U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

March 10, 2021

Mr. Aaron Siri, Esq.
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200 Park Avenue
17th Floor
New York, New York 10166

Dear Mr. Siri:

Thank you for your letters to Centers for Disease Control and Prevention (CDC) Director Rochelle P. Walensky, MD, MPH and Acting Secretary of Health and Human Services (HHS) Norris Cochran regarding adverse event reporting following a Coronavirus Disease 2019 (COVID-19) vaccine. I am responding on behalf of Dr. Walensky and Acting Secretary Cochran.

On February 19, 2021, CDC published an article in the *Morbidity and Mortality Weekly Report* titled "First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021."[1] Monitoring, conducted as part of the U.S. vaccination program, indicates reassuring safety profiles for COVID-19 vaccines.

I reviewed Dr. Redfield's response to your first letter; to elaborate further, the CDC COVID-19 Vaccination Provider agreements have the following provision about VAERS reporting:

> *Healthcare providers are **required** to report to* Vaccine Adverse Events Reporting System (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)*
> - *Severe COVID-19 illness (e.g., resulting in hospitalization)*
> - *Serious AEs regardless of causality. Serious AEs per the [U.S. Food and Drug Administration] 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*

[1] Gee J, Marquez P, Su J, et al. First Month of COVID-19 Vaccine Safety Monitoring — United States, December 14, 2020–January 13, 2021. MMWR Morb Mortal Wkly Rep. ePub: 19 February 2021. DOI: http://dx.doi.org/10.15585/mmwr.mm7008e3

> *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.*
>
> *[They must] 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 EUA.*

The above language parallels what is included by FDA in the provider fact sheets for the currently authorized COVID-19 vaccines.[2,3]

Further, the CDC-developed, web-based v-safe reporting system,[4] which CDC encourages vaccine recipients to join upon COVID-19 vaccination and which at first sends daily text and web-based inquiries seeking reports of any AEs observed after vaccination (and also has later follow-up), is another significant system for bringing CDC's attention, in real time, to AEs that are occurring after vaccination. V-safe was developed specifically for gathering AE information following COVID-19 vaccination.

As noted in Dr. Redfield's response to your first letter, v-safe provides telephone follow-up to anyone who reports medically significant AEs and if a serious AE is identified in v-safe, a VAERS report will be filed on behalf of the individual after the follow-up telephone call. The v-safe application also provides the weblink for directly filing VAERS reports. The assertion that the v-safe reporting system "directs adverse reaction reports to be submitted through this application and not to VAERS" is incorrect. The v-safe reporting system is an additional mechanism by which to monitor adverse vaccine reactions and does not supplant VAERS.

CDC has developed a robust monitoring system that helps assure timely, comprehensive AE reporting following COVID-19 vaccination with VAERS reporting requirements for providers through both the CDC COVID-19 Vaccination Program provider agreements and the FDA EUA fact sheets, the substance of those VAERS requirements, and use of v-safe. As mentioned in our previous response, vaccine safety monitoring does not stop after a vaccine is authorized under an EUA or licensed for use and CDC will continue to monitor the safety of COVID-19 vaccines.

HHS and CDC remain committed to protecting the American public during this pandemic. A copy of this response has been sent to Ms. Brehm.

Sincerely,

Sandra Cashman, MS
Executive Secretary
Office of the Chief of Staff, CDC

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[2] https://www.fda.gov/media/144413/download
[3] https://www.fda.gov/media/144637/download
[4] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html