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Congress of the United States
House of Representatives
Washington, DC 20515–4313

December 15, 2022

Rochelle Walensky, M.D., MPH
Director
Centers for Disease Control and Prevention
395 E Street SW
Washington, DC 20024

The Honorable Robert Califf, M.D
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, Maryland 20993

Dear Director Walensky and Commissioner Califf:

I write to you today concerned with the Centers for Disease Control and Prevention's (CDC) and the Food and Drug Administration's (FDA) continual lack of transparency with the American people regarding the safety of COVID-19 vaccines, specifically the data surrounding the adverse reactions an individual may experience after receiving a COVID-19 vaccine.

President Trump's Operation Warp Speed achieved the impossible by developing multiple vaccines in record time and is a testament to how the federal government and private sector can collaborate for the common good. Even so, there is still much unknown about COVID-19, including the true origins of the virus and the potential side effects of the vaccine. Therefore, it is the CDC's and FDA's responsibility to continuously study the effectiveness, longevity, and, most importantly, safety of the COVID-19 vaccines and inform the public of their findings so each individual can make a personal choice of whether receiving the COVID-19 vaccine is right for them.

As you know, one of several monitoring systems in the United States to study safety on vaccines authorized for use in the United States is the Vaccine Adverse Event Reporting System (VAERS). The CDC and FDA "use VAERS as a front-line system to monitor the safety of vaccines" after they hit the market. [1] According to the CDC, "the information collected by VAERS can quickly provide an early warning of a potential safety problem with a vaccine," however, VAERS is a passive reporting system with documented limitations.[2]

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[1] "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19." *Centers for Disease Control and Prevention*, 29 Jan. 2021, https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.

[2] "Vaccine Adverse Event Reporting System (VAERS)." *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 8 Sept. 2022, https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html#anchor_1616772696807.

In January 2021[3] and February 2022[4], the CDC's Immunization Safety Office laid out Standard Operating Procedures (SOPs) on its Vaccine Adverse Event Reporting System (VAERS) for COVID-19 vaccines authorized for use in the United States. Given some of the limitations associated with analyzing VAERS data, the SOPs tasked the CDC and FDA to perform two types of data mining analyses to make the VAERS data more meaningful and accurately identify safety signals. Specifically, the SOPs directed the CDC and FDA to use these different data mining methods to establish patterns and determine the rate at which the COVID-19 vaccines authorized in the U.S. produce adverse events (AEs), an AE being any unwanted experience related to receiving a COVID-19 vaccine. The SOPs state that the CDC will perform Proportional Reporting Ratio (PRR) data mining on a weekly basis to "compare the proportion of a specific AE following a specific vaccine versus the proportion of the same AE following another vaccine." Moreover, the "FDA will perform data mining at least biweekly… using empirical Bayesian (EB) data mining to identity AEs reported more frequently than expected following vaccination with COVD-19 vaccines." [5]

In September, *The Epoch Times* reported that both of your agencies have declined to publicize these analyses. In July, *The Epoch Times* asked the FDA for all "analyses performed by the agency for the COVID-19 vaccines using a method called Empirical Bayesian data mining." The FDA recently responded to *The Epoch Times*' Freedom of Information Act (FOIA) request stating that "it would not provide any of the analyses, even in redacted form." In that same article, *The Epoch Times* noted the CDC also refused to provide the results of the analyses they conducted using PRR mining.[6] Furthermore, the CDC has made inconsistent statements on the timing of the analyses. For example, in a letter to Senator Johnson on September 2, 2022, Director Walensky stated that the "CDC performed PRR analysis between March 25, 2022, through July 31, 2022, to corroborate the results of EB data mining," and that the "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."[7]

Promoting trust between the public health authorities and the public requires being forthcoming with the evidence and assumptions used in public health decision-making processes. Instead of building that trust, the Biden administration and Democrats vigorously alienated Americans who decided to forgo COVID-19 vaccine due to hesitancy or uncertainty of potential adverse reactions, which in turn ultimately undermined vaccine confidence. The data mining analyses your offices were directed to

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[3] "Vaccine Adverse Event Reporting System (VAERS) Standard Operating Procedures for COVID-19." *Centers for Disease Control and Prevention*, 29 Jan. 2021, https://www.cdc.gov/vaccinesafety/pdf/VAERS-v2-SOP.pdf.

[4] "Vaccine Adverse Event Reporting System (VAERS) Standard Operating for Procedures for COVID-19." *Centers for Disease Control and Prevention*, 2 Feb. 2022, https://www.cdc.gov/vaccinesafety/pdf/VAERS-COVID19-SOP-02-02-2022-508.pdf.

[5] Ibid

[6] Stieber, Zachary. "Exclusive: FDA Refuses to Provide Key COVID-19 Vaccine Safety Analyses." *Www.theepochtimes.com*, 11 Sept. 2022, https://www.theepochtimes.com/exclusive-fda-refuses-to-provide-key-covid-19-vaccine-safety-analyses_4722586.html?utm_source=News&utm_campaign=breaking-2022-09-10-3&utm_medium=email&est=hnVq25WEJBqNNN5S6Ei2DvVGdFgXJBTupa4NH9MXg%2FOwDegkFw4Eo4SOChoDQ6VZsPPYyfM%3D.

[7] Letter from Rochelle Walensky, Director, Centers for Disease Control and Prevention, to Senator Ron Johnson, Sept. 2, 2022, https://jackson.house.gov/uploadedfiles/director_walensky_response_letter_to_senator_johnson.pdf

complete are important to interpreting VAERS data and could help the public better weigh the benefits and potential risks associated with vaccines in order to make the best decisions for themselves and their families. As the institutions charged with protecting the public's health based on verifiable scientific data, I am concerned that your agencies either have yet to conduct these data mining analyses or, if the analyses have been done, your agencies have been reluctant to provide the results.

Your agencies' unwillingness to be candid is misleading to the public and erodes the American people's trust in our public health system. Therefore, I request that the CDC and FDA answer the following questions.

1. Have the CDC and FDA conducted the data mining analyses as directed in the CDC's Immunization Safety Office's Standard Operation Procedures?
    a. If not, please explain why these analyses have not been conducted, and provide all internal communications and documentation used to determine the decision to forgo these analyses.
    b. If so, please provide the dates when your agencies started conducting the analyses, including all tables and reports relating to these data mining analyses.

2. Why have the CDC and FDA declined to provide the results of this data to FOIA requests asking for this information? Please provide all internal communications and documentation used to consider denying such FOIA requests.

I appreciate your prompt attention to this matter. Please do not hesitate to contact my office if we may be of any assistance.

Sincerely,

Ronny L. Jackson, M.D.
Member of Congress

Barry Moore
Member of Congress

Brad R. Wenstrup, D.P.M
Member of Congress

Debbie Lesko
Member of Congress

W. Gregory Steube
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