 84; Dkt 34-22. She never alleges the government showed any interest in her complaints. Surely, if the government thought Relator had identified a material issue, it would have at least responded. But even though it knew of her allegations, it did not pursue them, and that fact is highly probative that the alleged fraud is immaterial. *Escobar*, 579 U.S. at 195 ("[I]f 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, that is strong evidence that the requirements are not material."); *cf. Jackson*, 667 F. Supp. 3d at 361 (reasoning that despite the government's knowledge of alleged noncompliance with emergency use authorization conditions, its continued re-authorization of COVID-19 vaccines failed to create an inference that alleged misrepresentations were material).

Additionally, Relator has not shown that the alleged noncompliance was substantial. Relator has identified only 4-5 patients who were allegedly vaccinated at a RRH clinic and were admitted to a RRH hospital some unknown time later. Dkt. 34 ¶ 81 (F.H.), ¶ 91 (M.D., N.M., D.A., C.M.).[6] Under Relator's theory, these patients necessarily left a RRH vaccine clinic and traveled to a RRH hospital location seeking care at an unknown later date. However, she fails to explain how the contractual VAERS reporting obligations could be deemed to accompany these vaccine recipients and impose obligations on RRH's treating providers when these vaccine recipients are later admitted as patients. Similarly, even setting aside the Vaccination Provider Agreement, she has not pointed to any statutory provisions in the Vaccine Injury Act or EUA Conditions that indicate a failure to report COVID-19 adverse reactions to VAERS bears on the government's payment decision for vaccine administration claims. In other words, Relator has not plausibly linked up VAERS reporting failures occurring at the hospital with violations of either contractual or statutory duties, which, to the extent they apply, only impose obligations in geographical and temporal proximity to the vaccine clinic and those who handle vaccines.

[6] As explained above in footnote 5, one of the four individuals identified in paragraph 91 seems to have been vaccinated at the University of Rochester Health System. *See* Dkt. 34-26.

5. Relator cannot satisfy *Chorches*' alternative pleading standard.

Although Rule 9(b) is rigorously enforced, *United States ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 26 (2d Cir. 2016), "a *qui tam* complaint need not always allege, based on personal knowledge, the actual submission of false claims to the federal government." *United States ex rel. Gelbman v. City of New York*, 790 F. App'x 244, 248 (2d Cir. 2019). "[S]o long as the relator makes plausible allegations . . . that [(1)] lead to a strong inference that specific claims were indeed submitted and that [(2)] information about the details of the claims submitted are peculiarly within the opposing party's knowledge[,]" a qui tam complaint could satisfy Rule 9(b) without alleging precise details about specific false claims actually submitted. *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865 F.3d 71, 93 (2d Cir. 2017). Relator has not satisfied this alternative pleading standard.

Relator fails to allege facts supporting a strong inference that specific false claims were submitted. First, as examples of patients for whom RRH did not make VAERS reports, Relator offers patients who she does not even allege received COVID-19 vaccines at a RRH clinic. *See, e.g.*, Dkt. 34 ¶¶ 87, 91–92 (referring to S.C., E.F., S.B., J.F. and the 170 individuals on the table). Of course, the basic failure to connect these patients to a RRH vaccine clinic raises no specter of fraud. Furthermore, Relator's fraud theory alleges facts focusing only on her observations at a RRH hospital and her communications with RRH leadership regarding her observations. She alleges nothing about events taking place at a RRH vaccine clinic nor does she allege she ever observed RRH personnel "involved in handling COVID-19 vaccine" fail to report to VAERS following a vaccine recipient experiencing a reportable adverse event. Her own experience is simply divorced geographically and temporally from the location where the obligations from the Vaccination Provider Agreement and EUA Conditions apply.

Unlike Relator, the experience of Fabula, the whistleblower in *Chorches*, was intimately connected to the specific fraud allegations arising from the submission of claims for ambulance transportation services. Fabula was an EMT who made the ambulance "runs," filled out PCRs after those runs with dates, time, addresses, transported patient names, medical facility destinations, and medical conditions necessitating the "run," was directed by his supervisors to falsify the content of these PCRs to render them reimbursable to CMS, received revised printouts of PCRs with handwritten notes of his supervisor's false changes to the PCRs, possessed knowledge that these altered PCRs with handwritten notes were later shredded, and was told by supervisors these falsified changes were for the purpose of conforming them to CMS' reimbursement requirements. *Chorches*, 865 F.3d at 76. While these allegations were sufficiently specific to create a strong inference that specific false claims were submitted, Relator cannot do the same because she did not work in a vaccine clinic, did not monitor patients following vaccinations, and in all other respects was not involved in handling or administering vaccines. She therefore fails to allege any facts that would support a strong inference that specific false claims were submitted.

Additionally, Relator offers no plausible allegations to explain how details of submitted claims are *peculiarly* within RRH's knowledge or control. Instead, she offers conclusory allegations purporting to describe her awareness of how RRH bills for claims. She admits she does "not work in billing[,]" and she claims that RRH utilizes "sophisticated accounting and billing systems" that allow for recording a vaccine recipient's COVID-19 vaccination in the "patient's medical record" and "document[ing] administration [of the vaccine] in the NYSIIS system[.]" Dkt. 34 ¶ 97. Yet elsewhere in the Amended Complaint, Relator alleges that she accessed these systems to learn more about her patients' vaccination status: "[Relator] confirmed the patients' Covid-19

vaccination status through the New York State Immunization Information System (NYIIS) and the RRH electronic records system called EPIC." *Id.* ¶ 53.

Presumably, the claims to be submitted for vaccine reimbursement would reference the date and location of the administration of the vaccine, and by Relator's own acknowledgment, she could access this information through the NYSIIS system and a patient's electronic medical record. *Id.*; *see also Duhaine*, 2022 WL 3226631, at *9 (in case where relator was a "Director of Nursing", rejecting Relator's request to apply *Chorches*' alternative pleading standard in part because as a Director of Nursing, she had access to patient's clinical records that contained some information that would be included in a claim for reimbursement). Moreover, Relator's contention that she did not have "direct access to these billing systems" leaves open the possibility that she could have gained access by taking some extra steps. Relator does not allege that she tried to access copies of submitted claims and was refused, nor does she allege that details of submitted claims were kept under lock and key by the billing department. *See, e.g.*, *Chorches*, 865 F.3d at 82 (describing the complaint' allegations that Fabula, the relator, was prohibited from unauthorized entrances to locations where billing took place, was not able to participate in billing procedures, and was restricted to areas that made it impossible to access information about submitted claims).

Relator simply has not shown that details of submitted bills were peculiarly in RRH's knowledge and her contentions to the contrary are belied by other allegations in the Amended Complaint. *See Pilat*, 2024 WL 177990, at *4 (affirming district court's holding that relator failed to show billing information peculiarly within knowledge of defendant when complaint's allegations "appear[] to be in tension . . ."). For these reasons, Relator cannot take advantage of *Chorches'* alternative pleading standard. Accordingly, under either approach to Rule 9(b), Counts I, II, and IV should be dismissed.

C. Relator Cannot Establish RRH Knew Claims Were False Or Material.

The Amended Complaint does not show that anyone at RRH acted with the requisite scienter to establish liability under the FCA. The FCA provides a tri-partite definition of "knowingly," which the Supreme Court declared requires proof the defendant acted with "actual knowledge, deliberate ignorance, or recklessness" with respect to the false claims, records, or statements at issue. *See United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739, 750 (2023). The scienter inquiry focuses on what the defendant knew at the time the alleged false claims/certifications were made. *See id.* at 752. And the complaint must show the defendant had knowledge of the falsity of the claim and that such falsity would be material to the government's payment decision. *FDIC ex rel. Moncho v. Fifth Third Bank, N.A.*, No. 23-209-cv, 2023 WL 7130553, at *4 (2d Cir. Oct. 30, 2023). While scienter can be pled generally under Rule 9(b), enough facts must be pled to create a "strong inference of fraud[,] [which] may be established either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." *Strock*, 982 F.3d at 66 (citation and quotations omitted).

Relator alleges no facts bearing on RRH's knowledge that could support a strong inference of fraudulent intent. The facts alleged in the Amended Complaint chronicle Relator's communications with RRH leadership about (1) an obligation to report to VAERS, and (2) whether RRH was satisfying that obligation with respect to the patients Relator identified and brought to RRH leadership's attention. *See* Dkt. 34 ¶¶ 57, 65, 66, 68–73, 77. With respect to whether a reporting obligation existed, Relator alleges that Dr. Gellasch confirmed "that she agreed with [Relator]'s assessment that RRH must report to VAERS *per their guidance*." *Id.* ¶ 65 (emphasis added). As to the second issue, Relator merely alleges that RRH investigated the patient files Relator claimed required VAERS reports but reached a different clinical decision based on these

physicians' own independent assessment. *Id.* ¶¶ 72–74, 77. The independent assessment concluded that Relator used broader reporting criteria than required by VAERS. *Id.* ¶¶ 74, 77. These events merely show that RRH investigated Relator's claims that certain patients required VAERS reports but reached a different medical opinion as to whether those patients' conditions triggered any reporting obligation. This is plainly insufficient to show any strong inference of fraud, as Relator has not identified any motive or opportunity to engage in fraud, nor has she shown a set of circumstantial facts from which conscious disregard of any legal obligation could be inferred.

Additionally, even assuming Relator could show that RRH leadership acted in a manner suggesting a strong inference of fraudulent intent (which she cannot), Relator has not pled any facts that would connect intentional VAERS underreporting in the *hospital or emergency room* to RRH leadership's intent to commit fraud arising from operations in a RRH *vaccine clinic*. As explained, Relator worked as a bedside hospitalist and has no knowledge of operations in the vaccine clinic. She simply cannot allege any facts that would suggest RRH knew it was submitting false claims/false certifications flowing from the vaccine clinic or that RRH knew that a vaccine provider's knowing failure to report to VAERS would be material to whether the government would pay COVID-19 vaccine administration claims.

Finally, at the heart of Relator's Amended Complaint is her opinion that hospital patients arrived at the hospital because they were having adverse reactions to the COVID-19 vaccine. But these are Relator's opinions, which should not be credited as fact since she has failed to allege facts to establish that any patient experienced a qualifying adverse reaction. To the contrary, the exhibits attached to the Amended Complaint establish that numerous individuals, entities, or government agencies disagreed with Relator's opinion—which include her supervising physicians, hospital leadership, the Finger Lakes vaccine hub, RRH's legal department, the New York Times,

and apparently the CDC, HHS, FDA, DNV, and New York state officials. Dkt. 34 ¶¶ 59–61, 65, 74, 77; Dkt. 34-20; Peacock Declaration, Exhibit C. Under these facts, Relator cannot show scienter to commit fraud. *See Duhaine*, 2022 WL 3226631, at *9 (granting motion to dismiss FCA claim in part where relator alleged violation of CMS' medical necessity requirement based on relator's "competing medical opinion as to what therapies were appropriate" and relied on her competing opinion as support for "the inference that false billing to Medicare must have been the motive"). Since Relator cannot make out an FCA claim over differences of medical opinion or differing interpretations of reporting obligations, she cannot establish that RRH knew at the time it submitted claims or made certifications that these submissions were false.

D. Relator Fails to Plead a Reverse FCA Claim.

Relator fails to sufficiently allege the existence of a reverse FCA claim (Count IV). Dkt. 34 ¶¶ 140–148. The FCA's reverse false claim provision attaches liability when the defendant "knowingly makes, uses, or causes to be made or used a false record or statement material to an obligation to pay or transmit money or property to the government, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the Government." 31 U.S.C. § 3729(a)(1)(G). The Second Circuit has previously dismissed reverse FCA claims where the complaint "makes no mention of any financial obligation that the [defendants] owed to the government" and "does not specifically reference any false records or statements used to decrease such an obligation." *United States ex rel. Foreman v. AECOM*, 19 F.4th 85, 119 (2d Cir. 2021). It has also rejected efforts to mold reverse false claims out of the same underlying conduct that forms the basis of "presentment" claims or "false records" claims under Subsection (a)(1)(A) and Subsection (a)(1)(B). *Id.* at 120.

Relator has not alleged any "obligation" RRH owes to the government that is independent from any alleged violation under Subsection (a)(1)(A) (Count I) and Subsection (a)(1)(B) (Count

II). As discussed, Relator's claims are rooted in alleged false certifications flowing from the submission of vaccine administration claims for reimbursement under the Vaccination Provider Agreement. Relator alleges no facts suggesting RRH made or used false records to avoid, reduce, or conceal a payment obligation. Relator's reverse FCA claim should be dismissed.

E. Relator Fails to Plead an FCA Conspiracy.

Relator fails to allege the existence of a conspiracy to violate the FCA (Count III). Dkt. 34. ¶¶ 134–139. To allege a conspiracy, Relator must show "(1) the defendant conspired with one or more persons to get a false or fraudulent claim allowed or paid by the United States and (2) one or more conspirators performed any act to effect the object of the conspiracy." *United States ex rel. Grubea v. Rosicki, Rosicki & Assocs., P.C.*, 318 F. Supp. 3d 680, 705 (S.D.N.Y. 2018) (citations omitted).

It is well established under the intra-corporate conspiracy doctrine that a corporate entity cannot conspire with its employees or corporate officers or wholly-owned subsidiaries. *See United States ex rel. Ross v. Indep. Health Corp.*, No. 12-CV-299-S, 2023 WL 24055, at *12–13 (W.D.N.Y. Jan. 3, 2023) (dismissing FCA conspiracy claim under the intra-corporate conspiracy doctrine); *see also United States ex rel. Schwartz v. Document Reprocessors of N.Y., Inc.*, No. 20-cv-6167 EAW, 2023 WL 6130313, at *6 n. 3 (W.D.N.Y. Sept. 19, 2023) ("Relator's cursory attempt to assert a conspiracy between a corporation and its owners/corporate officers runs afoul of the intra-corporate conspiracy doctrine.").

The Amended Complaint does not identify the alleged conspirators. That should be fatal. But even looking to all potential persons/entities identified in the Amended Complaint, the intra-corporate conspiracy doctrine would certainly bar any effort to allege a conspiracy. Relator names RRH and UMMC as defendants, but also alleges that RRH's "network includes nine hospitals . . . including UMMC." Dkt. 34 ¶ 10. Relator attached an exhibit to the Amended Complaint further

showing that service of process on UMMC should be made "c/o Rochester Regional Health." Dkt 34-2. Similarly, the individuals Relator identifies in the Amended Complaint who she claims impeded her VAERS reporting objectives are healthcare providers, employees, or officers of RRH or UMMC:

- Dr. Danielle Notebaert ("UMMC Lead Emergency Room Physician"). *Id.* ¶ 56.
- Dr. Tara Gellasch ("UMMC Chief Medical Officer"). *Id.* ¶ 57.
- Dr. Peter Janes ("Hospitalist" Doctor). *Id.* ¶ 77.
- Trisha Woodward ("Infection Preventionist, UMMC"). *Id.* ¶ 63.
- Dr. Shaw-Ree Chen ("Director of Quality"). *Id.*
- Dr. Hiloni Bhavsar ("Chief Quality Officer"). *Id.*
- Dan Ireland (UMMC "President"). *Id.* ¶ 81.

As a matter of law, none of these individuals could have conspired with RRH to violate the FCA. Even more, Relator has not alleged any facts to sustain a conspiracy to commit fraud, as none of her alleged conversations with RRH leadership related to compliance with the Vaccination Provider Agreement or the billing for COVID-19 vaccine administration claims. Thus, Relator has not alleged facts that could form the basis of a conspiracy to violate the FCA.

Relator's conspiracy claim should therefore be dismissed.

F. Relator Did Not Engage in Protected Activity and Was Terminated Permissibly For Refusing to Follow New York's Vaccine Mandate for Healthcare Workers.

Relator also asserts retaliation claims (Counts V and VI) under federal and state law for purportedly acting as a whistleblower. 31 U.S.C. § 3730(h); N.Y. Labor Law §§ 740–741. To properly allege an FCA retaliation claim, the plaintiff must show (1) she engaged in conduct protected by the FCA, (2) defendant was aware of her conduct, and (3) she was terminated in retaliation *because* of that conduct. *See Conte v. Kingston NH Operations LLC*, 585 F. Supp. 3d

218, 242 (N.D.N.Y. 2022) (emphasis added). Sections 740 and 741 of the New York Labor Laws require a similar causal nexus between the adverse employment action and the alleged protected activity. *See* N.Y. Labor Law § 740 ("An employer shall not take retaliatory action against an employee . . . *because* such employee [engages in protected activity.]"), § 741 ("[N]o employer shall take retaliatory action against any employee *because* the employee [engages in protected activity.]") (emphases added).

1. Relator did not engage in protected activity.

To properly plead protected activity, an alleged FCA whistleblower must show either: (1) she acted lawfully in furtherance of an FCA claim, or (2) she acted lawfully to stop a violation of the FCA. 31 U.S.C. § 3730(h); *see Conte*, 585 F. Supp. 3d at 242. The first category generally encompasses "conduct that was calculated to, or reasonably could lead to a viable FCA action." *Id.* (internal quotations and citation omitted). And the second category applies "so long as the employee was engaged in efforts to stop an FCA violation, even if the employee's actions were not necessarily in furtherance of an FCA claim." *Id.* at 243 (internal quotations and citation omitted). Under both categories, the FCA whistleblower must show that she subjectively believed in good faith that her employer was defrauding the government, and that a reasonable person would objectively believe the same as well. *Id.*

Here, the Amended Complaint alleges only that Relator was concerned whether RRH was complying with VAERS reporting obligations generally; in other words, she never alleged that fraud on the government was occurring because of any asserted noncompliance with the Vaccination Provider Agreement. Her own allegations confirm as much. Relator's factual allegations involve her efforts to get RRH to report *patients* to VAERS according to her own reporting criteria, with which RRH leadership disagreed. Neither in her direct communications to RRH leadership nor in her Siri Glimstad letters to RRH, FDA, CDC, or HHS did Relator ever

mention she suspected fraud. *See, e.g.*, Dkt. 34 ¶ 57 ("[Relator] emailed [RRH leadership] . . . about the requirement to report to VAERS."), ¶ 66 ("[Relator] exchanged emails with Dr. Gellasch regarding patients needing VAERS reports."), ¶¶ 79–85; Dkt. 34-19; Dkt. 34-21; Dkt. 34-22.

2. Relator was terminated because she refused to follow New York's vaccine mandate for healthcare workers.

While Relator alleges she was wrongfully terminated on October 6, 2021 (Dkt. 34 ¶ 90), her allegations refute the claim that RRH terminated her *because* of her efforts to raise concern about alleged VAERS underreporting. To the contrary and conclusively established, RRH terminated Relator because she chose not to receive a COVID-19 vaccine shortly before New York's vaccine mandate for healthcare workers became effective.

Around August 26, 2021, New York adopted regulations requiring qualifying healthcare workers to be "fully vaccinated" against COVID-19. *See* 10 N.Y. Code, Rules, & Regs. 2.61. (attached as Exhibit B to the Peacock Declaration). Under this vaccine mandate, "[c]overed entities shall continuously require personnel to be fully vaccinated against COVID-19, with the first dose for current personnel received by September 27, 2021 for general hospitals and nursing homes, and *by October 7, 2021* for all other covered entities absent receipt of an exemption[.]" *Id.* § 2.61(c) (emphasis added). "Covered entities" were generally defined to include hospitals, home health agencies, long term health care programs, among others. *Id.* § 2.61(a)(1). And "Personnel" was defined to include "all persons employed or affiliated with a covered entity . . . including but not limited to . . . members of the medical and nursing staff[.]" *Id.* § 2.61(a)(2). As discussed above, Relator alleges she was employed as a "Physician Assistant" at UMMC and later RRH up through the date of her termination. Dkt. 34 ¶ 49.

Relator was featured in a New York Times article, dated September 26, 2021, entitled "These Health Care Workers Would Rather Get Fired Than Get Vaccinated." *Id.* ¶ 89.[7] In the article, Relator discussed her "concern about vaccine side effects *as the reason she did not want to get vaccinated*." *Id.* (emphasis added). She discussed this New York Times article with RRH's HR director in addition to her concerns about "Covid-19 test-to-stay" on October 6, 2021—the day before New York's vaccine mandate took full effect. *Id.* ¶ 90; 10 N.Y. Code, Rules, & Regs. 2.61(c). Relator does not allege any facts that show her alleged termination had anything to do with her concerns about VAERS underreporting. Rather, based on her own allegations, she was terminated for refusing to follow New York's vaccine mandate. Relator's allegations therefore fail to show she was terminated *because* of any alleged protected activity. Indeed, Relator confirmed these facts in a sworn affidavit she signed on September 21, 2021 in support of an application to enjoin enforcement of 10 NYCRR § 2.61.[8] The affidavit states Relator was "unwilling to get vaccinated" and "unwilling to compromise [her] medical autonomy to comply with the requirements of 10 NYCRR § 2.61." She understood the consequences of this decision meant she would "face termination of [her] employment[.]" *Id.* Thus, Relator's termination had nothing to do with blowing the whistle on her VAERS underreporting theory.

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[7] Anne Barnard et al., *These Health Care Workers Would Rather Get Fired Than Get Vaccinated*, N.Y. TIMES (Sept. 26, 2001), https://www.nytimes.com/2021/09/26/nyregion/health-workers-vaccination.html (attached as Exhibit C to the Peacock Declaration).

[8] Relator's affidavit (attached as Exhibit D to the Peacock Declaration), was submitted in connection with *Serafin et al. v. New York State Dept' of Health et al.*, Index No. 908296-21 (N.Y. Sup. Ct.—Albany, 2021). RRH requests the Court take judicial notice of the docket in this case as well as the attached Exhibit D to the Peacock Declaration. FED. R. EVID. 201; *Mangiafico v. Blumenthal*, 471 F.3d 391, 398 (2d Cir. 2006) (finding no error in district court's consideration of prior docket sheet in evaluating whether to dismiss a complaint because "docket sheets are public records of which the court could take judicial notice").

Finally, to the extent all of Relator's federal claims are dismissed but the state law claims are not, RRH requests that this Court decline to exercise supplemental jurisdiction over the remaining state law claims. *See Conte*, 585 F. Supp. 3d at 245–46 (declining to exercise supplemental jurisdiction over remaining N.Y. Labor Law § 741 claim after dismissing all other federal claims).

V. CONCLUSION

Wherefore, RRH and UMMC respectfully request that the Court dismiss Relator's Amended Complaint (Dkt. 34), with prejudice, take judicial notice of Peacock Declaration Exhibits A, B, C, and D, and order all such further relief, whether in law or in equity, to which RRH and UMMC are justly entitled.

Dated: December 20, 2024

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and correct copy of the above and foregoing document has been served on all parties that have appeared through the Court's electronic filing system on December 20, 2024.

/s/ James E. Peacock
James E. Peacock