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VIA EMAIL AND FEDEX

Dr. Rochelle P. Walensky, Director
Centers for Disease Control and Prevention
Roybal Bldg. 21, Rm 12000
1600 Clifton Road
Atlanta, GA 30333
Aux7@cdc.gov

Re: *CDC recommendations regarding the fully vaccinated*

Dear Dr. Walensky:

We write on behalf of our client and its members with regard to certain recently announced updates in CDC recommendations, reflected on the CDC's *When You've Been Fully Vaccinated*[1] and *Interim Public Health Recommendations for Fully Vaccinated People*[2] webpages. These recommendations apply to only fully vaccinated individuals. We write to request clarification that the additional "freedoms" afforded to those that have been immunized will also be afforded to those that have had COVID-19 (the "**convalescent**"). As outlined below and in the attached Declaration of Peter A. McCullough, MD, MPH, restrictions on the rights and civil liberties of the convalescent beyond the restrictions placed on the vaccinated are not supported by the existing science.

A. CDC's Updated Recommendations

As of May 13, 2021, the CDC updated its *Interim Public Health Recommendations for Fully Vaccinated People*.[3] These recommendations lessens certain restrictions and allow more freedoms for those who have been vaccinated. For example, despite >10,000 breakthrough infections reported by the CDC up to April 30, 2021, individuals who have been fully vaccinated can:

- Resume activities without wearing masks or physically distancing, except where required by federal, state, local, tribal, or territorial laws, rules and regulations, including local business and workplace guidance;

[1] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html.

[2] *See* https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.

[3] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.

- Resume domestic travel and refrain from testing before or after travel or self-quarantine after travel;
- Refrain from testing before leaving the United States for international travel (unless required by the destination) and refrain from self-quarantine after arriving back in the United States;
- Refrain from testing following a known exposure, if asymptomatic, with some exceptions for specific settings;
- Refrain from quarantine following a known exposure if asymptomatic; and
- Refrain from routine screening testing if feasible.[4]

B. <u>Convalescent Immunity</u>

Based on all available science, there is no compelling state interest nor rational basis to treat individuals who have recovered from SARS-CoV-2 differently than those that have been vaccinated with regard to COVID-19 related restrictions and freedoms. This is because, among other reasons, after a world-wide hunt for any case of reinfection and transmission of SARS-CoV-2, **there is no evidence that an individual previously infected with SARS-CoV-2 is at risk of becoming re-infected and transmitting it to others**. Unlike fully vaccinated individuals, naturally immune individuals are not at risk for "breakthrough" or a second infection.

In animal studies, previous SARS-CoV-2 infection in monkeys prevented subsequent re-infection at any site tested – by nasal, throat, and anal swabs – upon being purposely reinfected.[5] Consistent with this finding, in the more than a year since the SARS-CoV-2 virus first appeared in this country, doctors and scientists have not identified a single case of an individual being reinfected and transmitting SARS-CoV-2. This is despite the worldwide scientific community turning its attention to studying this virus.

The hunt for re-infections has been a nationwide effort and out of the more than 11 million people that have tested positive for SARS-CoV-2 nationwide[6] – and the likely tens of millions more that have had COVID-19 but have not been tested – there are minimal cases in the United States where scientists think evidence may point to a possibility of a re-infection. And among these cases, there is not a single case where the individual purportedly reinfected then transmitted the virus to anyone. Likewise, rates of re-infection following a prior infection are astronomically low and similar to breakthrough infections following vaccination.[7]

But even for these extremely rare cases of potential re-infection, the science is not settled. For example, the authors of the study that analyzed one of these U.S. cases admit that "[i]t is

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[4] *Id*.

[5] https://pubmed.ncbi.nlm.nih.gov/32616673/.

[6] https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days (31,666,546 cases as of April 22, 2021).

[7] *See* https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1 ("the first large-scale study that has explored the protection due to prior SARSCoV-2 infection compared to the Pfizer BNT162b2 vaccine" and the "results question the need to vaccinate previously-infected individuals.").

possible that we have reported a case of continuous infection"[8] rather than re-infection. Furthermore, even in the extremely small number of potential re-infection cases, there was no evidence obtained that those individuals could or did transmit the virus. This is not surprising given the robust memory B-cell and the T-cell immunity against SARS-CoV-2 in the convalescent.[9]

As recently explained by an infectious-disease physician and professor at the University of California: "Natural immunity after COVID-19 infection is likely lifelong, extrapolating from data on other coronaviruses that cause severe illness, SARS and MERS."[10]

Simply stated: recovered individuals are protected. The human body knows how to develop immunity to newly emerging viruses. The adaptive immune system consists of an enormously diverse repertoire of B cells and T cells with a nearly unlimited capacity to recognize and 'adapt' to previously unseen pathogens. Immunologic studies using human subjects who have had the SARS-CoV-2 infection showed that patients have indeed developed sustained neutralizing antibodies[11] which protect from reinfection[12] and robust T-cell memory[13] to the virus. This means that the human adaptive immune system, after being successfully engaged in the immune response to SARS-CoV-2, will be capable of recognizing the virus in the future.

Indeed, one study of T-cell immunity six months after infection demonstrated that every single person tested showed "robust T cell responses to SARS-CoV-2 virus peptides [six months after primary infection] in all participants" which included those with "asymptomatic or mild/moderate COVID-19 infection."[14] A more recent study found that virus-specific B cells "increased over time [with] more memory B cells six months after symptom onset than at one month afterwards," and T cells for the virus "remained high after infection" so that six months after symptom onset, 92% of participants had CD4+ T cells that recognized the virus" and "about half the participants had CD8+ T cells, which kill cells that are infected by the virus." The study concluded that, "95% of the [previously infected and recovered] people had at least 3 out of 5 immune-system components that could recognize SARS-CoV-2 up to 8 months after infection."[15] The study leader commented that they were "hopeful that a similar pattern of responses lasting over time will also emerge for the vaccine-induced responses."[16] This has not yet been established.

Just this week, the most recent study finds that "SARS-CoV-2 infection induces a robust antigen-specific, long-lived humoral immune response in humans."[17] This study evaluated

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[8] https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30764-7/fulltext.

[9] *See* https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals.

[10] https://www.wsj.com/articles/herd-immunity-is-near-despite-faucis-denial-11616624554.

[11] *See* https://pubmed.ncbi.nlm.nih.gov/32743600/; https://www.medrxiv.org/content/10.1101/2020.07.21.20159178v1.

[12] *See* https://www.nih.gov/news-events/nih-research-matters/sars-cov-2-antibodies-protect-reinfection.

[13] *See* https://pubmed.ncbi.nlm.nih.gov/32979941/.

[14] https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals.

[15] https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19.

[16] *Id.*

[17] https://www.nature.com/articles/s41586-021-03647-4.

individuals who had been exposed to SARS-CoV-2 a year earlier and found that bone marrow plasma cells (BMPC) retain memory of the virus ("mild SARS-CoV-2 infection elicits a long-lived BMPC response") and may assist with providing protection when needed (increase in antibody titers after a previous decrease "could represent increases in antibody concentration from reencounter with the virus").[18] Taken together, there is now strong evidence that those who have been exposed to and recovered from SARS-CoV-2 are protected from future reinfection for upwards of one year, potentially longer. This has not yet been established in those who are vaccinated, evidenced by the increasing warnings of necessary boosters.[19]

C. COVID-19 Vaccine Immunity

Given that the immunity offered by having had COVID-19 is more efficacious and more robust than from the vaccine, your recommendations of loosening restrictions for those that have been vaccinated for COVID-19, but not for those that have had COVID-19, is unscientific.

First, in contrast to having had COVID-19, there is no proof that the COVID-19 vaccines prevent infection or transmission. The applications for emergency use authorization ("**EUA**") for all currently authorized COVID-19 vaccines were based on data which supports that these products may reduce certain symptoms of COVID-19 for some individuals, but the FDA's EUAs made clear that there is no evidence the COVID-19 vaccines can prevent recipients from becoming infected with and transmitting the virus.[20] As the FDA explains, at the time of the EUA approval, the data was "not available to make a determination about how long the vaccine will provide protection, **nor is there evidence that the vaccine prevents transmission of SARS-CoV-2 [*i.e.*, the virus that causes COVID-19] from person to person**."[21] Similarly, the FDA Briefing Documents for the COVID-19 vaccines supporting the grant of an EUA list the following as still **unknown**: "effectiveness against asymptomatic infection," and "effectiveness against transmission of SARS-CoV-2."[22] Nonetheless, your recommendations lift restrictions on individuals that have been vaccinated, despite the lack of proof that these products prevent infection and transmission, but do not lift restrictions on those that have had COVID-19 despite clear proof that having had the virus prevents them from becoming reinfected and transmitting the virus.

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[18] *Id*.

[19] *See* Dr. Anthony Fauci's May 26, 2021 Senate testimony at https://www.youtube.com/watch?v=rcVCN9gMK1E at 46:15.

[20] *See* https://www.fda.gov/media/144416/download, https://www.fda.gov/media/144673/download, and https://www.fda.gov/media/146338/download ("Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination.").

[21] https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid (emphasis added).

[22] FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine *available at* https://www.fda.gov/media/144245/download; FDA Briefing Document Moderna COVID-19 Vaccine *available at* https://www.fda.gov/media/144434/download; FDA Briefing Document Janssen COVID-19 Vaccine *available at* https://www.fda.gov/media/146217/download.

Second, while the efficacy of the COVID-19 vaccines (for only the tested strain and not for variants) is considered to be between 72 to 95 percent, depending on which COVID-19 vaccine, the efficacy rate of creating immunity after COVID-19 is considered to be 100 percent. It is again unscientific and lacks a rational basis, let alone a compelling reason, to lift restrictions on the vaccinated (which even after vaccination, 5 to 28 percent of individuals remain completely susceptible to COVID-19) but not the convalescent (which have a near 0 percent risk of being susceptible to COVID-19).

This same result of superior protection in the convalescent was seen in animal studies in which COVID-19 vaccines did not fully block viral infection and replication in the nose of monkeys upon viral challenge;[23] in contrast, as noted above, monkeys previously infected with SARS-CoV-2 completely prevented further re-infection at any site tested – by nasal, throat, and anal swabs.[24] The foregoing should not be surprising because no licensed vaccine for any virus has ever produced immunity that is more robust than the immunity conferred by a natural infection. Even the best vaccines do not confer immunity to all recipients, the temporary immunity created by any vaccine typically wanes over time, and some vaccines cannot even protect from viral carriage and shedding (e.g., pertussis vaccine).

Putting aside the immunity conferred by having been previously infected, there have been concerns raised by medical professionals that vaccinating those recently infected can lead to serious injury or death by causing antigen specific tissue inflammation in any tissues harboring viral antigens.[25] There is good reason, both empirical and observational, to be concerned about a higher rate of adverse events following COVID-19 vaccination in persons who were previously infected with SARS-CoV-2.[26]

An estimated 33 million individuals in the United States have had a reported case of COVID-19[27] and the CDC estimates that there have been over 114 million infections.[28] Their immunity is superior to that of individuals who are vaccinated, as recently recognized by the World Health Organization.[29]

Based on the foregoing, there is no justification to treat those who have been infected with and recovered from SARS-CoV-2 any different than those who have been vaccinated. If it is safe

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[23] *See* https://www.nejm.org/doi/full/10.1056/NEJMoa2024671; https://pubmed.ncbi.nlm.nih.gov/32511340/.

[24] *See* https://pubmed.ncbi.nlm.nih.gov/32616673/.

[25] *See* https://noorchashm.medium.com/a-letter-of-warning-to-fda-and-pfizer-on-the-immunological-danger-of-covid-19-vaccination-in-the-7d17d037982d.

[26] *See* https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1.

[27] *See* https://covid.cdc.gov/covid-data-tracker/#datatracker-home.

[28] *See* https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html.

[29] *See* https://apps.who.int/iris/bitstream/handle/10665/341241/WHO-2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf?sequence=3&isAllowed=y ("Current evidence points to most individuals developing strong protective immune responses following natural infection with SARS-CoV-2" and "recent evidence suggests that natural infection may provide similar protection against symptomatic disease as vaccination, at least for the available follow up period.")

for a fully vaccinated individual to have more freedoms and less restrictions, the same must be true for individuals who have recovered.

Our clients demand that CDC immediately include those who have recovered from SARS-CoV-2 in the same category as those fully vaccinated with regard to the agency's *What You Can Start To Do* and *Interim Public Health Recommendations for Fully Vaccinated People* recommendations and any future COVID-19 related guidance or recommendations.

Thank you for attention to this important matter which effects the liberty interests of millions of Americans.

Very truly yours,

Aaron Siri, Esq.
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