U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

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

September 2, 2022

The Honorable Ron Johnson
United States Senate
Washington, DC 20510

Dear Senator Johnson:

Thank you for your letters dated June 23 and July 25, 2022, regarding the Centers for Disease Control and Prevention's (CDC) tracking of reports of coronavirus disease 2019 (COVID-19) vaccine adverse events.

The Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures (SOP) for COVID-19 is a CDC planning document developed with internal and external partners, including federal entities.[1] Within the VAERS SOP disclaimer it states, the VAERS SOP was designed to be a dynamic resource that is used, revised, and implemented based on the current science of the COVID-19 pandemic and has since been updated from the version referenced in Freedom of Information Act (FOIA) Request #22-01479 and mentioned in your letters.[2]

The weekly data tables that were produced during the time period of February 26, 2021, to September 30, 2021, were provided to the FOIA requester and are included as an addendum to this response. The reported incident counts reflect preliminary information, details of which might not have been confirmed by a medical provider interview or medical record review.[3] Revised descriptions of the weekly tables and the information they provide are also found in the updated VAERS SOP.

Regarding your question about the use of proportional reporting ratio (PRR) analysis, CDC and the Food and Drug Administration (FDA) chose to rely on Empirical Bayesian (EB) data mining—a more robust technique used to analyze disproportionate reporting—rather than PRR calculations to mitigate potential false signals. CDC performed PRR analysis between March 25, 2022, through July 31, 2022, to corroborate the results of EB data mining. Notably, results from PRR analysis were generally consistent with EB data mining, revealing no additional unexpected safety signals. CDC also recently addressed a previous statement made to the *Epoch Times* to clarify PRRs were not run between February 26, 2021, to September 30, 2021. Given the strength of the EB data mining method, CDC and FDA plan to continue relying upon EB data mining moving forward.

[1] www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf
[2] www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-02-02-2022-508.pdf
[3] https://vaers.hhs.gov/data.html

CDC consistently performs extensive data collection and analysis to detect potential adverse events and safety signals and then communicates this information to the public. For example, VAERS staff conducted assessments showing that causal associations exist between thrombosis with thrombocytopenia syndrome and Janssen's COVID-19 vaccine and between myocarditis and mRNA COVID-19 vaccination. The outcomes of this work were presented at multiple Advisory Committee on Immunization Practices[4] meetings, and were published in the biomedical literature—which, in turn, informed national vaccine policy.

I appreciate your letter and support, and that of Congress overall, as we work together to fight COVID-19. CDC remains committed to leading with science, promoting equity, and protecting the American public during this pandemic. If you have further questions, please have your staff contact Jeff Reczek in our CDC Washington Office at (202) 245-0600 or JReczek@cdc.gov.

Sincerely,

Rochelle P. Walensky, MD, MPH
Director, CDC

[4] www.cdc.gov/vaccines/acip/index.html