July 22, 2021

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

Dear Director Walensky,

I write regarding the Centers for Disease Control and Prevention’s (CDC) monitoring of reported vaccine breakthrough cases. I understand that, as of April 30, 2021, the CDC reported 10,262 SARS-CoV-2 (COVID-19) vaccine breakthrough infections, and starting May 1, 2021, the CDC transitioned to investigating only breakthrough cases that involve patients who are hospitalized or patients that have died.\(^1\) I encourage the CDC to continue taking steps that ensure our national response to this global pandemic is comprehensive and that patients, families, and caregivers across the country have the necessary information, including on breakthrough cases, to care for themselves and others and local and state officials can track outbreaks or hotspots.

As the federal government continues its response to the COVID-19 pandemic, there is a strong need to monitor all breakthrough cases across the United States in order to measure vaccine effectiveness and to help inform local mitigation or prevention efforts. More than 700 COVID-19 breakthrough cases were reported by the Massachusetts Department of Health between July 10, 2021, and July 16, 2021, alone.\(^2\) These cases accounted for 43.4 percent of all new COVID-19 infections in the Commonwealth during this time period.\(^3\) As of June 12, 2021, there have been nearly 4,000 fully vaccinated residents of Massachusetts who have tested positive for COVID-19.\(^4\) New variants, such as the B.1.617.2 (Delta) variant, continue to rapidly

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\(^3\) Id.

spread throughout the United States. The CDC estimates that the highly contagious Delta variant is the dominant strain of COVID-19 in the United States, representing 83 percent of new cases and putting millions of Americans at risk.\(^5\)

Although COVID-19 vaccines are highly effective at preventing serious illness and most cases are occurring in unvaccinated people,\(^6\) it is important that the CDC remain vigilant and transparent in its surveillance of breakthrough cases. The American public must be informed of the continued risks posed by COVID-19 and variants, and public health and medical officials, as well as health care providers, must have robust data and information to guide their decisions on public health measures.

To help inform the public of the CDC’s actions regarding breakthrough cases, and to inform policy decisions about targeting medical resources, I respectfully request that you respond to the following questions in writing by August 12, 2021:

1. On May 1, 2021, why did the CDC announce that it would no longer require states to report information to the CDC on breakthrough cases that do not require hospitalization? Which states are still collecting data on breakthrough infections that don’t require hospitalization? What action is the CDC undertaking to monitor breakthrough cases for people who are not hospitalized?
2. What data, if any, is the CDC collecting on breakthrough cases not requiring hospitalization or resulting in death? Please provide detailed descriptions on categories of data, sources of information, and frequency of collection.
3. Is the CDC collecting and publishing racial, ethnic, gender, age, and location data on these breakthrough cases, including people who are not hospitalized?
4. Is the CDC analyzing the risk factors that may predispose an individual to contracting COVID after being fully vaccinated, including co-morbidities?
5. Is genomic sequencing being done on breakthrough cases that do not require hospitalization? What percent of these breakthrough cases are linked to the Delta variant? Are other variants that are emerging associated with breakthrough cases?
6. Is the CDC collecting information identifying the vaccine administered to people experiencing breakthrough cases, including those who have not been hospitalized, as well as the amount of time that elapsed from vaccine administration to the breakthrough COVID-19 infection?
7. Does the CDC plan to update its public health guidance regarding breakthrough cases, including testing and masking guidance, for fully vaccinated individuals? If not, why?
8. What steps is the CDC taking to continue ensuring states are still effectively responding to breakthrough cases and collecting important demographic and genomic sequencing data?

9. Is the effectiveness of COVID-19 vaccines decreasing in light of these breakthrough cases?

10. Is the CDC, alone or in collaboration with other federal agencies or partners, undertaking any research on the short and long-term health impacts of breakthrough cases?

Thank for your attention to this important matter. If you have any questions, please contact Brianna Battle in my office at 202-224-2742.

Sincerely,

Edward J. Markey
United States Senator