Siri | Glimstad

200 Park Avenue, Seventeenth Floor, New York, NY 10166 sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

April 28, 2021

VIA EMAIL AND FEDEX

Tomás J. Aragón, Director California Department of Public Health 1615 Capitol Avenue Sacramento, CA 95814 tomas.aragon@cdph.ca.gov

Governor Gavin Newsom 1303 10th Street, Suite 1173 Sacramento, CA 95814 governor@governor.ca.gov

Re: California's Blueprint for a Safer Economy

Dear Dr. Aragon and Governor Newsom:

We write on behalf of our client and its members, including numerous California residents, with regard to certain recently announced updates in California's Blueprint for a Safer Economy which apply to only fully vaccinated individuals. We write to request clarification that the additional "freedoms" afforded to those that have been immunized will also apply to those that have had COVID-19 (the "**convalescent**"). Any restrictions on the convalescent beyond the restrictions placed on the vaccinated would be a plain violation of various constitutional and statutory rights of these individuals.

A. California's Policy

On April 13, 2021, the California Department of Public Health ("**CDPH**") announced "Updated Activity & Business Tiers for Fully Vaccinated Persons" which lessens certain restrictions and allows more freedoms for those who have been vaccinated.¹ Subsequently, on April 15, 2021, CDPH shared updated guidance documents focusing on gatherings based on an individual's vaccination status, again lessening certain restrictions and allowing more freedoms for those who have been vaccinated.²

B. 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. This is because, among other reasons, after a world-wide hunt for any case of reinfection and transmission of SARS-CoV-

¹ https://www.cdph.ca.gov/Programs/OPA/Pages/NR21-122.aspx.

² <u>https://www.cdph.ca.gov/Programs/OPA/Pages/NR21-126.aspx.</u>

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.

In animal studies, monkeys previously infected with SARS-CoV-2 prevented further reinfection at any site tested – by nasal, throat, and anal swabs – upon being purposely reinfected.³ 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 entire world's 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 nationwide⁴ – and the likely tens of millions more that have had it 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.

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" ⁵ 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 member B-cell and the T-cell immunity against SARS-CoV-2 in the convalescent.⁶

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."⁷

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 antibodies⁸ which protect from reinfection⁹ and robust T-cell memory¹⁰ 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.

³ <u>https://pubmed.ncbi.nlm.nih.gov/32616673/</u>.

⁴ <u>https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days</u> (31,666,546 cases as of April 22, 2021)

⁵ <u>https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30764-7</u>.

⁶https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals.

⁷ https://www.wsj.com/articles/herd-immunity-is-near-despite-faucis-denial-11616624554.

⁸ <u>https://pubmed.ncbi.nlm.nih.gov/32743600/; https://www.medrxiv.org/content/10.1101/2020.07.21.20159178v1</u>.

⁹ <u>https://www.nih.gov/news-events/nih-research-matters/sars-cov-2-antibodies-protect-reinfection.</u>

¹⁰ <u>https://pubmed.ncbi.nlm.nih.gov/32979941/</u>.

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."¹¹ 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."¹² 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."¹³ This has not yet been established.

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 policy of loosening restrictions for those that have been vaccinated for COVID-19, but not for those that have had COVID-19, is unscientific and illegal.

First, in contrast to having had COVID-19, there is no evidence to prove 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.¹⁴ 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.*"¹⁵ 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."¹⁶ Nonetheless, your policy lifts restrictions on individuals that have been vaccinated, despite the lack of proof that these products prevent infection and transmission, while not lifting 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.

¹¹ <u>https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals.</u>

¹² https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19.

¹³ *Id*.

¹⁴ 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.").

¹⁵ <u>https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-</u> emergency-use-authorization-second-covid (emphasis added).

¹⁶ 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> Briefing Document Janssen COVID-19 Vaccine *available at* <u>https://www.fda.gov/media/146217/download</u>.

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 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 challenge¹⁷; 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.¹⁸ 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.

An estimated 3.6 million individuals in California have had COVID-19.¹⁹ Their immunity is at least as protective as, and likely superior to, that of individuals who are vaccinated.

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, the same must be true for individuals who have recovered.

Our clients demand that CDPH and the State of California immediately include those who have recovered from SARS-CoV-2 in the same category as those fully vaccinated with regard to the state's "Blueprint for a Safer Economy" and any future COVID-19 related guidance. Failure to afford the convalescent at least the same liberties as the vaccinated will result in a lawsuit.²⁰ Govern yourselves accordingly.

Very truly yours,

Aaron Siri, Esq. Elizabeth A. Brehm, Esq.

¹⁷ https://www.nejm.org/doi/full/10.1056/NEJMoa2024671; https://pubmed.ncbi.nlm.nih.gov/32511340.

¹⁸ https://pubmed.ncbi.nlm.nih.gov/32616673/.

¹⁹ https://covid19.ca.gov/state-dashboard/.

²⁰ We will be seeking *pro hac vice* admission in this matter.