

United States Senate
WASHINGTON, DC 20510

September 12, 2022

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

Dear Director Walensky:

I write to you regarding your inadequate and unacceptable response to my letters about the Centers for Disease Control and Prevention's (CDC) surveillance of COVID-19 vaccine adverse events. You have failed to explain why the CDC made inconsistent statements about the data it generates to track these adverse events. Moreover, even though I clearly asked CDC to provide the data that it supposedly generated to track vaccine adverse events, you failed to do so. This data should be made public immediately to better inform the American people about risks of specific adverse events relating to the COVID-19 vaccines. Your lack of clarity calls into question whether CDC has and continues to sufficiently monitor COVID-19 vaccine adverse events.

On June 23, 2022, I requested that you provide data on CDC's surveillance of COVID-19 vaccine adverse events that the agency claimed it would compile in its Standard Operating Procedures (SOP) document dated January 29, 2021.¹ The data that I requested included CDC's Proportional Reporting Ratio (PRR) analyses that, according to the SOP, is meant "to identify [adverse events] that are disproportionately reported relative to other [adverse events]."²

My June 23 letter was based on CDC's reported failure to produce this data in response to a Freedom of Information Act (FOIA) request.³ Specifically, the SOP stated that, "CDC will perform PRR data mining on a weekly basis or as needed."⁴ However, in response to a May 9, 2022 FOIA request for these records, CDC wrote, "no PRRs were conducted" and that "data mining is outside of th [sic] agency's purview."⁵

¹ Letter from Senator Ron Johnson, to Rochelle Walensky, Director, Centers for Disease Control and Prevention, June 23, 2022, <https://www.ronjohnson.senate.gov/services/files/9914278B-A73B-4434-8349-91091138E18B> (enclosed).

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 11.

³ Letter from Senator Ron Johnson, to Rochelle Walensky, Director, Centers for Disease Control and Prevention, June 23, 2022, <https://www.ronjohnson.senate.gov/services/files/9914278B-A73B-4434-8349-91091138E18B>.

⁴ 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 16.

⁵ Letter from Roger Andoh, 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>.

On July 25, 2022, I sent you a follow up letter on this topic after a CDC official reportedly contradicted your agency's previous assertion.⁶ Although CDC claimed that "no PRRs were conducted," Dr. John Su, a CDC official that works on the Vaccine Safety Team, reportedly told a media outlet that "CDC has been performing PRRs since Feb 2021, and continues to do so to date."⁷

In addition to reiterating my requests from the June 23 letter, I also asked for the following information:⁸

1. Is Dr. Su's statement that "CDC has been performing PRRs since Feb 2021, and continues to do so to date" true?⁸
 - a. If so, why did CDC claim that "no PRRs were conducted" in response to a May 9, 2022 FOIA request?⁹
 - b. If Dr. Su's statement is true, please provide all of the PRRs performed since February 2021.
2. Please make Dr. Su available for an interview with my office to discuss the types of surveillance CDC has performed regarding COVID-19 vaccine adverse events and the data CDC has generated based on its surveillance.

On September 6, 2022, over two months after I sent my initial letter on this matter, the CDC provided your response.⁹ In that letter you confirmed that, "CDC performed PRR analysis between March 25, 2022, through July 31, 2022[.]"¹⁰ However, despite my July 25 request for *all* of the PRRs performed since February 2021, you failed to provide any of this information.¹¹ You also noted that, "PRRs were not run between February 26, 2021, to September 30, 2021."¹² However, your response lacked any justification for why CDC performed PRRs during certain periods and not others. You also provided no explanation as to why Dr. Su's assertion that,

⁶ Letter from Senator Ron Johnson, to Rochelle Walensky, Director, Centers for Disease Control and Prevention, July 25 2022, <https://www.ronjohnson.senate.gov/services/files/D48FBED6-BDF3-4FB7-8B24-D52A2EDCE39E> (enclosed).

⁷ Zachary Stieber, EXCLUSIVE: CDC Says It Performed Vaccine Safety Data Mining After Saying It Didn't, Epoch Times, July 23, 2022, https://www.theepochtimes.com/exclusive-cdc-says-it-performed-vaccine-safety-data-mining-after-saying-it-didnt_4617563.html; John Su, Advisory Committee on Immunization Practices, Vaccine Safety Team, Centers for Disease Control and Prevention, Jan. 5, 2022, <https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-01-05/02-covid-su-508.pdf>.

⁸ Letter from Senator Ron Johnson, to Rochelle Walensky, Director, Centers for Disease Control and Prevention, July 25 2022, <https://www.ronjohnson.senate.gov/services/files/D48FBED6-BDF3-4FB7-8B24-D52A2EDCE39E>.

⁹ The CDC's response is dated September 2, 2022, but the agency did not send it to my office until September 6, 2022. Letter from Rochelle Walensky, Director, Centers for Disease Control and Prevention, to Senator Ron Johnson, Sept. 2, 2022 (enclosed).

¹⁰ *Id.*

¹¹ Letter from Senator Ron Johnson, to Rochelle Walensky, Director, Centers for Disease Control and Prevention, July 25 2022, <https://www.ronjohnson.senate.gov/services/files/D48FBED6-BDF3-4FB7-8B24-D52A2EDCE39E>.

¹² Letter from Rochelle Walensky, Director, Centers for Disease Control and Prevention, to Senator Ron Johnson, Sept. 2, 2022.

“CDC has been performing PRRs since Feb 2021, and continues to do so to date,” completely contradicts the CDC’s response to a FOIA request as well as your September 6, 2022 response to me.¹³

In addition, you claimed that, “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.”¹⁴ You also noted that CDC and FDA plan to continue to use EB data mining moving forward.¹⁵ Yet, despite my June 23 request for Bayesian data mining described in 2.3.2 of the January 2021 SOP, you failed to provide this information as well.¹⁶

In your response, you claimed that, “results from PRR analysis were generally consistent with EB data mining.”¹⁷ However, because of your failure to provide these analyses to Congress and to the American people, the public cannot verify your assertion. Although your response did include an addendum containing weekly data tables CDC produced from February 26, 2021 to September 30, 2021, your overall lack of transparency is unacceptable particularly in light of CDC’s inconsistent statements on this matter.¹⁸

If CDC is truly conducting proper analyses of COVID-19 vaccine adverse events, it should not take you over two months to provide this information. Accordingly, I ask that you provide complete responses to my June 23 and July 25 letters (enclosed) and the questions below by no later than September 19, 2022.

1. Your response indicated that CDC “recently addressed a previous statement made to the *Epoch Times*[.]”¹⁹ Was this “previous statement” connected to Dr. Su’s assertion that, “CDC has been performing PRRs since Feb 2021, and continues to do so to date”?²⁰ If so:
 - a. Was Dr. Su’s statement false?
 - b. When and how did CDC address this “previous statement”?

¹³ Zachary Stieber, EXCLUSIVE: CDC Says It Performed Vaccine Safety Data Mining After Saying It Didn’t, *Epoch Times*, July 23, 2022, https://www.theepochtimes.com/exclusive-cdc-says-it-performed-vaccine-safety-data-mining-after-saying-it-didnt_4617563.html.

¹⁴ Letter from Rochelle Walensky, Director, Centers for Disease Control and Prevention, to Senator Ron Johnson, Sept. 2, 2022.

¹⁵ *Id.*

¹⁶ Letter from Senator Ron Johnson, to Rochelle Walensky, Director, Centers for Disease Control and Prevention, June 23, 2022, <https://www.ronjohnson.senate.gov/services/files/9914278B-A73B-4434-8349-91091138E18B>.

¹⁷ Letter from Rochelle Walensky, Director, Centers for Disease Control and Prevention, to Senator Ron Johnson, Sept. 2, 2022.

¹⁸ In its response, CDC noted that the data it enclosed was the same data that was provided to a FOIA requestor. *Id.*

¹⁹ *Id.*

²⁰ Zachary Stieber, EXCLUSIVE: CDC Says It Performed Vaccine Safety Data Mining After Saying It Didn’t, *Epoch Times*, July 23, 2022, https://www.theepochtimes.com/exclusive-cdc-says-it-performed-vaccine-safety-data-mining-after-saying-it-didnt_4617563.html.

2. Why did CDC not conduct PRRs from February 26, 2021 to September 30, 2021 and then decide to conduct PRRs from March 25, 2022 through July 31, 2022?
3. Why and when did CDC decide that it would stop conducting PRRs?
4. When did CDC begin conducting EB data mining?
5. When did CDC choose 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”?²¹
6. Why did CDC misinform the public when it asserted “no PRRs were conducted” and that “data mining is outside of th [sic] agency’s purview”?²² Who at CDC approved the release of this misinformation?

Thank you for your attention to this important matter.

Sincerely,



Ron Johnson
United States Senator

Enclosures

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

²¹ Letter from Rochelle Walensky, Director, Centers for Disease Control and Prevention, to Senator Ron Johnson, Sept. 2, 2022.

²² Letter from Roger Andoh, 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>.