



October 20, 2021

Delivered via E-Mail

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

Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Director Walensky and Acting Commissioner Woodcock:

Vaccines have helped to prevent hospitalizations and deaths from COVID-19, a fact that is made more clear by the high rates of hospitalization and death among unvaccinated individuals. Nevertheless, as the sad death of Secretary of State Colin Powell reminds us, breakthrough cases of COVID can and do occur even among the fully vaccinated, and those who are immunocompromised are particularly at risk. At a time when there has already been public confusion on the decision making process around boosters, it is crucial that the CDC and FDA be trusted sources of accessible information on the efficacy of the three vaccines.

We have heard from vaccinated health care professionals, seniors, and individuals who are immunocompromised or have certain chronic conditions who have questions about the data surrounding serious breakthrough infections and how the different vaccine products compare in protecting against hospitalizations and deaths. They also have questions about how these data have informed the recent FDA and CDC announcements on booster shots and how they will be taken into account on recommendations on the mixing and matching of vaccines.

We appreciate that the CDC has started to make some additional information available on vaccine effectiveness, particularly in tracking the rates of COVID-19 cases and deaths by vaccination status and vaccine product. Data on hospitalizations by vaccine product, however, are not publicly available at this time. Another limitation is that only a handful of public health departments appear to be reporting information on breakthrough cases that result in hospitalization or death to the CDC. Separately, CDC's COVID-NET provides information on hospitalizations of patients with breakthrough cases, but it does not provide that information by vaccine product and there appears to be a significant lag in making such data publicly available. Again, only a limited number of states are reporting into this system.

The public would benefit from more robust data on which vaccine was received by fully vaccinated individuals who are hospitalized due to a breakthrough case, in addition to more data overall on breakthrough cases. Do the CDC and FDA collect nationwide data on which vaccine was received by fully vaccinated individuals who nevertheless contract COVID-19 and are hospitalized? If not, what are the barriers to collecting and disseminating this vital information? Are there limitations on the ability of the CDC and FDA to make such data publicly

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available? How are the CDC and FDA assessing trends in breakthrough infections and the variant or variants that are resulting in such breakthroughs?

Please provide your responses in advance of the next scheduled hearing of the federal COVID task force before the Senate Health, Education, Labor, and Pensions Committee. Thank you for your prompt response and attention to these important questions.

Sincerely,



Susan M. Collins
Ranking Member
Subcommittee on Primary Health and
Retirement Security



Richard Burr
Ranking Member
Committee on Health, Education,
Labor, and Pensions