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VIA E-MAIL AND FEDEX

CAL OSHA Doug Parker Chief Cal/OSHA/Division of Occupational Safety and Health Eric Berg Deputy Chief of Research and Standards 1515 Clay Street, Suite 1901 Oakland, CA 94612 <u>eberg@dir.ca.gov</u>

Re: CAL OSHA recommendations regarding the fully vaccinated

Dear Deputy Berg:

We write on behalf of our client and its members with regard to the anticipated June 17, 2021 revisions to CAL OSHA's pandemic-related worker rules. News publications have reported that CAL OSHA's June 17, 2021 updated recommendations will align with recent guidelines from the Centers for Disease Control and Prevention ("CDC") and follow the guidelines announced by the California Department of Public Health on June 9, 2021. To the extent that CAL OSHA'S June 17, 2021 recommendations will allow less stringent mask rules for fully vaccinated individuals, we write to request that the less stringent mask rules also be applied 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, including mask rules, beyond the restrictions placed on the fully vaccinated are not supported by the existing science.

A. Convalescent Immunity

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, including mask policies. 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 reinfection at any site tested – by nasal, throat, and anal swabs – upon being purposely reinfected.¹ 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 nationwide² – 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.³

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 possible that we have reported a case of continuous infection" ⁴ 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.⁵

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."⁶

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

¹ <u>https://pubmed.ncbi.nlm.nih.gov/32616673/</u>.

² <u>https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days</u> (31,666,546 cases as of April 22, 2021).

³ See <u>https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1</u> ("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.").

⁴ <u>https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30764-7/fulltext.</u>

⁵ See <u>https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals.</u>

⁶ <u>https://www.wsj.com/articles/herd-immunity-is-near-despite-faucis-denial-11616624554</u>.

antibodies⁷ which protect from reinfection⁸ and robust T-cell memory⁹ 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."¹⁰ 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." 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."¹¹ 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."¹² This has not yet been established.

A recent study finds that "SARS-CoV-2 infection induces a robust antigen-specific, longlived humoral immune response in humans."¹³ This study evaluated 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").¹⁴ 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.¹⁵

⁷ See <u>https://pubmed.ncbi.nlm.nih.gov/32743600/;</u>

https://www.medrxiv.org/content/10.1101/2020.07.21.20159178v1.

⁸ See <u>https://www.nih.gov/news-events/nih-research-matters/sars-cov-2-antibodies-protect-reinfection</u>.

⁹ See <u>https://pubmed.ncbi.nlm.nih.gov/32979941/</u>.

 $^{^{10}\ \}underline{https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals}.$

¹¹ https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19.

 $^{^{12}}$ Id.

¹³ <u>https://www.nature.com/articles/s41586-021-03647-4</u>.

¹⁴ Id.

¹⁵ See Dr. Anthony Fauci's May 26, 2021 Senate testimony at <u>https://www.youtube.com/watch?v=rcVCN9gMK1E</u> at 46:15.

B. 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.¹⁶ 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."¹⁷ 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."¹⁸ 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.

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;¹⁹ 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

¹⁶ See <u>https://www.fda.gov/media/144416/download</u>, <u>https://www.fda.gov/media/144673/download</u>, and <u>https://www.fda.gov/media/146338/download</u> ("Data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination.").

¹⁷ <u>https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid (emphasis added).</u>

¹⁸ FDA Briefing Document Pfizer-BioNTech COVID-19 Vaccine *available at* <u>https://www.fda.gov/media/144245/download</u>; FDA Briefing Document Moderna COVID-19 Vaccine *available at* <u>https://www.fda.gov/media/144434/download</u>; FDA Briefing Document Janssen COVID-19 Vaccine *available at* <u>https://www.fda.gov/media/146217/download</u>.

¹⁹ See https://www.nejm.org/doi/full/10.1056/NEJMoa2024671; https://pubmed.ncbi.nlm.nih.gov/32511340/.

anal swabs.²⁰ 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.²¹ 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-2.²²

An estimated 33 million individuals in the United States have had a reported case of COVID-19²³ and the CDC estimates that there have been over 114 million infections.²⁴ Their immunity is superior to that of individuals who are vaccinated, as recently recognized by the World Health Organization.²⁵ Dr. Marty Makary, a professor at Johns Hopkins School of Medicine recently called the failure to list restrictions on the convalescent as is being done for the vaccinated "one of the biggest failures of our current medical leadership."²⁶

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

Our clients request that CAL OSHA include those who have recovered from SARS-CoV-2 in the same category as those fully vaccinated with regard to CAL OSHA'S anticipated June 17, 2021 recommendations and in any future COVID-19 related guidance or recommendations.

²⁰ See <u>https://pubmed.ncbi.nlm.nih.gov/32616673/</u>.

²¹ See <u>https://noorchashm.medium.com/a-letter-of-warning-to-fda-and-pfizer-on-the-immunological-danger-of-covid-19-vaccination-in-the-7d17d037982d.</u>

²² See <u>https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1</u>.

²³ See <u>https://covid.cdc.gov/covid-data-tracker/#datatracker-home</u>.

²⁴ See <u>https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html</u>.

²⁵ See <u>https://apps.who.int/iris/bitstream/handle/10665/341241/WHO-2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf?sequence=3&isAllowed=y</u> ("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.")

²⁶ <u>https://summit.news/2021/05/26/johns-hopkins-prof-half-of-americans-have-natural-immunity-dismissing-it-is-biggest-failure-of-medical-leadership/</u>.

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

Very truly yours,

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