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June 28, 2021

VIA EMAIL AND FEDEX

Rochester Regional Health
Dr. Robert Mayo, Chief Medical Officer
100 Kings Highway South
Rochester, NY 14617
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
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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—

> **(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."

[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

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July 21, 2021

VIA EMAIL AND FEDEX

Erin W.S. Heintz
Deputy General Counsel
Rochester Regional Health
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Re: *Underreporting to VAERS at Rochester Regional Health*

Dear Erin:

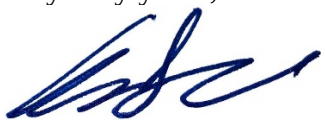
We write again on behalf of our client, Deborah Conrad, a Physician Assistant at United Memorial Medical Center (the "Hospital"), in response to your July 21, 2021 reply letter.

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,



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