U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

January 19, 2021

Ms. Elizabeth Brehm, Esq.
Siri & Glimstad
200 Park Avenue
17th Floor
New York, New York 10166

Dear Ms. Brehm:

Thank you for your letter to Secretary of Health and Human Services Alex M. Azar II requesting that all adverse events following a Coronavirus Disease 2019 (COVID-19) vaccine, with the exception of mild events, be reported by vaccine manufacturers and all health care providers to the Vaccine Adverse Events Reporting System (VAERS). I am responding on behalf of Secretary Azar.

The public's knowledge of vaccine safety and effectiveness, both initially and during extended use, is an important part of a successful national vaccination effort. To date, the U.S. Food and Drug Administration (FDA) has granted Emergency Use Authorizations (EUAs) for two COVID-19 vaccines, which have been shown to be safe and effective as determined by data from the manufacturers and findings from large clinical trials. These data demonstrate that the known and potential benefits of these vaccines outweigh the known and potential harms of becoming infected with COVID 19.

Vaccine safety monitoring is always a priority, even when the safety of vaccines was studied in robust clinical trials. After a vaccine is authorized or approved for use, vaccine safety monitoring never stops. The Centers for Disease Control and Prevention (CDC), FDA, and other federal agencies use many complementary systems to watch for any serious adverse events (possible side effects) following vaccination[1]. This continued monitoring can pick up on adverse events that may not have been seen in clinical trials. If an unexpected adverse event signal is detected, experts quickly study it further to assess whether it is a true vaccine safety concern. This information is also presented to a work group of vaccine safety experts. These experts conduct an independent review and provide guidance on whether changes are needed in current U.S. vaccine recommendations. This monitoring is critical to help ensure that the benefits continue to outweigh the risks for people who receive vaccines.

CDC and FDA are reviewing all COVID-19 VAERS reports classified as "serious" which may not be mentioned under the 42 U.S.C. § 300aa-25. The FDA issued additional reporting requirements to VAERS under the EUAs. In addition, the provider agreements for the CDC COVID-19 Vaccination Program require every enrolled provider to report adverse events following receipt of COVID-19 vaccine through VAERS. CDC has also issued specific guidance

[1] http://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety.html

on VAERS reporting for COVID-19 vaccines under FDA's EUA[2]. We have scaled up existing safety monitoring systems and expanded safety surveillance through new systems and additional information sources. For example, V-safe is a new smartphone-based, active surveillance program and post-vaccination health checker for people who receive COVID-19 vaccines.[3] V-safe uses text messaging and web surveys from CDC to check in with vaccine recipients following COVID-19 vaccination. V-safe also provides second vaccine dose reminders if needed, and telephone follow up to anyone who reports medically significant (important) adverse events. In the event a serious adverse event is identified in V-safe, a VAERS report will be filed on behalf of the individual after the follow-up telephone call.

CDC also recognizes the importance of providing timely data to health officials during the ongoing COVID-19 pandemic which is why we continue to enhance our monitoring programs and add additional data sources to meet those needs. On December 20, 2020, CDC launched a new module in our existing National Healthcare Safety Network (NHSN) system to monitor healthcare professional and resident COVID-19 vaccinations in long-term care facilities, as well as healthcare professionals in acute care hospitals. NHSN connects with VAERS allowing for determination of COVID-19 vaccine adverse event reporting rates.

The U.S. vaccine safety monitoring systems are designed to rapidly detect potential safety signals. These systems have been in place for more than 30 years and they are used to detect possible safety problems with vaccines given to the American public. The federal government remains committed to ensuring that public health officials, healthcare providers, and the public have accurate and timely information about the safety of COVID-19 vaccines. CDC will continue to be vigilant in monitoring the safety of COVID-19 vaccines and will be transparent in its communications with the public.

Thank you for your interest in this ongoing response. We appreciate your support as we all work together to fight COVID-19. CDC remains committed to protecting the American public during this pandemic. A copy of this response has been sent to Mr. Siri.

Sincerely,

Robert R. Redfield, MD
Director, CDC

[2] http://www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-4-Dec-2020-508.pdf
[3] http://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/vsafe.html