United States Senate
WASHINGTON, DC 20510

June 23, 2022

Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention

Dear Director Walensky:

I write regarding the Centers for Disease Control and Prevention (CDC) tracking of COVID-19 vaccine adverse events. According to a recent article, the CDC failed to provide records responsive to a Freedom of Information Act (FOIA) request relating to the CDC's Standard Operating Procedures (SOP) document dated January 29, 2021.[1]

This SOP identified how CDC and the Food and Drug Administration (FDA) would "perform routine [Vaccine Adverse Event Reporting System (VAERS)] surveillance to identify potential new safety concerns for COVID-19 vaccines."[2] Specifically, the surveillance would include, "generating tables summarizing automated data from fields on the VAERS form for persons who received COVID-19 vaccines (e.g., age of vaccinee, COVID-19 vaccine type, adverse event)."[3] The FOIA request asked CDC to provide these tables, but the agency failed to do so.

For example, CDC failed to produce all of the "VAERS weekly tables" listed in the January 29, 2021 SOP.[4] According to the SOP, these VAERS tables would consist of at least eight different tables including, "all reports [of adverse events] following COVID-19 vaccines by severity and selected manufacturer/brand name" and the "top 25 most frequently reported [adverse events]."[5] CDC claimed that these tables would be assembled "weekly" and "available every Monday."[6] In response to the May 9, 2022 FOIA request, the CDC did not provide all of the requested tables and information.[7] CDC claimed, however, that "no information was

[1] Josh Guetzkow, New FOIA Release Shows CDC Lied About Its VAERS Safety Monitoring Efforts, Substack, June 16, 2022, https://jackanapes.substack.com/p/new-foia-release-shows-cdc-lied-about.
[2] Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at 3.
[3] *Id.*
[4] Josh Guetzkow, New FOIA Release Shows CDC Lied About Its VAERS Safety Monitoring Efforts, Substack, June 16, 2022, https://jackanapes.substack.com/p/new-foia-release-shows-cdc-lied-about; Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at 15.
[5] Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at 15.
[6] *Id.*
[7] Josh Guetzkow, New FOIA Release Shows CDC Lied About Its VAERS Safety Monitoring Efforts, Substack, June 16, 2022, https://jackanapes.substack.com/p/new-foia-release-shows-cdc-lied-about.

withheld from release."[8] This raises questions about whether CDC ever collected the information on vaccine safety it originally claimed that it would in the January 2021 SOP.

In addition to CDC's failure to produce the complete set of the "VAERS weekly tables," CDC failed to provide other data reports and assessments detailed in the SOP. For example, the SOP stated that "CDC will perform Proportional Reporting Ratio (PRR) analysis . . . to identify [adverse events] that are disproportionately reported relative to other [adverse events]."[9] The SOP also noted that, "CDC will perform PRR data mining on a weekly basis or as needed."[10] However, in response to the May 9, 2022 FOIA request for these records, CDC stated, "no PRRs were conducted[.]"[11]

Public health agencies' ability to track and warn the public of potential adverse events connected to the COVID-19 vaccines is dependent on those agencies performing routine and thorough data analyses. As discussed during the October 22, 2020 teleconference on vaccine surveillance systems, a CDC official noted that CDC and FDA planned to use VAERS to conduct "data mining . . . every one to two weeks."[12] That official praised VAERS stating that it can "rapidly detect safety signals and can detect rare adverse events."[13] Indeed, as of June 10, 2022, VAERS reported 28,859 deaths worldwide following COVID-19 vaccination with 7,890 or 27 percent of those deaths occurring on day 0, 1, or 2 following COVID-19 vaccination.[14] Given the effectiveness of VAERS to "detect safety signals," it is unclear why CDC did not generate all the tables using VAERS and other surveillance data on COVID-19 vaccine adverse events even though it initially indicated that it would perform such analyses.

In order to better understand the VAERS data CDC has produced and its apparent decision not to compile certain data detailed in the January 29, 2021 SOP, please provide the following information:

1. All documents requested in the May 9, 2022 FOIA request, #22-01479-FOIA, which included the following based on the January 29, 2021 SOP:[15]
    a. Copies of all "VAERS weekly tables" described in section 2.2.2 from February 1,

[8] Letter from Roger Andow, FOIA Officer, Centers for Disease Control and Prevention, to Divyanshi Dwivedi, Children's Health Defense, June 16, 2022, https://jackanapes.substack.com/api/v1/file/afc9ad6a-9330-4a80-a2c2-5f3bde28422e.pdf.
[9] Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19, Centers for Disease Control and Prevention, Jan. 29, 2021, https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf at 11.
[10] *Id.* at 16.
[11] Letter from Roger Andow, FOIA Officer, Centers for Disease Control and Prevention, to Divyanshi Dwivedi, Children's Health Defense, June 16, 2022, https://jackanapes.substack.com/api/v1/file/afc9ad6a-9330-4a80-a2c2-5f3bde28422e.pdf.
[12] Tom Shimabukuro, Presentation before the Vaccines and Related Biological Products Advisory (Oct. 22, 2020), transcript available at https://www.fda.gov/media/143982/download, (*See* page 95).
[13] *Id.* at 94.
[14] United States Department of Health and Human Services (DHHS), Public Health Service (PHS), Centers for Disease Control (CDC) / Food and Drug Administration (FDA), Vaccine Adverse Event Reporting System (VAERS) 1990 - 06/10/2022, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers html on Jun. 17, 2022 4:16:13 PM.
[15] FOIA request, May 9, 2022, https://jackanapes.substack.com/api/v1/file/44421d00-9c02-4fc9-9471-65fcdb24152c.pdf.

2021, through Sept. 30, 2021, inclusive. These are described in the SOP document as "Data tables demonstrating frequency, reporting ratios and general characteristics will be generated automatically using pre-defined variables populated by VAERS data."

b. Copies of all tables, analyses and reports generated in connection with the "Signal Detection Analyses" described under sections 2.3 of the SOP document (including PRR's described in 2.3.1; Bayesian data mining described in 2.3.2; crude reporting ratios described in 2.3.3) from February 1, 2021, through Sept. 30, 2021, inclusive.

c. All tables, analyses and reports generated in connection with the "Signal Assessment" described in section 2.5 of the SOP document from February 1, 2021, through Sept. 30, 2021, inclusive.

2. If CDC did not collect any of the above information, please explain why and detail who made the decision to not follow the SOP and when that decision was made.

Please provide this information as soon as possible but no later than July 7, 2022. Thank you for your attention to this matter.

Sincerely,

Ron Johnson
United States Senator

cc: The Honorable Robert M. Califf
Commissioner
Food and Drug Administration