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SENT VIA EMAIL

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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

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,

[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
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[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