UNITED STATES DISTRICT COURT
FOR WESTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA [UNDER SEAL]	)	**CIVIL ACTION NO.:**
	)	
Relator,	)	**JUDGE:** Sinatra
	)	
vs.	)	
	)	**COMPLAINT**
[UNDER SEAL]	)	
	)	**FILED IN CAMERA AND**
Respondents.	)	**UNDER SEAL PURSUANT TO**
	)	**31 U.S.C. §3730(b)(2)**

DOCUMENT TO BE KEPT UNDER SEAL
DO NOT ENTER ON PACER

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.:** **JUDGE:** **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** **FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. §3730(b)(2)**

Relator, on behalf of the United States of America, for this 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 monetary damages, civil penalties, and Relator's reasonable attorneys' fees.

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.

4. Respondents failed to report most adverse events to the VAERS system from the start of the Covid-19 Vaccination Program to present. Relator has direct and independent knowledge that from about May 27, 2021 to October 6, 2021, RRH blocked Relator from submitting about 170 serious adverse events to the VAERS reporting system. To date, RRH failed to submit over 1200 adverse events after it administered the vaccine and over 12,000 adverse events from patients who received an injection from other providers.

5. Respondents' scheme violated the FCA, 31 U.S.C § 3729 *et. seq.*, and other relevant federal and state laws, rules, and regulations because mandatory reporting to VAERS is a material condition of participation in the Covid-19 Vaccination Program which RRH agreed to via CDC Covid-19 Vaccination Program Provider Agreement. Respondents informed staff of this obligation 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.

6. 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.

7. 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

8. 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]

9. 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.

10. 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).

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[1] Exhibit 1

[2] Exhibit 2

11. 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.

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

13. 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.

14. 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

15. Under section 3730(b)(2), Relator filed this action in camera and under seal with the Court and will serve a copy of this Complaint and 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 Rules of Civil Procedure.

16. In addition, Relator voluntarily provided all material evidence and information to the federal government before suing.

IV. THE NATIONAL CHILDHOOD VACCINE INJURY ACT

17. 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.

18. 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.

19. The NCVIA requires healthcare providers to report:

(A) Any event listed by the vaccine manufacturer as a contraindication to subsequent doses of the vaccine.

(B) Any event listed in the Reportable Events Table[3] that occurs within the specified time period after vaccination.

20. The NCVIA mandates health care providers report certain adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).

V. VAERS SYSTEM AND BACKGROUND

21. VAERS is a national vaccine safety surveillance program created as an outgrowth of the National Childhood Vaccine Injury Act of 1986 (NCVIA) and is administered by the Centers for Disease Control and Prevention (CDC) and 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.[4]

22. 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.

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[3] Exhibit 23

[4] https://www.vaers.hhs.gov

23. 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.[5] By tracking such events, VAERS helps to identify any safety concerns.

24. Health care providers are strongly encouraged to report to VAERS "any adverse event that occurs 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."[6] The importance of filing VAERS reports is acute 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").

25. 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[7], 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. [8]

- Under the FDA and its EUA, all vaccine and health care providers who administer the COVID-19 vaccine must report the following to the VAERS in accordance with the Fact Sheet for Healthcare Providers Administering

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[5] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

[6] https://vaers.hhs.gov/reportevent.html

[7] Exhibit 23

[8] 42 U.S. Code § 300aa–25 - Recording and reporting of information | U.S. Code | US Law | LII / Legal Information Institute (cornell.edu)

Vaccine (Vaccine Providers):[9]Vaccine administration errors whether or not associated with an adverse event.

- Serious adverse events (irrespective of attribution to vaccination).
- Cases of Multisystem Inflammatory Syndrome in children and adults.
- Cases of COVID-19 that result in hospitalization or death."[10]

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

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- 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.[11]

26. 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:

- Cases of myocarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine
- Cases of pericarditis after a Pfizer-BioNTech, Moderna, or Novavax vaccine
- Cases of Multisystem Inflammatory Syndrome in children and adults

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

[10] 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).

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

- Cases of COVID-19 that result in hospitalization or death[12]

27. To participate in the CDC's Covid-19 Vaccination Program and receive funds related to the administrative 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.[13]

The certification for the Provider Agreement explicitly states[14]:

> 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.

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

29. In addition, 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.

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[12] https://www.fda.gov/safety/reporting-serious-problems-fda/what-serious-adverse-event

[13] https://www.cdc.gov/vaccines/covid-19/provider-enrollment.html

[14] Exhibit 24

30. 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.

31. 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.

IV. RELATOR'S DIRECT AND INDEPENDENT KNOWLEDGE

32. 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, diagnoses, 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.

33. 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.

34. 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.[15]

[15] Exhibit 3

35. In April 2021, Ms. Conrad was recognized by the UMMC Board of Directors for her nomination of 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.[16]

36. 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.

37. 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.

38. 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. Ms. Conrad did so after her paid shifts ended because she understood the critical importance and mandatory nature of the task.

39. 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.[17] Ms. Conrad was ultimately cut off from communication with Dr. Notebaert.

40. On March 12, 2021, Ms. Conrad first notified via email Dr. Tara Gellasch, UMMC Chief Medical Officer and Dr. Peter Janes, United Memorial Hospitalist Director, about the requirement

[16] Exhibit 4
[17] Exhibit 5

to report to VAERS.[18] Ms. Conrad volunteered report on her colleagues' behalf until RRH provided education or training to its employees and had a better system for reporting purposes.

41. 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.

42. 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.[19] [20]

43. 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[21] 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.

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

45. On April 15, 2021, RRH issued an email about vaccine side effects from the J and J vaccine.[22] 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)."

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[18] Exhibit 6

[19] Exhibit 7

[20] Exhibit 8

[21] DNV stands for Det Norske Veritas a hospital accrediting body.

[22] Exhibit 9

46. 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.[23]

47. 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.[24]

48. On May 24, 2021, Ms. Conrad emailed RRH management.[25] In the email, Ms. Conrad stated "We as health care providers are required **by law** to report these cases." Ms. Conrad advised 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.

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[23] Exhibit 10
[24] Exhibit 11
[25] Exhibit 12

49. On May 25, 2021, Ms. Conrad exchanged emails with Dr. Gellasch regarding patients needing VAERS reports. The email identified seven patient deaths. Ms. Conrad's understood these patients were included in the audit of her VAERS reports.[26] On May 27, 2021, Ms. Conrad met 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 …

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

51. 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

[26] Exhibit 13

> 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.

52. 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.

53. On May 27, 2021, Ms. Conrad received an email from Dr. Gellasch following the meeting warning Ms. Conrad to only report adverse events in her patients.[27] In addition, due to Ms. Conrad's role as a leader in the organization, he demanded she support RRH's approach to the vaccine by following CDC and DOH guidance.

54. On June 2, 2021, RRH employees received a second email regarding VAERS.[28] This was the last email about VAERS from the system and RRH did nothing to enforce reporting or assure that the reports that went in Safe Connect or that were sent to RRH CMO were completed.

55. Instead of praising her efforts, RRH audited Ms. Conrad's VAERS submissions on May 27, 2021. RRH told Ms. Conrad they would audit the VAERS reports she submitted 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."

[27] Exhibit 14
[28] Exhibit 15

56. 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.

57. 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."[29] To Ms. Conrad's knowledge, L.C. was not reported to VAERS.

58. 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 to VAERS.[30] 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 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."

[29] Exhibit 16
[30] Exhibit 17

59. 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.[31] These cases went unreported in VAERS.

60. 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.[32] 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.

61. 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 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."[33]

62. 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.[34]

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[31] Exhibit 18
[32] Exhibit 19
[33] Exhibit 20
[34] Exhibit 21

63. On July 16, 2021, Ms. Conrad met with UMH President Dan Ireland. 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 CEO to certify that all relevant officers, directors, employees, and agents of the organization understand and would follow the agreement.[35]

64. 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.[36]

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

66. 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.

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[35] Exhibit 24

[36] Exhibit 22

67. 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.

68. 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.

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

70. 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.

71. Among the more than 12,000 Covid-19 vaccine injured patients treated by Respondents for post vaccination adverse events but not reported to VAERS, here are some specific examples:

- Patient E.F., 13 years old, presented to the ER with sudden shortness of breath and fatigue one day after receiving the vaccine.
- Patient S.B presented to the ER one day after receiving the Moderna vaccine after experiencing syncope, witnessed convulsions, fevers, chills and myalgias.
- 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.

72. 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			

Count I
False Claims Act 31 U.S.C. §3729(a)(1)(A)

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

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

75. 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.

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

77. 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)

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

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

80. 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.

81. 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.

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

83. 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)

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

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

86. 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).

87. The Government, unaware of the concealment by the Respondent, has not made demand for or collected funds due from the Respondent.

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

89. 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)

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

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

92. 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.

93. The Government, unaware of the concealment by the Respondent, has not made demand for, or collected funds due from the Respondent.

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

95. 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)

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

97. In violation of 31 U.S.C. § 3730(h), Respondents retaliated against Relator because of her efforts to stop Relators from committing violations of the False Claims Act.

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

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

Count VI

New York Labor Laws §§ 740 and 741

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

101. 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.

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

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

104. 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 over 12,000 violations of the False Claims Act totaling at least $140,000,000.00.

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,

MENDENHALL LAW GROUP

Warner Mendenhall (0070165)
190 N. Union St., Ste. 201
Akron, OH 44304
(330) 535-9160; fax (330) 762-9743
warner@warnermendenhall.com

Counsel for Relator

JURY DEMAND

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

Warner Mendenhall (0070165)

Department of State
Division of Corporations

Entity Information

Return to Results | Return to Search

Entity Details

ENTITY NAME: ROCHESTER REGIONAL HEALTH
FOREIGN LEGAL NAME:
ENTITY TYPE: DOMESTIC NOT-FOR-PROFIT CORPORATION
SECTIONOF LAW: 402 NCL - NOT-FOR-PROFIT CORPORATION LAW
DATE OF INITIAL DOS FILING: 07/01/2014
EFFECTIVE DATE INITIAL FILING: 07/01/2014
FOREIGN FORMATION DATE:
COUNTY: MONROE
JURISDICTION: NEW YORK, UNITED STATES

DOS ID: 4600326
FICTITIOUS NAME:
DURATION DATE/LATEST DATE OF DISSOLUTION:
ENTITY STATUS: ACTIVE
REASON FOR STATUS:
INACTIVE DATE:
STATEMENT STATUS: NOT REQUIRED
NEXT STATEMENT DUE DATE:
NFP CATEGORY: CHARITABLE

ENTITY DISPLAY | NAME HISTORY | FILING HISTORY | MERGER HISTORY | ASSUMED NAME HISTORY

Service of Process Name and Address

Name: THE CORPORATION
Address: ATTN: GENERAL COUNSEL, 100 KINGS HIGHWAY S., ROCHESTER, NY, UNITED STATES, 14617

Chief Executive Officer's Name and Address

Name:
Address:

Principal Executive Office Address

Address:

Registered Agent Name and Address

Name:
Address:

Entity Primary Location Name and Address

Name:
Address:

Farmcorpflag

Is The Entity A Farm Corporation: NO

Stock Information

EXHIBIT 1

Share Value	Number Of Shares	Value Per Share

Entity Information

Return to ResultsReturn to Search

Entity Details

ENTITY NAME:UNITED MEMORIAL MEDICAL CENTER
DOS ID:26238
FOREIGN LEGAL NAME:
FICTITIOUS NAME:
ENTITY TYPE:DOMESTIC NOT-FOR-PROFIT CORPORATION
DURATION DATE/LATEST DATE OF DISSOLUTION:
SECTIONOF LAW: -
ENTITY STATUS:ACTIVE
DATE OF INITIAL DOS FILING:07/30/1900
REASON FOR STATUS:
EFFECTIVE DATE INITIAL FILING:07/30/1900
INACTIVE DATE:
FOREIGN FORMATION DATE:
STATEMENT STATUS:NOT REQUIRED
COUNTY:GENESEE
NEXT STATEMENT DUE DATE:
JURISDICTION:NEW YORK, UNITED STATES
NFP CATEGORY:CHARITABLE

?

ENTITY DISPLAY

NAME HISTORY

FILING HISTORY

MERGER HISTORY

ASSUMED NAME HISTORY

?

Service of Process Name and Address

Name:UNITED MEMORIAL MEDICAL CENTER C/O ROCHESTER REGIONAL HEALTH
Address:SYSTEM; ATTN: GENERAL COUNSEL, 89 GENESEE STREET, ROCHESTER, NY, UNITED STATES, 14611

EXHIBIT

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NEW YORK STATE OF OPPORTUNITY. Department of Health

ANDREW M. CUOMO
Governor

HOWARD A. ZUCKER, M.D., J.D.
Commissioner

LISA J. PINO, M.A., J.D.
Executive Deputy Commissioner

July 23, 2020

Deborah Conrad, PA-C
2638 Pearl Street Road
Corfu, New York 14036

Dear Ms. Conrad:

The New York State Society of Physician Assistants has recommended you 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. The Board is also responsible for ensuring that the disciplinary process is correctly perceived as being fair and effective by both physicians and the public.

It is important that the Board be representative of the population it serves and that its members meet the high standards demanded by the significant nature of their work. Therefore, several factors are taken into consideration when reviewing candidates for possible appointment to the Board. Among these are: the need for various specialties and/or professions, proper geographic representation, ability to meet service requirements, as well as other variables required to insure a well-proportioned Board. Submission of an application does not assure appointment. The application is considered at several levels.

You will be considered as a Lay Member Candidate. Please ask the NYSSPA to provide you with a letter of reference and you will need one letter of reference from a non-relative which supports your character and competence to serve on the Board. This letter should indicate the relationship between you and the individual providing the reference.

Thank you for your interest in becoming a board member and providing your Curriculum Vitae. Please complete and forward the enclosed application and Curriculum Vitae Summary forms. Upon receipt of the information requested, your application will be processed, and you will be considered for appointment.

Please understand that the review and appointment process is a lengthy procedure, which culminates with an appointment by the New York State Commissioner of Health. This process frequently takes a significant amount of time and COVID has slowed things down.

If you have any questions concerning your nomination or the Board for Professional Medical Conduct

EXHIBIT
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ROCHESTER REGIONAL HEALTH | UNITED MEMORIAL MEDICAL CENTER
127 North St | Batavia, NY 14020
P 585.343.6030 | rochesterregional.org

April 6, 2021

Dear Deborah Conrad, PA,

We members of the United Memorial Medical Center Board of Directors applaud your nomination for the **2021 Diane C. London Physician Excellence Award.**

Your hard work, skill, and dedication during one of the most difficult years of this hospital's history brought hope and healing to our patients, our community, and our hospital teams. Your passion to improve quality, facilitate teamwork, and deliver outstanding compassionate care—in the tradition of Diane London, MD—helped elevate United Memorial to an extraordinary level of excellence.

Every year, United Memorial surveys employees and medical staff for nominations. That you were so recognized shows your colleagues' deep respect and appreciation. The UMMC Board of Directors then reviews the nominations and selects an honoree—this year Jennifer Griffith, MD. It is always hard to single out one doctor when so many, like you, embody excellence.

So please, know how profoundly we honor your great role in our health care mission, and accept this Certificate of Recognition as a heartfelt gesture of thanks.

Sincerely,

Mark C. Schoell
United Memorial Medical Center Board Chair

EXHIBIT
4

appointment process, please email me or contact me at 518-402-6718. Your interest in ensuring quality medical care in New York State is appreciated.

Sincerely,

Michael S. Jakubowski, MD
Interim Executive Secretary
Office of Professional Medical Conduct
michael.jakubowski@health.ny.gov

MSJ/df
Encl.

From: Con ad, Debo ah
Sent: 5/28/202 2:3 :0 PM
To: "debcpa28@aol.com" <debcpa28@aol.com>
Cc:
Subject: RE: vacc nat on s de effect follow up

EXHIBIT 5

From: Conrad, Deborah
Sent: Thursday, April 15, 2021 10:13 PM
To: Notebaert, Danielle
Subject: Re: vaccination side effect follow up

Danielle,

That MRN brings me to a 27 yr old female. I don't see a guy in the ICU for alcohol withdrawal just one with rapid atrial fib. Any other identifiers? Thanks, Deb

From: Notebaert, Danielle
Sent: Thursday, April 15, 2021 1:40 PM
To: Conrad, Deborah
Subject: RE: vaccination side effect follow up

My guy yesterday was [redacted]
I didn't think to ask [redacted] the vaccine he got- assume he isstill in ICU

It would help if there was a box in CC that would capture this at some point- like a screen question similar to abuse/SUD/ HIV screen etc
You could even run a report based on it
It requires an RFC and not sure where it would be required
In the ED advisory last week we discussed something regarding vaccines and they said no way could triage ask another question!

From: Conrad, Deborah
Sent: Thursday, April 15, 2021 1:32 PM
To: Notebaert, Danielle
Subject: Re: vaccination side effect follow up

Hi Danielle, Yes I am still religiously reporting. We are at 50 cases and 4 possible deaths at UMMC reported to VAERS alone in 4 weeks. It is not our job to determine any possible cause/effect, that ultimately is the job of the FDA and CDC. However, without data full transparency will never be truly known. I am still trying to bring awareness to the system as to mandatory reporting requirement by law. If we fail to ask pts coming in with acute medical problems if/when they had their covid 19 vaccines we cannot capture data for VAERS/CDC and the FDA. The system tells me they are not seeing this except for at UMMC and I know it is because people are not asking pts and no one is therefore reporting anything because there is no awareness of the need to report. This is happening in buffalo as well. I have colleagues in buffalo who are seeing the same thing as us at UMMC including cases of covid 19 despite vaccination, however they have no system in place to report these cases to VAERS, therefore they go unreported.

Please continue to bring awareness to ER staff and keep notifying me of possible pts either by email or directly in the envelope. If you can have nursing get which vaccine, lot number and date of vaccine it will save me a lot of phone calls. Thank you! Deb

Below is an example of an email I recently sent to system leaders of quality to bring awareness to this issue. The attachment is for fully licensed vaccines not under EUA but is an example of known possible side effects seen in the past.

Thank you all for your response and maybe I can help clarify some things. With the massive vaccine roll-out across the US (and the world)

Pfizer's emergency use authorization document alone explains that a minimum time frame for monitoring for immune mediated adverse side effects should be 6 weeks as these adverse events usually show up within 6 weeks of vaccine receipt. The problem is there is very little awareness that all providers/nursing should be asking pts who are coming in with new acute issues (dvt/pe, covid 19 infection, b/l pneumonia/MI/stroke/thrombocyopenia/seizure) when/if they received their covid 19 vaccination to identify and therefore report pts who are in this minimum time-frame of 6 weeks. VAERS is a passive reporting system which the FDA uses to decide on safety issues surrounding a drug, vaccine or product that is either under EUA or on the market. Despite it being mandatory by law to report these issues, if the question is not asked of the pt the data will never be captured. Of the 50 cases now reported at UMMC none of them would of been known about or reported had I not reached out to our ER providers, nurses, hospital staff, etc to be asking pts and notifying me so I can report them to VAERS. One of the things all of us providers are taught is when a pt is admitted for an acute medical issue it is important to ask if they are taking a new drug, supplement or substance. Why then are we are not being encouraged to ask the same question about a vaccination that is out on an emergency use basis?
Below is right from the VAERS website on what we should be doing and what is required in regards to reporting issues post covid 19 vaccination:

Healthcare providers are required by law to report to VAERS the following adverse events after COVID-19 vaccination [under Emergency Use Authorization (EUA)], and other adverse events if later revised by CDC:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
- Death;
- A life-threatening AE;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- 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.
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers are required by law to report to VAERS:

- Any adverse event listed in the VAERS Table of Reportable Events Following Vaccination that occurs within the specified time period after vaccinations
- An adverse event listed by the vaccine manufacturer as a contraindication to further doses of the vaccine

Healthcare providers are strongly encouraged to report to VAERS:

- Any adverse event that occurs 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
- Vaccine administration errors

Please note, it is not our job to determine a cause and effect relationship if any, this is the job of the FDA. However, the FDA cannot do their job and due diligence to the safety of all if we do not ask the questions and report these patients. I have plenty of patient scenarios to provide as examples. I have had 5 patient's alone coming in with new unprovoked DVT or PE within that 6 week time frame of the vaccine, or new stroke, bleed, autoimmune hepatitis, sudden b/l pneumonia or covid 19 infection,syncope with head injury, STEMI, new arrhythmia, new seizure disorder, new choreaform movement disorder, etc. The other day I had 4 pts alone who came in with sudden b/l pneumonia within a week of their vaccination. It is not my job to determine any cause/effect but it is our duty to society that we recognize these patients and report these cases to the appropriate agency. Children below age 16 are the next in line, and as a mom I want true transparency as to safety data in adults before these are rolled out to children.
As covid 19 vaccination is under EUA, possible cause and effect has NOT been established yet. I am asking that as a system we make all healthcare providers/nursing staff aware of the need to ask the question and report to VAERS or send the information to myself so I can report to VAERS for the said pt. I am willing to step up for the system to be the main person who does the reporting and am not asking for compensation for my time. I usually just need the pts name or MRN, the date of vaccination, which vaccination and the Lot number which will minimize the need to call the pt to get this data. Once the awareness gets out I guarantee you, you will see what we are seeing at UMMC in other hospitals across the system. It is sad that when I bring up VAERS reporting to patients and to medical providers that so many have no idea what I am talking about. The attachment is the table of reportable events and time-frame following fully liscened and approved vaccines on the market. Why, then are we shocked to recognize and report possible acute/long term issues with these new vaccines that are under emergency use?

Thank You, Deb

Sent: Thursday, April 15, 2021 1:11 PM
To: Conrad, Deborah
Subject: RE: vaccination side effect follow up

Are yo still collecting or are individuals reporting now?
I think the guy I put in icu yesterday for etoh withdrawal might qualify

From: Conrad, Deborah >
Sent: Tuesday, March 23, 2021 6:54 PM
To: Notebaert, Danielle >
Subject: vaccination side effect follow up

Hi there! I have left envelopes in the ER and fast tract for providers to leave a demographic sheet and/or dates of vaccinations on pts with suspected covid 19 vaccine reactions/adverse side effects or suspicious new medical conditions post vaccination for me to pick up weekly to report to vaers until we get a better system in place for reporting. Keep in mind that adverse side effects can be seen up to 6 weeks following vaccination and up to 2 months or longer according to the emergency use authorization and longer term data is unknown.

This is directly from VAERS and the FDA. So if someone has their vaccine and comes in 2 weeks later with a sudden stemi it could be plausibly linked with the vaccine. They are looking for trends in disease patterns following vaccination blood clots, MI's, GI issues. Interestingly more MI's , CVA's and appendicitis were seen in the vaccine arm vs the placebo arm in Pfizer in the 22,000 subjects followed in the trial.

Interestingly vaccination following known infection with covid seems to have an increased risk of more severe side effects esp if it is done soon after recovery.

Testing positive for covid post vaccination is also reportable.

Healthcare providers are required to report to VAERS the following adverse events after COVID-19 vaccination [under Emergency Use Authorization (EUA)], and other adverse events if later revised by CDC

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:

- Death;
- A life-threatening AE;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- 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.

- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.

Directly from Pfizers EUA "adverse events considered plausibly linked to vaccination generally START within 6 weeks of vaccine receipt. Therefore a 2 month follow up period may allow for identification of potential immune medicated adverse events that began within 6 weeks of vaccination. The EUA should include a plan for active follow up for safety (including deaths, hospitalizations, and other serious or clinically significant adverse events) among individuals administered the vaccine under an EUA in order to inform ongoing benefit-risk review and assessment to support continuation of the EUA.

Most people have no idea that this is happening or to even ask pts about when they were vaccinated. Please make the ER staff aware of this so the nurses, aides and providers can help with collecting the data.

Thank you! Deb

From: "debcpa28@aol.com"
Sent: 5/30/2021 12:04:31 PM
To: "Elizabeth Brehm" <ebrehm@sirillp.com>
Cc:
Bcc:
Subject: Fw: Question on reporting vaccine reactions

— Forwarded Message —
From: Conrad, Deborah <dconrad@ummc.org>
To: debcpa28@aol.com <debcpa28@aol.com>
Sent: Saturday, May 29, 2021, 12:57:27 PM EDT
Subject: Fw: Question on reporting vaccine reactions

From: Gellasch, Tara
Sent: Tuesday, March 23, 2021 6:44 PM
To: Conrad, Deborah
Subject: Re: Question on reporting vaccine reactions

have not and I did ask a second time. Let me try one last time

Sent from my iPhone

On Mar 23, 2021, at 6:43 PM, Conrad, Deborah <dconrad@ummc.org> wrote:

Hi Tara, I was wondering if you heard back from Dr Bhavsar any information about system reporting of possible adverse events/reactions following covid 19 vaccination. I have now reported 2 deaths possibly related to the vaccines. Nearly every day I am reporting cases to Vaers with some cases additionally being reported to Pfizer and moderna as well. I have left envelopes in the ER and fast track to try to capture some of the cases as well. Adverse reactions do not necessarily occur right after an can be seen up to 6 weeks to 2 months or longer and anything suspicious should be reported. Its a daunting task and I usually stay at the end of my shift to do it. Thanks Deb

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From: Gellasch, Tara
Sent: Friday, March 12, 2021 10:54 AM
To: Conrad, Deborah; Ireland, Dan; Notebaert, Danielle
Subject: RE: Question on reporting vaccine reactions

Thank you Deb for bringing this to our attention. Let me reach out the Dr. Bhavsar to see if there are folks looking at this from a system level who we can connect you too.

From: Conrad, Deborah <dconrad@ummc.org>
Sent: Friday, March 12, 2021 10:45 AM
To: Gellasch, Tara <tgellasch@ummc.org>; Ireland, Dan <direland@ummc.org>; Notebaert, Danielle <dnotebaert@ummc.org>
Subject: Question on reporting vaccine reactions

Hi to you both. In the last month or so we have been admitting a fairly large amount of patient's who are having adverse side effects after getting their covid 19 vaccines. These are happening either the day of or the day after and sometimes 4-5 days after with pts reporting that they were sick all week but didn't know to come in. None of these case have been reported to VAERS. I checked with the ER and the pts they are seeing in the ER for the same and they are not reporting these either. with an EUA where these vaccines are not fully licensed or approved full transparency and all vaccine reactions are reported to VAERS. We have no protocol or guidance on how to do this for hospital systems. My sister who works in an ICU in buffalo is seeing these same reactions and they are not being reported to VAERS as they are not told they don't have to and have no protocol either. Some of these have been quite serious- one with a brain bleed and one who died from multifocal pneumonia 2 days after her second dose. In the last month I have known of or taken care of 10-15 pts with issues related to the vaccines. I have called VAERS and emailed them with no response on how to proceed and make the process easier for hospital systems. studies have shown that 90% of vaccine reactions go unreported. Give again that these vaccines are under EUA full transparency is imperative. I am willing to take this project on myself and be the person whom providers from the ER and the hospital report cases to so I can get them reported to VAERS. My very healthy best friend just suffered a severe autoimmune reaction after receiving the Johnson and Johnson vaccine so I have some interest in this project. As you all know I am very passionate about always doing the right thing and putting patient care first which is why I am so passionate about this project. These are happening way to frequently for them to just be considered "coincidences."

Thank you, I am interested in starting this right away as I have been keeping a log of some of the instances I know of.
Deb

EXHIBIT
6

From: "debcpa28@aol.com"
Sent: 4/15/2021 8:25:23 AM
To: "paul.richards@fda.hhs.gov" <paul.richards@fda.hhs.gov>
Cc:
Bcc:
Subject: High level VAERS reporting concern

To whom it may concern,

I am writing this email with high level importance regarding what I believe is gross under reporting of possible covid 19 vaccine related adverse events/side effects/possible immune mediated adverse events. I work in a small community hospital in Upstate New York and as a medical provider and professional have taken on the responsibility for my hospital of reporting to VAERS the significant influx of patients we are seeing in our emergency room and hospital wards in the past few months with new medical problems or sudden worsening of medical problems following covid 19 vaccination. In the last 4 weeks I have reported 50 cases to VAERS and 4 possible deaths. These are only the patients I have taken care of or who were brought to my attention by ER providers or some of my colleagues and I'm sure are not all. The only reason we are starting to capture these cases is I brought awareness to our hospital that the question needs to be asked of patients when they are coming in the ER if they have recently had their covid 19 vaccination and I have volunteered to be the person for now who reports cases to VAERS.
I do not feel that hospital systems were prepared or adequately notified of this possibility or how we should be managing it. There was no notification or training about who should be reported, what should be reported and how far out post vaccination that possible immune mediate adverse events would be seen. Pfizers EUA recommends a minimum of 6 weeks post vaccination to capture this data. VAERS notes that ANY hospitalization post vaccination, infection with covid 19, inability to perform daily functions, vaccine administration errors, deaths shou be reported and that reporting is MANDATORY. If it is mandatory then why was no education sent out to hospital systems and administrators??? I've contacted the FDA, Moderna, Pfizer, our DNV/hospital accrediting body, our state health department and many hospital system leaders and physicians in my state with either no answer in regards to how we deal with this issue or a complete unawareness that this is even necessary or mandatory. Had I not taken on this task none of these cases would of been reported to VAERS. Just yesterday we had it in the hospital for covid 19 infection despite being 3 weeks out from both vaccines and had a nurse not contacted me her case would of gone unreported. The safety of these vaccines for the public lies with a passive reporting system that is in place, but if hospital systems and medical providers are not educated on the importance of reporting, especially an EUA product, very large volumes of problems will go unreported and the vaccines could be fully licensed for use without complete and accurate information on possible immediate and long term side effects. I reported 5 patients with deep vein thrombosis/pulmonary emboli following vaccination with Pfizer/Moderna which is the same condition the pause is currently for with the J and J vaccine. I'm sure there are many more out there I am unaware of. I have contacted 2 large tertiary hospitals within 1 hr from us and there is no system for reporting in either. A colleague of mine is seeing the same thing in her hospital and cases upon cases of patients with acute strokes, myocardial infarction, blood clots, covid 19 infection, new autoimmune conditions arrhythmia, seizures/neurological conditions and bleeds are not being reported to VAERS or the drug companies. Every case of covid 19 is being recorded in the state but the question if infection is following vaccination is not even on the questionnaire, so the data will never be captured.
This is NOT true transparency and puts all Americans health and possible future health at risk.
Most physicians and nurses, health care staff don't even know that they should be asking patients who are getting admitted about their covid 19 vaccines and patients don't know that there possibly could be a link to their current acute medical problem and the vaccine. We will never know unless the data is captured. This issue must be addressed ASAP and I am pleading with the FDA to bring awareness of this to hospital systems as the FDA is responsible for protecting public health by ensuring the safety, efficacy and security of human and veterinary drugs, vaccines and other biological products for human use.

Thank you and I hope to hear a response soon,

Anonymous writer

EXHIBIT
7

From: debcpa28
Sent: 3/26/2021 6:16:32 AM
To: ayv6@cdc.gov
Cc:
Subject: Covid 19 Vaccine eventvreporting

Hi Tom, I wanted to bring to your attention that covid 19 vaccine data is not being consistently reported. I work in a hospital in New York and until I started reporting to vaers the daily admissions we are getting to the hospital following covid 19 vaccination of the public none were going reported. Hospital systems were not prepared for the amounts of pts presenting with problems post vaccination as we have never seen this before. I have contacted other physicians and health system leaders in the state and nearly all are unaware of the need to report these admitted pts. We are admitting syncope post vaccination, pneumonia, mi's, seizures, strokes, 2 poss related deaths, transamitits, pericarditis, wierd neurologic conditions, etc. These are either in the days following vaccination or few weeks after with no explanation. Please comment. I fear this is happening on a national level. Hospital systems were never notified of this possibility and who would be responsible for the reporting. Thanks Deb

Sent from my Verizon, Samsung Galaxy smartphone

EXHIBIT
8

From: Conrad, Deborah
Sent: 5/29/2021 12:53:58 PM
To: "debcpa28@aol.com" <debcpa28@aol.com>
Cc:
Subject: Fw: Vaccine-Induced Thrombosis Thrombocytopenia (VITT) Protocol

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From: Medical & Dental Staff Communication
Sent: Thursday, April 15, 2021 7:20 AM
To: Medical Staff Office
Subject: Vaccine-Induced Thrombosis Thrombocytopenia (VITT) Protocol

To: Rochester Regional Health MDS

From: Robert Mayo, MD, Chief Medical Officer, RRH
Hiloni Bhavsar, MD, Chief Quality Officer, RRH
Robert Sham, MD, Hematology/Oncology, RRH

Subject: **Vaccine-Induced Thrombosis Thrombocytopenia (VITT) Protocol**

April 15, 2021

We wanted to address concern surrounding the Johnson & Johnson (J&J) vaccine being associated with an autoimmune thrombosis that mimics heparin-induced thrombocytopenia similar to what has been seen with the AstraZeneca vaccine. This is considered very rare (approximately 6.85 million doses of the J&J vaccine have been administered in the US and 6 cases of this type of blood clot have been reported).

At this time, these cases seem to occur mostly in younger women who also develop moderate to severe thrombocytopenia with their thrombosis. The onset is between 4 to 20 days post-vaccination, and the venous thromboembolism usually occurs in an unusual site (cerebral venous thrombosis, splanchnic vein thrombosis).

If vaccine-induced thrombosis with thrombocytopenia (VITT) is suspected, please do the following:

1. Avoid all heparin/LMWH products
2. Obtain PF4 testing
3. Request hematology consultation immediately and start the following:
    a. Cautious anticoagulation with bivalirudin depending on the degree of thrombocytopenia and site of thrombosis
    b. IVIG 1 g/kg daily x 2 days

Also, please remember to input any adverse effects from the vaccine in the Vaccine Adverse Event Reporting System (VAERS).

For more information and talking points about the Johnson and Johnson vaccine and adverse effects, please check the COVID-19 toolkit under COVID-19 Vaccine Information.

EXHIBIT
9

From: "debcpa28@aol.com"
Sent: 5/30/2021 12:05:35 PM
To: "Elizabeth Brehm" <ebrehm@sirillp.com>
Cc:
Bcc:
Subject: Fw: Standards for hospital systems for mandatory reporting of possible vaccine adverse side effects

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— Forwarded Message —
From: Conrad, Deborah <dconrad@ummc.org>
To: debcpa28@aol.com <debcpa28@aol.com>
Sent: Saturday, May 29, 2021, 12:56:20 PM EDT
Subject: Fw: Standards for hospital systems for mandatory reporting of possible vaccine adverse side effects

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From: Conrad, Deborah
Sent: Friday, March 26, 2021 12:02 PM
To: Woodward, Tricia
Subject: Re: Standards for hospital systems for mandatory reporting of possible vaccine adverse side effects

Trisha, This is what I got back from VAERS as to what we are **REQUIRED** to report. Again according to the Pfizer EUA a **minimum** of 2 months post vaccination is recommended for surveillance as "adverse events plausibly linked to vaccination generally START within 6 weeks of vaccine receipt." This may be shocking for some people to accept but these are not like other vaccines we have ever worked with. I would love to be involved in the meetings on this as I have so much information to share and have personally talked with the FDA, Pfizer and Moderna. Thanks Deb

Healthcare providers are **required** to report to VAERS the following adverse events after COVID-19 vaccination [under Emergency Use Authorization (EUA)], and other adverse events if later revised by CDC:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
    1. Death;
    2. A life-threatening AE;
    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.
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Healthcare providers are encouraged to report to VAERS any additional clinically significant AEs following vaccination, even if they are not sure if vaccination caused the event.
Also report any additional select AEs and/or any revised safety reporting requirements per FDA's conditions of authorized use of vaccine(s) throughout the duration of any COVID-19 Vaccine being authorized under an Emergency Use Authorization (EUA).

From: Woodward, Tricia
Sent: Friday, March 26, 2021 9:07 AM
To: Conrad, Deborah
Subject: RE: Standards for hospital systems for mandatory reporting of possible vaccine adverse side effects

Deb,
Just wanted to update you on this:
I have been discussing this issue about reporting with Dr. Bhasvar, Shaw-Ree Chen (Director of Quality) and Dr. Gellasch and from the system group this work is in progress. They are identifying a way to educate and inform those who need to repor what needs to be completed for reporting purposes. I did not get a time of when this will happen but it is being worked on currently and hopefully will be done soon. I am happy to follow up with you and let you know any updates as I am made aware.
Thank you for bringing this forward.
Tricia

From: Woodward, Tricia <Tricia.Woodward@ummc.org>
Sent: Thursday, March 18, 2021 6:59 PM
To: Woodward, Tricia <Tricia.Woodward@rochesterregional.org>
Subject: FW: Standards for hospital systems for mandatory reporting of possible vaccine adverse side effects

EXHIBIT
10

From: Conrad, Deborah <dconrad@ummc.org>
Sent: Wednesday, March 17, 2021 9:02 AM
To: Woodward, Tricia <Tricia.Woodward@ummc.org>
Subject: Fw: Standards for hospital systems for mandatory reporting of possible vaccine adverse side effects

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From: Conrad, Deborah
Sent: Wednesday, March 17, 2021 8:11 AM
To: john.webster@dnv.com
Subject: Standards for hospital systems for mandatory reporting of possible vaccine adverse side effects

Hi John, To follow up on our call yesterday I was hoping you could provide me with the state mandatory hospital systems compliance requirements for reporting possible Covid 19 vaccine adverse side effects to VAERS and/or the vaccine manufacturers themselves. I spoke with the FDA and they told me that each state must have standards for hospital systems for reporting possible Covid 19 vaccine adverse side effects and to contact you for the information. Th FDA said that anyone hospitalized after vaccination for any reason even weeks out needs to be reported to VAERS as outlined in each emergency use authorization submitted by each vaccine manufacturer. Even if one does not think he issue may be related it should be submitted as they are looking for trends in disease patterns and activity following Covid 19 vaccination before the vaccines are fully licensed and approved. In the last month we have seen over a 50% increase in ER visits for STEMI. ?related to the vaccine or a coincidence? We have also admitted over 15 pts in the last month and a half with various acute issues either acutely following vaccination or shortly thereafter and none went reported to VAERS up until I took on this project. Much of our staff called in following vaccination due to side effects and none went reported which is considered a "serious" side effect per VAERS and the EUA's as "one was unable to perform normal, daily activities." I have spoken to some contacts in Rochester and Buffalo and it seems the same thing is happening elsewhere. If this issue goes unaddressed we may never have true transparency as to if here is any possible connection between various acute medical problems such as blood clots, new onset arrhythmia, syncope, cva's or heart attacks, etc possibly associated with covid 19 vaccination causing harm to more people down the road. This quote is directly from Pfizer's EUA "From a safety prospective, a 2 month median follow-up following completion of the full vaccination regimen will allow identification of potential adverse events that were not apparent in the immediate post-vaccination period. **Adverse events considered plausibly linked to vaccination generally start withing 6 weeks of vaccine receipt.** Therefore a 2 month follow-up period may allow for identification of potential immune-mediated adverse events that began within 6 weeks of vaccination. A 2-month follow up is the shortest follow-up period to achieve some confidence that any protection against Covid-19 is likely to be more than short-lived. The EUA request should include a plan for active follow up for safety (including deaths, hospitalizations, and other serious or clinically significant adverse effects) among individuals administered the vaccine under an EUA in order to inform ongoing benefit-risk review and assessment to support continuation of the EUA."

Thank You,
Deborah Conrad PA-C
UMMC Director of Advanced Practice Providers

Please Note: The information contained in this message may be privileged and confidential, protected from disclosure, and/or intended only for the use of the individual or entity named above. If the reader of this message is not the intended recipient, or an employee or agent responsible for delivering this message to the intended recipient, you are hereby notified that any dissemination, distribution or copying of this communication is strictly prohibited. If you have received this communication in error, please notify us immediately by replying to the message and deleting it from your computer. Thank you. Rochester Regional Health

From: Conrad, Deborah
Sent: 5/29/2021 12:52:23 PM
To: "debcpa28@aol.com" <debcpa28@aol.com>
Cc:
Subject: Fw: Cutaneous reactions reported after Moderna and Pfizer COVID-19 vaccination: A registry-based study of 414 cases

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From: Conrad, Deborah
Sent: Thursday, May 6, 2021 9:19 AM
To: Woodward, Tricia
Subject: Re: Cutaneous reactions reported after Moderna and Pfizer COVID-19 vaccination: A registry-based study of 414 cases

Trisha, Thank you for this. What I find most interesting is the admitted limitations of the registry and the fact that these cutaneous reactions mimic those same reactions seen in covid 19 infection. What concerns me the most of the pt data I've collected is I am seeing the same thing with other conditions. The same vascular sequela seen following covid 19 infection is being seen in some vaccinated subjects ie stroke, mi's, dvt/pe, link to new dm-1, etc. since the vaccine contains the antigen spike protein only, which is what is implicated in the known vascular/immune complications following covid 19 infection, how do we know when that same spike protein antigen is introduced in the body the same complications cant happen in some vaccine subjects?? the problem with the rapid development and roll out of these vaccines is they overlapped clinical phase trials/animal trials and greatly shortened the observation time after vaccination to roll them out to everyone under "emergency use." Other vaccines take 10-15 years to get through all the trial phases and animal phases before they are brought to full FDA approval. People don't realize that vaccines normally go through much more scrutiny than drugs do. However, rapidly skipping the known routine trial lengths can prove to be disastrous into the future as in my opinion nothing that is rushed turns out well, and many errors are discovered that would not have been missed had we taken our time. No matter how much I search I cannot find any finished phase 1 trial data on the animal models that were tested before we rolled them out to human trial subjects. Its because we overlapped the phases and the animal trials are not complete yet which is very scary considering what happened to the animal trial subjects in the past when we tried to come up with coronavirus vaccines. They never made it to human trials in all vaccine attempts tried! BYW I have references for all the info I have provided. I so wish someone would just take the time to listen to my concerns and understand that my motivation is in people's safety and especially our children's safety!! Thank you for being one of the few who are willing to hear my concerns. I haven't even began to tell you my concerns regarding fertility and syncytin 1 and 2. I just know I am right in what I am seeing. Its sad that many will be harmed in my opinion before this becomes fully transparent.
Deb

We additionally observed reactions to Moderna and Pfizer vaccines that had been noted after theSARS-CoV-2 infection itself, including pernio/chil-blains (eg, "COVID toes"), erythromelalgia, and pityriasis-rosea-like exanthems.3,8,9That these exan-thems mimic dermatologic manifestations of COVID-19 potentially suggests that (1) the host immuneresponse to the virus is being replicated bythe vaccine and (2) some components of these derma-tologic manifestations of the virus are likelyto befrom an immune response to the virus rather than direct viral effects.10,11Erythromelalgia and pityriasis rosea have been noted in response to other vaccines,such as those for influenza and hepatitis B, although not commonly.

From: Woodward, Tricia
Sent: Thursday, May 6, 2021 8:16 AM
To: Conrad, Deborah
Subject: FW: Cutaneous reactions reported after Moderna and Pfizer COVID-19 vaccination: A registry-based study of 414 cases

Just wanted to share.

Sent from my Verizon, Samsung Galaxy smartphone

-------- Original message --------
From: "Curtin, Raymond" <Raymond.Curtin@rochesterregional.org>
Date: 5/6/21 8:04 AM (GMT-05:00)
To: "Chen, Shaw-Ree" <Shaw-ree.Chen@rochesterregional.org>, "Adams, Robert (Pharmacy)" <Robert.Adams@rochesterregional.org>, "Anderson, Maria" <Maria.Anderson@rochesterregional.org>, "Atkinson, Jarrod" <Jarrod.Atkinson@rochesterregional.org>, "Balicki, Larry" <Larry.Balicki@rochesterregional.org>, "Bishop, Bryce" <Bryce.Bishop@rochesterregional.org>, "Carey, Jennifer" <Jennifer.Carey@rochesterregional.org>, "Caruso, Richard" <Richard.Caruso@rochesterregional.org>, "Clement, Ivonne" <Ivonne.Clement@rochesterregional.org>, "Della Rocco, James" <James.Della.Rocco@rochesterregional.org>, "Doyle, Maureen" <Maureen.Doyle@rochesterregional.org>, "El-Daher, Nayef" <Nayef.El-Daher@rochesterregional.org>, "Farnsworth, Donna" <Donna.Farnsworth@rochesterregional.org>, "Gales, Jennifer" <Jennifer.Gales@rochesterregional.org>, "Gintner, Alise" <Alise.Gintner@rochesterregional.org>, "Goosey, Michelle" <Michelle.Goosey@rochesterregional.org>, "Ince, Sevinc" <Sevinc.Ince@rochesterregional.org>, "Jones, Mary (UH, Director of Nursing)" <Mary.Jones@rochesterregional.org>, "Leonardi, Janice" <Janice.Leonardi@rochesterregional.org>, "Lopez, Katie" <Katie.Lopez@rochesterregional.org>, "Matos, Manuel (MD)" <mmatos@rochesterregional.org>, "Medeiros, Donna" <Donna.Medeiros@rochesterregional.org>, "Mothersell, Jeff" <Jeff.Mothersell@rochesterregional.org>, "O'Leary, Kathleen" <katie.oleary@rochesterregional.org>, "Pullano, Clare" <Clare.Pullano@rochesterregional.org>, "Scholl, Tami" <Tami.Scholl@rochesterregional.org>, "Scott, Jan" <Jan.Scott@rochesterregional.org>, "Stewart, Douglas" <Douglas.Stewart@rochesterregional.org>, "Vogl, Susan" <Sue.Vogl@rochesterregional.org>, "Wagner, Patti" <Patti.Wagner@rochesterregional.org>, "Welch, Amy" <Amy.Welch@rochesterregional.org>, "White, Shannon" <Shannon.White@rochesterregional.org>
Subject: Cutaneous reactions reported after Moderna and Pfizer COVID-19 vaccination: A registry-based study of 414 cases

Dear Colleagues,

Perhaps a talking point with a patient/friend/anyone reluctant that as of May 5 there have been **Total vaccination doses given globally so far:1,194,858,298.**

ORIGINAL ARTICLE| ARTICLES IN PRESS

Cutaneous reactions reported after Moderna and Pfizer COVID-19 vaccination: A registry-based study of 414 cases

- Devon E. McMahon, BA
- Erin Amerson, MD
- Misha Rosenbach, MD
-
- Kimberly G. Blumenthal, MD, MSc
- Lindy P. Fox, MD
- Esther E. Freeman, MD, PhD
- Show all authors

JAAD, Journal of the American Academy of Dermatology. Published: April 07, 2021.

From MedpageToday:
"The findings came from the COVID-19 Dermatology Registry, a joint effort of the American Academy of Dermatology (AAD) and the International League of Dermatologic Societies. They were discussed during the recent AAD virtual meeting and published simultaneously in the *Journal of the American Academy of Dermatology*.

"We have been involved with following skin reactions to COVID-19 vaccines, but the paper is pretty novel in that it covers a whole range of reactions that had not been reported from vaccine clinical trials," registry principal investigator Esther Freeman, MD, PhD, of Massachusetts General Hospital in Boston, told *MedPage Today*. "Understandably, the clinical trials were focused on their major endpoints and didn't really provide a lot of detail on the skin reactions seen in patients."

Established in March 2020 to accumulate information on cutaneous manifestations of COVID-19, the registry expanded in December to include vaccine-related skin reactions, shortly after the FDA issued the first emergency use authorizations (EUAs) for the vaccines. Registry participants collected information on the type and timing of vaccine doses and the morphology, timing, duration, and treatment of reactions."

Background
Cutaneous reactions after messenger RNA (mRNA)-based COVID-19 vaccines have been reported but are not well characterized.

Objective
To evaluate the morphology and timing of cutaneous reactions after mRNA COVID-19 vaccines.

Methods
A provider-facing registry-based study collected cases of cutaneous manifestations after COVID-19 vaccination.

Results
From December 2020 to February 2021, we recorded 414 cutaneous reactions to mRNA COVID-19 vaccines from Moderna (83%) and Pfizer (17%). Delayed large local reactions were most common, followed by local injection site reactions, urticarial eruptions, and morbilliform eruptions. Forty-three percent of patients with first-dose reactions experienced second-dose recurrence. Additional less common reactions included pernio/chilblains, cosmetic filler reactions, zoster, herpes simplex flares, and pityriasis rosea-like reactions.

Limitations
Registry analysis does not measure incidence. Morphologic misclassification is possible.

Conclusions
We report a spectrum of cutaneous reactions after mRNA COVID-19 vaccines. We observed some dermatologic reactions to Moderna and Pfizer vaccines that mimicked SARS-CoV-2 infection itself, such as pernio/chilblains. Most patients with first-dose reactions did not have a second-dose reaction and serious adverse events did not develop in any of the patients in the registry after the first or second dose. **Our data support that cutaneous reactions to COVID-19 vaccination are generally minor and self-limited, and should not discourage vaccination.**

Ray Curtin, Librarian
Unity Hospital Medical Library
The Unity Hospital of Rochester
1555 Long Pond Road
Rochester, NY 14626-4122
(585) 723-7755
Raymond.curtin@rochesterregional.org

RRH_Logo_CMYK (2)

From: "debcpa28@aol.com"
Sent: 5/30/2021 12:08:10 PM
To: "Elizabeth Brehm" <ebrehm@sirillp.com>
Cc:
Bcc:
Subject: Fw: Update on VAERS reporting for UMMC

— Forwarded Message —
From: Conrad, Deborah <dconrad@ummc.org>
To: debcpa28@aol.com <debcpa28@aol.com>
Sent: Saturday, May 29, 2021, 12:39:04 PM EDT
Subject: Fw: Update on VAERS reporting for UMMC

From: Conrad, Deborah
Sent: Tuesday, May 25, 2021 12:28 AM
To: Gellasch, Tara
Subject: Re: Update on VAERS reporting for UMMC

Hi Tara, Thank you for responding. This would be easier to discuss in person for sure. I am waiting for full clarification from the CDC and the FDA but I have no doubt that ER visits are included in the required reporting as are office visits and urgent care visits. This is required of other vaccines on the market so it should be the same with these. When I fill out the VAERS report it explicitly asks in the report if the pt was seen in a doctors office, emergency room or if they were hospitalized and their outcome -recovered, death, disability, etc.
In regards to what diagnosis to report, an EUA product is different than a fully approved and licensed product in that we do not know the short term and long term safety like we do for vaccines that go through the usual 10-15 years of study before they are brought to market and approved. We are the study, so ANY diagnosis is appropriate as VAERS/CDC and the FDA are looking for trends in disease patterns following vaccination and compare them to the general population to see if there is a correlation. The vaccine arm subjects were generally healthy people with little to no comorbidities and were not pregnant or planning to become pregnant, were not immunocompromized and were screened to be sure they never had covid 19 infection. This is not representative of the population that is now being vaccinated which is why Pfizer's EUA summary states that the "minimum requirement of reporting is 6 weeks following vaccination as immune mediated side effects/events usually occur within 6 weeks of vaccine receipt." They followed the trial participants for a minimum of 2 months before EUA. For the influenza vaccine, guillian barre is considered a vaccine related adverse event covered by the vaccine injury act if it happens within 6 months of vaccine receipt. Vaers lists the table of reportable events subject to compensation following fully licensed and approved vaccines and the time frame within which they occur. see attached. We do not know the reportable events yet as they are relying on us to report everything so they can sort the data out. Unfortunately noone gets compensated for their injury even if a link is found later and the vaccines get fully approved. You can only be compensated if you are vaccinated AFTER approval.
If we did not report ER or urgent care visits we would never capture data such as Bell's Palsy, syncope or miscarriage as these things usually do not get admitted and all were seen higher in the vaccine arm in the trials than placebo with the exception of miscarriage because the trials did not include pregnant women. Interestingly MI, strokes and appendicitis were also higher in the vaccine arm than placebo. I have reported 2 appendicitis cases if I remember.
For your other questions. I do not recal getting any email about reporting from RRH other than the one about the J and J pause and watching for blood clots/ITP or something. At the bottom it said remember to report to VAERS which was vague. If you have a different email that was sent please forward it to me. On an average day if you ask a physician or a nurse about VAERS they have no idea what you are talking about. The nurses did not get any emails about reporting when I asked them and most have no idea what VAERS is.
The reason we have so many reports from UMMC is because I alerted people myself and am doing the reporting. Other providers have taken notice of my documentation and have now started documenting themselves. It is not a task to be taken lightly as it requires a lot of paperwork and recurrent emails and follow up reports where you have to call the pt to see how they are doing, then update VAERS, etc. I also try to give all the patients their permanent VAERS number when I get it so they have it for their records. No one is going to want to do all this without compensation, so it doesn't get done otherwise which is why estimates are that only 1% of vaccine side effects go reported. I have no doubt this is fact. I have volunteered to do this task as a result of having 2 family members and my best friend come down with sudden illnesses following their vaccine(s) which have now permanently caused them damage. They are footing their own medical bills as a result. If we recognize other vaccines can cause injury which then gets compensated by a government fund set aside, why is it so hard to believe these can too? Don't we want to know for our kids future? The myocarditis issue is frankly terrifying. This is so rare in the young adult population and 2 dozen cases when we just started vaccinating that age group is unacceptable in my opinion. And those are just the ones reported, I'm sure there are more that weren't.
The other issue is that some of the docs/PAs in the ER or nurses will put the vaccine dates or info about recently getting the vaccine in their note but then the admitting provider will not include anything about it in the H and P so it doesn't get captured unless a nurse on the floor who knows I am reported tells me or leaves the demographic sheet in my drawer. Cause and effect is not our job to determine nor is figuring out which diagnosis or conditions should be included, its the job of the FDA to sort that out when they review all the data submitted. Without the data reported, however it will never be truly known. The many diagnosis I am reporting are being reported over and over again by other people across the nation and can be seen by just doing a search on VAERS. I am happy to set up a meeting to bring in my reports and discuss this further if needed. All I;m asking for is a clear email to nurses and providers the importance of VAERS and that I am doing the reporting and to reach out to me with any patients in the ER or admitted with new or sudden worsening of conditions at the minimum of 2 months of vaccine receipt. We had 4 admitted patients with covid 19 infection despite being fully vaccinated that would of never been captured if the nurses didn't let me know about them. Whether they required oxygen or icu care is irrelevant as neither do many unvaccinated covid positive patients who have pneumonia on cxr. The providers admitting them didn't even ask about the vaccines. Noone seems to know what to do which has been my argument with the FDA and the CDC for months across my many emails and discussions with them. They never alerted us to what we were supposed to be doing when these patients show up in our offices, ERs and urgent cares and hospitals. I talk to many outside physicians and they are seeing the same issues in their office and some have starting doing reporting to VAERS as a result.
Let me know if you still want to set up a meeting or if this clarifies things better. I will let you know if I hear back from the FDA or the CDC.
Thanks as always for hearing my concerns! And as always sorry for the long email.
Deb

From: Gellasch, Tara
Sent: Monday, May 24, 2021 2:17 PM

Subject: RE: Update on VAERS reporting for UMMC

Hi Deb,
Thank you for sharing your concerns. I completely agree with your assessment that we must report to VAERS per their guidance. What I see from VAERS (and what RRH has previously sent out to providers) is the following guidance:

Healthcare providers are **required** to report to VAERS the following adverse events after COVID-19 vaccination [under Emergency Use Authorization (EUA)], and other adverse events if later revised by CDC:

- Vaccine administration errors, whether or not associated with an adverse event (AE)
- Serious AEs regardless of causality. Serious AEs per FDA are defined as:
    1. Death;
    2. A life-threatening AE;
    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.
- Cases of Multisystem Inflammatory Syndrome
- Cases of COVID-19 that result in hospitalization or death

Comments in your email below suggest you have been using broader criteria for reporting. Can you please share that criteria? For example, you mention ED visits which I do not see listed as reportable to VAERS unless of course one of the other criteria is met during that visit. Additionally miscarriages are not listed above but you mention them as reportable.

There appear to be 2 issues: 1. Are we appropriately reporting per VAERS guidance? and 2. Do we think we are seeing a safety issue within our hospital? In terms of #1 RRH has previously encouraged reporting based on the guidance above. The guidance leaves wiggle room for interpretation but as an organization we are doing this and we have provided information to our providers/teams regarding the process. In terms of #2 – as with any quality/safety concern we should complete an internal review and escalate our findings (positive or negative) to the appropriate entities. I have spoken with Pete and I would like us to internally review the cases you have identified, in particular the deaths. Can you please share your list of reportec patients (maybe highlighting the deaths)?

I have reached out directly to Dr. Lesho as it sounds like he may have some perspective on what is happening across RRH. Once you have shared the patient list I would like to schedule a meeting with you, Pete, Jess and myself to review.
Thank you for your diligence. I know you want to make sure we compliant with the law and doing our best for our patients.
Have a great day!
Tara

From: Conrad, Deborah <dconrad@ummc.org>
Sent: Monday, May 24, 2021 10:13 AM
To: Ireland, Dan <direland@ummc.org>; Patnode, Jessica <jpatnode@ummc.org>; Gellasch, Tara <tgellasch@ummc.org>; Janes, Peter <pjanes@ummc.org>; Notebaert, Danielle <dnotebaert@ummc.org>; Spence, Wendy <wspence@ummc.org>; Woodward, Tricia <Tricia.Woodward@rochesterregional.org>; Crossett, Crystal <ccrossett@ummc.org>
Subject: Update on VAERS reporting for UMMC

Hi all! As of this writing since I started this project there have now been at least 75 reports to VAERS including 6 deaths from United Memorial's ER and hospitalized patients. I have also sent the reports to each vaccine manufacturer, a surprisingly they do not have anything to do with VAERS and each manufacturer requires their own form filled out. I have been tracking since mid February and the importance of transparency to our community cannot be stressed enough. Every patient and family affected has been so grateful for the work I am doing. I am asking that we stress to the medical staff and nurses the importance of alerting me to patients coming into the ER or admitted up to 2 months a the minimum following their covid vaccines with: sudden death/cardiac arrest, new stroke, MI, first trimester miscarriage, new onset heart failure, pericarditis/myocarditis, seizure, new neurological conditions, new atrial fib, covid 19 infection especially, brain bleeds, new thrombocytopenia, syncope, blood clots, sudden sepsis, appendicitis, bells palsy and unusual rashes. These by far are the most common things being seen. I find it very interesting that the same complications we see after covid 19 infection we are seeing in some patients after vaccination.
I plan at some point to do a spread sheet comparing the conditions/time frame/age/etc of the data collected. I will be sharing my data with Dr Lesho from RGH who is also collecting data and working with me.
I just got word that since reducing the recommended age for vaccination to 12 yrs old the CDC and VAERS are now receiving reports of new myocarditis and heart problems in several dozen teenagers and young adults after vaccination which seem to occur in males more than females 4 or more days after the second dose. Myocarditis occurs in <1%/100,000 in these age goups in the general population/year.
I am in contact with the CDC/vaccine manufacturers and the FDA on a weekly basis and talk with VAERS representatives all the time. I am asking if any of these young adults come through the ER that their face sheets go in the envelopes in the ER and fast track or that I am alerted by email, phone or secure chat.
It is our duty to be advocates for these often terrified patients and parents looking for answers. Their VAERS case number gives them documentation and validation of their potential injury and is the least we can do to thank them for their sacrifice to help humanity as there will be no compensation for them under the national vaccine injury compensation program because these vaccines are voluntary and under emergency use authorization, however any causation determined by the FDA if fully approved in the future will allow for those vaccinated after approval to be eligible for compensation.
We as health care providers are required **by law** to report these cases. It is not our job to determine cause and effect or manipulate, eliminate or withhold data, but it is our legal obligation to report any ER visits or hospitalizations following vaccination regardless of belief of causation or outcome. We must ensure true transparency surrounding a product that is still under only emergency use and is not fully approved by the FDA, so that we may all know if the benefits of these vaccines really outweigh the risks and that they are truly safe and effective for all and not just certain groups. Some countries are starting to limit some of the vaccines to certain age groups and have permanently suspended use of some, having recognized that the benefits do not always outweigh the risks in all age groups and individuals across all vaccines out on emergency use.
Helping to collect this data and informing the proper organizations of these trends will help to ensure those with the most benefit will receive vaccination while those at greater risk of side effects will understand those risks and make an informed decision on their own health, allowing us to better serve our community as a whole.
I am asking that an email go out to the medical staff and nursing staff to alert them of what I am seeing and that the patient's Lot numbers, type of vaccine and date of vaccines are documented in the chart to make it easier to do the reporting in a timely manner. Mandatory reporting of adverse reactions to the vaccines can be an overwhelming and daunting task with the abundance of cases we are currently seeing, but with a united front and goal being the safety ar well being of our patients, I believe we can efficiently adhere to the law mandated task assigned to all of us for our community. We are required to report by law.
I have attached links to references expressing our legal obligation to reporting the vaccine.
Thank you everyone for your time and sorry for the long e-mail.

ttp://www.acog.org/education-and-events/publications/liability-and-adverse-event-reporting-vaers

ttps://vaers.hhs.gov/reportevent.html

ttps://vaers.hhs.gov/faq.html

ttps://www.nejm.org/doi/full/10.1056/NEJMp2034438

From: Con ad, Debo ah
Sent: 6/8/202 6:3 :04 AM
To: "debcpa28@aol.com" <debcpa28@aol.com>
Cc:
Subject: Fw: add t onal comment on epo t ng

EXHIBIT 13

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rom: Co ad, Debo a
ent: Tuesday, May 25, 202 2 05 M
o: Ge asc , Ta a
ubject: Re add o a comme o epo g

a a, OK so a have ound 7 deaths have 4 othe s that we e t ans e ed to othe hospita s so need to ook into thei outcome and i they u timate y expi ed
[redacted] eviewed this case with D Conno y who ag eed the vaccine cou d o had something to do with he death

[redacted] dont have his MRN numbe He was P ize STEM p og essed to mu tio gan ai u e/ b/ pna i emembe He was not my pt but in the e i think

[redacted] He was a Mode na coded in the ER, seve e sepsis/shock/ ena ai u e etc 48h s post vax was in his no ma state o hea th p io spoke to the daughte to con i m eve ything be o e did the epo t as he was ot my pt

[redacted] mode na 2nd dose on 4/16 came in with wo sening sob a day o so ate , i emembe he coded sudden y and died on the oo the night o admission

[redacted] 94 y o d 2nd vac 4/1 came in 4/16 i be ieve with poo po intake, dia hea x 3 days and inc eased con usion and weakness she came in with a NSTEM , encepha opathy and weakness Daughte did a mo st an he expi ed du ing he stay

[redacted] high unctioning 97 y o d om home came in o non t aumatic SAH, seve e sepsis and b/ pneumonia on 3/25 she had had he and vaccine on 3/5 the ami y made he com o t ca e and she expi ed 3/28

[redacted] 1/9/47 He was a comp icated pt su e ed a st oke 2 weeks o owing his vaccine at home then came in 2 weeks ate with atigue thought due to ecent y being sta ted on a etany patch, comp icated hospita stay but i timate y extended the st oke to a massive one and we p aced him on com o t ca e and he expi ed in the hospita

Anothe one to ook at is

[redacted] 97 y o d did save him om what thought was a most ce tain death but i m not su e he won t expi e in the coming weeks a te discha ge to d the son to keep in touch with me

[redacted] i e has been pe manent y changed 50 y o d with an acute st oke 2 weeks o owing his J and p etty hea thy othe than cont o ed HTN o which he took hctz and obesity He is a machinist He now cant speak we and has exp essiv iphasia and memo y de icits i ta ked to his wi e the othe day [redacted]

[redacted] p evious y hea thy othe than cont o ed HTN, u y unctiona 72 y o d eceived he 2nd mode na vaccine on 4/15 hospita ized 4/18 with a a ge L tha amic c yptogenic st oke, sepsis, acute bacte emia, encepha opathy and actic acidosis She is now pe manent y disab ed with memo y and unctiona de icits

have soo many mo e pts ust ike this

[redacted] with b east cance on chemo u y vaccinated on 3/23 came in 4/20 with covid 19 pneumonia and seve e sepsis p ot acted hospita ization but we pu ed he th ough with a ot o ove and hugs

[redacted] been a pt at ummc o yea s and know him and his wi e we 2nd vaccine 3/19 not ight since pe wi e saw pcp who p esc ibed ste oids o pna no imp as o 3/25 admitted to st ong on 3/31 o b/ pna and uti dc d hom /3 eadmitted 4/26 with idiopathic panc eatitis

have so many mo e and cou d w ite a day t is not ou ob to dete mine i the e is any connection he e, it is the ob o the gove ning bodies who a e supposed to be ooking a te ou hea th and p otecting us om unsa e p oducts they cannot do hei ob i we do not epo t This is ou duty ust ike epo ting chi d abuse we do not make the dete mination, we epo t a suspicion and et CPS make the dete mination
ta ked to the cdc today and they said yes any e /u gent ca e visit/hospita ization o docto s visit must be epo ted any and a new o sudden wo sening o conditions shou d be epo ted inc uding misca iages The e a e a eady nea y 2000 nisca iages epo ted ast checked They a e getting back to me about the ecommended time ame but i eminded them that they app oved the EUAs that stated the minimum was 6 weeks to 2 months
3TW the news today ust epo ted 16 cases o myoca ditis coming out o the state o Conneticut in adu ts, epo ted to vae s o owing thei vaccines VAERS has a 3 4 week back og and we a e a eady at 230,000 epo ts and ove 5500 deaths
e ieve the ast checked We pu ed the H1N1 vaccine in 1976 a te ust 50 deaths
am wi ing to sha e mo e patient s with you The CDC is now making it even mo e di icu t to epo t and to d me today they wi now be asking o a copy o the vaccine ca d o each patient epo ted P obab y because they a e sca ed and cant e ieve what they a e seeing in my opinion o they a e pu pose y t ying to make this ha de than it a eady is was u ious with them today and to d them they keep adding new u es to make it ha de and ha de to epo t and sti no guidance o otice to hospita systems on the impo tance o epo ting o the pub ic s sa ety i know o ce tain that ess than 1% o vaccine eactions a e being epo ted, this is an impossib e task cannot be ieve they e eased EUA p oducts with no sho t o ong te m sa ety data without i st assu ing that they had an e icient system o epo ting in p ace and that hea thca e p ovide s we e p ope y in o med o thei ega ob igation to epo t and we e p ope y educated on what to epo t am waiting t ea back om someone highe in the chain o command doubt they wi ca me
Deb

rom: Ge asc , Ta a
ent: Tuesday, May 25, 202 7 27 AM
o: Co ad, Debo a
ubject: RE add o a comme o epo g

low abou we s a w you pu g e MRNs of e dea s you epo ed a d s a e em w me a d e e Does a wo k? ave ' ead fu y you o e ema bu w a e oday ☺

rom: Co ad, Debo a <dco ad@ummc o g>
ent: Tuesday, May 25, 202 7 25 AM
o: Ge asc , Ta a < ge asc @ummc o g>
ubject: add o a comme o epo g

a a, can eithe b ing in my packets o VAERS epo ts in with me to a meeting o send you some examp es w MRN numbe s o the patients A ew o them you wi see how ER documented ecent y eceiving a vaccine in thei note and then how it vas ost in documentation upon o a te admission We ust has a be s pa sy in the ER that D Noteba dt emai ed me about which epo ted
hank you,
)eb

From: Conrad, Deborah
Sent: 5/29/2021 12:36:50 PM
To: "debcpa28@aol.com" <debcpa28@aol.com>
Cc:
Subject: Fw: Follow up

From: Gellasch, Tara
Sent: Thursday, May 27, 2021 11:28 AM
To: Conrad, Deborah; Janes, Peter
Subject: Follow up

Hi Deb,
Just a quick email to follow up after our call today regarding VAERS reporting. Thank you again for taking time to speak to us during your day off. First, I want to acknowledge you have our full support in reporting to VAERS as indicated. Per our discussion, moving forward you will only report adverse events you encounter on your patients. If another provider sends you patient information and requests you file a report you will advise them they need to complete the report with VAERS themselves. If you have concerns another provider is not completing a VAERS report when it is indicated you will either complete a Safe Connect and/or bring that concern to Pete or myself.

Additionally, in your clinical role and as a leader in the organization you will support RRH's approach to the vaccine which is following CDC and DOH guidance.

As mentioned, I will be meeting with System incident command leaders specifically to discuss the RRH approach to VAERS reporting. Currently, VAERS reporting is the responsibility of the provider caring for the patient. If any changes are made in this approach you and our medical staff will be informed.

Thank you for your ongoing efforts to ensure our patients get the highest quality care and ensuring we are doing our best to keep them safe.
Have a great weekend!
Tara

Tara L. Gellasch, MD, MBA, FACOG
Chief Medical Officer
United Memorial Medical Center
Rochester Regional Health
gellasch@ummc.org
Cell: 585-260-4727
Office: 585-344-5413

From: Conrad, Deborah
Sent: 7/21/2021 10:13:25 PM
To: "debcpa28@aol.com" <debcpa28@aol.com>
Cc:
Subject: Fw: Potential Adverse Events Related to COVID-19 Vaccination

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rom: Medical & Dental Staff Communication
ent: Wednesday, June 2, 2021 7:43 AM
o: Medical Staff Office
ubject: Potential Adverse Events Related to COVID-19 Vaccination

o: Rochester Regional Health MDS

rom: Robert Mayo, MD, Chief Medical Officer, RRH
Hiloni Bhavsar, MD, Chief Quality Officer, RRH

E: Potential Adverse Events Related to COVID-19 Vaccination

ate: June 2, 2021

he New York State Department of Health recently issued an advisory about potential adverse events related to the COVID-19 vaccines for clinicians. A recent report from the U.S. Centers for Disease Control and Prevention (CDC's) Advisory Committee on mmunization Practices (ACIP) COVID-19 and Vaccine Safety Technical (VaST) workgroup found relatively few reports of myocarditis and pericarditis to date. In the few cases found they were:

- Predominantly in adolescents and young adults.
- More often in males than females.
- More often following the second dose.
- Typically within four days after vaccination.
- Most cases appear to be mild, and the condition often goes away without complications
- Can be caused by a variety of viruses

DC monitoring systems have **not** found more cases of myocarditis and pericarditis than would be expected in the population. For more information, please refer to the two articles from the CDC: "Clinical Considerations: Myocarditis and Pericarditis after Recei f mRNA COVID-19 Vaccines Among Adolescents and Young Adults" and "Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination -- What You Need to Know".

s a reminder, healthcare providers are **required** to report specific adverse reactions to the COVID-19 vaccine in VAERS and are encouraged to report any type of reaction they believe may be due to the vaccination. **To report an event, visit the VAERS website.**

n addition to the online reporting system, the CDC has a smartphone-based tool called V-safe. This tool is designed for vaccine recipients to report any adverse effects directly to the CDC. Information about V-Safe can be found on the COVID-19 toolkit.

EXHIBIT
15

From: "debcpa28@aol.com"
Sent: 5/3 /202 7:35:48 AM
To: "El zabeth B ehm" <eb ehm@s llp.com>
Cc:
Bcc:
Subject: Fw: un epo ted pt

— Forwarded Message —
From: Conrad Deborah <dconrad@ummc org>
To: debcpa28@aol com <debcpa28@aol com>
Sent: Monday May 31 2021 07 34 16 AM EDT
Subject: Fw unreported pt

From: Co ad, Debo a
Sent: Mo day, May 3 , 202 7 34 AM
To: Ge asc , Ta a
Subject: u epo ed p

\ u y vaccinated pt [redacted])who was ecent y hospita ized and discha ged who tested positive o covid 19 on admission has been b ought to my attention by an inte na hea thca e individua was to d the vaccination dates we e locumented by nu sing in the cha t The p ovide did not epo t this to VAERS and did not a e t ou in ection cont o nu se to epo t to the state o the pe son hand ing epo ting these cases to the state in ou system despite being awa e o the nee o do this want this case epo ted and want thei VAERS case numbe o my eco ds because now having know edge o this case and not epo ting it myse as have been inst ucted to do by the system, puts me in a position to knowing y vio at he aw

This is di ect y om the CDC website

Defining a vaccine breakthrough infection

o the pu pose o this su vei ance, a vaccine b eakth ough in ection is de ined as the detection o SARS CoV 2 RNA o antigen in a espi ato y specimen co ected om a **person ≥14 days after they have completed all recommended doses of a J.S. Food and Drug Administration (FDA)-authorized COV D-19 vaccine.**

dentifying and investigating hospitalized or fatal vaccine breakthrough cases

\s o May 1, 2021, CDC t ansitioned om monito ing a epo ted vaccine b eakth ough cases to ocus on identi ying and **investigating only hospitalized or fatal cases due to any cause.** This shi t wi he p maximize the qua ity o the data o ected on cases o g eatest c inica and pub ic hea th impo tance
evious data on a vaccine b eakth ough cases epo ted to CDC om Janua y Ap i 2021 a e avai ab e
itate health departments report vaccine breakthrough cases to CDC. CDC now monito s epo ted hospita ized o ata vaccine b eakth ough cases o c uste ing by patient demog aphics, geog aphic ocation, time since vaccination, vaccine typ ind SARS CoV 2 ineage **Reported data include hospitalized or fatal breakthrough cases due to any cause, including causes not related to COV D-19.**

ttps //www cdc gov/vaccines/covid 19/hea th depa tments/b eakth ough cases htm

lea thca e p ovide s a e **required** to epo t to VAERS the o owing adve se events a te COV D 19 vaccination unde Eme gency Use Autho ization (EUA)], and othe adve se events i ate evised by CDC

- Vaccine administ ation e o s, whethe o not associated with an adve se event (AE)
- Se ious AEs ega d ess o causa ity Se ious AEs pe FDA a e de ined as
  1 npatient hospita ization o p o ongation o existing hospita ization
- **Cases of COV D-19 that result in hospitalization or death**

EXHIBIT 16

From: "debcpa28@aol.com"
Sent: 6/25/202 6:52:45 AM
To: "eb ehm@s llp.com" <eb ehm@s llp.com>
Cc:
Bcc:
Subject: Fwd: pts need ng VAERS epo ts

—Original Message—
From Conrad Deborah <dconrad@ummc org>
To debcpa28@aol com <debcpa28@aol com>
Sent Fri Jun 25 2021 6 50 am
Subject Fw pts needing VAERS reports

From: Ge asc , Ta a
Sent: Mo day, Ju e 2 , 202 0 5 AM
To: Ja es, e e ; Co ad, Debo a
Subject: W p s eed g VAERS epo s

Hi Deb
Ultimately it is the overseeing provider s clinical decision on whether or not to report to VAERS Once you input a case into Safe Connect it will be reviewed and sent back to the responsible provider for consideration regarding reporting While the provider has an obligation to report per the VAERS website this is still based on the provider s clinical decision making From our prior discussions do understand you interpret the VAERS guidance broadly however after reviewing with RRH leadership and the Finger Lakes Vaccine hub this is not a universal interpretation

t would not be appropriate for us to share patient information with people who are not part of the care team f patient or families have concerns about an adverse reaction or VAERS reporting they can contact the hospital or their primary care provider Patients and family can also file their own VAERS report if they believe they have suffered an adverse event

know you have significant concerns about the vaccine and appreciate this is frustrating for you That said we need you to follow the process in place We cannot tell you how to interpret the VAERS guidance on reporting however we do expect you to respect that your viewpoint on what is reportable is not shared by all
Thank you
Tara

From: Conrad Deborah <dconrad@ummc org>
Sent: Wednesday June 16 2021 7 06 AM
To: Gellasch Tara <tgellasch@ummc org> Janes Peter <pjanes@ummc org>
Subject: pts needing VAERS reports

Hi Tara and Pete

At some point will try to put these in safe connect but the census has been so high lately haven't had the time
Here are pts that meet the VAERS reporting criteria who were not reported by their overseeing providers would greatly appreciate an email back letting me know they were reported so i don't worry as some of them spoke to already or their family when they were admitted whic was before our discussion and they are waiting for callbacks on their VAERS numbers for their records

Breakthrough Cases
[redacted] He had a few admissions He was fully vaccinated back in march believe and admitted 2 or 3 times since then for covid infection/pneumonia and he ultimately died a few weeks ago in our icu of covid

[redacted]- fully vaccinated with Moderna 3/29 and 4/28 and admitted for from 5/25-5/27 with sob due to chf and covid 19- she was treated with remdesivir and dexamethasone

covid pneumonia after 1 dose case

[redacted] -vaccinated 4/30- moderna- came in with covid pneumonia on 5/26

[redacted]- admitted 5/28 and still hospitalized for acute resp failure encephalopathy aki chf which ultimeately resulted in a protracted icu course resulting in intubation with sxs starting 1 week after her second covid vaccine moderna 4/16 lot 07C21A 5/14 33B21A the son felt she rapidly declined since her second vaccine

[redacted] presented to er with sepsis lactic acidosis hypotensive coded in the ER 6/15 and intubated and sent to rgh

[redacted] admitted 5/30 with acute stroke respiratory failure- placed on comfort care and sent back to the VA

[redacted] d Moderna 1/29/21 Lot 012M20A 2/26/21 Lot 014M20A

EXHIBIT
17

ER pts

[redacted] 13yr old c/o sob fatigue after getting her covid vaccine the day before

[redacted] presented to the ER 5/31 with left arm pain and induration in the arm she had the vaccine in

[redacted] -presented 5/5 to ER with syncope fevers chills myalgias and woke up syncopized on the floor

[redacted] presented to ER on 5/3 with 1 week of nausea diarrhea fever chills myalgias he was febrile and tachycardic CT scan showed prominent lymphadenopathy of the hepatis and peripancreatic area for which he is now pursuing work up as an out pt- this is my 3rd pt sudden adenopathy with this same thing shortly after vaccination

Thank You
Deb

From: Con ad, Debo ah
Sent: 6/25/202 8:25:55 AM
To: "debcpa28@aol.com" <debcpa28@aol.com>
Cc:
Subject: Fw: VAERS pts be ng epo ted

---

rom: Co ad, Debo a
ent: day, Ju e 25, 202 8 25 AM
o: Ge asc , Ta a; Ja es, e e
ubject: Re VAERS p s be g epo ed

a a, Un o tunate y have no time to put a these patients who meet the VAERS epo ting c ite ia that a e not being epo ted in sa e connect You di ected me to emai you and Pete about them or put them in sa e connect am too busy du ing the vo k week to do it and cannot access sa e connect om home Be ow again is what we a e equi ed as hea thca e p ovide s to epo t, it says nothing that it is up to inte p etation npatient hospita ization o owing covid 19 vaccination is onside ed a se ious sa ety event as a e cases o covid 19 o owing hospita ization o esu ting in death am not ove epo ting o inte p eting the VAERS guidance too b oad y as suggested t a so states that p ovide s a e encou aged to epo t ven i they don t think it may be due to the vaccine This is the ethica thing to do Why wou d the hospita not want to be t anspa ent with the FDA and the community we se ve? Each one o these VAERS epo ts ep esents a i e possib y ected negative y om the vaccines and they dese ve to have thei epo ts made We have 2 patients u y vaccinated who we e hospita ized and t eated o covid 19, one o which died
ou and Pete we e made awa e o these, we e they epo ted? These a e not open to inte p etation and c ea y a e e po tab e events A e you awa e that FEMA is o e ing a death bene it to ami ies i a patient possib y died om the vaccine?
hese VAERS epo ts suppo t the needed documentation o this

hat being said he e is a ist o additiona pts this past week b ought to my attention that need VAERS epo ts

[redacted] eceived Mode na vaccine 6/16 hospita ized with ep dist ess 6/18

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[redacted] New ca diac a hythmia Mode na

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[redacted] 2/8 and 3/1 p ize espi ato y ai u e

ou shou d know, the ast week wo k epo ted a 63 y o d with new onset type 1 diabetes o owing he vaccines The icu team ag eed with me this was epo tab e a so epo ted 2 men 1 day apa t with new seve e pancytopenia o owing thei node na vaccines one a so who had eukoc astic vascu itis, i don t doubt Leukoc astic vascu itis has been inked to the covid 19 vaccines have esea ch pape s on this The one has AML and the othe ike y does too and is now eadmitted at GH ighting o his i e That is not statistica y possib e to have 2 men with sudden pancytopenia ike y both om AML a day apa t, having had the same vaccines AML is ve y a e in the gene a popu ation a so epo ted a ady with seve e lia hea and weight oss and nausea with panco itis that stated sudden y 2 weeks a te he vaccine He patho ogy showed p ominent peye s patches which p oved an immune phenomenon was at p ay wou d ove to show you a copy o the P ize biodist ibution epo t on ats and mice and the many o gans whe e the vaccine m na and the spike p otein/bound to ACE2 concent ated at 48 h s This may he p to exp ain what we a e seeing now in umans have many a tic es discussing possib e immune mechanisms o the conditions we a e seeing o owing vaccination We e you awa e that the Hepatitis B vaccine is inked to type 1 diabetes in chi d en? have an esea ch a tic e on this e you awa e that covid 19 is causing new diabetes ? P ease ead my p og ess note on M s Shi ey Gaw ick, its ve y compe ing
am doing the ight thing o these patients and am not ove epo ting o inte p eting the VAERS c ite ia too b oad y and am ve y o ended and ho i ied that you o anyone e se wou d suggest that Not once has anyone asked to see my esea ch ow have 104 patients epo ted myse hea d nothing back om the audit you did on the patients you asked me to submit to you nstead o app auding my e o ts and the many unpaid hou s spent doing the ight thing o the patients o ou ommunity you a e vi i ying me o it

eb

nce again, di ect y om the VAERS website it states
ea thca e p ovide s a e **<u>required</u>** to epo t to VAERS the o owing adve se events a te COV D 19 vaccination unde Eme gency Use Autho ization (EUA)], and othe adve se events i ate evised by CD

-
- Se ious AEs ega d ess o causa ity Se ious AEs pe FDA a e de ined as
  1 Death;
  2 A i e th eatening AE;
  3 **<u>npatient hospitalization or prolongation of existing hospitalization</u>**;
  4 A pe sistent o signi icant incapacity o substantia dis uption o the abi ity to conduct no ma i e unctions;
  5 A congenita anoma y/bi th de ect;
  6 An impo tant medica event that based on app op iate medica udgement may eopa dize the individua and may equi e medica o su gica inte vention to p event one o the outcomes isted above
- Cases o Mu tisystem n ammato y Synd ome

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lea thca e p ovide s a e encou aged to epo t to VAERS any additiona c inica y signi icant AEs o owing vaccination, even i they a e not su e i vaccination caused the event

Siri | Glimstad

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June 28, 2021

VIA EMAIL AND FEDEX

Rochester Regional Health
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rmayo@rochesterregionalhealth.org

United Memorial Medical Center
Daniel Ireland, President
Dr. Tara Gellasch
Dr. Peter Janes
127 North Street Batavia
NY 14020
direland@ummc.org
tgellasch@ummc.org
pjanes@ummc.org

Re: *Underreporting to VAERS and NYSDOH of post-COVID-19 vaccine adverse events at Rochester Regional Health*

Dear Doctors Mayo, Gellasch, and Janes, and Mr. Ireland:

We write on behalf of our client, Deborah Conrad, a Physician Assistant at United Memorial Medical Center, a hospital within the Rochester Regional Health system (the "**Hospital**"). Ms. Conrad is in constant communication with patients and other hospital staff and has knowledge of numerous serious post-COVID-19 vaccine adverse events, including breakthrough cases and deaths, that have not been reported to either the Vaccine Adverse Events Reporting System ("**VAERS**") or the New York State Department of Health ("**NYSDOH**"). For the past few months, on her own time, Ms. Conrad has been assisting doctors and other medical professionals at the hospital to report such events to VAERS. Instead of praising her efforts, numerous individuals at the Hospital, including Tara Gellasch and Peter Janes, ordered Ms. Conrad to stop reporting to VAERS altogether unless the patient she was reporting on was her patient. Since being given this order, Ms. Conrad has knowledge of dozens patients whose conditions necessitate a VAERS report and whose treating nurses and doctors have not filed a VAERS report.

As you are likely aware, healthcare workers are mandated by federal law to report certain medical events arising after vaccination to VAERS. Pursuant to 42 U.S.C. § 300aa-25:

> Each health care provider and vaccine manufacturer **shall report** to the Secretary—

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> **(A)** the occurrence of any event set forth in the Vaccine Injury Table, 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.[1]

Additionally, pursuant to the Food and Drug Administration ("**FDA**"), all vaccine and healthcare providers "must report the following information associated with the administration of Pfizer-BioNTech COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death."[2]

"Serious adverse events" are defined by the FDA to include:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- 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.[3]

In addition to these mandated reports, healthcare providers are strongly encouraged to report to VAERS "*any adverse event that occurs after the administration of a vaccine* licensed in

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[1] https://www.law.cornell.edu/uscode/text/42/300aa-25 (emphasis added).

[2] https://www.fda.gov/media/144412/download; *see also* https://www.fda.gov/media/144636/download (same for Moderna), https://www.fda.gov/media/146303/download (same for Johnson & Johnson); https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html.

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

the United States, whether it is or is not clear that a vaccine caused the adverse event."[4] In the case of vaccines that are not yet FDA licensed and approved and are only in use whilst their clinical trials progress, pursuant to emergency use authorization, certainly as healthcare providers, you understand the importance of reporting all adverse events presenting to a hospital following vaccination.

When Ms. Conrad observed that serious adverse events directly following initial use of COVID-19 vaccinations were not being reported to VAERS, she volunteered to submit the necessary reports to VAERS on her colleagues' behalf. Ms. Conrad was doing so after her paid shifts ended because she understands the critical importance of the task. In response, the Hospital told Ms. Conrad they were going to audit the VAERS reports that Ms. Conrad submitted and that "in [her] clinical role and as a leader in the organization" she was to "support [the Hospital's] approach to the vaccine." Submitting VAERS reports for adverse events following vaccination should not be contrary to any "approach to the vaccine." It should be part of the Hospital's approach. It is alarming that the Hospital's "approach to the vaccines" has not included educating healthcare providers about VAERS and encouraging them to efficiently and consistently make reports. Contrary to this, healthcare providers at the Hospital are not being directed to ask patients about recent vaccination nor are they able to efficiently submit or track VAERS reports within the Hospital's electronic system. And it now appears they are being deterred from doing so.

As Ms. Conrad told the Hospital, she has personally treated five patients that presented with new, unprovoked deep vein thrombosis or pulmonary embolisms within 6 weeks of COVID-19 vaccination. She has also seen patients that, after receipt of COVID-19 vaccination, presented with a new stroke, bleed, autoimmune hepatitis, sudden bilateral pneumonia or COVID-19 infection, as well as syncope with head injury, STEMI, new arrhythmias, new seizure disorders, new chorea movement disorder, and more. In one day alone, Ms. Conrad had four patients with sudden bilateral pneumonia within a week of their COVID-19 vaccination. Ms. Conrad understands that it is not her responsibility to determine any causation but that it is her duty to report these instances to VAERS so that the FDA and CDC have adequate data by which to detect potential safety signals. The Hospital has prohibited Ms. Conrad from filing a VAERS reports for any of these serious events after COVID-19 vaccination unless she directly treats the patient.

In auditing the VAERS reports submitted by Ms. Conrad for a four-week period – totaling 50 adverse event reports, which includes 4 deaths – the Hospital's Chief Quality Officer, Hiloni Bhavsar stated that she has "not heard this level of reporting from anywhere else and didn't hear similar reports from URMC."

This is Ms. Conrad's precise concern: if she is not submitting the VAERS reports, they are not being submitted. The Hospital, through Ms. Gellasch, told Ms. Conrad: "we need to make sure we are providing a consistent message to our team and we need to make sure that that is also in alignment with what our health system is asking us to do."

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[4] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html (emphasis added).

The Hospital's conclusion was therefore, quizzically, that Ms. Conrad only be permitted to report to VAERS for her own patients:

> 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 …

Ms. Conrad reiterated that the reason she took this task on is because no one else wants to do it nor are they doing it. However, Ms. Gellasch 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 the report in… and we do need to follow how the system is approaching this currently.

When Ms. Conrad again explained why she has the concerns she has about underreporting, she was called an anti-vaxxer by Ms. Gellasch:

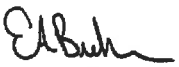
> I don't want us to go down any kind of rabbit hole here but the thing I think we need to be clear about and I am just going to be frank with you …in reading the few emails you sent me and reading the email that went out to the provider, it does come across a bit…uh very vaccine...ugh I won't say very 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.

Ms. Conrad voiced additional concerns of adverse events following the emergency use vaccines 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.

"Towing the company line" does not relieve the Hospital of its obligations. Please forthwith confirm that the Hospital's mission is consistent with taking all necessary steps to fulfill its legal and ethical obligations to report the mandated medical events following COVID-19 vaccination to VAERS pursuant to federal law, including: (i) educating the staff about their responsibility to report to VAERS, (ii) creating internal policies and procedures ensuring that VAERS reports will 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 repercussions or hostility.

Very truly yours,



Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Caroline Tucker, Esq.

ROCHESTER REGIONAL HEALTH | OFFICE OF COUNSEL
1360 Portland Ave
Rochester, NY 14621

July 14, 2021

Elizabeth A. Brehm, Esq.
Siri & Glimstad LLP
200 Park Ave #17
New York, NY 10166

Dear Ms. Brehm:

This letter responds to your written communication dated June 28, 2021 and addresses the serious allegations you have made against Rochester Regional Health and its healthcare providers relative to reporting adverse events following COVID-19 vaccinations to the Vaccine Adverse Event Reporting System (VAERS). As an initial matter, Rochester Regional Health ("RRH") takes its obligations to report adverse events related to the COVID-19 vaccination very seriously. RRH has developed and distributed robust educational and training tools to assist its healthcare providers in complying with their responsibility to report adverse events related to COVID-19 vaccinations, has issued multiple written communications outlining the requirements of its healthcare providers to report to VAERS specific adverse reactions to the COVID-19 vaccine, and has encouraged healthcare providers to ask questions and confer with their clinical leaders about their reporting obligations. RRH's senior leadership, Incident Command Team, and counsel's office are in routine communication with their Medical and Dental Staff members about reporting and have worked diligently to ensure that healthcare providers are educated on their reporting obligations. RRH has distributed educational materials published by the CDC outlining how and what to report, has encouraged use of the CDC's smartphone-based tool to report adverse events, has reminded providers to access RRH's internal COVID-19 toolkit resources, and has urged providers to ask questions about their reporting obligations. The education process has been continuous and robust.

RRH has similarly advised its healthcare providers to report adverse events after COVID-19 vaccines that have been brought to their attention by their patients. Ms. Conrad is responsible for reporting her patients' adverse events to VAERS and she has been encouraged to comply with her legal and ethical obligation to do so, as has every provider affiliated with RRH. RRH has never discouraged one of its healthcare providers from reporting any adverse events experienced by one of their patients, whether related or unrelated to a COVID-19 vaccine.

Please contact me directly with any further questions.

Sincerely,

Erin W.S. Heintz
Deputy General Counsel

EXHIBIT
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July 21, 2021

VIA EMAIL AND FEDEX
Erin W.S. Heintz
Deputy General Counsel
Rochester Regional Health
1360 Portland Avenue
Rochester, NY 14621
eheintz@rochesterregional.org

Re: *Underreporting to VAERS and NYSDOH of post-COVID-19 vaccine adverse events at Rochester Regional Health*

Dear Erin:

We write again on behalf of our client, Deborah Conrad, a Physician Assistant at United Memorial Medical Center (the "Hospital"), in response to your July 21, 2021 reply letter.

Our client strenuously disputes the steps you claim were taken to advise health care workers at the Hospital of the existence of VAERS, what they should report to VAERS, and their legal obligation to do so. Her communications from and with the Hospital clearly reflect that the Hospital is not only failing to take the steps laid out in your letter, but also actively sought to prevent reports being submitted to VAERS. This includes a recent conversation with Daniel Ireland, President of the Hospital, who told Ms. Conrad in response to her complaint that the Hospital was not educating its staff regarding VAERS that "the providers should educate *themselves* when they are dealing with patients related to COVID vaccination. That information is out there, it is available."

Your letter is tellingly silent regarding the fact that the Hospital is aware that its healthcare providers, aside from Ms. Conrad, are not reporting legally required adverse events to VAERS.

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She is confident that the evidentiary record on these points will unquestionably support the Hospital's serious shortcomings laid out in our opening letter.

Very truly yours,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Caroline Tucker, Esq.

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July 19, 2021

SENT VIA EMAIL

Mr. Xavier Becerra
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c/o Sean McCluskie
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Dr. Rochelle P. Walensky
Director, Centers for Disease Control and Prevention
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Dr. Peter Marks
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Food & Drug Administration
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Dr. Tom Shimabukuro
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Re: *Underreporting to VAERS & Violation of COVID-19 Vaccine EUAs*

Dear Mr. Becerra, Dr. Walensky, Dr. Woodcock, Dr. Marks, and Dr. Shimabukuro:

We write with urgency to provide a first-hand report from Ms. Deborah Conrad, a Physician Assistant at a regional New York hospital, of serious injuries from COVID-19 vaccines and her hospital system's failure to report to VAERS.

Ms. Conrad's hospital serves a community in which less than 50% of individuals have received the COVID-19 vaccine yet approximately 90% of individuals admitted to her hospital are documented to have received the COVID-19 vaccine. Even more troubling is the fact that many individuals being admitted are presenting with complication months after vaccination and the hospital has more admitted patients now on average than it had last year during the pandemic. Even worse is that Ms. Conrad attests that even injuries occurring directly after COVID-19 vaccination are *not* being reported to the CDC and FDA's Vaccine Adverse Events Reporting System ("**VAERS**").

In fact, after she began assisting doctors and nurses in her hospital with submission of VAERS reports, she was prohibited by the hospital from doing so for a majority of the reports. Ms. Conrad's first-hand experience reinforces the serious concerns previously raised that there is

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an incredible level of underreporting to VAERS of adverse events following the COVID-19 vaccine. Please advise forthwith what steps you intend to take to (1) inform all health care providers that all serious adverse events they observe after COVID-19 vaccination should be reported to VAERS and (2) punish hospitals and health care professionals that fail to file VAERS reports.

I. Underreporting to VAERS

As you are aware, an AHRQ-funded study by Harvard Medical School of 715,000 patients tracked reporting to VAERS over a three-year period at Harvard Pilgrim Health Care. It concluded that "fewer than 1% of vaccine adverse events are reported."[1]

This disturbingly low rate is confirmed by the rate at which anaphylaxis after COVID-19 vaccine is reported to VAERS. The CDC Director claims that "Anaphylaxis after COVID-19 vaccination is **rare** and occurred in approximately **2 to 5 people per million** vaccinated in the United States based on events reported to VAERS."[2] That claim is contradicted by a recent study at Mass General Brigham that assessed anaphylaxis in a clinical setting after the administration of COVID-19 vaccines and found "severe reactions consistent with anaphylaxis occurred at a rate of **2.47 per 10,000 vaccinations.**"[3] This is equivalent to 50 to 120 times more cases than what VAERS and the CDC are reporting.

The underreporting of anaphylaxis by the CDC and VAERS is particularly troubling because it is mandatory for medical providers to report anaphylaxis after any COVID-19 vaccine to VAERS,[4] most of these reactions occur within 30 minutes of vaccination,[5] and there has been an intense campaign by health authorities to inform medical providers that they need to report anaphylaxis after COVID-19 vaccination to VAERS. Nonetheless, the rate of reporting still appears to be only around 0.8 to 2 percent of all cases of anaphylaxis.

This raises serious concerns regarding the underreporting of adverse events following COVID-19 vaccination to VAERS, especially for adverse events that do not occur immediately after vaccination and where health care providers have not been specifically directed to report such adverse events to VAERS.

II. Confirmation from the Front Line

The first-hand observation of Deborah Conrad, a Physician Assistant from a New York regional hospital (**"Hospital"**), confirms this concerning and dangerous underreporting to VAERS. Her direct daily observation over the last two years of hospital admissions and vaccination status

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[1] https://healthit.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf. *See also* a U.S. House Report similarly stated: "Former FDA Commissioner David A. Kessler has estimated that VAERS reports currently represent only a fraction of the serious adverse events." https://www.congress.gov/106/crpt/hrpt977/CRPT-106hrpt977.pdf.

[2] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html

[3] https://jamanetwork.com/journals/jama/fullarticle/2777417

[4] See, e.g., https://www.fda.gov/media/144413/download.

[5] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html; *see also* https://jamanetwork.com/journals/jama/fullarticle/2777417 (mean time to reaction is 17 minutes post-vaccination).

also confirm that the COVID-19 vaccine has caused a surge of admissions to her hospital exceeding even that which occurred at the height of the pandemic.

Ms. Conrad raised these concerns to her superiors at the Hospital. After they failed to act, she reached out Dr. Shimabukuro on March 26, 2021 and to the Food and Drug Administration ("**FDA**") via email on April 15, 2021, April 30, 2021, and May 24, 2021 explaining that she was seeing concerning adverse events that were not being reported to VAERS, including pericarditis. These messages were never acknowledged. Ms. Conrad also raised the issue with the New York State Department of Health ("**NYSDOH**") and with the Office of Professional Medical Conduct. She has, to date, not received satisfactory answers nor has she seen any steps taken by the Hospital to remediate the issues.

i. Ms. Conrad Assists Hospital Staff to File VAERS Reports

Ms. Conrad is in constant communication with patients, patients' families, and other hospital staff and has knowledge of numerous serious post-COVID-19 vaccine adverse events, including breakthrough cases and deaths, as well as other adverse events on the CDC's "adverse events of special interest" list[6] that have not been reported to either VAERS or the NYSDOH. Among other serious conditions following COVID-19 vaccination, Ms. Conrad has observed: clotting events, myocarditis cases, type one diabetes new onset, Acute myelogenous leukemia, breakthrough COVID-19 cases, death, and more.

For the past few months, on her own time, Ms. Conrad has been assisting doctors and other medical professionals at the hospital to report such events to VAERS. Instead of praising her efforts, numerous individuals at the Hospital ordered Ms. Conrad to stop reporting to VAERS altogether unless she was submitting a report for her direct patient. Since being given this order, Ms. Conrad has knowledge of dozens of patients whose conditions necessitate a VAERS report and whose treating nurses and doctors have not filed a VAERS report. This was entirely predictable as Ms. Conrad was, to her knowledge, the only health care provider at the Hospital submitting reports.

ii. Requirement to Submit VAERS Reports

Health care workers are mandated by federal law to report certain medical events arising after vaccination to VAERS. Pursuant to 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, 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,

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[6] *See* https://www.bestinitiative.org/wp-content/uploads/2021/02/C19-Vaccine-Safety-AESI-Background-Rate-Protocol-FINAL-2020.pdf at 12-13.

(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.[7]

Additionally, pursuant to the FDA and its emergency use authorizations ("**EUA**"), all vaccine and health care providers "must report the following information associated with the administration of … COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers[8]):

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

"Serious adverse events" are defined by the FDA to include:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- 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]

Health care providers are also strongly encouraged to report to VAERS "*any adverse event that occurs 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."[11] The importance of filing VAERS reports is acute with regard to COVID-19 vaccines which were developed based on novel technology and which have only been granted emergency use authorization.

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[7] https://www.law.cornell.edu/uscode/text/42/300aa-25 (emphasis added).

[8] Ms. Conrad's Hospital is a vaccine provider.

[9] https://www.fda.gov/media/144412/download (Pfizer); https://www.fda.gov/media/144636/download (Moderna), https://www.fda.gov/media/146303/download (Johnson & Johnson); https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html.

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

[11] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html (emphasis added).

iii. Hospital Prevents Ms. Conrad From Filing VAERS Reports

When Ms. Conrad observed that serious adverse events occurring directly after COVID-19 vaccination were not being reported to VAERS, she volunteered to submit the necessary reports to VAERS on her and her colleagues' behalf. Ms. Conrad was doing so after her paid shifts ended because she understands the critical importance of the task. In response, the Hospital told Ms. Conrad they were going to audit the VAERS reports that Ms. Conrad submitted 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 apparently is contrary to its "approach to the vaccine."

It is alarming that the Hospital's "approach to the vaccines" does not and has not included educating health care providers about VAERS and encouraging them to efficiently and consistently file reports. Instead, its apparent approach is to actively deter them from doing so.

As Ms. Conrad told the Hospital, she has personally treated at least five patients that presented with new, unprovoked deep vein thrombosis or pulmonary embolisms within 6 weeks of COVID-19 vaccination. She has also seen patients who, after receipt of COVID-19 vaccination, presented with a new stroke, bleed, autoimmune hepatitis, sudden bilateral pneumonia or COVID-19 infection, as well as syncope with head injury, STEMI, new arrhythmias, new seizure disorders, new chorea movement disorder, and more. In one day alone, Ms. Conrad had four patients with sudden bilateral pneumonia within a week of their COVID-19 vaccination. Ms. Conrad understands that it is not her responsibility to determine any causation but that it is her duty to report these instances to VAERS so that the FDA and CDC have adequate data by which to detect potential safety signals. The Hospital has prohibited Ms. Conrad from filing a VAERS reports for any of these serious events after COVID-19 vaccination unless she directly treats the patient.

In auditing the VAERS reports submitted by Ms. Conrad for a four-week period – totaling 50 adverse event reports, which includes 4 deaths – the Hospital's Chief Quality Officer stated that she has "not heard this level of reporting from anywhere else and didn't hear similar reports from [another hospital in the system]." This is Ms. Conrad's precise concern: if she is not submitting the VAERS reports, they are not being submitted. The Hospital did not take issue with the reports themselves, which were all valid, but rather that unlike other hospitals, Ms. Conrad is actually causing the Hospital to submit reports to VAERS. The Hospital told Ms. Conrad: "we need to make sure we are providing a consistent message to our team and we need to make sure that that is also in alignment with what our health system is asking us to do."

The Hospital's conclusion was therefore, quizzically, that Ms. Conrad only be permitted to report to VAERS for her own patients:

> 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 …

Ms. Conrad reiterated that the reason she took this task on is because no one else wants to do it nor are they doing 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 the report in… and we do need to follow how the system is approaching this currently.

When Ms. Conrad again explained why she has the concerns she has 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 provider, 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.

Of course, the assessment of "safe" is based on reports of adverse reactions and if such reports are not being made, this conclusion could be false.

Ms. Conrad voiced additional concerns of adverse events following the emergency use vaccines 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.

"Towing the company line" does not relieve the Hospital of its obligations.

Ms. Conrad's voiced concern that the Hospital was not even bothering to inform its personnel about VAERS and filing reports was, incredible, to state that "the providers should

educate *themselves* when they are dealing with patients related to COVID vaccination. That information is out there, it is available."

We reached out to the Hospital and asked it to please forthwith confirm that the Hospital's mission is consistent with taking all necessary steps to fulfill its legal and ethical obligations to report the mandated medical events following COVID-19 vaccination to VAERS pursuant to federal law, including: (i) educating the staff about their responsibility to report to VAERS, (ii) creating internal policies and procedures ensuring that VAERS reports will be made and establishing the process for doing so, and (iii) allowing Ms. Conrad and any other health care professional employees to submit VAERS reports without repercussions or hostility. We have received no response.

iv. Hospital Admissions Increase Dramatically & Approximately 90% of All Admitted Patients Have Received the COVID-19 Vaccine Even Though Less than 50% of the Community the Hospital Serves is Vaccinated

Ms. Conrad notes that hospital admissions are higher now than they were during the pandemic and are increasing every day. Despite the fact that the county served by the Hospital has less than a 50% vaccination rate, approximately 90% of the patients in the hospital have received the COVID-19 vaccine. What makes this particularly troubling is that many of these patients are considerably young, often in their 30s, 40s, and 50s and hence are from an age group where the vaccination rate is far lower than 50 percent in the community served by the Hospital.

The only reason that the Hospital even has this data is because Ms. Conrad insisted repeatedly that the Hospital note the COVID-19 vaccination status of each new patient. This provided the Hospital and Ms. Conrad a unique insight into the reason that hospital admissions were surging beyond the level seen during the pandemic.

The purpose of deploying the COVID-19 vaccine is to improve overall public health. The first-hand daily observation of Ms. Conrad over the last two years, including the last six months that the COVID-19 vaccine has been deployed, does not support that these products are improving the overall health of those in her community, at least with regard to hospital admissions for serious health issues.

III. Conclusion

If nothing else, the first-hand account of Ms. Conrad reflects that the reporting requirements of the EUAs for the COVID-19 vaccines are not being adhered to. Without robust post-authorization and post-licensure safety monitoring, many Americans may end up being harmed by improperly tested products. To avoid this potentially calamitous outcome, and to address any issues that arise as quickly as possible, health care facilities must be educated and held responsible to track and report all adverse events following vaccination, including breakthrough

cases. The above also contradicts Dr. Fauci and Dr. Walensky's repeated, but still unsupported, claim that "over 97 percent of people who are entering the hospital right now are unvaccinated."[12]

This should seriously concern HHS, CDC, and FDA but, given the response to our previous letters addressing this topic, it does not appear there is any concern. There are serious safety signals that are likely being missed and for the ones that are identified, such as anaphylaxis, CVST in conjunction with thrombocytopenia, myocarditis, and Guillain-Barre Syndrome, the actual rate seen in VAERS may be only the tip of the iceberg. Ignoring and casting aside these issues in the drive to vaccinate and promote vaccine confidence may eventually be the undoing of the very confidence you seek to instill.

As explained before, unless and until underreporting to VAERS is addressed, underreporting to a passive signal detection system will continue to blind health agencies, medical professionals, and patients from what is really occurring in the clinic and will render true informed consent impossible. With the drive to vaccinate every single American with COVID-19 vaccines, the safety of all Americans, literally, depends on this broken system. Fix it.

The first step to fix it is, at the least, to automate hospital and clinical medical records to automatically send VAERS reports for all clinically significant events occurring within a window of time after vaccination. This already exists for other purposes. It can be done for vaccines as well, which is clear from the CDC's own publications on this topic and pages 31 to 34 of a letter exchange with HHS on this issue available here: https://icandecide.org/hhs/vaccines-safety-12-31-18.pdf. Additionally, the FDA should be enforcing its EUAs to the fullest extent of the law.

Please confirm that you will fulfill your duties as public servants and implement these simple but critical corrections needed to convert VAERS from a passive, broken system to an active, useful system that generates data that can quickly and confidentially identify and address safety issues. In the end, the more robust the system, the more it will increase vaccine confidence.

Very truly yours,
/s/ Aaron Siri
Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Caroline Tucker, Esq.

[12] https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/16/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-45/; https://www.nbcnews.com/meet-the-press/meet-press-july-4-2021-n1273065

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June 23, 2021

VIA EMAIL AND FEDEX

Rochester Regional Health
ADDRESS
ADDRESS
EMAIL

Re: *Underreporting to VAERS and NYSDOH of post-COVID-19 vaccine adverse events at Rochester Regional Health*

Dear xxx:

We write on behalf of our client, Deborah Conrad, a Physician Assistant at United Memorial Medical Center, a hospital within the Rochester Regional Health system (the "**Hospital**"). Ms. Conrad is in constant communication with patients and other hospital staff and has knowledge of numerous serious post-COVID-19 vaccine adverse events, including breakthrough cases and deaths, that have not been reported to either the Vaccine Adverse Events Reporting System ("**VAERS**") or the New York State Department of Health ("**NYSDOH**"). For the past few months, on her own time, Ms. Conrad has been assisting doctors and other medical professionals at the hospital to report such events to VAERS. Instead of praising her efforts, numerous individuals at the Hospital, including Tara Gellasch and Peter Janes, ordered Ms. Conrad to stop reporting to VAERS altogether unless the patient she was reporting on was her patient. Since being given this order, Ms. Conrad has knowledge of numerous patients whose conditions necessitate a VAERS report and whose treating nurses and doctors have not filed a VAERS report.

As you are likely aware, healthcare workers are mandated by federal law to report certain medical events arising after vaccination to VAERS. Pursuant to 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, 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.[1]

Additionally, pursuant to the Food and Drug Administration ("**FDA**"), all vaccine and healthcare providers "must report the following information associated with the administration of Pfizer-BioNTech COVID-19 Vaccine of which they become aware to VAERS in accordance with the Fact Sheet for Healthcare Providers Administering Vaccine (Vaccination Providers):

- Vaccine administration errors whether or not associated with an adverse event
- Serious adverse events (irrespective of attribution to vaccination)
- Cases of Multisystem Inflammatory Syndrome in children and adults
- Cases of COVID-19 that result in hospitalization or death."[2]

"Serious adverse events" are defined by the FDA to include:

- Death;
- A life-threatening adverse event;
- Inpatient hospitalization or prolongation of existing hospitalization;
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions;
- A congenital anomaly/birth defect;
- 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.[3]

In addition to these mandated reports, healthcare providers are strongly encouraged to report to VAERS "*any adverse event that occurs 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."[4] In the case of vaccines that are not yet FDA licensed and approved and are only in use whilst their clinical trials progress, pursuant to emergency use authorization, certainly as healthcare

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[1] https://www.law.cornell.edu/uscode/text/42/300aa-25 (emphasis added).

[2] https://www.fda.gov/media/144412/download; *see also* https://www.fda.gov/media/144636/download (same for Moderna), https://www.fda.gov/media/146303/download (same for Johnson & Johnson); https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html.

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

[4] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/reportingaes.html (emphasis added).

providers, you understand the importance of reporting all adverse events presenting to a hospital following vaccination.

When Ms. Conrad observed that serious adverse events directly following initial use of COVID-19 vaccinations were not being reported to VAERS, she volunteered to submit the necessary reports to VAERS on her colleagues' behalf. Ms. Conrad was doing so after her paid shifts ended because she understands the critical importance of the task. In response, the Hospital told Ms. Conrad they were going to audit the VAERS reports that Ms. Conrad submitted and that "in [her] clinical role and as a leader in the organization" she was to "support [the Hospital's] approach to the vaccine." Submitting VAERS reports for adverse events following vaccination should not be contrary to any "approach to the vaccine." It should be part of the Hospital's approach. It is alarming that the Hospital's "approach to the vaccines" has not included educating healthcare providers about VAERS and encouraging them to efficiently and consistently make reports. Contrary to this, healthcare providers at the Hospital are not being directed to ask patients about recent vaccination nor are they able to efficiently submit or track VAERS reports within the Hospital's electronic system. And it now appears they are being deterred from doing so.

As Ms. Conrad told the Hospital, she has personally treated five patients that presented with new, unprovoked deep vein thrombosis or pulmonary embolisms within 6 weeks of COVID-19 vaccination. She has also seen patients that, after receipt of COVID-19 vaccination, presented with a new stroke, bleed, autoimmune hepatitis, sudden bilateral pneumonia or COVID-19 infection, as well as syncope with head injury, STEMI, new arrhythmias, new seizure disorders, new chorea movement disorder, and more. In one day alone, Ms. Conrad had four patients with sudden bilateral pneumonia within a week of their COVID-19 vaccination. Ms. Conrad understands that it is not her responsibility to determine any causation but that it is her duty to report these instances to VAERS so that the FDA and CDC have adequate data by which to detect potential safety signals. The Hospital has prohibited Ms. Conrad from filing a VAERS reports for any of these serious events after COVID-19 vaccination unless she directly treats the patient.

In auditing the VAERS reports submitted by Ms. Conrad for a four-week period – totaling 50 adverse event reports, which includes 4 deaths – the Hospital's Chief Quality Officer, Hiloni Bhavsar stated that she has "not heard this level of reporting from anywhere else and didn't hear similar reports from URMC."

This is Ms. Conrad's precise concern: if she is not submitting the VAERS reports, they are not being submitted. The Hospital, through Ms. Gellasch, told Ms. Conrad: "we need to make sure we are providing a consistent message to our team and we need to make sure that that is also in alignment with what our health system is asking us to do."

The Hospital's conclusion was therefore, quizzically, that Ms. Conrad only be permitted to report to VAERS for her own patients:

> 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 …

Ms. Conrad reiterated that the reason she took this task on is because no one else wants to do it nor are they doing it. However, Ms. Gellasch 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 the report in… and we do need to follow how the system is approaching this currently.

When Ms. Conrad again explained why she has the concerns she has about underreporting, she was called an anti-vaxxer by Ms. Gellasch:

> 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 provider, 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.

Ms. Conrad voiced additional concerns of adverse events following the emergency use vaccines 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.

"Towing the company line" does not relieve the Hospital of its obligations. Please forthwith confirm that the Hospital's mission is consistent with taking all necessary steps to fulfill its legal and ethical obligations to report the mandated medical events following COVID-19 vaccination to VAERS pursuant to federal law, including: (i) educating the staff about their responsibility to report to VAERS, (ii) creating internal policies and procedures ensuring that VAERS reports will 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 repercussions or hostility.

Very truly yours,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Caroline Tucker, Esq.

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July 21, 2021

VIA EMAIL AND FEDEX

Erin W.S. Heintz
Deputy General Counsel
Rochester Regional Health
1360 Portland Avenue
Rochester, NY 14621
erin.s@rochesterregional.org

Re: *Underreporting to VAERS at Rochester Regional Health*

Dear Erin:

We write again on behalf of our client, Deborah Conrad, a Physician Assistant at United Memorial Medical Center (the "Hospital"), in response to your July 21, 2021 reply letter.

Our client strenuously disputes the steps you claim were taken to advise health care workers at the Hospital of the existence of VAERS, what they should report to VAERS, and their legal obligation to do so. Her communications from and with the Hospital clearly reflect that the Hospital is not only failing to take the steps laid out in your letter, but also actively sought to prevent reports being submitted to VAERS. This includes a recent conversation with Daniel Ireland, President of the Hospital, who told Ms. Conrad in response to her complaint that the Hospital was not educating its staff regarding VAERS that "the providers should educate *themselves* when they are dealing with patients related to COVID vaccination. That information is out there, it is available."

Your letter is tellingly silent regarding the fact that the Hospital is aware that its healthcare providers, aside from Ms. Conrad, are not reporting legally required adverse events to VAERS.

She is confident that the evidentiary record on these points will unquestionably support the Hospital's serious shortcomings laid out in our opening letter.

Very truly yours,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Caroline Tucker, Esq.

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July 21, 2021

VIA EMAIL AND FEDEX

Erin W.S. Heintz
Deputy General Counsel
Rochester Regional Health
1360 Portland Avenue
Rochester, NY 14621
eheintz@rochesterregional.org

Re: ***Underreporting to VAERS and NYSDOH of post-COVID-19 vaccine adverse events at Rochester Regional Health***

Dear Erin:

We write again on behalf of our client, Deborah Conrad, a Physician Assistant at United Memorial Medical Center (the "Hospital"), in response to your July 21, 2021 reply letter.

Our client strenuously disputes the steps you claim were taken to advise health care workers at the Hospital of the existence of VAERS, what they should report to VAERS, and their legal obligation to do so. Her communications from and with the Hospital clearly reflect that the Hospital is not only failing to take the steps laid out in your letter, but also actively sought to prevent reports being submitted to VAERS. This includes a recent conversation with Daniel Ireland, President of the Hospital, who told Ms. Conrad in response to her complaint that the Hospital was not educating its staff regarding VAERS that "the providers should educate *themselves* when they are dealing with patients related to COVID vaccination. That information is out there, it is available."

Your letter is tellingly silent regarding the fact that the Hospital is aware that its healthcare providers, aside from Ms. Conrad, are not reporting legally required adverse events to VAERS.

She is confident that the evidentiary record on these points will unquestionably support the Hospital's serious shortcomings laid out in our opening letter.

Very truly yours,

Aaron Siri, Esq.
Elizabeth A. Brehm, Esq.
Caroline Tucker, Esq.

ROCHESTER REGIONAL HEALTH | OFFICE OF COUNSEL
1360 Portland Ave
Rochester, NY 14621

July 14, 2021

Elizabeth A. Brehm, Esq.
Siri & Glimstad LLP
200 Park Ave #17
New York, NY 10166

Dear Ms. Brehm:

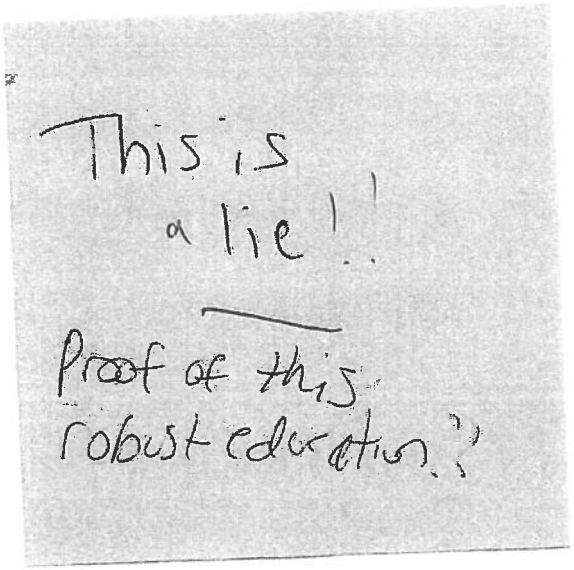
This letter responds to your written communication dated June 28, 2021 and addresses the serious allegations you have made against Rochester Regional Health and its healthcare providers relative to reporting adverse events following COVID-19 vaccinations to the Vaccine Adverse Event Reporting System (VAERS). As an initial matter, Rochester Regional Health ("RRH") takes its obligations to report adverse events related to the COVID-19 vaccination very seriously. RRH has developed and distributed robust educational and training tools to assist its healthcare providers in complying with their responsibility to report adverse events related to COVID-19 vaccinations, has issued multiple written communications outlining the requirements of its healthcare providers to report to VAERS specific adverse reactions to the COVID-19 vaccine, and has encouraged healthcare providers to ask questions and confer with their clinical leaders about their reporting obligations. RRH's senior leadership, Incident Command Team, and counsel's office are in routine communication with their Medical and Dental Staff members about reporting and have worked diligently to ensure that healthcare providers are educated on their reporting obligations. RRH has distributed educational materials published by the CDC outlining how and what to report, has encouraged use of the CDC's smartphone-based tool to report adverse events, has reminded providers to access RRH's internal COVID-19 toolkit resources, and has urged providers to ask questions about their reporting obligations. The education process has been continuous and robust.

RRH has similarly advised its healthcare providers to report adverse events after COVID-19 vaccines that have been brought to their attention by their patients. Ms. Conrad is responsible for reporting her patients' adverse events to VAERS and she has been encouraged to comply with her legal and ethical obligation to do so, as has every provider affiliated with RRH. RRH has never discouraged one of its healthcare providers from reporting any adverse events experienced by one of their patients, whether related or unrelated to a COVID-19 vaccine.

Please contact me directly with any further questions.

Sincerely,

Erin W.S. Heintz
Deputy General Counsel



VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	**Event and interval** from vaccination**
Tetanus in any combination; DTaP, DTP, DTP-Hib, DT, Td, TT, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Brachial neuritis (28 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pertussis in any combination; DTaP, DTP, DTP-Hib, Tdap, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (7 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles, mumps and rubella in any combination; MMR, MMRV, MM	A. Anaphylaxis or anaphylactic shock (7 days) B. Encephalopathy or encephalitis (15 days) C. Shoulder Injury Related to Vaccine Administration (7 days) D. Vasovagal syncope (7 days) E. Any acute complications or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rubella in any combination; MMR, MMRV	A. Chronic arthritis (42 days) B. Any acute complications or sequelae (including death) of above event (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Measles in any combination; MMR, MMRV, MM	A. Thrombocytopenic purpura (7-30 days) B. Vaccine-strain measles viral infection in an immunodeficient recipient o Vaccine-strain virus identified (interval - not applicable) o If strain determination is not done or if laboratory testing is inconclusive (12 months) C. Any acute complications or sequelae (including

EXHIBIT
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VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	**Event and interval** from vaccination**
	death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Oral Polio (OPV)	A. Paralytic polio o in a non-immunodeficient recipient (30 days) o in an immunodeficient recipient (6 months) o in a vaccine-associated community case (interval - not applicable) B. Vaccine-strain polio viral infection o in a non-immunodeficient recipient (30 days) o in an immunodeficient recipient (6 months) o in a vaccine-associated community case (interval - not applicable) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Inactivated Polio in any combination-IPV, DTaP-IPV, DTaP-IPV/Hib, DTaP-HepB-IPV	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of the above event (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis B in any combination- HepB, HepA-HepB, DTaP-HepB-IPV, Hib-HepB	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complications or sequelae (including death) of the above event (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Haemophilus influenzae type b in any combination (conjugate)- Hib, Hib-HepB, DTaP-IPV/Hib, Hib-MenCY	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	**Event and interval** from vaccination**
	(interval - see package insert)
Varicella in any combination- VAR, MMRV	A. Anaphylaxis or anaphylactic shock (7 days) B. Disseminated varicella vaccine-strain viral disease. o Vaccine-strain virus identified (time interval unlimited) o If strain determination is not done or if laboratory testing is inconclusive (42 days) C. Varicella vaccine-strain viral reactivation (time interval unlimited) D. Shoulder Injury Related to Vaccine Administration (7 days) E. Vasovagal syncope (7 days) F. Any acute complication or sequelae (including death) of above events (interval - not applicable) G. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Rotavirus (monovalent or pentavalent) RV1, RV5	A. Intussusception (21 days) B. Any acute complication or sequelae (including death) of above events (interval - not applicable) C. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Pneumococcal conjugate(7-valent or 13-valent) PCV7, PCV13	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Hepatitis A in any combination- HepA, HepA-HepB	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Seasonal influenza--trivalent inactivated influenza, quadrivalent inactivated influenza, live attenuated	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days)

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	**Event and interval** from vaccination**
influenza-IIV, IIV3, IIV4, RIV3, ccIIV3, LAIV4	D. Guillain-Barré Syndrome (42 days) E. Any acute complication or sequelae (including death) of above events (interval - not applicable) F. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Meningococcal - MCV4, MPSV4, Hib-MenCY, MenACWY, MenB	A. Anaphylaxis or anaphylactic shock (7 days) B. Shoulder Injury Related to Vaccine Administration. (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Human Papillomavirus (Quadrivalent, Bivalent, or 9 valent) - 9vHPV, 4vHPV, 2vHPV	A. Anaphylaxis or anaphylactic shock (7days) B. Shoulder Injury Related to Vaccine Administration (7 days) C. Vasovagal syncope (7 days) D. Any acute complication or sequelae (including death) of above events (interval - not applicable) E. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)
Any new vaccine recommended by the Centers for Disease Control and Prevention for routine administration to children	A. Shoulder Injury Related to Vaccine Administration (7 days) B. Vasovagal syncope (7 days) C. Any acute complication or sequelae (including death) of above events (interval - not applicable) D. Events described in manufacturer's package insert as contraindications to additional doses of vaccine (interval - see package insert)

* Effective date: March 21, 2017. The Reportable Events Table (RET) reflects what is reportable by law (42 USC 300aa-25) to the Vaccine Adverse Event Reporting System (VAERS) including conditions found in the manufacturer package insert. In addition, healthcare professionals are encouraged to report any clinically significant or unexpected events (even if not certain the vaccine caused the event) for any vaccine, whether or not it is listed on the RET. Manufacturers are also required by regulation (21CFR 600.80) to report to the VAERS program all adverse events made known to them for any vaccine.

Note that the RET differs from the Vaccine Injury Table (VIT) regarding timeframes of adverse events. Timeframes listed on the RET reflect what is required for reporting, but not what is required for compensation. To view timeframes for compensation, please see the VIT at

VAERS Table of Reportable Events Following Vaccination*	
Vaccine/Toxoid	**Event and interval** from vaccination**
https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf **Represents the onset interval between vaccination and the adverse event. For a detailed explanation of terms, see the Vaccine Injury Table at **https://www.hrsa.gov/vaccinecompensation/vaccineinjurytable.pdf**	

A list of vaccine abbreviations is located at: **https://www.cdc.gov/vaccines/terms/vacc-abbrev.html**

CDC COVID-19 Vaccination Program Provider Agreement

Please complete Sections A and B of this form as follows:

The Centers for Disease Control and Prevention (CDC) greatly appreciates your organization's (Organization) participation in the CDC COVID-19 Vaccination Program. Your Organization's chief medical officer (or equivalent) and chief executive officer (or chief fiduciary)—collectively, Responsible Officers—must complete and sign the *CDC COVID-19 Vaccination Program Provider Requirements and Legal Agreement* (Section A). *CDC COVID-19 Vaccination Program Provider Profile Information* (Section B) must be completed for each vaccination Location covered under the Organization listed in Section A.

Section A. COVID-19 Vaccination Program Provider Requirements and Legal Agreement

ORGANIZATION IDENTIFICATION		
Organization's legal name:		
Number of affiliated vaccination locations covered by this agreement: _____		
Organization telephone number:	Email *(must be monitored and will serve as dedicated contact method for the COVID-19 Vaccination Program)*:	
Organization address:		

RESPONSIBLE OFFICERS		
For the purposes of this agreement, in addition to Organization, Responsible Officers named below will also be accountable for compliance with the conditions specified in this agreement. The individuals listed below must provide their signature after reviewing the agreement requirements.		
Chief Medical Officer (or Equivalent) Information		
Last name	First name	Middle initial
Title	Licensure (state and number)	
Telephone number:	Email:	
Address:		
Chief Executive Officer (or Chief Fiduciary) Information		
Last name	First name	Middle initial
Telephone number:	Email:	
Address:		

EXHIBIT 24

CDC COVID-19 Vaccination Program Provider Agreement

AGREEMENT REQUIREMENTS	
I understand this is an agreement between Organization and CDC. This program is a part of collaboration under the relevant state, local, or territorial immunization's cooperative agreement with CDC. To receive one or more of the publicly funded COVID-19 vaccines (COVID-19 Vaccine), constituent products, and ancillary supplies at no cost, Organization agrees that it will adhere to the following requirements:	
1.	Organization must administer COVID-19 Vaccine in accordance with all requirements and recommendations of CDC and CDC's Advisory Committee on Immunization Practices (ACIP).[1]
2.	Within 24 hours of administering a dose of COVID-19 Vaccine and adjuvant (if applicable), Organization must record in the vaccine recipient's record and report required information to the relevant state, local, or territorial public health authority. Details of required information (collectively, Vaccine-Administration Data) for reporting can be found on CDC's website.[2] Organization must submit Vaccine-Administration Data through either (1) the immunization information system (IIS) of the state and local or territorial jurisdiction or (2) another system designated by CDC according to CDC documentation and data requirements.[2] Organization must preserve the record for at least 3 years following vaccination, or longer if required by state, local, or territorial law. Such records must be made available to any federal, state, local, or territorial public health department to the extent authorized by law.
3.	Organization must not sell or seek reimbursement for COVID-19 Vaccine and any adjuvant, syringes, needles, or other constituent products and ancillary supplies that the federal government provides without cost to Organization.
4.	Organization must administer COVID-19 Vaccine regardless of the vaccine recipient's ability to pay COVID-19 Vaccine administration fees.
5.	Before administering COVID-19 Vaccine, Organization must provide an approved Emergency Use Authorization (EUA) fact sheet or vaccine information statement (VIS), as required, to each vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative.
6.	Organization's COVID-19 vaccination services must be conducted in compliance with CDC's Guidance for Immunization Services During the COVID-19 Pandemic for safe delivery of vaccines.[3]
7.	Organization must comply with CDC requirements for COVID-19 Vaccine management. Those requirements include the following: a) Organization must store and handle COVID-19 Vaccine under proper conditions, including maintaining cold chain conditions and chain of custody at all times in accordance with the manufacturer's package insert and CDC guidance in CDC's Vaccine Storage and Handling Toolkit[4], which will be updated to include specific information related to COVID-19 Vaccine; b) Organization must monitor vaccine-storage-unit temperatures at all times using equipment and practices that comply with guidance located in CDC's Vaccine Storage and Handling Toolkit[4]; c) Organization must comply with each relevant jurisdiction's immunization program guidance for dealing with temperature excursions;

This agreement expressly incorporates all recommendations, requirements, and other guidance that this agreement specifically identifies through footnoted weblinks. Organization must monitor such identified guidance for updates. Organization must comply with such updates.

[1] https://www.cdc.gov/vaccines/hcp/acip-recs/index.html

[2] https://www.cdc.gov/vaccines/programs/iis/index.html

[3] https://www.cdc.gov/vaccines/pandemic-guidance/index.html

[4] https://www.cdc.gov/vaccines/hcp/admin/storage-handling.html

CDC COVID-19 Vaccination Program Provider Agreement

	d) Organization must monitor and comply with COVID-19 Vaccine expiration dates; and e) Organization must preserve all records related to COVID-19 Vaccine management for a minimum of 3 years, or longer if required by state, local, or territorial law.
8.	Organization must report the number of doses of COVID-19 Vaccine and adjuvants that were unused, spoiled, expired, or wasted as required by the relevant jurisdiction.
9.	Organization must comply with all federal instructions and timelines for disposing COVID-19 vaccine and adjuvant, including unused doses.[5]
10.	Organization must report moderate and severe adverse events following vaccination to the Vaccine Adverse Event Reporting System (VAERS).[6]
11.	Organization must provide a completed COVID-19 vaccination record card to every COVID-19 Vaccine recipient, the adult caregiver accompanying the recipient, or other legal representative. Each COVID-19 Vaccine shipment will include COVID-19 vaccination record cards.
12.	a) Organization must comply 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. b) Organization must administer COVID-19 Vaccine in compliance with all applicable state and territorial vaccination laws.

By signing this form, I certify that all relevant officers, directors, employees, and agents of Organization 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.

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.

Non-compliance with the terms of Agreement may result in suspension or termination from the CDC COVID-19 Vaccination Program and criminal and civil penalties under federal law, including but not limited to the False Claims Act, 31 U.S.C. § 3729 *et seq.*, and other related federal laws, 18 U.S.C. §§ 1001, 1035, 1347, 1349.

By entering Agreement, Organization does not become a government contractor under the Federal Acquisition Regulation.

Coverage under the Public Readiness and Emergency Preparedness (PREP) Act extends to Organization if it complies with the PREP Act and the PREP Act Declaration of the Secretary of Health and Human Services.[7]

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[5] The disposal process for remaining unused COVID-19 Vaccine and adjuvant may be different from the process for other vaccines; unused vaccines must remain under storage and handling conditions noted in Item 7 until CDC provides disposal instructions; website URL will be made available.

[6] https://vaers.hhs.gov/reportevent.html

[7] *See* Pub. L. No. 109-148, Public Health Service Act §§ 319F-3 and 319F-4, 42 U.S.C. § 247d-6d and 42 U.S.C. § 247d-6e; 85 Fed. Reg. 15,198, 15,202 (March 17, 2020).

CDC COVID-19 Vaccination Program Provider Agreement

Chief Medical Officer (or Equivalent)		
Last name	First name	Middle initial
Signature:		Date:

Chief Executive Officer (or Chief Fiduciary)		
Last name	First name	Middle initial
Signature:		Date:

For official use only:

VTrckS ID for this Organization, if applicable: _____

Vaccines for Children (VFC) PIN, if applicable: _____ *Other PIN (e.g., state, 317):* _____

IIS ID, if applicable: _____

Unique COVID-19 Organization ID (Section A):* _____

**The jurisdiction's immunization program is required to create a unique COVID-19 ID for the organization named in Section A that includes the awardee jurisdiction abbreviation (e.g., an organization located in Georgia could be assigned "GA123456A"). This ID is needed for CDC to match Organizations (Section A) with one or more Locations (Section B). These unique identifiers are required even if there is only one location associated with an organization.*

Section B. CDC COVID-19 Vaccination Program Provider Profile Information

Please complete and sign this form for your Organization location. If you are enrolling on behalf of one or more other affiliated Organization vaccination locations, complete and sign this form for each location. Each individual Organization vaccination location must adhere to the requirements listed in Section A.

ORGANIZATION IDENTIFICATION FOR INDIVIDUAL LOCATIONS	
Organization location name:	Will another Organization location order COVID-19 vaccine for this site? ☐ Yes; provide Organization name: _____ ☐ No

CONTACT INFORMATION FOR LOCATION'S PRIMARY COVID-19 VACCINE COORDINATOR		
Last name:	First name:	Middle initial:
Telephone:	Email:	

CONTACT INFORMATION FOR LOCATION'S BACK-UP COVID-19 VACCINE COORDINATOR		
Last name:	First name:	Middle initial:
Telephone:	Email:	

ORGANIZATION LOCATION ADDRESS FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS			
Street address 1:	Street address 2:		
City:	County:	State:	ZIP:
Telephone:		Fax:	

ORGANIZATION ADDRESS OF LOCATION WHERE COVID-19 VACCINE WILL BE ADMINISTERED (IF DIFFERENT FROM RECEIVING LOCATION)			
Street address 1:	Street address 2:		
City:	County:	State:	ZIP:
Telephone:		Fax:	

DAYS AND TIMES VACCINE COORDINATORS ARE AVAILABLE FOR RECEIPT OF COVID-19 VACCINE SHIPMENTS				
Monday	Tuesday	Wednesday	Thursday	Friday
AM:	AM:	AM:	AM:	AM:
PM:	PM:	PM:	PM:	PM:

For official use only:

VTrckS ID for this location, if applicable: _____ *Vaccines for Children (VFC) PIN, if applicable:* _____

IIS ID, if applicable: _____ *Unique COVID-19 Organization ID (from Section A):* _____ *Unique Location ID**:* _____

***The jurisdiction's immunization program is required to create an additional unique Location ID for each location completing Section B. The number will include the awardee jurisdiction abbreviation. For example, if an organization (Section A) in Georgia (e.g., GA123456A), has three locations (main location plus two additional) completing section B, they could be numbered as GA123456B1, GA123456B2, and GA123456B3.*

CDC COVID-19 Vaccination Program Provider Profile Information

COVID-19 VACCINATION PROVIDER TYPE FOR THIS LOCATION (SELECT ONE)

- ☐ Commercial vaccination service provider
- ☐ Corrections/detention health services
- ☐ Health center – community (non-Federally Qualified Health Center/non-Rural Health Clinic)
- ☐ Health center – migrant or refugee
- ☐ Health center – occupational
- ☐ Health center – STD/HIV clinic
- ☐ Health center – student
- ☐ Home health care provider
- ☐ Hospital
- ☐ Indian Health Service
- ☐ Tribal health
- ☐ Medical practice – family medicine
- ☐ Medical practice – pediatrics
- ☐ Medical practice – internal medicine
- ☐ Medical practice – OB/GYN
- ☐ Medical practice – other specialty
- ☐ Pharmacy – chain
- ☐ Pharmacy – independent
- ☐ Public health provider – public health clinic
- ☐ Public health provider – Federally Qualified Health Center
- ☐ Public health provider – Rural Health Clinic
- ☐ Long-term care – nursing home, skilled nursing facility, federally certified
- ☐ Long-term care – nursing home, skilled nursing facility, non-federally certified
- ☐ Long-term care – assisted living
- ☐ Long-term care – intellectual or developmental disability
- ☐ Long-term care – combination (e.g., assisted living and nursing home in same facility)
- ☐ Urgent care
- ☐ Other (Specify: _____)

SETTING(S) WHERE THIS LOCATION WILL ADMINISTER COVID-19 VACCINE (SELECT ALL THAT APPLY)

- ☐ Childcare or daycare facility
- ☐ College, technical school, or university
- ☐ Community center
- ☐ Correctional/detention facility
- ☐ Health care provider office, health center, medical practice, or outpatient clinic
- ☐ Hospital (i.e., inpatient facility)
- ☐ In-home
- ☐ Long-term care facility (e.g., nursing home, assisted living, independent living, skilled nursing)
- ☐ Pharmacy
- ☐ Public health clinic (e.g., local health department)
- ☐ School (K – grade 12)
- ☐ Shelter
- ☐ Temporary or off-site vaccination clinic – point of dispensing (POD)
- ☐ Temporary location – mobile clinic
- ☐ Urgent care facility
- ☐ Workplace
- ☐ Other (Specify: _____)

APPROXIMATE NUMBER OF PATIENTS/CLIENTS ROUTINELY SERVED BY THIS LOCATION

Number of children 18 years of age and younger: _____ *(Enter "0" if the location does not serve this age group.)*
☐ Unknown

Number of adults 19 – 64 years of age: _____ *(Enter "0" if the location does not serve this age group.)*
☐ Unknown

Number of adults 65 years of age and older: _____ *(Enter "0" if the location does not serve this age group.)*
☐ Unknown

Number of unique patients/clients seen per week, on average: _____
☐ Unknown
☐ Not applicable (e.g., for commercial vaccination service providers)

INFLUENZA VACCINATION CAPACITY FOR THIS LOCATION

Number of influenza vaccine doses administered during the peak week of the 2019–20 influenza season:
_____ *(Enter "0" if no influenza vaccine doses were administered by this location in 2019-20)*
☐ Unknown

CDC COVID-19 Vaccination Program Provider Profile Information

POPULATION(S) SERVED BY THIS LOCATION (SELECT ALL THAT APPLY)

- ☐ General pediatric population
- ☐ General adult population
- ☐ Adults 65 years of age and older
- ☐ Long term care facility residents (nursing home, assisted living, or independent living facility)
- ☐ Health care workers
- ☐ Critical infrastructure/essential workers (e.g., education, law enforcement, food/agricultural workers, fire services)
- ☐ Military – active duty/reserves
- ☐ Military – veteran
- ☐ People experiencing homelessness
- ☐ Pregnant women
- ☐ Racial and ethnic minority groups
- ☐ Tribal communities
- ☐ People who are incarcerated/detained
- ☐ People living in rural communities
- ☐ People who are under-insured or uninsured
- ☐ People with disabilities
- ☐ People with underlying medical conditions* that are risk factors for severe COVID-19 illness
- ☐ Other people at higher-risk for COVID-19 (Specify: _____)

DOES YOUR ORGANIZATION CURRENTLY REPORT VACCINE ADMINISTRATION DATA TO THE STATE, LOCAL, OR TERRITORIAL IMMUNIZATION INFORMATION SYSTEM (IIS)?

- ☐ Yes [List IIS Identifier: _____]
- ☐ No
- ☐ Not applicable

If "No," please explain planned method for reporting vaccine administration data to the jurisdiction's IIS or other designated system as required:

If "Not applicable," please explain:

ESTIMATED NUMBER OF 10-DOSE MULTIDOSE VIALS (MDVs) YOUR LOCATION IS ABLE TO STORE DURING PEAK VACCINATION PERIODS (E.G., DURING BACK-TO-SCHOOL OR INFLUENZA VACCINE SEASON) AT THE FOLLOWING TEMPERATURES:

Refrigerated (2°C to 8°C):	☐ No capacity	☐ Approximately _____ additional 10-dose MDVs
Frozen (-15° to -25°C):	☐ No capacity	☐ Approximately _____ additional 10-dose MDVs
Ultra-frozen (-60° to -80°C):	☐ No capacity	☐ Approximately _____ additional 10-dose MDVs

STORAGE UNIT DETAILS FOR THIS LOCATION

List brand/model/type of storage units to be used for storing COVID-19 vaccine at this location:

1. *Example: CDC & Co/Red series two-door/refrigerator*
2.
3.
4.
5.

I attest that each unit listed will maintain the appropriate temperature range indicated above: (*please sign and date*)

_____

Medical/pharmacy director or location's vaccine coordinator signature

_____

Date

* https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-at-increased-risk.html

CDC COVID-19 Vaccination Program Provider Profile Information

PROVIDERS PRACTICING AT THIS FACILITY *(additional spaces for providers at end of form)*

Instructions: *List below all licensed healthcare providers at this location who have prescribing authority (i.e., MD, DO, NP, PA, RPh).*

Provider Name	Title	License No.

COVID-19

ROCHESTER
REGIONAL HEALTH

COVID-19 VACCINE CLINIC PLAYBOOK

REVISED 5/04/2021

EXHIBIT
25

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Note: Revised Sections Highlighted

KEY CONTACTS

CLIFTON SPRINGS HOSPITAL: 585-260-5792

Department/Role	Primary Contact	Contact Number	Secondary Contact	Contact Number
Clinic Leader	Amy Carey	585-698-5425	Christi Rollo	315-945-0817
Security	Joseph Alampi	315-576-1542	Sabrina Peters	315-759-8417
Pharmacy	William (Bill) Patterson	315-651-5720	Sylvia Manly	585-755-5466
Supply Management	Adam LaBounty	315-830-6585	Amanda Tyler	585-867-1021
Employee Health	Rebecca Goodman	315-462-1560		
Environmental Services	Tiffany Nelson	315-759-4151	Eddie Rodriguez	585-730-0986
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

NEWARK-WAYNE HOSPITAL: 585-260-4275

Department/Role	Primary Contact	Number	Secondary Contact	Number
Clinic Leader	Christi Rollo	315-945-0817	Amy Carey	585-698-5425
Security	Don Wentworth	585-507-1558	Security guard	315-332-2221
Pharmacy	Joan Hurley	315-573-1147	David Verdine	315-332-2205
Supply Management	Amanda Tyler	585-867-1021	David Hammond	315-945-7566
Employee Health	Rebecca Goodman	315-462-1560		
Environmental Services	Deb Sanford	315-945-8834	Maura Snyder	585-259-6211
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

ROCHESTER GENERAL HOSPITAL: 585-771-7358

Department/Role	Primary Contact	Contact Number	Secondary Contact	Contact Number
Clinic Leader	Casey Wilbert	315-796-5852	Nick Manning	801-499-9155
Security	Aaron Springer	585-705-5888	Chuck St. John	585-732-1680
Pharmacy	Casey Wilbert	315-796-5852	Nancy Nicoletta	
Supply Management	John Fazio	585-278-3597	Jennifer Sato	585-290-1775
Employee Health	Bonnie Mott	585-922-9098		
Environmental Services	Jamie Seals	585-260-9450	Scott Sleeper	585-732-2659
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

UNITED MEMORIAL MEDICAL CENTER: 585-755-1663

Department/Role	Primary Contact	Contact Number	Secondary Contact	Contact Number
Clinic Leader	Shane Nickerson	585-471-4604	Stacey Pastuszynski	585-344-5656
Security	Dave Hetrick	585-727-8185	Brad Hilchey	585-409-6029
Pharmacy	Michael (Mike) Koncilja	585-344-5495	Korey Brauen	585-344-5321
Supply Management	Josh Wallace	585-344-5417	Jennifer Brooks	585-409-9029
Employee Health	Sherry Watkins	585-344-5403		
Environmental Services	Chris Dehaven	716-984-6864	Dave Hetrick	585-727-8185
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

UNITY HOSPITAL: 585-417-0237

Department/Role	Primary Contact	Contact Number	Secondary Contact	Contact Number
Clinic Leader	Shaw-Ree Chen	585-481-3795	Evan Tinder	607-743-1318
Security	Paul Donahue	585-683-5961	Paul Staub	585-298-2875
Pharmacy	Robert (Bob) Adams	585-455-2448	Shashi Patel	585-451-5302
Supply Management	Maria Rosario	585-613-6423	Cedria Wright	585-723-7058
Employee Health	Kelly Kuczynski	585-723-7882	Shannon McCarty-Leone	585-363-0491
Environmental Services	Vic Zeno	585-752-3941	Will Smith	585-738-5901
IT	Service Desk	585-922-4357	ITservice@rochesterregional.org	

VACCINE TRACKING

Vaccine primary coordinators will utilize the Vaccine Freezer, Refrigerator, and Preparation logs included in the appendix to track all COVID-19 vaccine doses thawed, dispensed, prepared, and returned to the primary storage location. In addition, vaccine primary coordinators will be responsible for tracking the number of individuals vaccinated daily and the number of individuals scheduled to receive vaccine the next day. This information should remain readily available as state agency representatives may request these details at any time.

POST ADMINISTRATION MONITORING/ADVERSE EVENT REPORTING

- Recommend 15 minute monitoring
- In case of emergency: please utilize emergency medication box and follow local emergency response protocol (see appendix)
    - **Adverse reactions should be entered into SafeConnect and also reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be filed at https://vaers.hhs.gov/ or by calling 1-800-822-7967**
    - Per the CDC COVID-19 Vaccination Program Provider Agreement, COVID-19 vaccination providers are required to report the following to VAERS:
        - Vaccine administration errors (whether associated with an AE or not),
        - Serious AEs (even if they are not sure if the vaccination caused the event)
        - Multisystem inflammatory syndrome (MIS) in children or adults, and
        - Cases of COVID-19 that result in hospitalization or death to VAERS.

      They are also required to report to VAERS any additional AEs and/or adhere to any revised safety reporting requirements per FDA's conditions of authorized vaccine use posted on FDA's website throughout the duration of the EUA, as applicable.
      Vaccination providers should also report any additional clinically significant adverse events following COVID-19 vaccination to VAERS, even if they are not sure if the vaccination caused the event.

MANAGING DOWNTIME PROCEDURES

- If loss of power: return vaccine to central pharmacy to be stored under refrigeration

- If EMR goes down: move to paper forms
- Document all downtime administrations in EMR once it becomes available

MANAGING DECLINATIONS, NO SHOW'S, & EXTRA PREPARED VACCINE

- Clinic leaders and clinic pharmacy teams will work closely to ensure limited doses of vaccine are prepared in advance to minimize waste.
- Recognizing that some candidates may decline the vaccine or not be eligible after the dose has already been prepared, the clinic lead will work with their local SLT member to identify on call/ standby team members to receive the vaccine prior to expiration.
- Clinic leaders should escalate all questions and concerns to Margie Lim-Morison and Emily O'Banion as needed.

PARTNER HOSPITAL CLINIC PROCESS

RRH STAFF:

RRH security, pharmacy, and registration support will be available for each partner hospital vaccine clinic held at an RRH facility. Security will allow access to and monitor the clinic venue, pharmacy will transport vaccine to the clinic location, materials management will provide supplies, and registration support will be available to assist with scheduling second doses.

VACCINE ALLOCATION:

The state has partnered select hospitals across the state to share certain allocations of the Pfizer COVID-19 vaccine. These dose allocations are based on the FDA EUA-approval with labeling of 5 doses contained in each vial.

When pharmacy prepares the partner hospital's dose allocation, the pharmacy must use a 5 dose per vial assumption when allocating vials. ***This applies to RRH partner hospitals as well***. This guidance is based on directive from RRH legal who is aware of the recent advice from the NYSDOH, FDA, and Pfizer to use vial overfill to obtain 6 doses per vial.

PARTIAL VIAL ALLOCATION:

For partial vial allocations, the RRH allocation will be administered to RRH employees at the beginning of the partner clinic. For example, if a partner clinic is allocated 2 doses out of 1 vial, 3 RRH on call/ standby employees will be vaccinated and the remaining 2 doses will be left for the partner clinic. This will be managed locally by the clinic leader, employee health, pharmacy, and Senior Leadership Team (SLT) member.

VIAL PREPARATION FOR PARTNER CLINICS:

Partner clinics will provide the number of scheduled vaccinations to the RRH hospital pharmacy leadership no later than 3pm the day before the clinic.

Thaw enough vials to meet the partner hospital dose allocation based on the assumption that each vial will yield ***only 5 doses***. Document on the Vaccine Freezer and central pharmacy Vaccine Refrigerator Logs.

1 hour before the scheduled partner clinic, pharmacy will transport the partner hospital vial allocation, emergency drug boxes, and Vaccine Preparation Logs to the clinic site with security escort. Vials will be placed in the clinic refrigerator and the clinic Vaccine Refrigerator Log will be updated and signed. Materials Management will provide supplies.

Partner hospital is responsible for bringing their own PPE, sharps containers, cleaning supplies, and extra supplies (i.e. syringes, etc) that exceed what was provided by McKesson.

The partner clinic will prepare and administer vaccine to their team members.

TRACKING & REPORTING:

NYSIIS Reporting

Partner clinics must complete the COVID-19 Vaccine log included in the Playbook Appendix to track the patient vaccination information.

HERDS Reporting

At the end of the clinic, Partner Clinic Leaders shall provide to the RRH registration associate the COVID-19 Vaccine log which includes the patient vaccination information, the total number of doses administered and vials used.

This information will be passed on to the RRH pharmacy leaders and Dorothy Day. Dorothy Day will complete the NYSIIS upload process.

CLOSING PARTNER CLINIC:

Once the partner's dose allocation is reached and the clinic is over, the partner clinic lead is to notify the security officer to initiate clinic closure. Security will contact central pharmacies at Rochester General Hospital (585-922-4481) and Unity Hospital (585-723-7330) and the nursing supervisor at Newark-Wayne Hospital (315-945-8903) to retrieve any leftover vaccine and to secure supplies.

RRH will manage the partner clinic waste.

If there is leftover diluted vaccine available, the partner hospital is required to document this as waste on the Preparation Log. If there are refrigerated vials remaining, these should be removed from the clinical refrigerator (logged on the clinical Refrigerator Vaccine Log), returned to pharmacy under security escort, placed in the refrigerator, and central pharmacy Refrigerator Log updated.