

# United States Senate

WASHINGTON, DC 20510

January 10, 2023

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

Dear Director Walensky:

Since June 2022, despite multiple requests for information, the Centers for Disease Control and Prevention (CDC) has repeatedly failed to provide my office with complete data regarding its surveillance of COVID-19 vaccine adverse events.<sup>1</sup>

My requests have included all Proportional Reporting Ratio (PRR) analyses since February 2021 that, according to CDC's January 29, 2021 Standard Operating Procedures (SOP), is meant to "identify [adverse events] that are disproportionately reported relative to other [adverse events]."<sup>2</sup> CDC has also failed to provide all Bayesian data mining described in 2.3.2 of the January 2021 SOP.<sup>3</sup> As I noted in my September 12, 2022 letter to you, the only response CDC has provided to date—on September 6, 2022—ignored nearly all of my previous data requests and failed to explain why CDC made inconsistent statements about the data it generates to track COVID-19 vaccine adverse events.<sup>4</sup>

On January 3, 2023, the *Epoch Times* published multiple PRR tables that it reportedly obtained through a Freedom of Information Act (FOIA) request.<sup>5</sup> According to the news outlet, the PRR analyses appear to show "hundreds of adverse events" potentially linked to the Moderna and Pfizer COVID-19 vaccines.<sup>6</sup> These PRR tables appear to be responsive to my previous

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<sup>1</sup> 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); 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), Letter from Senator Ron Johnson, to Rochelle Walensky, Director, Centers for Disease Control and Prevention, Sept. 12, 2022, <https://www.ronjohnson.senate.gov/services/files/0CBE044E-4F2C-47F2-8272-4DB4F14D3359> (enclosed).

<sup>2</sup> 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; see also 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> at 2.

<sup>3</sup> 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> at 3.

<sup>4</sup> 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 Senator Ron Johnson, to Rochelle Walensky, Director, Centers for Disease Control and Prevention, Sept. 12, 2022, <https://www.ronjohnson.senate.gov/services/files/0CBE044E-4F2C-47F2-8272-4DB4F14D3359>.

<sup>5</sup> Zachary Stieber, *EXCLUSIVE: CDC Finds Hundreds of Safety Signals for Pfizer and Moderna COVID-19 Vaccines*, *Epoch Times*, Jan. 3, 2023, [https://www.theepochtimes.com/health/exclusive-cdc-finds-hundreds-of-safety-signals-for-pfizer-and-moderna-covid-19-vaccines\\_4956733.html](https://www.theepochtimes.com/health/exclusive-cdc-finds-hundreds-of-safety-signals-for-pfizer-and-moderna-covid-19-vaccines_4956733.html).

<sup>6</sup> *Id.*

letters, and yet, CDC continues to hide this and other information from my office and ultimately, the American people.

In your September 6, 2022 response to my previous letters you wrote that the “results from PRR analysis were generally consistent with [Empirical Bayesian] data mining, revealing no additional unexpected safety signals.”<sup>7</sup> Given the “hundreds of adverse events” listed in the published PRR tables, CDC must explain how it determined what is and is not an “unexpected safety signal.”<sup>8</sup>

The American people have a right to know the extent to which your agency was aware of and tracked COVID-19 vaccine adverse events. Your lack of transparency is unacceptable. Without immediately providing complete and reliable information about COVID-19 vaccine adverse events, you are obstructing Congressional oversight and leaving the public in the dark. I expect you to provide a full response to this letter and to the requests in my June 23, July 25, and September 12, 2022 letters by no later than January 17, 2023.

Sincerely,



Ron Johnson  
United States Senator

Enclosure

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

The Honorable Christi A. Grimm  
Inspector General  
Health and Human Services

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<sup>7</sup> Letter from Rochelle Walensky, Director, Centers for Disease Control and Prevention, to Senator Ron Johnson, Sept. 2, 2022 (enclosed).

<sup>8</sup> *Id.*; Zachary Stieber, *EXCLUSIVE: CDC Finds Hundreds of Safety Signals for Pfizer and Moderna COVID-19 Vaccines*, Epoch Times, Jan. 3, 2023, [https://www.theepochtimes.com/health/exclusive-cdc-finds-hundreds-of-safety-signals-for-pfizer-and-moderna-covid-19-vaccines\\_4956733.html](https://www.theepochtimes.com/health/exclusive-cdc-finds-hundreds-of-safety-signals-for-pfizer-and-moderna-covid-19-vaccines_4956733.html).

**Enclosure**

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.<sup>1</sup>

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.”<sup>2</sup> 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).”<sup>3</sup> 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.<sup>4</sup> 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].”<sup>5</sup> CDC claimed that these tables would be assembled “weekly” and “available every Monday.”<sup>6</sup> In response to the May 9, 2022 FOIA request, the CDC did not provide all of the requested tables and information.<sup>7</sup> CDC claimed, however, that “no information was

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<sup>1</sup> 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>.

<sup>2</sup> 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.

<sup>3</sup> *Id.*

<sup>4</sup> 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.

<sup>5</sup> 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.

<sup>6</sup> *Id.*

<sup>7</sup> 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.”<sup>8</sup> 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].”<sup>9</sup> The SOP also noted that, “CDC will perform PRR data mining on a weekly basis or as needed.”<sup>10</sup> However, in response to the May 9, 2022 FOIA request for these records, CDC stated, “no PRRs were conducted[.]”<sup>11</sup>

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.”<sup>12</sup> That official praised VAERS stating that it can “rapidly detect safety signals and can detect rare adverse events.”<sup>13</sup> 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.<sup>14</sup> 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:<sup>15</sup>
  - a. Copies of all “VAERS weekly tables” described in section 2.2.2 from February 1,

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<sup>8</sup> 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>.

<sup>9</sup> 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.

<sup>10</sup> *Id.* at 16.

<sup>11</sup> 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>.

<sup>12</sup> 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).

<sup>13</sup> *Id.* at 94.

<sup>14</sup> 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.

<sup>15</sup> FOIA request, May 9, 2022, <https://jackanapes.substack.com/api/v1/file/44421d00-9c02-4fc9-9471-65fdb24152c.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

# United States Senate

WASHINGTON, DC 20510

July 25, 2022

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

Dear Director Walensky:

On June 23, 2022, I wrote to you about whether the Centers for Disease Control and Prevention (CDC) performed sufficient surveillance of COVID-19 vaccine adverse events (enclosed).<sup>1</sup> To date, the CDC has failed to provide a response to that letter.

In that letter, I described the CDC and the Food and Drug Administration's Standard Operating Procedures (SOP) document dated January 29, 2021, which declared that the agencies would "perform routine [Vaccine Adverse Event Reporting System (VAERS)] surveillance to identify potential new safety concerns for COVID-19 vaccines."<sup>2</sup> Yet, in response to a Freedom of Information Act (FOIA) request for these surveillance records, CDC failed to provide data it originally claimed it would generate.<sup>3</sup>

As I noted in my letter, 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]."<sup>4</sup> The SOP also stated that, "CDC will perform PRR data mining on a weekly basis or as needed."<sup>5</sup> However, in response to the 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."<sup>6</sup>

The validity of this assertion has recently been called into question. 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."<sup>7</sup> CDC's assertion and Dr. Su's statement cannot both be true.

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<sup>1</sup> 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>.

<sup>2</sup> 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.

<sup>3</sup> 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>.

<sup>4</sup> 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.

<sup>5</sup> *Id.* at 16.

<sup>6</sup> 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>.

<sup>7</sup> 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->

The American people deserve the truth and you have not been providing it. That is why I, together with millions of Americans, have completely lost faith in the CDC and other federal health agencies. It is time to start regaining their confidence and your agency's integrity by coming clean, being transparent, and telling the truth.

Accordingly, please provide an immediate and complete response to my June 23, 2022 letter and the following information by no later than July 29, 2022:

1. Is Dr. Su's statement that "CDC has been performing PRRs since Feb 2021, and continues to do so to date" true?<sup>8</sup>
  - a. If so, why did CDC claim that "no PRRs were conducted" in response to a May 9, 2022 FOIA request?<sup>9</sup>
  - 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.

Thank you for your attention to this important matter.

Sincerely,



Ron Johnson  
United States Senator

Enclosure

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

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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>.

<sup>8</sup> 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](https://www.theepochtimes.com/exclusive-cdc-says-it-performed-vaccine-safety-data-mining-after-saying-it-didnt_4617563.html).

<sup>9</sup> 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>.



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.<sup>1</sup> 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]."<sup>2</sup>

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.<sup>3</sup> Specifically, the SOP stated that, "CDC will perform PRR data mining on a weekly basis or as needed."<sup>4</sup> 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."<sup>5</sup>

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<sup>1</sup> 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).

<sup>2</sup> 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.

<sup>3</sup> 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>.

<sup>4</sup> 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.

<sup>5</sup> 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.<sup>6</sup> 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."<sup>7</sup>

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

1. Is Dr. Su's statement that "CDC has been performing PRRs since Feb 2021, and continues to do so to date" true?<sup>8</sup>
  - a. If so, why did CDC claim that "no PRRs were conducted" in response to a May 9, 2022 FOIA request?<sup>9</sup>
  - 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.<sup>9</sup> In that letter you confirmed that, "CDC performed PRR analysis between March 25, 2022, through July 31, 2022[.]"<sup>10</sup> However, despite my July 25 request for *all* of the PRRs performed since February 2021, you failed to provide any of this information.<sup>11</sup> You also noted that, "PRRs were not run between February 26, 2021, to September 30, 2021."<sup>12</sup> 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,

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<sup>6</sup> 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).

<sup>7</sup> 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](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>.

<sup>8</sup> 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>.

<sup>9</sup> 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).

<sup>10</sup> *Id.*

<sup>11</sup> 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>.

<sup>12</sup> 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.<sup>13</sup>

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.”<sup>14</sup> You also noted that CDC and FDA plan to continue to use EB data mining moving forward.<sup>15</sup> 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.<sup>16</sup>

In your response, you claimed that, “results from PRR analysis were generally consistent with EB data mining.”<sup>17</sup> 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.<sup>18</sup>

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*[.]”<sup>19</sup> 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”?<sup>20</sup> If so:
  - a. Was Dr. Su’s statement false?
  - b. When and how did CDC address this “previous statement”?

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<sup>13</sup> 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](https://www.theepochtimes.com/exclusive-cdc-says-it-performed-vaccine-safety-data-mining-after-saying-it-didnt_4617563.html).

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

<sup>15</sup> *Id.*

<sup>16</sup> 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>.

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

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

<sup>19</sup> *Id.*

<sup>20</sup> 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](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”?<sup>21</sup>
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”?<sup>22</sup> 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

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

<sup>22</sup> 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>.



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.<sup>1</sup> 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.<sup>2</sup>

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.<sup>3</sup> 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.

<sup>1</sup> [www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf](http://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf)

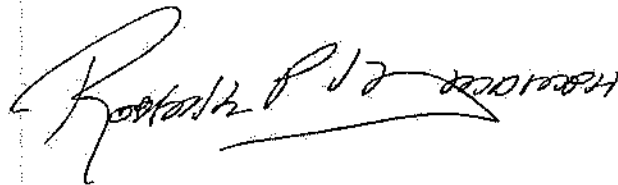
<sup>2</sup> [www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-02-02-2022-508.pdf](http://www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-02-02-2022-508.pdf)

<sup>3</sup> <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<sup>4</sup> 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](mailto:JReczek@cdc.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "Rochelle P. Walensky", with a horizontal line underneath.

Rochelle P. Walensky, MD, MPH  
Director, CDC

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<sup>4</sup> [www.cdc.gov/vaccines/acip/index.html](http://www.cdc.gov/vaccines/acip/index.html)