UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, *ex rel.*, **Deborah Conrad** **c/o Mendenhall Law Group** **190 North Union Street, Ste 201** **Akron, Ohio 44304** **Relator,** **vs.** **ROCHESTER REGIONAL HEALTH** **89 Genesee Street Rochester,** **New York 14611** **and** **UNITED MEMORIAL MEDICAL CENTER** **127 North Street** **Batavia, New York 14020** **Respondents.**	)	**CASE NO.: 1:23-cv-00438-JLS** **JUDGE: SINATRA** **AMENDED COMPLAINT FOR VIOLATION OF FEDERAL FALSE CLAIMS ACT [31 U.S.C. § 3729 et seq.] and New York Labor Laws §§ 740 and 741** **JURY TRIAL DEMANDED**

Relator, on behalf of the United States of America, for this Amended Complaint against Respondents alleges:

I. INTRODUCTION

1) This is an action to recover damages and civil penalties for the United States arising from false and/or fraudulent statements, records, and claims made and caused to be made by Respondents, their agents, and employees in violation of the federal False Claims Act, 31 U.S.C. § 3729 et seq. as amended (the "FCA" or the "Act") and New York Labor Law § 740.

2) Without limitation, Relator seeks treble monetary damages, civil penalties, and Relator's reasonable attorneys' fees, expense and costs.

3) Rochester Regional Health (RRH) and United Memorial Medical Center (UMMC) (collectively RRH) violated and continue to violate the FCA by knowingly failing to report adverse events to the Vaccine Adverse Event Reporting System (VAERS) while claiming money from the United States under the Centers for Disease Control and Prevention's Covid-19 Vaccination Program knowing that were in noncompliance with their obligation to report adverse events.

4) Congress imposed the VAERS reporting obligation because it determined, with liability immunity conferred on manufacturers, there was little incentive to make vaccines safe. In its statutory scheme, Congress required that information on potential safety signals be made available to public and private experts. RRH's decision to undermine the VAERS reporting system undermined the very measure of public health and safety which Congress determined was a material component in the participation of any vaccination program.

5) Respondents failed to report most adverse events to the VAERS system from the start of the Covid-19 Vaccination Program to present. Relator witnessed RRH's disregard of reporting obligations. In fact, RRH worked hard and in concert with some providers to prevent her and other providers from fulfilling their obligations under the vaccination program. This behavior escalated and, from May 27, 2021 to October 6, 2021, RRH blocked Relator from submitting 170 serious adverse events to the VAERS reporting system. After Ms. Conrad's firing RRH continued to block submission to VAERS of thousands adverse events from patients who received an injection from it and other providers.

6) Respondents violated the False Claims Act (FCA), 31 U.S.C § 3729 et seq., by submitting thousands of claims for payment for Covid-19 vaccine administration while failing to comply with mandatory VAERS reporting requirements. Each claim for payment constituted a false claim because:

a. VAERS reporting is mandatory under Section 564 of the Federal Food, Drug, and Cosmetic Act codified at 21 U.S.C. 360bbb-3, 3a, and 3b regarding authorization for medical products for use in emergencies.

b. VAERS reporting was an express material condition of the CDC Covid-19 Vaccination Program Provider Agreement (Provider Agreement).

c. RRH had agreed to the terms of the Provider Agreement.

d. RRH documented this obligation in their own Covid-19 Vaccine Clinic Playbook.

e. Each claim falsely expressly and impliedly certified compliance with all program requirements, including VAERS reporting.

f. RRH actively suppressed reporting by staff members and fired Ms. Conrad which made her an example to other staff.

7) Respondents informed staff of its obligations in the RRH Covid-19 Vaccine Clinic Playbook. Respondents' violations of federal law, rules, and regulations provide separate and independent predicates for additional violations of the FCA.

8) Respondents' wrongful and unlawful conduct caused: (a) money to be directly or indirectly falsely claimed and received by Respondents from the United States; (b) Respondents knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims; (c) Respondents conspired to falsely claim the funds; and (d) monies were not returned or rebated to the United States; all in violation of the FCA and to the damage of the United States, its political subdivisions, budgets, programs, and taxpayers.

9) Because of ongoing violations, the relevant period for this action and related damages is from the earliest period allowed under the FCA up through the time of trial (the "Relevant Time Period").

II. PARTIES, JURISDICTION AND VENUE

10) RRH is a New York corporation with its principal place of business in Rochester, New York. The network includes nine hospitals spanning from the Greater Rochester area across Western New York, Finger Lakes regions, and the St. Lawrence region of Northern NY including United Memorial Medical Center (UMMC). RRH was created on July 1, 2014, when it filed its initial articles of incorporation with the New York Department of State.[1] UMMC was created on July 30, 1900, when it filed its initial articles of incorporation with the New York Department of State.[2]

11) Relator Deborah Conrad is a Physician Assistant (PA) and resident of the State of New York and was employed by UMMC. Relator personally knows of the allegations in the Complaint.

12) The information upon which the Complaint is based was not disclosed in a criminal, civil, or administrative hearing, in a congressional, administrative, or Government Accounting Office report, hearing, audit or investigation, or gained from the news media, and the Relator remains the "original source" of the information on which this action is based within the meaning of 31 U.S.C. § 3730(e)(4)(B). Relator may file these claims on behalf of the United States under 31 U.S.C. § 3730(b).

13) Jurisdiction of this Court is based on 28 U.S.C. §§ 1331 and 1345 because the United States is a party and the claims herein derive from laws and regulations of the United States, including the FCA, 31 U.S.C. § 3730 et seq.

14) Under the False Claims Act, Title 31 U.S.C. § 3729, this Court has exclusive jurisdiction over actions brought under the FCA.

[1] Exhibit 1
[2] Exhibit 2

15) Under the False Claims Act, Title 31 U.S.C. § 3732(a), venue is proper and suit may be filed in any judicial district in which Respondents may be found, reside or transact business or engage in any act or omission in violation of 31 U.S.C. § 3729, et seq.

16) At all times relevant to this cause of action, Respondents were found, resided, transacted business and/or committed acts and/or omissions in violation of 31 U.S.C. § 3729, et seq., within the Western District of New York. Venue is proper in the Western District of New York.

III. CONDITIONS PRECEDENT

17) Under section 3730(b)(2), Relator filed her original Complaint in camera and under seal with the Court and served a copy of this Complaint along with a written disclosure of the material evidence and information the Relator has upon the Attorney General of the United States and the United States Attorney for the Western District of New York under Rule 4 of the Federal Ru1es of Civil Procedure.

18) Relator Conrad voluntarily provided all material evidence and information to the federal government before suing.

IV. STATUTORY AND REGULATORY BACKGROUND

A. THE NATIONAL CHILDHOOD VACCINE INJURY ACT

19) The National Childhood Vaccine Injury Act (NCVIA) of 1986 (42 U.S.C. §§ 300aa-1 to 300aa-34) was signed into law by United States President Ronald Reagan as part of a larger health bill on November 14, 1986.

20) NCVIA's purpose was to eliminate the potential financial liability of vaccine manufacturers due to vaccine injury claims to ensure a stable supply of vaccines, and to provide cost-effective arbitration for vaccine injury claims.

21) In granting immunity, Congress disincentivized companies to make vaccines safer so it imposed an obligation on healthcare providers to report certain adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

B. THE VAERS SYSTEM

22) As part of the NCVIA, VAERS is a national vaccine safety surveillance program administered by the Centers for Disease Control and Prevention (CDC) and the U.S Food and Drug Administration (FDA) through a contract with General Dynamics Information Technology, Inc. VAERS collects and analyzes data from reports of adverse events following vaccination.[3]

23) VAERS is an early-warning system that detects problems possibly related to vaccines. The system relies on reports from healthcare providers, vaccine manufacturers, and the public. Reporting gives the CDC and FDA vital information to help quickly identify potential health concerns and ensure vaccines are safe.

24) Healthcare professionals are **mandated by federal law** to report certain medical events arising after vaccination to VAERS. Under 42 U.S.C. § 300aa-25:

> Each health care provider and vaccine manufacturer **shall report** to the Secretary-
>
> (A) the occurrence of any event set forth in the Vaccine Injury Table[4], including the events set forth in section 300aa–14(b) of this title which occur within 7 days of the administration of any vaccine set forth in the Table or within such longer period as is specified in the Table or section,
> (B) the occurrence of any contraindicating reaction to a vaccine which is specified in the manufacturer's package insert, and
> (C) such other matters as the Secretary may by regulation require. [5]

[3] https://www.vaers.hhs.gov
[4] Exhibit 23
[5] 42 U.S. Code § 300aa–25 - Recording and reporting of information | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu)

The VAERS system is also used to track injuries for drugs and vaccines authorized under an EUA.

C. EMERGENCY USE AUTHORIZATION FOR UNAPPROVED DRUGS AND VAERS REQUIREMENTS

25) In 2004, Congress granted the FDA emergency authorization powers through Section 564 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bbb-3). Under Section 564, the FDA may authorize unapproved medical products, or unapproved uses of approved products, to address serious or life-threatening diseases when no adequate alternatives exist. However, because these products have not completed standard safety and efficacy testing, Congress mandated the Secretary of Health and Human Services to set appropriate conditions to protect public health, including mandatory safety monitoring requirements.

26) On February 4, 2020, the Secretary of Health and Human Services determined under Section 564 of the Federal Food, Drug, and Cosmetic Act that Covid-19 presented a public health emergency that could significantly affect national security and the health of United States citizens. This determination enabled emergency use authorizations for vaccines and other medical countermeasures to address the Covid-19 pandemic.

27) In December 2020, the Secretary authorized the use of unapproved vaccines to combat Covid-19.

28) Subsequent regulations required adverse event reporting to VAERS. Under federal regulations, vaccination providers administering Covid-19 vaccines have specific mandatory reporting obligations. As the FDA formally stated in the Federal Register, "VAERS is a safety and monitoring system" crucial for tracking vaccine adverse events. While Covid-19 vaccines were being used under Emergency Use Authorization, "vaccination providers, manufacturers, and EUA sponsors must, in accordance with the National Childhood Vaccine Injury Act (NCVIA) of 1986

(42 U.S.C. 300aa–1 to 300aa–34), report select adverse events to VAERS (that is, serious adverse events, cases of multisystem inflammatory syndrome (MIS), and COVID–19 cases that result in hospitalization or death)." 86 Fed. Reg. 26,311 (May 13, 2021).

29) The FDA emphasized that it was "closely monitoring the safety of the COVID–19 vaccines authorized for emergency use" and explicitly placed responsibility for mandatory reporting on vaccination providers. 86 Fed. Reg. 26,312 (May 13, 2021).

30) On November 5, 2021, the FDA reinforced these requirements, reiterating that providers must report select adverse events following receipt of Covid-19 vaccines, including serious adverse events, cases of MIS, and Covid-19 cases resulting in hospitalization or death.

31) The FDA continued monitoring vaccine safety through both emergency and licensed use, with providers "responsible for mandatory reporting to VAERS of certain adverse events as listed on the Health Care Provider Fact Sheets." The FDA required providers to "adhere to any revised safety reporting requirements" and regularly check authorization letters and fact sheets for updates.

32) While VAERS remained open for voluntary reporting from anyone, providers had specific mandatory obligations that formed an essential part of the government's multi-layered safety monitoring system, which included electronic health record and claims-based surveillance through CDC's Vaccine Safety Datalink and FDA's Biologics Effectiveness and Safety System (BEST).

33) Since the onset of Covid-19 vaccination, VAERS has received over one million adverse event reports and "19,476 preliminary reports of death" through March 1, 2023.[6] By tracking such events, VAERS helps to identify safety concerns.

34) These requirements do not involve a determination of causality or professional judgement. Healthcare providers are strongly encouraged to report to VAERS "any adverse event that occurs

[6] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html: Last accessed 10-31-2024

after the administration of a vaccine licensed in the United States, whether it is or is not clear that a vaccine caused the adverse event."[7] The importance of filing VAERS reports is acute and therefore mandatory regarding Covid-19 vaccines developed based on technology never used on such a broad scale or for this purpose before and which has only been granted emergency use authorization ("EUA").

35) The EUA Authorization Letters for Covid-19 vaccines listed additional mandatory reporting requirements.

36) Under the FDA and its EUA, all vaccine and healthcare providers who administer the Covid-19 vaccine must report the following to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccine Providers):[8]

a. Vaccine administration errors whether or not associated with an adverse event.
b. Serious adverse events (irrespective of attribution to vaccination).
c. Cases of Multisystem Inflammatory Syndrome in children and adults.
d. Cases of COVID-19 that result in hospitalization or death."[9]

"Serious adverse events" "regardless of whether the reporter thinks the vaccine caused the [adverse event]" are defined by the FDA to include:

1. Death;
2. A life-threatening adverse event;
3. Inpatient hospitalization or prolongation of existing hospitalization;
4. A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
5. A congenital anomaly/birth defect;
6. An important medical event that based on appropriate medical judgement may jeopardize the individual and may require medical or surgical intervention to prevent one of the outcomes listed above.[10]

[7] https://vaers.hhs.gov/reportevent.html: Last accessed 10-31-2024

[8] Relator's Hospital is a vaccine provider.

[9] Pfizer-BioNTech COVID-19 Vaccine EUA Letter of Authorization reissued 05-10-2021 (fda.gov) (Pfizer); Moderna COVID-19 Vaccine EUA Letter of Authorization 10122022 (fda.gov) (Moderna), Janssen Letter Granting EUA Amendment (May 5, 2022) (fda.gov) (Johnson & Johnson).

[10] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html

37) For Covid-19 vaccines, the FDA sought to "closely monitor" the safety of approved and authorized (unapproved) Covid-19 vaccines for adverse events and, therefore, made it mandatory to report select adverse events regardless of the provider's clinical judgment as to causation.

38) The Emergency Use Authorization statute, 21 U.S.C. § 360bbb-3, creates ongoing safety monitoring obligations that extend beyond vaccine administration. Congress established a comprehensive framework requiring:

a. Conditions of authorization, including safety monitoring and VAERS reporting, remain effective throughout the emergency declaration period unless specifically revoked by the Secretary of Health and Human Services.

b. The Secretary must periodically review the circumstances and appropriateness of the authorization, including safety data. This review relies on healthcare providers like RRH fulfilling their reporting obligations so the Secretary can assess whether "circumstances make such revision or revocation appropriate to protect the public health or safety." 21 U.S.C. § 360bbb-3(g)(2)(C).

c. Even after the emergency declaration ends or authorization is revoked, the statute mandates continued monitoring of patients who received the vaccine during the authorization period, as necessary for patient care. 21 U.S.C. § 360bbb-3(f)(2).

D. THE PROVIDER AGREEMENT

39) In addition to vaccine administration errors and the "serious adverse events" listed above, healthcare providers who administer Covid-19 vaccines are required by

FDA, and under the provider agreements for the CDC Covid-19 Vaccination Program, to report the following to VAERS:

a. Cases of myocarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine.
b. Cases of pericarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine.
c. Cases of Multisystem Inflammatory Syndrome in children and adults.
d. Cases of Covid-19 that result in hospitalization or death.[11]

40) To participate in the CDC's Covid-19 Vaccination Program, and receive funds related to the administration of Covid-19 vaccines, providers such as RRH must sign the CDC Covid-19 Vaccination Program Provider Agreement ("Provider Agreement"). The Provider Agreement explicitly states, as an "Agreement Requirement," "Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS)." This requirement points the signer to the VAERS website.[12]

The certification for the Provider Agreement explicitly states[13]:

> The above requirements are material conditions of payment for COVID-19 Vaccine-administration claims submitted by Organization to any federal healthcare benefit program, including but not limited to Medicare and Medicaid, or submitted to any HHS-sponsored COVID-19 relief program, including the Health Resources & Services Administration COVID-19 Uninsured Program. 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 dose. 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.

41) In the preceding section the certification for the Provider Agreement explicitly states:

> By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization involved in handling COVID-19 Vaccine understand and

[11] https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event
[12] https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html: last accessed 5-16-2023
[13] Exhibit 24

will comply with the agreement requirements listed above and that the information provided in sections A and B is true.

42) Conrad knew RRH was a vaccination provider and had personal knowledge of vaccinations administered at UMMC, RRH Reidman campus, the Unity Hospital drive through clinic, the Newark Wayne clinic, the Clifton Springs Clinic and about RRH advertisements for appointments.[14]

43) News reports also told the public of the availability of vaccines at RRH.[15] Press releases were reported stating that 'Rochester Regional Health announced that it would be contacting primary care patients age 75-and-up to begin scheduling Covid-19 vaccinations. "As of today, we are hosting a total of ten clinics this week on the Unity Hospital campus, Newark-Wayne Community Hospital campus, Jerome Center (Batavia), and the Riedman Health Center (Irondequoit)," Rochester Regional Health said in a statement.'[16]

44) RRH was a vaccination provider and bore organizational responsibility for VAERS reporting by statute and contract. The Provider Agreement explicitly imposed reporting obligations on the "Organization," which RRH's CEO and CMO acknowledged when certifying that "all relevant officers, directors, employees, and agents of Organization understand and will comply with the agreement requirements."

45) As detailed more fully below, RRH exercised organizational control through systematic suppression of adverse event reporting and organization-wide decisions that limited staff education and reporting. Rather than fulfill its organizational duty to educate staff and ensure reporting

[14]https://www.rochesterregional.org/coronavirus-covid19/vaccine: last accessed 10-31-2024.

[15]https://www.rochesterfirst.com/coronavirus/watch-live-rrh-to-provide-update-on-vaccinations-for-phase-1b-patients/: Last accessed on 10-31-2024.

[16]https://www.fingerlakes1.com/2021/01/11/rochester-regional-health-will-start-rolling-out-vaccine-to-seniors-at-newark-wayne-hospital/: Last accessed on 10-31-2024.

compliance, RRH actively undermined the reporting system while continuing to certify organizational compliance and claim payment for vaccine administration.

46) The federal government can seek administrative and civil remedies prescribed by the False Claims Act, 31 U.S.C. 3729–3733 and under the Program Fraud Civil Remedies Act, 31 U.S.C. 3801–3812.

47) Further, the federal government may seek administrative and criminal remedies as described at Sections 16(a) and (d) of the Small Business Act, 15 U.S.C. 645(a) and (d), as amended.

48) The federal government may also prosecute Respondents for criminal penalties under 18 U.S.C. 1001 and any other penalties as may be available under law.

V. RELATOR'S ALLEGATIONS

49) Ms. Conrad is a Physician Assistant (PA) and was employed by UMMC from 2007-2015 and then with UMMC / RRH from January 2015 to October 6, 2021, Ms. Conrad's day-to-day responsibilities as a PA included the evaluation, diagnosis, and treatment of hospital admissions with acute and chronic disease. Ms. Conrad assessed, stabilized, and determined the disposition of patients with emergent conditions and admitted, managed, and discharged all levels of hospitalized patients. As a PA, Ms. Conrad constantly communicated with patients, patients' families, and hospital staff.

50) As Director of Advanced Practice Providers (APPs), Ms. Conrad provided oversight, coordination, and improved Integration of APPs across inpatient and ambulatory settings. She oversaw credentialing, competency, education, compliance, and consistency of patient services delivered by APPs and was a member of the medical executive committee and the medical staff.

51) In July 2020, Ms. Conrad was recommended by the New York State Society of PA's (NYSSPA) to the Office of Professional Medical Conduct for consideration as a candidate for appointment to the Board for Professional Medical Conduct. The mission of this Board is to protect the public from professional misconduct by physicians and physician assistants.[17]

52) In April 2021, Ms. Conrad was recognized by the UMMC Board of Directors by being nominated for the 2021 Diane C. London Physician Excellence Award. Ms. Conrad was nominated for the award by her RRH colleagues based on her hard work, skill, and dedication to improve quality, facilitate teamwork, and deliver outstanding compassionate care.[18]

53) During and post Covid-19 pandemic, Ms. Conrad observed serious adverse events in some RRH patients directly following initial Covid-19 vaccinations including breakthrough cases and deaths. She confirmed the patients' Covid-19 vaccination status through the New York State Immunization Information System (NYSIIS) system and the RRH electronic records system called EPIC.

54) Ms. Conrad was curious if other practitioners were having the same observations. Ms. Conrad conducted an internet search and learned that adverse events must be reported, by law, to the VAERS system.

55) Ms. Conrad knew of many serious post Covid-19 vaccine adverse events not reported by her employer to either VAERS or the NYSDOH and submitted VAERS reports for her patients and colleagues beginning in March 2021. Prior to May 27th, Ms. Conrad completed and filed 160 total VAERS reports for the hospital system. Ms. Conrad did so after her paid shifts ended because she understood the critical importance and mandatory nature of the task.

[17] Exhibit 3
[18] Exhibit 4

56) Ms. Conrad, helped by Dr. Danielle Notebaert, UMMC Lead Emergency Room Physician, identified ER patients who needed VAERS reports or who were potentially having adverse side effects from their vaccines.[19] Ms. Conrad was ultimately cut off from communication with Dr. Notebaert by RRH administrators.

57) On March 12, 2021, Ms. Conrad emailed Dr. Tara Gellasch, UMMC's Chief Medical Officer (CMO), Dan Ireland, UMMC President, and Dr. Notebaert about the requirement to report to VAERS.[20] Ms. Conrad volunteered to report on her colleagues' behalf until RRH provided education or training to its employees and had a better system for reporting purposes.

58) Before the March 12, 2021 notification, RRH employees received no education or training from the hospital or leadership about the requirement to report to VAERS.

59) Ms. Conrad contacted the Food and Drug Administration ("FDA") and Centers for Disease Control (CDC) for clarification regarding who and what hospital providers were to be reporting to VAERS due to her concern for the lack of VAERS reporting by her colleagues.[21] [22]

60) The CDC did not respond to Ms. Conrad's communications. Paul Richards, Director for Consumer Affairs at the FDA responded via the phone and email and told Ms. Conrad, "each state's DNV[23] or joint commission must have standards in place for hospitals to report vaccine reactions/suspected side effects." Ms. Conrad contacted the New York DNV which denied knowledge of this.

61) Ms. Conrad also raised the issue with the New York State Department of Health ("NYSDOH") (recorded) and with the Office of Professional Medical Conduct. She has not

[19] Exhibit 5
[20] Exhibit 6
[21] Exhibit 7
[22] Exhibit 8
[23] DNV stands for Det Norske Veritas a hospital accrediting body.

received satisfactory answers, nor has she seen any steps taken by the Hospital to remediate the issues.

62) On April 15, 2021, RRH issued an email about vaccine side effects from the J and J vaccine.[24] At the bottom of the email one line says, "Also, please remember to input any adverse effects from the vaccine in the Vaccine Adverse Event Reporting System (VAERS)."

63) During March 2021, Ms. Conrad had several email communications with Trisha Woodward, Infection Preventionist, UMMC, regarding VAERS reporting, the issues with the lack of education surrounding VAERS reporting and how it can be improved. Ms. Woodward, on behalf of Ms. Conrad, tried multiple times to escalate these concerns to high leadership at RRH (Dr. Shaw-Ree Chen, Director of Quality and Dr. Hiloni Bhavsar, Chief Quality Officer) but did not receive a response about what they were planning to do about it or how they planned to educate staff.[25]

64) On May 6, 2021, there was an internal email exchange amongst multiple people in leadership in the system talking about dermatologic side effects being seen following Covid-19 vaccination. The general medical staff never received this email. It was forwarded to Ms. Conrad by Ms. Woodward. In the email, leadership talks about VAERS and side effects but does not discuss this with providers seeing these patients. They minimized the VAERS reports by saying over a million people were vaccinated already so a few with problems didn't matter.[26]

65) On May 24, 2021, Ms. Conrad emailed RRH management.[27] In the email, Ms. Conrad stated "We as health care providers are required **by law** to report these cases." Ms. Conrad advised

[24] Exhibit 9
[25] Exhibit 10
[26] Exhibit 11
[27] Exhibit 12

that the VAERS case number gives the patient the documentation needed and validation of potential injury to support claims filed with the National Vaccine Injury Compensation Program (NVICP) or the Countermeasures Injury Compensation Program (CICP). Dr. Gellasch responded that she agreed with Ms. Conrad's assessment that RRH must report to VAERS per guidance. Dr. Gellasch suggested Ms. Conrad used broader criteria for her reporting.

66) On May 25, 2021, Ms. Conrad exchanged emails with Dr. Gellasch regarding patients needing VAERS reports. The email identified seven patient deaths. Dr. Gellasch indicated that they would review the VAERS reports and Ms. Conrad understood these patients were included in an audit of her VAERS reports.[28]

67) That same day Ms. Woodward informed Ms. Conrad of another vaccinated patient hospitalized with Covid-19.

68) On May 27, 2021, Ms. Conrad spoke with Dr. Gellasch and Dr. Janes regarding the email Ms. Conrad sent to Hospital leadership on May 24, 2021. Dr. Gellasch said although Ms. Conrad's heart was in the right place, she needed to make sure the message being provided to employees was consistent. Dr. Gellasch further advised:

> From what our risk team is telling us, really you can only be reporting on the patients that you are providing direct care for and so you cannot, and I know you've been volunteering and trying to be helpful, but we need you to try to kind of dial it back and focus on the patients that you are directly responsible for …

69) Ms. Conrad said she took on this task because no one else wanted to do it. However, the Hospital dismissed that with the statement that:

> The approach has been that this is the responsibility of the individual provider who believes they have identified a potential adverse event and that has been our approach… You can't control, and I know this is frustrating, but you can't control whether someone else is putting

[28] Exhibit 13

> the report in… and we do need to follow how the system is approaching this currently.

70) When Ms. Conrad again explained her concerns about underreporting, she was called an anti-vaxxer by the hospital:

> I don't want us to go down any kind of rabbit hole here but the thing I think we need to be clear about and I am just going to be frank with you …in reading the few emails you sent me and reading the email that went out to the providers, it does come across a bit…uh very vaccine...ugh I won't say very but it comes out quite, it comes out quite almost anti-vaxxy, right, and you know, clearly as an organization, as a health system, right and as … an organization that is working on following CDC guidelines and following the guidance of the department of health, we are very much advocating for patients to receive the vaccine. And we are very much working on the…effort to work to try and reduce vaccine hesitancy… We want people to understand that on the whole this is a very safe vaccine and that the science supports that.

71) Ms. Conrad voiced more concerns of adverse events following vaccination and was told:

> Yes, just like other vaccines, there are folks that are going to be negatively impacted but, on the whole, we have seen a tremendous benefit to the vaccine … you and I are not individual providers, we're employee providers and we do on some level need to kind of .. for lack of a better way of saying it, we tow the company line. That is part of our responsibility is to be supporting the mission of the organization.

72) Later that day, Dr. Gellasch claimed Dr. Janes had begun a review of her VAERS filings. Ms. Conrad also received an email from Dr. Gellasch following the meeting warning Ms. Conrad to only report adverse events in her patients.[29] In addition, due to Ms. Conrad's role as a leader in the organization, she demanded she support RRH's approach to the vaccine wrongly claiming they were following CDC and DOH guidance.

[29] Exhibit 14

73) Instead of praising her efforts, RRH claimed it audited Ms. Conrad's VAERS submissions on May 27, 2021. RRH told Ms. Conrad their audit of VAERS the reports she submitted was necessary because, "in [her] clinical role and as a leader in the organization, "she was to "support [the Hospital's] approach to the vaccine," and submitting reports to VAERS was contrary to its "approach to the vaccine."

74) In auditing the VAERS reports submitted by Ms. Conrad – the Hospital's Chief Quality Officer stated that she had "not heard this level of reporting from anywhere else and didn't hear similar reports from [another hospital in the system]." The audit concluded Ms. Conrad was overreporting to VAERS.

75) Ms. Conrad continued to report patients that should have been reported to VAERS including patient L.C. On May 31, 2021, Ms. Conrad emailed Dr. Gellasch information directly from the CDC website as to why L.C. should be reported. Ms. Conrad requested the patient's VAERS case number for her records "because now having knowledge of this case and not reporting it myself as I have been instructed to do by the system, puts me in a position to knowingly violate the law."[30] To Ms. Conrad's knowledge, L.C. was not reported to VAERS.

76) On June 2, 2021, RRH employees received a second email regarding VAERS.[31] This was the last email about VAERS from the system and RRH did nothing to enforce reporting or ensure that the reports that went in Safe Connect or sent to the RRH CMO were completed.

77) On June 16, 2021, Ms. Conrad emailed UMMC CMO Dr. Tara Gellasch and Hospitalist Dr. Peter Janes regarding eleven breakthrough Covid-19 infection cases of vaccinated people in the hospital that needed VAERS reports done where the overseeing provider had not reported them

[30] Exhibit 16
[31] Exhibit 15

to VAERS.[32] Ms. Conrad asked for a follow-up email letting her know they were reported because some patients were waiting on VAERS numbers. Dr. Gellasch responded that it is the "overseeing provider's clinical decision on whether or not to report to VAERS." Furthermore, she said "from our prior discussions I do understand you interpret the VAERS guidance broadly however after reviewing the RRH leadership and the Finger Lakes Vaccine hub, this is not a universal interpretation. The overseeing provider determines if the report is done."

78) On June 25, 2021, Ms. Conrad sent Dr. Gellasch and Dr. Janes another email regarding the requirement to report to VAERS and identified six more patients that needed VAERS reports.[33] These cases went unreported in VAERS.

79) On June 28, 2021, a letter from Siri & Glimstad LLP was sent to RRH CMO and UMMC leadership about the underreporting to VAERS and NYSDOH of post-Covid-19 vaccine adverse events.[34] The hospital was asked to confirm it was meeting its legal and ethical obligations including: (i) educating the staff about its responsibility to report to VAERS, (ii) creating internal policies and procedures ensuring VAERS reports would be made and establishing the process for doing so, and (iii) allowing Ms. Conrad and any other healthcare professional employees to submit VAERS reports without retaliation.

80) Ms. Conrad received a response on July 14, 2021, addressing the serious allegations made against RRH and its healthcare providers relative to reporting adverse events to VAERS. RRH stated they developed and distributed robust educational and training tools to help healthcare providers comply with their responsibility to report adverse events related to the Covid-19 vaccination. RHH further stated that the education process was continuous and robust. "RRH has

[32] Exhibit 17
[33] Exhibit 18
[34] Exhibit 19

never discouraged one of its healthcare providers from reporting any adverse events experienced by one of their patients, whether related or unrelated to Covid-19 vaccine."[35]

81) On July 16, 2021, Ms. Conrad met with UMMC President Dan Ireland to inform him of recent vaccinated patients who came into RRH with cardiomyopathies, a blood clot, several strokes, a sudden cancer, and a death of F.H. who had been vaccinated at RRH. During the conversation, Mr. Ireland stressed that Ms. Conrad could only report on the patients in her care. Mr. Ireland stressed that the approach the system took toward VAERS reporting was that it was the responsibility of individual providers to report and that they would not enforce VAERS reporting. In addition, he stated "it is not the organization's duty to educate providers about the VAERS system and what to report, it is the providers duty to educate themselves on this." This contradicts the Vaccination Program Provider Agreement which states it is the duty of the CMO and Chief Executive Officer (CEO) to certify that all relevant officers, directors, employees, and agents of the organization understand and would follow the agreement.[36]

82) In that same conversation, Ireland admitted the hospital was administering Covid-19 vaccines in its own clinic and that it submits vaccine records to the New York State Immunization Information System (NYSIIS) of all the vaccines RRH administered.

83) On July 21, 2021, Siri & Glimstad LLP sent a letter to RRH Deputy General Counsel notifying RRH that they were not meeting their VAERS reporting obligation.[37]

[35] Exhibit 20
[36] Exhibit 24
[37] Exhibit 21

84) On July 19, 2021, Siri & Glimstad LLP sent a letter to the federal agencies (HHS, CDC, FDA) about Ms. Conrad's first-hand account of violations of VAERS reporting requirements for the Covid-19 vaccines.[38]

85) On July 21, 2021, Ms. Conrad's legal Counsel responded to RRH disputing the steps RRH claimed were taken to advise healthcare workers of VAERS reporting obligations.

86) On September 22 and September 27, 2021, Ms. Conrad was interrogated by Dr. Gellasch and Dr. Janes about various "patient family/friend complaints" surrounding VAERS reporting of patients' vaccine injuries and threatened report her to the New York State Society for Physician Assistants (NYSSPA) for spreading misinformation about the vaccines. Dr. Gellasch provided Ms. Conrad a copy of a NYSSPA Statement on Dissemination of Misinformation dated September 13, 2021 during the interrogation on September 27, 2021.

87) These doctors tried to conceal the Covid-19 vaccine related death of patient S.C. who died of sudden multiorgan failure 48-hours after his vaccine. The vaccine was mentioned throughout his medical record from the ER admitting note by Drs Erik Peterson MD, Kathleen O'Donell DO and admitting Dr Myung Sun Choi MD. It was later eliminated from the discharge summary and death certificate by Dr Peter Janes. Dr. Janes failed to make a VAERS report on the patient. Ms. Conrad was alerted to the patient by a resident that a VAERS report must be filed and filed one. She then contacted S.C.'s daughter G.D. about this documentation being completed.

88) Ms. Conrad came out publicly on The Highwire which aired nationally 9/17/2021 exposing the suppression of vaccine side effect reporting to the VAERS system.

89) On September 26, 2021, the New York Times published an article entitled "these healthcare workers would rather be fired than get vaccinated." In it, Ms. Conrad mentioned

[38] Exhibit 22

concern about vaccine side effects as the reason she did not want to get vaccinated. It was mentioned that Ms. Conrad worked at UMMC.

90) On October 6, 2021, Ms. Conrad was interrogated by RRH's HR Director about the High Wire episode, the New York Times article, Covid-19 test-to-stay concerns and her GoFundMe account. Ms. Conrad was asked if she would leave quietly, or if she needed to be escorted out of the hospital. Ms. Conrad was escorted to her workstation on the main medical floor, humiliated before her peers in the middle of her 12-hour shift, asked to leave the hospital immediately and observed closely by HR staff as she was walked out. Ms. Conrad was unable to record as she was suddenly surrounded while charting her patients after lunch.

91) Among the thousands of Covid-19 vaccine injured patients treated by Respondents for post vaccination adverse events but not reported to VAERS, here are some specific examples:

a. Patient E.F., 13 years old, presented to the ER with sudden shortness of breath and fatigue one day after receiving the vaccine. Vaccination site unknown.

b. Patient S.B. presented to the ER one day after receiving the Moderna vaccine after experiencing syncope, witnessed convulsions, fevers, chills and myalgias. Vaccination site unknown.

c. Patient J.F. presented to the ER three days after her vaccination with arm pain and induration of the injected arm. This is reportable to VAERS regardless of the type of vaccine administered. Vaccination site unknown.

These patients' vaccination cards are at Exhibit 26:

d. Patient M.D. admitted due to hypertensive urgency. Vaccinated at RRH.

e. Patient N.M. admitted for bradycardia, AMS, weakness. Vaccinated at RRH.

f. Patient D.A. unknown illness. Vaccinated at RRH.

g. Patient C.M. dizziness and unsteady gate. Vaccinated at RRH.

92) Since being given the order to report on only her patients on May 27, 2021, Ms. Conrad learned of other patients whose conditions required a VAERS report and whose treating nurses and doctors did not file a VAERS report including:

		Date of Service			**Date of Service**			**Date of Service**			**Date of Service**
1	E.F.	5/1/2021	**51**	E.M.	6/28/2021	**101**	P.S.	8/2/2021	**151**	L.D.	9/6/2021
2	PC.	5/1/2021	**52**	L.G.	6/28/2021	**102**	R.B.	8/2/2021	**152**	L.C.	9/7/2021
3	J.K.	5/1/2021	**53**	P.H.	6/29/2021	**103**	**G.F.**	8/3/2021	**153**	M.L.	9/7/2021
4	J.S.	5/3/2021	**54**	V.R.	6/29/2021	**104**	M.D.	8/3/2021	**154**	R.S.	9/8/2021
5	S.B.	5/5/2021	**55**	J.N.	6/30/2021	**105**	D.G.	8/3/2021	**155**	S.S.	9/8/2021
6	I.Y.	5/28/2021	**56**	C.S.	6/30/2021	**106**	G.B.	8/3/2021	**156**	B.K.	9/8/2021
7	F.H.	5/15/2021	**57**	C.L.	6/30/2021	**107**	C.H.	8/9/2021	**157**	N.C.	9/9/2021
8	L.C.	5/25/2021	**58**	A.B.	6/30/2021	**108**	M.L	8/9/2021	**158**	F.B.	9/9/2021
9	P.F.	5/26/2021	**59**	L.K.	7/2/2021	**109**	D.S.	8/9/2021	**159**	J.B.	9/9/2021
10	R.A.	5/30/2021	**60**	B.R.	7/4/2021	**110**	T.C.	8/12/2021	**160**	D.B.	9/9/2021
11	L.H.	5/30/2021	**61**	L.R.	7/5/2021	**111**	D.M.	8/12/2021	**161**	J.S.	9/10/2021
12	J.F.	5/31/2021	**62**	C.M.	7/5/2021	**112**	G.P.	8/12/2021	**162**	J.T.	9/10/2021
13	P.R.	6/1/2021	**63**	H.H.	7/5/2021	**113**	H.R.	8/13/2021	**163**	D.S.	9/2/2021
14	E.D.	6/1/2021	**64**	R.G.	7/6/2021	**114**	J.B.	8/13/2021	**164**	D.C.	9/23/2021
15	K.W.	6/1/2021	**65**	R.L.	7/6/2021	**115**	H.P.	8/14/2021	**165**	L.G.	9/23/2021
16	G.S.	6/1/2021	**66**	C.S.	7/6/2021	**116**	R.G.	8/16/2021	**166**	G.P.	9/23/2021
17	**B.K.**	6/1/2021	**67**	R.M.	7/6/2021	**117**	R.R.	8/16/2021	**167**	M.G.	9/23/2021
18	V.J.	6/7/2021	**68**	D.C.	7/6/2021	**118**	A.W.	8/16/2021	**168**	J.B.	9/23/2021

19	R.J.	6/7/2021	**69**	T.S.	7/7/2021	**119**	B.W.	8/16/2021	**169**	K.L.	9/23/2021
20	L.P.	6/7/2021	**70**	M.D.	7/7/2021	**120**	J.N.	8/19/2021	**170**	B.R.	9/23/2021
21	D.C.	6/8/2021	**71**	E.V.	7/7/2021	**121**	H.J.	8/19/2021			
22	P.F.	6/8/2021	**72**	S.S.	7/7/2021	**122**	K.K.	8/19/2021			
23	L.S.	6/9/2021	**73**	M.D.	7/8/2021	**123**	J.P.	8/19/2021			
24	F.M.	6/9/2021	**74**	V.F.	7/8/2021	**124**	C.B.	8/19/2021			
25	N.M.	6/9/2021	**75**	R.T.	7/8/2021	**125**	J.N.	8/21/2021			
26	E.G.	6/9/2021	**76**	J.M.	7/9/2021	**126**	L.S.	8/21/2021			
27	D.G.	6/10/2021	**77**	J.A.	7/9/2021	**127**	G.F.	8/23/2021			
28	F.C.	6/10/2021	**78**	M.D.	7/9/2021	**128**	E.S.	8/23/2021			
29	E.V.	6/10/2021	**79**	S.S.	7/9/2021	**129**	L.D.	8/23/2021			
30	M.C.	6/15/2021	**80**	C.R.	7/12/2021	**130**	D.P.	8/23/2021			
31	G.M.	6/16/2021	**81**	N.M.	7/12/2021	**131**	J.S.	8/24/2021			
32	A.P.	6/16/2021	**82**	R.G.	7/12/2021	**132**	J.M.	8/24/2021			
33	D.B.	6/16/2021	**83**	J.C.	7/12/2021	**133**	R.S.	8/24/2021			
34	S.F.	6/18/2021	**84**	T.G.	7/12/2021	**134**	F.W.	8/27/2021			
35	R.M.	6/17/2021	**85**	W.E.	7/12/2021	**135**	G.L.	8/27/2021			
36	D.M.	6/18/2021	**86**	C.M.	7/13/2021	**136**	M.V.	8/27/2021			
37	E.D.	6/18/2021	**87**	L.K.	7/13/2021	**137**	C.K.	8/27/2021			
38	C.M.	6/18/2021	**88**	J.L.	7/13/2021	**138**	R.G.	8/27/2021			
39	K.W.	6/18/2021	**89**	E.P.	7/14/2021	**139**	M.M.	8/27/2021			
40	C.D.	6/18/2021	**90**	R.C.	7/14/2021	**140**	S.W.	8/29/2021			
41	P.C.	6/18/2021	**91**	C.M.	7/14/2021	**141**	J.W.	8/29/2021			

42	G.S.	6/18/2021	**92**	M.H.	7/15/2021	**142**	S.H.	8/30/2021			
43	B.K.	6/18/2021	**93**	G.K.	7/15/2021	**143**	C.B.	8/30/2021			
44	S.W.	6/19/2021	**94**	R.P.	7/21/2021	**144**	J.P.	8/30/2021			
45	T.T.	6/21/2021	**95**	R.B.	8/2/2021	**145**	Z.M.	8/31/2021			
46	D.M.	618/2021	**96**	E.P.	7/13/2021	**146**	G.E.	9/3/2021			
47	A.G.	6/18/2021	**97**	C.M.	8/1/2021	**147**	E.W.	9/3/2021			
48	L.G.	6/26/2021	**98**	M.L.	8/1/2021	**148**	A.T.	9/3/2021			
49	G.B.	6/28/2021	**99**	J.L.	8/1/2021	**149**	M.A.	9/3/2021			
50	H.L.	6/28/2021	**100**	M.S.	8/2/2021	**150**	L.D.	9/3/2021			

93) The vaccination site(s) used by the above patients is unknown at this time. Many were admitted for Covid-19, heart problems, renal failure, stroke post-vaccine.

94) Ms. Conrad was not the only staff member threatened or intimidated by management over VAERS reporting. These staff members told Ms. Conrad the administration was suppressing VAERS reporting:

a) Erin Paulter, LSW
b) Sarah Stoneham, ER RN
c) Lisa Phillians, PA and colleague
d) Denise Admaski, Floor RN/Case manager
e) Dr. Kathleen Odonnell, DO
f) Tamara Gleason, ICU RN
g) Colleen Bruntz, ICU RN

Most of these people have left the RRH organization since Ms. Conrad was fired.

A. CLAIMS

95) RRH submitted claims for reimbursement for thousands of Covid-19 vaccinations under a simplified HHS process that allowed enrolled providers to "submit individual claims or roster bill,

without enrolling as a mass immunizer." [39] While Ms. Conrad did not work in billing, she was aware of these claims through staff conversations and publicly available information.[40] The legal significance of these claims stems from RRH administrators signing the Provider Agreement on behalf of the entire organization, which established VAERS reporting as a material condition of participation - a requirement RRH explicitly acknowledged in their own Vaccine Clinic Playbook.

96) This congressional directive establishing VAERS became even more crucial for Covid-19 vaccines administered under emergency authorization, where rapid identification of safety signals was essential. By signing the Provider Agreement, RRH administrators acknowledged this congressionally mandated obligation for the entire organization and explicitly documented it in their own Vaccine Clinic Playbook. The materiality of VAERS reporting to payment thus flows directly from Congress's determination that safety monitoring through adverse event reporting was an essential component of any vaccination program, not from administrative enforcement decisions.

97) RRH, like all healthcare organizations, uses sophisticated accounting and billing systems to track services and ensure payment. For each Covid-19 vaccine dose administered, RRH's systems record the service in the patient's medical record, document administration in the NYSIIS system, and generate a claim for payment. These internal systems, controlled exclusively by RRH, track every dose from administration through payment processing. While Ms. Conrad does not have direct access to these billing systems, she knows RRH's billing department processes vaccine administration records into claims seeking the standard $40

[39] https://www.hhs.gov/guidance/document/enrollment-administering-covid-19-vaccine-shots: accessed 10-31-2024

[40]https://www.cms.gov/medicare/payment/covid-19-vaccine-toolkit/medicare-covid-19-vaccine-shot-payment: accessed 10-31-2024.

payment per dose through established federal healthcare program billing procedures, including Medicare, Medicaid and the HRSA Covid-19 Uninsured Program.

98) The falsity of RRH's claims does not stem from any irregularity in the billing process itself, but from RRH's systematic failure to fulfill its VAERS reporting obligations while certifying compliance to obtain those payments. Each time RRH's billing staff transmitted claims for vaccine administration payments, those claims implicitly certified RRH met all material conditions of the Provider Agreement - including VAERS reporting requirements. While the technical aspects of claims submission remained entirely within RRH's control, Ms. Conrad has direct knowledge of the factual prerequisites that made those claims false: RRH's deliberate suppression of mandatory adverse event reporting while continuing to seek federal funds for vaccine administration.

99) The strong inference that false claims were submitted arises not from the billing details known only to RRH, but from Ms. Conrad's detailed documentation of RRH's coordinated effort to avoid VAERS reporting obligations while maintaining high vaccination rates and associated federal payments. Through specific examples like patient S.C., whose vaccine-related death went unreported while RRH claimed payment for administering his vaccine, Ms. Conrad demonstrates how RRH's systematic non-compliance rendered each claim false, regardless of the technical accuracy of the billing submission.

100) Despite acknowledging this duty through their Playbook and various internal communications, RRH systematically suppressed VAERS reporting by Ms. Conrad and others. The gravity of this suppression is underscored by RRH's documented evidence of patients returning as inpatients for treatment of Covid-19 and vaccine injuries, which went unreported to VAERS.

101) This pattern of behavior meant that each claim RRH submitted for vaccine administration payment was a false claim under the False Claims Act. The claims were false because VAERS reporting was required by multiple federal authorities: the National Childhood Vaccine Injury Act (42 U.S.C. § 300aa-25), the Emergency Use Authorization statute (21 U.S.C. § 360bbb-3(e)(1)(A)(iii)), implementing regulations and FDA reporting requirements. [41] These obligations were material conditions of participation in the Covid-19 Vaccination Program, as reinforced through RRH's Provider Agreement where each claim for payment expressly and implicitly certified compliance with all program requirements - compliance RRH knowingly failed to maintain while continuing to submit claims for payment for vaccine administration.

B. FACTUAL AND LEGAL FALSITY

102) RRH submitted claims for payment that were factually and legally false. Each claim for $40 per vaccine dose misrepresented the services provided and falsely certified compliance with mandatory safety monitoring requirements.

103) The claims were factually false because RRH misrepresented the nature of services provided when seeking payment. While RRH claimed to provide comprehensive vaccine administration services, including mandatory safety monitoring as envisioned by Congress, it systematically failed to report required adverse events, rendering the service materially incomplete.

104) For example, when Patient S.C. died within 48 hours of vaccination, RRH not only failed to report this mandatory adverse event but altered medical records to conceal the recent vaccination

[41] https://www.federalregister.gov/d/2021-23831/p-185

while retaining payment for purportedly complete services. RRH's claims for complete vaccine administration while omitting required safety monitoring misrepresented the services provided.

105) The claims were also legally false under multiple theories. First, RRH made express false certifications each time it submitted a claim. The Provider Agreement explicitly required reporting of adverse events as a material condition of payment.

106) When submitting each $40 claim, RRH expressly certified compliance with all requirements while knowing it was systematically failing to report adverse events. Second, the claims contained implied false certifications because they represented RRH was authorized to administer vaccines under the EUA while failing to disclose non-compliance with the EUA's statutory safety monitoring requirements. RRH's claims were 'half-truths' because they accurately represented that vaccines were administered but misleadingly implied full program compliance while RRH was actively suppressing adverse event reporting to VAERS.[42]

107) Finally, RRH fraudulently induced its participation in the vaccination program by initially certifying it would comply with all safety monitoring requirements while never intending to implement comprehensive adverse event reporting. This fraudulent inducement rendered all subsequent claims legally false. RRH demonstrated the falsity of its claims through systematic suppression of adverse event reporting, active discouragement of staff who attempted to report, alteration of medical records to conceal reportable events, and continued submission of claims certifying compliance it knew did not exist.

108) Beyond Patient S.C., RRH's records document numerous other examples where RRH: (1) administered vaccines and submitted claims certifying full compliance; (2) became aware of

[42] In *Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016), the Supreme Court explained that when a defendant submits a claim for payment, they must disclose any non-compliance with material statutory, regulatory, or contractual requirements that makes their representations misleading. The Court described these as "half-truths."

qualifying adverse events requiring VAERS reporting; (3) failed to report despite knowledge of the events; and (4) retained payment despite knowing non-compliance. The billing records documenting these false claims remain in RRH's exclusive possession but include claim submission dates, certification language, and administration details demonstrating systematic false claims.

109) This pattern of false claims caused substantial damage to the United States by undermining critical vaccine safety monitoring while fraudulently obtaining payment for purportedly complete services. RRH knew its claims were false, demonstrated by its active concealment of reportable events and retaliation against staff who attempted to ensure compliance with reporting requirements.

C. SCIENTER

110) RRH knowingly submitted these false claims as demonstrated by actual knowledge, deliberate ignorance, and reckless disregard of its reporting obligations. RRH's actual knowledge is evidenced by its leadership's explicit acknowledgment of VAERS requirements, including Dr. Gellasch's May 24, 2021 agreement that "we must report to VAERS per guidance" and RRH's July 14, 2021 letter confirming understanding of these obligations.

111) RRH's knowing submission of false claims is also shown by their certifications in the Provider Agreement, where they explicitly represented that "all relevant officers, directors, employees, and agents of Organization involved in handling Covid-19 Vaccine understand and will comply with the agreement requirements." This certification was not a mere formality - it required RRH's CEO and Chief Medical Officer to verify they had investigated and confirmed their organization's compliance capabilities before making these representations to the

government. Yet despite certifying their understanding and compliance, RRH actively suppressed VAERS reporting through systematic organizational actions.

112) Despite this knowledge, RRH suppressed reporting by cutting off communication between Dr. Notebaert and Ms. Conrad, ordering Ms. Conrad to "dial it back," and retaliating against other staff who attempted compliance.

113) RRH knowingly chose to prioritize the goal of maximizing vaccinations and reducing “vaccine hesitancy" over the legal obligation to report adverse events, while continuing to falsely certify compliance to obtain federal payments. This deliberate strategy of suppressing safety information while maximizing vaccination rates and associated federal payments further demonstrates RRH's knowing submission of false claims.

114) RRH showed deliberate ignorance by refusing to educate staff about VAERS requirements, with President Dan Ireland explicitly stating "it is not the organizations duty to educate providers" – directly contradicting the Provider Agreement's requirement that all relevant staff understand reporting obligations.

115) Finally, RRH showed reckless disregard through its systematic failure to implement effective reporting procedures while continuing to certify compliance and submit claims for payment.

116) This knowing conduct culminated in explicit actions to conceal reportable events, such as removing vaccine information from Patient S.C.'s death certificate and discharge summary, while maintaining policies that prioritized high vaccination numbers over mandatory safety monitoring and firing Ms. Conrad.

D. MATERIALITY

117) When Ms. Conrad raised concerns about underreporting to RRH, HHS, CDC, and FDA on July 19, 2021, RRH responded not by correcting their non-compliance but by actively concealing it. RRH's understanding that VAERS reporting was material to payment is demonstrated by their elaborate efforts to hide non-compliance, including: altering Patient S.C.'s death certificate and medical records to remove vaccine information, issuing explicit directives to staff to suppress adverse event reporting, retaliating against employees who attempted to comply with reporting requirements, and concealing the true scope of unreported adverse events while continuing to submit claims and certify compliance.

118) The FDA and CDC consistently maintained VAERS reporting as a material condition of both the Emergency Use Authorization under Section 564(e)(1)(A)(iii) and the Provider Agreement. No government agency has ever declared VAERS reporting optional, especially for an EUA product, or permitted providers to systematically suppress reporting while claiming payment. RRH's aggressive concealment efforts show they understood that disclosure of their systematic non-compliance would threaten their continued receipt of federal funds.

119) RRH understood VAERS reporting was a material condition of payment, as demonstrated by its aggressive efforts to conceal non-compliance. RRH maintained this concealment while continuing to submit claims and certify compliance for each $40 payment received for vaccine administration to thousands of people. The materiality of these requirements is further demonstrated by their inclusion in the statutory EUA framework and Provider Agreement, and at no time has any government agency declared VAERS reporting optional or permitted providers to systematically suppress reporting of adverse events while claiming payment for vaccine administration.

E. CONSPIRACY

120) RRH and its administrators entered into agreements with each other to violate the False Claims Act by agreeing to systematically suppress VAERS reporting while continuing to claim federal funds. This was not merely ministerial coordination, but rather each participant had an independent stake in achieving the illegal objective: administrators maintained high vaccination rates to meet organizational goals, providers avoided documentation burdens and potential "vaccine hesitancy" that could result from accurate reporting, and the organization continued receiving federal payments while avoiding safety monitoring obligations.

121) The conspiracy is evidenced by coordinated actions across multiple levels of the organization: the CMO and hospital president issued directives limiting reporting, supervisors enforced these limitations, medical records were altered to remove vaccine information (as with patient S.C.), communication channels were deliberately cut off between providers identifying reportable events, and staff members who attempted to comply with reporting requirements faced retaliation.

122) Each participant understood that VAERS reporting was required but agreed to suppress reporting while maintaining the false appearance of compliance to continue receiving federal funds. This conspiracy went beyond normal corporate operations - it represented a coordinated effort by individuals with independent obligations to report adverse events agreeing instead to conceal them while falsely certifying compliance to obtain payment.

Count I

False Claims Act 31 U.S.C. §3729(a)(1)(A): Presenting and causing false claims

123) Relator realleges and incorporates by reference the allegations in the paragraphs above as though fully set forth herein.

124) This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. 3729, et seq. as amended.

125) Through the acts described above, Respondents knowingly presented or caused to be presented false or fraudulent claims for payment or the government, unaware of the falsity of all such claims made or caused to be made by Respondents, has paid such false or fraudulent claims that would not be paid but for Respondents' illegal conduct.

126) By Respondents' acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined.

127) The United States may receive the maximum penalty of up to $27,018 for every violation alleged.

Count II

False Claims Act 31 U.S.C. § 3729(a)(1)(B): False records

128) Relator realleges and incorporates the above paragraphs as though fully set forth herein.

129) This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. 3729, et seq. as amended.

130) Through the acts described above, Respondent knowingly made, used, or caused to be made or used false records or statements material to false or fraudulent claims.

131) The government, unaware of the falsity of the records, statements, and claims made or caused to be made by Respondent, has paid claims that would not be paid but for Respondent's illegal conduct.

132) By Respondent's acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined.

133) The United States may receive the maximum penalty of up to $27,018 for every violation alleged.

Count III

False Claims Act U.S.C. § 3729(a)(1)(C): Conspiracy

134) Relator realleges and incorporates the above paragraphs as though fully set forth herein.

135) This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. § 3729, et seq. as amended.

136) Through the acts described above, Respondent knowingly conspired to commit a violation of U.S.C. § 3729(a)(1)(A), U.S.C. § 3729(a)(1)(B), U.S.C. § 3729(a)(1)(D), and U.S.C. § 3729(a)(1)(G).

137) The government, unaware of the concealment by the Respondent, has not made demand for or collected funds due from the Respondent.

138) By Respondent's acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined.

139) The United States is entitled to the maximum penalty of up to $27,018 for every violation alleged.

Count IV

False Claims Act U.S.C. § 3729(a)(1)(G): Reverse false claims

140) Relator realleges and incorporates the above paragraphs as though fully set forth herein.

141) This is a claim for treble damages and penalties under the False Claims Act, 31 U.S.C. 3729, et seq. as amended.

142) Through the acts described above, Respondent has knowingly made or used, or caused to be made or used, false records or false statements material to an obligation to return money to the government.

143) The Provider Agreement explicitly established that "reimbursement for administering Covid-19 Vaccine is not available under any federal healthcare program if Organization fails to comply with these requirements."

144) This created an independent obligation to return payments received while non-compliant with VAERS reporting requirements, separate from any liability under the False Claims Act. Each time RRH submitted a claim while failing to meet reporting requirements, they incurred an obligation to return those funds to the government.

145) Instead of reporting their non-compliance and returning these payments, RRH knowingly concealed their systematic suppression of adverse event reporting to retain funds they were obligated to repay. This obligation to repay arose directly from the Provider Agreement's terms and exists independently of whether RRH is found liable under other provisions of the False Claims Act. By retaining these payments while actively concealing their non-compliance with VAERS reporting requirements, RRH knowingly and improperly avoided their obligation to return these funds to the government.

146) The government, unaware of the concealment by the Respondent, has not made demand for, or collected funds due from the Respondent.

147) By Respondent’s acts, the United States has been damaged, and continues to be damaged, in a substantial amount to be determined.

148) The United States is entitled to the maximum penalty of up to $27,018 for every violation alleged.

Count V

Retaliation 31 U.S.C. § 3730(h)

149) Relator realleges and incorporates the above paragraphs as though fully set forth herein.

150) In violation of 31 U.S.C. § 3730(h), Respondents retaliated against Relator because of her good faith efforts to stop Respondents from committing one or more violations of the False Claims Act and other unlawful conduct.

151) From March 2021 through her termination, Relator undertook specific actions to stop defendants' False Claims Act violations. She identified and reported over 160 adverse events to VAERS, documented additional unreported cases, alerted management to their reporting obligations, and maintained records of systematic non-compliance.

152) Based on her direct knowledge of defendants' practices and the Provider Agreement requirements, Relator held a reasonable, good faith belief that defendants were violating their statutory and contractual obligations by failing to report adverse events while continuing to claim reimbursement from CDC vaccination programs. Relator's efforts to ensure compliance with these material conditions of payment constitute protected activity under the False Claims Act.

153) Defendants were aware of Relator's protected activity. Management specifically acknowledged her VAERS reporting efforts, audited her submissions, and received multiple communications from her regarding their legal obligations to report. Rather than address these compliance concerns, defendants engaged in escalating retaliation including restricting her reporting activities, cutting off communication channels, subjecting her to hostile interrogations, and ultimately terminating her employment.

154) Prior to engaging in protected activity, Relator had an exemplary employment record spanning 14 years with defendants. She was recognized for excellence in April 2021 through

nomination for the Diane C. London Physician Excellence Award based on her "hard work, skill, and dedication to improve quality, facilitate teamwork and deliver outstanding compassionate care." She consistently fulfilled her duties as both a Physician Assistant and Director of Advanced Practice Providers, maintaining all required credentials and competencies.

155) But for her protected efforts to prevent False Claims Act violations, Relator would not have faced retaliation or termination. The temporal proximity between her protected activity and adverse actions, combined with defendants' stated objections to her VAERS reporting efforts, demonstrates her termination was causally connected to her attempts to prevent false claims.

156) Relator suffered economic loss and emotional harm because of her termination by Respondents.

Count VI

New York Labor Laws §§ 740 and 741

157) Relator realleges and incorporates the above paragraphs as though fully set forth herein.

158) In violation of New York Labor Laws §§ 740 and 741, Respondents retaliated against Relator because of her efforts to stop Respondents from committing violations of the False Claims Act and for matters which may present a substantial and specific danger to public health or safety and a significant threat to the health of specific patients.

159) Relator fully informed Respondents of their fraudulent and illegal acts, verbally and in writing, before bringing this action.

160) Respondents punished Relator for her lawful and statutorily protected activity with harassment and termination.

161) Relator suffered economic loss and emotional harm because of her termination by Respondents. front pay, civil penalties not to exceed $10,000, and punitive damages (in addition to back pay)

PRAYER FOR RELIEF

WHEREFORE, Relator prays for judgment against Respondents that:

a. Respondents cease violating 31 U.S.C. § 3729 et seq. and New York Labor Laws §§ 740 and 741;

b. This Court enter judgment against Respondents equal to three times the damages the United States has sustained because of Respondents' actions, plus a civil penalty of not less than $13,508 and not more than $27,018 for thousands of violations of the False Claims Act exceeding $100,000,000.00.

c. Relator be awarded the maximum amount allowed under §3730(d) of the False Claims Act and the False Claims Act;

d. Relator be awarded two times Relator's back pay, interest on Relator's back pay, front pay, and punitive damages because Respondents' actions were willful, malicious, and wanton.

e. Relator be awarded all costs, including attorneys' fees and expenses; and

f. The United States and Relator recover such other and further relief the Court deems just and proper.

Respectfully submitted,

/s/Warner Mendenhall
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Pro hac vice forthcoming
Counsel for Relator

JURY DEMAND

Relator demands a trial by jury on all issues so triable.

/s/Warner Mendenhall
Warner Mendenhall (0070165)

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 Friday, November 1, 2024.

/s/ Warner Mendenhall
Warner Mendenhall