



September 17, 2021

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Dear Mr. Siri:

This letter follows the Centers for Disease Control and Prevention's (CDC) July 20, 2021, acknowledgment of receipt of your May 28, 2021, letter to Dr. Rochelle Walensky, Director of CDC, and your subsequently filed July 6, 2021 self-styled "citizen petition." Your cover "petition" requests "...that the Director of the Centers for Disease Control and Prevention update the agency's guidance, recommendations, and rules to provide for the same freedoms for the convalescent as provided for those vaccinated for COVID-19." This letter addresses the CDC document and webpages; *Interim Public Health Recommendation for Fully Vaccinated People* (recommendations).

Upon review, and as explained below, we find that your petition does not satisfy the definition of a petition for rulemaking under the Administrative Procedure Act (APA) and is therefore denied. Moreover, even if it were considered a valid petition, an agency is not required to grant the request; it is only mandated to consider the petition and respond within a reasonable timeframe. In addition, the material upon which the "petition" is based has been updated and revised (as of July 27, 2021) based on the changing conditions of the pandemic and we find no basis to further modify the current CDC recommendation in this area until the science warrants it.

While the agency has not provided a detailed response to the many inaccuracies in your "petition," in the interest of transparency and public health, the Agency offers this substantive response. Since the time of your initial letter to Dr. Walensky on May 28, 2021, the data are even more compelling that individuals eligible to receive a coronavirus disease 2019 (COVID-19) vaccine should do so at the earliest opportunity. In addition, as stated above, the CDC *Interim Public Health Recommendations for Fully Vaccinated People*¹ referenced in your letter were updated with additional measures that fully vaccinated individuals should take to protect themselves and others from SARS-CoV-2 infection. CDC's response to the public health issues in your "citizen petition" is set forth below.

¹ www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.

APA Claims:

As stated above, the petition’s request does not satisfy the definition of a rule under the APA. The document and webpages referenced are not a rule as defined by the APA. Moreover, upon receipt of a petition, an agency is not required to grant the request; it is only mandated to consider the petition and respond within a reasonable timeframe.² Upon consideration, because of the reasons outlined above, CDC will not update its guidance to lessen “restrictions” on the “convalescent” as the agency did for those who are fully vaccinated.

Issuing Guidance:

Generally, before issuing guidance, CDC evaluates available evidence, the quality of available and pertinent evidence and studies, and the benefits and potential harms from the intervention being evaluated. Specific to the pandemic, CDC continues to monitor scientific and case studies of transmission and spread of SARS-CoV-2, the virus that causes COVID-19, as well as safety and effectiveness of COVID-19 vaccines currently authorized or approved for use in the United States. In this regard, CDC’s efforts have focused on proven effective public health measures to prevent disease, including vaccination, social distancing, masking, and frequent hand washing. As additional data become available, CDC updates, modifies, or revises previously issued guidance, as appropriate.

Modifications to CDC’s Interim Public Health Recommendations for Fully Vaccinated People:

Your “petition” urges CDC to update the agency’s guidance, recommendations, and rules to provide for the same freedoms for the convalescent as provided for those vaccinated for COVID-19, specifically referencing CDC’s Interim Public Health Recommendations for Fully Vaccinated People.³ CDC updated its recommendations on July 27, 2021. CDC revised this guidance based on new evidence relating to the B.1.617.2 (Delta) variant currently circulating in the United States. CDC made the following modifications:

- Added a recommendation for fully vaccinated people to wear a mask in public indoor settings in areas of substantial or high transmission.
- Added information that fully vaccinated people might choose to wear a mask regardless of the level of transmission, particularly if they are immunocompromised or at increased risk for severe disease from COVID-19, or if they have someone in their household who is immunocompromised, at increased risk of severe disease, or not fully vaccinated.
- Added a recommendation for fully vaccinated people who have come into close contact with someone with suspected or confirmed COVID-19 to be tested three to five days after exposure, and to wear a mask in public indoor settings for 14 days or until they receive a negative test result.

² 5 U.S.C. §§ 553(e), 555(b), and 555(e).

³ www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html

CDC recommends universal indoor masking for all teachers, staff, students, and visitors to schools, regardless of vaccination status. CDC modified this guidance to recommend increased public health measures even for fully vaccinated individuals based on evolving data. Specifically, preliminary evidence suggests that fully vaccinated people who become infected with the Delta variant can spread the virus to others. To reduce their risk of becoming infected with the Delta variant and potentially spreading it, CDC recommended the increased measures for fully vaccinated individuals as described above.

New CDC Study: Vaccination Offers Higher Protection than Previous SARS-CoV-2 Infection Among the Convalescent:

CDC published a report in its Morbidity and Mortality Weekly Report on August 6, 2021 titled “Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021.”⁴ The report notes that although laboratory evidence suggests that antibody responses following COVID-19 vaccination provide better neutralization of some circulating variants than does natural infection, few real-world epidemiologic studies exist to support the benefit of vaccination for previously infected persons. The report details the findings of a case-control evaluation of the association between vaccination and SARS-CoV-2 reinfection in Kentucky during May–June 2021 among persons previously infected with SARS-CoV-2 in 2020. This study showed that Kentucky residents who were not vaccinated had 2.34 times the odds of reinfection compared with those who were fully vaccinated (odds ratio [OR] = 2.34; 95% confidence interval [CI] = 1.58–3.47). This study found that among Kentucky residents who were previously infected with SARS-CoV-2 in 2020, those who were unvaccinated against COVID-19 had significantly higher likelihood of reinfection during May and June 2021. This finding supports CDC’s recommendation that all eligible persons be offered COVID-19 vaccination, regardless of previous SARS-CoV-2 infection status.

The following is from the Discussion section of the report:

Reinfection with SARS-CoV-2 has been documented, but the scientific understanding of natural infection-derived immunity is still emerging (5). The duration of immunity resulting from natural infection, although not well understood, is suspected to persist for ≥ 90 days in most persons.** The emergence of new variants might affect the duration of infection-acquired immunity, and laboratory studies have shown that sera from previously infected persons might offer weak or inconsistent responses against several variants of concern (2,6). For example, a recent laboratory study found that sera collected from previously infected persons before they were vaccinated provided a relatively weaker, and in some cases absent, neutralization response to the B.1.351 (Beta) variant when compared with the original Wuhan-Hu-1 strain (1). Sera from the same persons after vaccination showed a heightened neutralization response to the Beta variant,

⁴ www.cdc.gov/mmwr/volumes/70/wr/pdfs/mm7032e1-H.pdf.

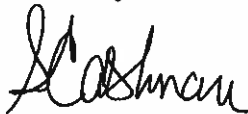
suggesting that vaccination enhances the immune response even to a variant to which the infected person had not been previously exposed. Although such laboratory evidence continues to suggest that vaccination provides improved neutralization of SARS-CoV-2 variants, limited evidence in real-world settings to date corroborates the findings that vaccination can provide improved protection for previously infected persons. The findings from this study suggest that among previously infected persons, full vaccination is associated with reduced likelihood of reinfection, and, conversely, being unvaccinated is associated with higher likelihood of being reinfected.

We are still learning about SARS-CoV-2, but we know that reinfection with human coronaviruses, including SARS-CoV-2, has been documented. In this case-control study, being unvaccinated was associated with 2.34 times the odds of reinfection compared with being fully vaccinated. The report concludes that to reduce their likelihood for future infection, all eligible persons should be offered COVID-19 vaccine, even those with previous SARS-CoV-2 infection.

CDC acts on the best and most accurate scientific information available when developing guidance. The agency finds no discernable basis for modifying CDC guidance as your petition asserts. However, our understanding of SARS-CoV-2 and how to best protect people from the virus and variants thereof, are still evolving as we seek to understand duration of immune protection and the impact of new circulating variants on both infected and vaccinated immunity. As described above, when additional data become available, CDC updates, modifies, or revises previously issued guidance, as appropriate.

Ongoing critical review of scientific evidence is essential to ensure CDC guidance documents are based on the best available information, whether regarding recommendations for well-understood medical conditions and practices or for use when responding to novel and emerging threats. CDC will continue to conduct studies on and monitor the scientific literature of SARS-CoV-2 infection among fully vaccinated and unvaccinated, including those with previous SARS-CoV-2 infection.

Sincerely,



Sandra Cashman, MS
Executive Secretary
Office of the Chief of Staff, CDC