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ONE HUNDRED SEVENTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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September 28, 2021

Rochelle P. Walensky, MD, MPH
Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329

Dear Dr. Walensky:

We write to request information and a briefing from the Centers for Disease Control and Prevention (CDC) regarding the CDC's decision not to collect data on breakthrough cases of SARS-CoV-2 (COVID-19) among Americans unless the breakthrough cases result in hospitalization or death. We are concerned such a decision has led the CDC to make decisions based on limited or unreliable data.

According to the CDC, most states and jurisdictions are experiencing high or substantial levels of community transmission.¹ In addition, projections estimate that the national proportion of COVID-19 cases attributed to the Delta variant is greater than 98 percent.² As of September 24, 2021, the current 7-day moving average of daily new COVID-19 cases is 121,533.³

According to the CDC, as of August 27, 2021, 183.9 million people in the U.S. are fully vaccinated.⁴ The three COVID-19 vaccines that have been authorized by the U.S. Food and Drug Administration (FDA) and are being used throughout the U.S. are effective and a critical tool to combat the COVID-19 pandemic and save lives. In addition, last month the FDA

¹ Centers for Disease Control and Prevention, COVID Data Tracker, COVID-19 Integrated County View, *available at* <https://covid.cdc.gov/covid-data-tracker/#county-view> (last visited Sept. 27, 2021).

² Centers for Disease Control and Prevention, COVID-19, Weekly Review, Interpretive Summary for September 24, 2021, *available at* <https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html> (last visited Sept. 27, 2021).

³ *Id.*

⁴ Centers for Disease Control and Prevention, COVID Data Tracker, COVID-19 Vaccinations in the United States, *available at* https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total (last visited Aug. 24, 2021).

approved the first COVID-19 vaccine—the Pfizer-BioNTech vaccine—for the prevention of COVID-19 disease in individuals 16 years of age and older.⁵ However, the vaccines, like all vaccines, are not 100 percent effective at preventing breakthrough infections. Thus, it is expected that there will be a small percentage of fully vaccinated people who contract COVID-19 that may be asymptomatic or in rare cases result in hospitalization or death.

From January 1 to April 30, 2021, CDC worked with state and territorial health departments to investigate COVID-19 infections among people who are fully vaccinated and to monitor trends in case characteristics and variants identified from persons with COVID-19 infections.⁶ A total of 10,262 COVID-19 vaccine breakthrough infections were reported from 46 states and territories as of April 30, 2021.⁷ However, as of May 1, 2021, the CDC transitioned from monitoring all reported vaccine breakthrough cases to focus on identifying and investigating only hospitalized or fatal cases due to any cause.⁸ The CDC stated that “this shift will help maximize the quality of the data collected on cases of greatest clinical and public health importance.”⁹ According to the CDC, as of September 20, 2021, the CDC has received reports from 50 states and territories of 19,136 patients with COVID-19 vaccine breakthrough infections who were hospitalized or died.¹⁰ Of those, there were 4,493 deaths, and 14,643 hospitalized, non-fatal cases.¹¹ While this data is critical and should be collected and monitored, it is concerning that the CDC has not collected data on the total number of breakthrough cases since April, especially since the Delta variant became the dominant variant of COVID-19 in the U.S. in early July, and is believed to be a more infectious variant of COVID-19.¹²

In addition, CDC’s decision to limit its reporting on breakthrough cases has resulted in states varying in their approach to data collection on COVID-19 breakthrough cases. Recent reports have found that while 35 states have disclosed some data on fully vaccinated individuals who later experience breakthrough cases, 15 states have decided not to publish any data on breakthrough cases.¹³ Even among the 35 states who are disclosing data, the publicly available information ranges from a one-time percentage of residents who experienced breakthrough

⁵ U.S. Food and Drug Administration, FDA Approves First COVID-19 Vaccine (Aug. 23, 2021), *available at* <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>.

⁶ *COVID-19 Vaccine Breakthrough Infections Reported to CDC – United States, January 1-April 3, 2021*, Centers for Disease Control and Prevention, Morbidity and Mortality Weekly Report (MMWR) (May 28, 2021), *available at* <https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm>.

⁷ *Id.*

⁸ Centers for Disease Control and Prevention, Vaccines & Immunizations, COVID-19 Breakthrough Case Investigations and Reporting, *available at* <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html> (last visited Sept. 27, 2021).

⁹ *Id.*

¹⁰ *Id.*

¹¹ *Id.*

¹² Arielle Mitropoulos and Morgan Winsor, *Delta now dominant coronavirus variant in the US, CDC says*, ABC NEWS (July 7, 2021), *available at* <https://abcnews.go.com/Health/delta-now-dominant-coronavirus-variant-us-cdc/story?id=78704682>.

¹³ Christine Mui, *15 states are keeping COVID-19 breakthrough cases under wraps*, THE HILL (Aug. 6, 2021), *available at* <https://thehill.com/homenews/state-watch/566755-15-states-are-keeping-covid-breakthrough-cases-under-wraps>.

infections to detailed weekly updates that include demographics of individuals who experienced breakthrough infections.¹⁴

In late July, the CDC estimated that 153,000 symptomatic breakthrough cases occurred in the prior week, representing approximately 0.098 percent of those who were fully vaccinated at the time.¹⁵ Further, according to the CDC, less than one percent of people who have contracted COVID-19 despite being vaccinated have either been hospitalized or died.¹⁶ However, it is difficult to understand how the CDC is able to have confidence in such statistics when it stopped collecting data on all breakthrough infections, aside from hospitalizations and deaths, in May. Because the CDC decided to not collect information about all breakthrough infections in the U.S., we do not have a full understanding of the total number and characteristics of all the breakthrough infections that are occurring across the U.S., including how many breakthrough cases have occurred; where, geographically, the breakthrough infections are occurring; which variants are causing the breakthrough infections; which vaccine the individuals who are experiencing breakthrough cases received, when the individuals were vaccinated; who may be more susceptible to breakthrough infections; what symptoms these individuals are experiencing, if any; how many asymptomatic cases are occurring; and whether these individuals are experiencing long-COVID symptoms after they recover. These are all critical pieces of information that would help us better understand how the pandemic is evolving in the U.S. and how we can respond more effectively.

Since the CDC recently suggested, based on a study comparing the viral load in vaccinated and unvaccinated individuals, that fully vaccinated individuals have the potential to transmit the virus, tracking breakthrough infections, even if they do not result in hospitalization or death, would help us better understand and control the ongoing spread of COVID-19. In addition, recent reports indicate that the U.S. has become increasingly reliant on data from other countries or from drug companies about vaccine effectiveness over time, especially their effectiveness with respect to the Delta variant.¹⁷ Tracking which vaccine these individuals who experience a breakthrough infection received and when they received the vaccine would help the FDA and pharmaceutical companies who developed the COVID-19 vaccines collect real world data on how well the vaccines are working against certain variants, when immunity may start to wane from the vaccines, and help to inform decisions about when booster shots will be needed, and if there are certain populations for whom booster shots should be prioritized.

¹⁴ *Id.*

¹⁵ Arielle Mitropoulos, *Symptomatic breakthrough COVID-19 infections are rare, CDC data estimates*, ABC NEWS (July 26, 2021), available at <https://abcnews.go.com/US/symptomatic-breakthrough-covid-19-infections-rare-cdc-data/story?id=79048589>.

¹⁶ Austin Williams, *CDC: Less than 1% of breakthrough COVID-19 cases led to hospitalization or death*, FOX 5 (Aug. 3, 2021), available at <https://www.fox5dc.com/news/cdc-less-than-1-of-breakthrough-covid-19-cases-led-to-hospitalization-or-death>.

¹⁷ Caitlin Owens, *America's Delta data problem*, AXIOS (Aug. 9, 2021), available at https://www.axios.com/america-coronavirus-vaccines-delta-data-ababc99b-df6b-4ddb-b4b2-341733933a27.html?utm_source=newsletter&utm_medium=email&utm_campaign=newsletter_axiosvitals&stream=top.

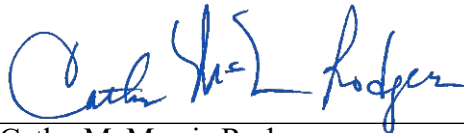
We are still in the midst of a global pandemic, and national, state, local, and tribal leaders as well as vaccine developers are having to make decisions about how best to protect Americans against COVID-19. In addition, the threat that COVID-19 poses to our nation continues to evolve. For example, the situation we were facing in April is very different than the situation we are currently facing due to the Delta variant. Providing decision-makers with better, more complete data and information on breakthrough infections will be essential as they continue to respond to this evolving pandemic.

Given the continued risk of COVID-19 in the U.S., the Committee Republicans have questions about the CDC's decision in May to shift from monitoring all reported breakthrough infections of COVID-19 to monitoring only those that result in hospitalization or death. We therefore request a briefing by October 12, 2021 on the CDC's data collection of COVID-19 breakthrough infections, including, but not limited to:

- CDC's decision to stop monitoring all reported breakthrough infections of COVID-19;
- Why this decision helps maximize the quality of data collected on cases of greatest clinical and public health importance;
- What data the CDC uses to estimate the percentage of breakthrough cases of COVID-19 that led to hospitalization or death compared to those that do not require hospitalization; and
- If the CDC plans to revise this decision and resume collecting data on and monitoring all breakthrough infections of COVID-19 in the U.S. given the characteristics of the Delta variant in vaccinated individuals.

Please contact Brittany Havens or Kristen Shatynski of the Minority Committee staff with any questions and to schedule the requested briefing. Thank you for your attention to this request.

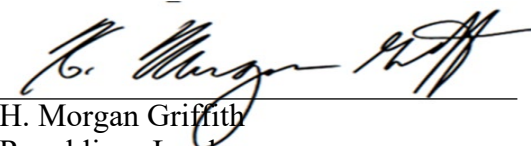
Sincerely,



Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce



Brett Guthrie
Republican Leader
Subcommittee on Health



H. Morgan Griffith
Republican Leader
Subcommittee on Oversight and Investigations

Letter to Director Rochelle P. Walensky

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CC: The Honorable Frank Pallone, Jr., Chairman

The Honorable Anna Eshoo, Chair, Subcommittee on Health

The Honorable Diana DeGette, Chair, Subcommittee on Oversight and Investigations