United States Senate

COMMITTEE ON
HOMELAND SECURITY AND GOVERNMENTAL AFFAIRS

WASHINGTON, DC 20510–6250

September 5, 2023

The Honorable Robert M. Califf
Commissioner
Food and Drug Administration

Dear Commissioner Califf:

On June 15, 2023, the Food and Drug Administration (FDA) refused to provide my office with data relating to the safety of the COVID-19 vaccines.[1] FDA's intentional withholding of information relating to the safety of the COVID-19 vaccines is outrageous and shows a complete disregard for the health and safety of the American people.

Since June 2022, I have copied you on multiple requests to the Centers for Disease Control and Prevention (CDC) regarding its surveillance of COVID-19 vaccine adverse events.[2] These requests were based off of a January 29, 2021 Standard Operating Procedure (SOP) document describing how "CDC and FDA will perform routine VAERS [Vaccine Adverse Event Reporting System] surveillance to identify potential new safety concerns for COVID-19 vaccines."[3] CDC failed to fully comply with my requests for the data it supposedly compiled in order to track vaccine adverse events. Based on a recent response from FDA to my office for similar information, it appears that your agency is also refusing to be transparent.[4]

The January 2021 SOP described the types of data mining analyses CDC and FDA would conduct to identify potential safety concerns linked to the COVID-19 vaccines.[5] These analyses included Proportional Reporting Ratio (PRR) and empirical Bayesian (EB) data mining.[6] In a September 2, 2022 response to my requests, CDC Director Rochelle Walensky informed my office that:

> "CDC and the Food and Drug Administration (FDA) chose to rely on Empirical Bayesian (EB) data mining—a more robust technique used to

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[1] Email from FDA to staff, June 15, 2023 (on file).
[2] *See* 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); Letter from Senator Ron Johnson, to Rochelle Walensky, Director, Centers for Disease Control and Prevention, Jan. 10, 2023, https://www ronjohnson.senate.gov/services/files/AB68101B-CDA4-49F1-8174-4274DDEB0120 (enclosed).
[3] 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.
[4] Email from FDA to staff, June 15, 2023 (on file).
[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 16-17.
[6] *Id.*

> analyze disproportionate reporting—rather than PRR calculations to mitigate potential false signals. . . . Given the strength of the EB data mining method, CDC and FDA plan to continue relying upon EB data mining moving forward."[7]

Although CDC confirmed that it relied on EB data mining, it refused to comply with my June 23, 2022 request to produce the EB data.[8] It was not until March 14, 2023, nearly nine months after my initial letter, that CDC informed my office in writing that "EB data mining [is] performed by FDA" and to "direct future inquiries regarding EB data mining to FDA."[9] That same day, following receipt of CDC's response, my staff emailed FDA to confirm that it has performed all EB data mining as it relates to the COVID-19 vaccines and requested FDA to provide the data as soon as possible.[10]

Three months later, on June 15, 2023, FDA provided this unacceptable response:

> "FDA's EB data mining analyses of adverse events contained in VAERS reports for COVID-19 vaccines are currently the subject of pending FOIA [Freedom of Information Act] litigation. FDA is unable to comment on pending litigation or provide information or data that is currently being considered in pending litigation."[11]

As you are well aware, Congress has a right to information contained at U.S. federal agencies as it conducts its constitutional oversight responsibilities. It is outrageous that FDA would assert that pending litigation, and particularly FOIA litigation, would allow your agency to obstruct my Congressional oversight.[12] Any pending litigation FDA may have relating to its EB data mining records has no bearing on its responsibility to comply with a Congressional request.

The notion that FDA is actively hiding information about vaccine safety signals from Congress and the American people is beyond despicable, particularly given the fact that COVID-19 vaccine adverse events can and do occur. According to VAERS, as of September 1, 2023, there have been 1,589,970 adverse events and 36,080 deaths associated with the COVID-19 vaccines.[13] Other countries are also finding adverse events associated with the COVID-19

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[7] Letter from Rochelle Walensky, Director, Centers for Disease Control and Prevention, to Senator Ron Johnson, Sept. 2, 2022, https://www.ronjohnson.senate.gov/services/files/AB68101B-CDA4-49F1-8174-4274DDEB0120 at 13-14 (enclosed).

[8] See question 1.b in the June 23, 2022 letter. 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.

[9] Letter from Jeff Reczek, Dir., CDC Washington Office, Centers for Disease Control and Prevention, Mar. 14, 2023 at 2 (enclosed).

[10] Email from staff to CDC, Mar. 14, 2023 (on file).

[11] Email from FDA to staff, June 15, 2023 (on file).

[12] I have routinely received documents and records that were subject to simultaneous FOIA litigation from federal agencies, including the Department of Health and Human Services, of which FDA is a subcomponent.

[13] *See* VAERS database query: 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

vaccines. For example, as of October 31, 2022, the Paul Ehrlich Institute, Germany's health agency, had received 333,492 reports of adverse events associated with the COVID-19 vaccines.[14] Based on information reported to the Danish Medicines Agency, researchers found that 13,635 individuals reported 43,496 suspected adverse events following Pfizer's COVID-19 vaccination.[15] By May 2023, the European Medicines Agency, which monitors the safety of COVID-19 vaccines in the European Union, reported "almost 1.7 million spontaneous reports of suspected side effects" following COVID-19 vaccination.[16]

With FDA's Vaccine and Related Biological Products Advisory Committee voting to recommend updates and continued use of the mRNA COVID-19 vaccines, the public has a right to know the extent to which their health may be negatively affected by this vaccine technology.[17]

Therefore, I expect FDA to be transparent with Congress and produce all EB data mining analyses relating to the COVID-19 vaccines by no later than September 19, 2023.

Sincerely,

Ron Johnson
Ranking Member
Permanent Subcommittee on Investigations

Reporting System (VAERS) 1990 - 8/25/2023, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers html on September 5, 2023 3:30:57 PM. Query criteria –Vaccine Products: COVID-19 Vaccine (COVID19); COVID-19-2 (COVID-192). Group By: Month Received. State/Territory: All locations. Event Category: All Events. Show Totals: True. Show Zero Values: False; VAERS database query: 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 - 8/25/2023, CDC WONDER On-line Database. Accessed at http://wonder.cdc.gov/vaers.html on September 5, 2023 3:30:57 PM. Query criteria – Vaccine Products: COVID-19 Vaccine (COVID19); COVID-19-2 (COVID-192). Group By: Month Received. State/Territory: All locations. Event Category: Death. Show Totals: True. Show Zero Values: False.

[14] Lorenz Duchamps, *COVID-19 Vaccines Can Cause 'Permanent Disabilities': German Health Minister*, Epoch Times, Mar. 16, 2023, https://www.theepochtimes.com/covid-19-vaccines-can-cause-permanent-disabilities-says-german-health-minister_5129027 html?utm_source=open&utm_medium=search.

[15] Harry Lee, Study Shows 4.2 Percent of Pfizer COVID Vaccine Batches Made up Most Adverse Events, Raising Serious Concerns, Epoch Times, Apr. 14, 2023, https://www.theepochtimes.com/health/only-4-2-percent-of-pfizer-covid-vaccine-batches-accounted-for-71-percent-of-adverse-events-danish-study_5193114 html?utm_source=open&utm_medium=search.

[16] Safety of COVID-19 vaccines, European Medicines Agency, May 2023, https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-medicines/safety-covid-19-vaccines.

[17] Press release, Vaccines and Related Biological Products Advisory Committee June 15, 2023 Meeting Announcement, Food and Drug Administration, June 15, 2023, https://www fda.gov/advisory-committees/advisory-committee-calendar/vaccines-and-related-biological-products-advisory-committee-june-15-2023-meeting-announcement; Nathaniel Weixel, *FDA panel recommends updating COVID vaccine for the fall*, The Hill, June 15, 2023, https://thehill.com/policy/healthcare/4052290-fda-updated-covid-vaccine-boosters/.

Enclosure

cc: The Honorable Richard Blumenthal
Chairman
Permanent Subcommittee on Investigations

Dr. Mandy Cohen
Director
Centers for Disease Control and Prevention

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

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.[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

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).[1] 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."[2] 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.[3]

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]."[4] The SOP also stated that, "CDC will perform PRR data mining on a weekly basis or as needed."[5] 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."[6]

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."[7] CDC's assertion and Dr. Su's statement cannot both be true.

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[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.
[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] 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.
[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 11.
[5] *Id.* at 16.
[6] 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.
[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-

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?[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.

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

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] 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.

[9] 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.[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,

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[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"?

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[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.

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.[1]

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]."[2] CDC has also failed to provide all Bayesian data mining described in 2.3.2 of the January 2021 SOP.[3] 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.[4]

On January 3, 2023, the *Epoch Times* published multiple PRR tables that it reportedly obtained through a Freedom of Information Act (FOIA) request.[5] 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.[6] These PRR tables appear to be responsive to my previous

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[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); 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).

[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; 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.

[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 at 3.

[4] 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.

[5] 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.

[6] *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."[7] 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."[8]

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

[7] Letter from Rochelle Walensky, Director, Centers for Disease Control and Prevention, to Senator Ron Johnson, Sept. 2, 2022 (enclosed).
[8] *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.

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

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

March 14, 2023

The Honorable Ron Johnson
United States Senate
Washington, DC 20510

Dear Senator Johnson:

Thank you for your January 10, 2023, letter regarding the Centers for Disease Control and Prevention's (CDC) surveillance of coronavirus disease 2019 (COVID-19) vaccine adverse events. I am pleased to respond on behalf of CDC.

Transparency and vaccine safety are top priorities for CDC and the Food and Drug Administration (FDA). U.S. government agencies use multiple, complementary safety monitoring systems to help detect possible safety concerns (or "safety signals") for vaccines and other medical countermeasures as early as possible and to facilitate further investigation, as appropriate. These safety systems may detect signals that could be due to factors other than the vaccine itself. When one system detects a signal, other safety monitoring systems are checked to help evaluate if the signal may represent an actual safety concern, if it may be a spurious finding, or what clinical relevance, if any, it represents. Safety issues that are known and expected, such as those observed and evaluated previously in clinical trials or other studies, are not necessarily considered new safety signals or findings.

This coordinated vaccine safety infrastructure ensures that COVID-19 vaccines are undergoing intensive safety monitoring. If, for example, Vaccine Adverse Event Reporting System[1] (VAERS) monitoring identifies a potential safety signal, additional scientifically rigorous active surveillance studies or investigations can be conducted by CDC in the Vaccine Safety Datalink,[2] by FDA through its Biologics Effectiveness and Safety Initiative,[3] and through Centers for Medicare & Medicaid claims data. The totality of the data guides decisions about whether a signal represents a genuine safety problem with a vaccine.

CDC strives to be responsive to Congress and has provided several written responses and briefings to your staff on the topic of vaccine safety. CDC responded to your June 23, 2022, and July 25, 2022, letters with correspondence dated September 2, 2022. As requested in your June 23 letter, CDC provided documents released through a May 2022 Freedom of Information Act (FOIA) request as an addendum to the September 2, 2022, response. The documents responsive to the May 2022 FOIA request were weekly data tables that were produced during the time

[1] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html
[2] https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html
[3] https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/cber-biologics-effectiveness-and-safety-best-system

period of February 26, 2021, to September 30, 2021. CDC later provided additional documents released through a subsequent FOIA request.

Regarding Empirical Bayesian (EB) data mining, CDC's September 2, 2022, response clarified that the VAERS Standard Operating Procedures for COVID-19[4] is a dynamic resource that is used, revised, and implemented based on the current science of the COVID-19 pandemic. FDA began EB data mining in December 2020. CDC reiterated to your staff on January 3, 2023, that EB data mining continues to be performed by FDA. Please direct future inquiries regarding EB data mining to FDA.

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. If you have further questions, please contact me at (202) 245-0600 or JReczek@cdc.gov.

Sincerely,

Jeff Reczek
Director, CDC Washington Office

[4] https://www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-02-02-2022-508.pdf