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## VIA E-MAIL AND FEDERAL EXPRESS

July 6, 2021

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](mailto:Aux7@cdc.gov)

### UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION

#### **CITIZEN PETITION FOR THE ISSUANCE OF A RULE REGARDING FREEDOMS FOR THE CONVALESCED FOLLOWING COVID-19 DISEASE**

This petition for administrative action is submitted on behalf of Informed Consent Action Network<sup>1</sup> (“**Petitioner**”) pursuant to 5 U.S.C. § 553(e) to request 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. Attached as Exhibit A is a letter submitted on May 28, 2021 regarding same. Attached as Exhibit B is the CDC’s June 21, 2021 response.

If we do not receive a substantive response to this request within 21 days, we have been directed by Petitioner to file an action in federal court.

Best regards,



Aaron Siri, Esq.  
Elizabeth A. Brehm, Esq.  
Caroline Tucker, Esq.  
Jessica Wallace, Esq.

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<sup>1</sup> Including, but not limited to, on behalf of its members, including those who work for Petitioner.

# **Exhibit A**

May 28, 2021

**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](mailto: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*<sup>1</sup> and *Interim Public Health Recommendations for Fully Vaccinated People*<sup>2</sup> 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*.<sup>3</sup> 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;

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<sup>1</sup> See <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated.html>.

<sup>2</sup> See <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html>.

<sup>3</sup> <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.<sup>4</sup>

## **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-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.<sup>5</sup> 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<sup>6</sup> – 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.<sup>7</sup>

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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<sup>4</sup> *Id.*

<sup>5</sup> <https://pubmed.ncbi.nlm.nih.gov/32616673/>.

<sup>6</sup> [https://covid.cdc.gov/covid-data-tracker/#cases\\_casesinlast7days](https://covid.cdc.gov/covid-data-tracker/#cases_casesinlast7days) (31,666,546 cases as of April 22, 2021).

<sup>7</sup> 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”<sup>8</sup> 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.<sup>9</sup>

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.”<sup>10</sup>

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<sup>11</sup> which protect from reinfection<sup>12</sup> and robust T-cell memory<sup>13</sup> 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.”<sup>14</sup> 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.”<sup>15</sup> 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.”<sup>16</sup> 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.”<sup>17</sup> This study evaluated individuals who had been exposed to SARS-CoV-2 a year earlier and found that bone marrow

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

<sup>9</sup> See <https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals>.

<sup>10</sup> <https://www.wsj.com/articles/herd-immunity-is-near-despite-faucis-denial-11616624554>.

<sup>11</sup> See <https://pubmed.ncbi.nlm.nih.gov/32743600/>; <https://www.medrxiv.org/content/10.1101/2020.07.21.20159178v1>.

<sup>12</sup> See <https://www.nih.gov/news-events/nih-research-matters/sars-cov-2-antibodies-protect-reinfection>.

<sup>13</sup> See <https://pubmed.ncbi.nlm.nih.gov/32979941/>.

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

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

<sup>16</sup> *Id.*

<sup>17</sup> <https://www.nature.com/articles/s41586-021-03647-4>.

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”).<sup>18</sup> 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.<sup>19</sup>

### 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.<sup>20</sup> 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.**”<sup>21</sup> 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.”<sup>22</sup> 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

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<sup>18</sup> *Id.*

<sup>19</sup> See Dr. Anthony Fauci’s May 26, 2021 Senate testimony at <https://www.youtube.com/watch?v=rcVCN9gMK1E> at 46:15.

<sup>20</sup> 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.”).

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

<sup>22</sup> 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>.

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;<sup>23</sup> 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.<sup>24</sup> 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.<sup>25</sup> 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.<sup>26</sup>

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

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.

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<sup>23</sup> See <https://www.nejm.org/doi/full/10.1056/NEJMoa2024671>; <https://pubmed.ncbi.nlm.nih.gov/32511340>.

<sup>24</sup> See <https://pubmed.ncbi.nlm.nih.gov/32616673/>.

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

<sup>26</sup> See <https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1>.

<sup>27</sup> See <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

<sup>28</sup> See <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html>.

<sup>29</sup> See [file:///C:/Users/teach/Dropbox%20\(Siri%20&%20Glimstad%20LLP\)/ICAN/Backup/Graham/PowerPoints/WHO-2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf](file:///C:/Users/teach/Dropbox%20(Siri%20&%20Glimstad%20LLP)/ICAN/Backup/Graham/PowerPoints/WHO-2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf) (“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.”)

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,

A handwritten signature in blue ink, appearing to be 'AS', is written over a horizontal line.

Aaron Siri, Esq.  
Elizabeth A. Brehm, Esq.  
Caroline Tucker, Esq.  
Jessica Wallace, Esq.



## DECLARATION OF PETER A. MCCULLOUGH, MD, MPH

Pursuant to 28 U.S.C. §1746, I, Peter A. McCullough, MD, MPH, declare under the penalty of perjury of the laws of the United States of America, and state upon personal knowledge that:

1. I am an adult of sound mind, 58 years old, and make this statement voluntarily, based upon my own personal knowledge, education, and experience, and under the penalty of perjury of the laws of the United States of America.

### Experience & Credentials

2. I am competent to testify to the facts and matters set forth herein. A true and accurate copy of my *curriculum vitae* is attached hereto as **Exhibit A**.

3. After receiving a bachelor's degree from Baylor University, I completed my medical degree as an Alpha Omega Alpha graduate from the University of Texas Southwestern Medical School in Dallas. I went on to complete my internal medicine residency at the University of Washington in Seattle, a cardiology fellowship including service as Chief Fellow at William Beaumont Hospital, and a master's degree in public health at the University of Michigan.

4. I am board certified in internal medicine and cardiovascular disease and hold an additional certification in clinical lipidology, and previously echocardiography. I am on the medical staff at Baylor University Medical Center and Baylor Jack and Jane Hamilton Heart and Vascular Hospital, in Dallas, Texas. I am also on staff at Baylor Heart and Vascular Institute, which promotes cardiovascular research and education. I practice internal medicine and clinical cardiology as well as teach, conduct research, and I am an active scholar in medicine with roles as an author, editorialist, and reviewer at dozens of major medical journals and textbooks. I am Professor of Medicine at Texas A & M University School of Medicine, Baylor Dallas Campus.

5. I have led clinical, education, research, and program operations at major academic centers (Henry Ford Hospital, Oakland University William Beaumont School of Medicine) as well as academically oriented community health systems. I spearheaded the clinical development of *in vitro* natriuretic peptide and neutrophil gelatinase associated lipocalin assays in diagnosis, prognosis, and management of heart and kidney disease now used worldwide. I also led the first clinical study demonstrating the relationship between severity of acute kidney injury and mortality after myocardial infarction. I have contributed to the understanding of the epidemiology of chronic heart and kidney disease through many manuscripts from the Kidney Early Evaluation Program Annual Data Report published in the American Journal of Kidney Disease and participated in clinical trial design and execution in cardiorenal applications of acute kidney injury, hypertension, acute coronary syndromes, heart failure, and chronic cardiorenal syndromes. I participated in event adjudication (involved attribution of cause of death) in trials of acute coronary syndromes, chronic kidney disease, heart failure, and data safety and monitoring of anti-diabetic agents, renal therapeutics, hematology products, and gastrointestinal treatments. I have served as the chairman or as a member of over 20 randomized trials of drugs,

devices, and clinical strategies. Sponsors have included pharmaceutical manufacturers, biotechnology companies, and the National Institutes of Health.

6. I frequently lecture and advise on internal medicine, nephrology, and cardiology to leading institutions worldwide. I am recognized by my peers for my work on the role of chronic kidney disease as a cardiovascular risk state. I have over 1,000 related scientific publications, including the “Interface between Renal Disease and Cardiovascular Illness” in Braunwald’s Heart Disease Textbook. My works have appeared in the New England Journal of Medicine, Journal of the American Medical Association, and other top-tier journals worldwide. I am an associate editor of the American Journal of Cardiology and the American Journal of Kidney Diseases. I have testified before the U.S. Senate Committee on Homeland Security and Governmental Affairs, the U.S. Food and Drug Administration Cardiorenal Advisory Panel and its U.S. Congressional Oversight Committee, and the Texas Senate Committee on Health and Human Services.

7. I am a Fellow of the American College of Cardiology, the American Heart Association, the American College of Physicians, the American College of Chest Physicians, the National Lipid Association, and the National Kidney Foundation. I am also a Diplomate of the American Board of Clinical Lipidology.

8. In 2013, I was honored with the International Vicenza Award for Critical Care Nephrology for my contribution and dedication to the emerging problem of cardiorenal syndromes. I am the President of the Cardiorenal Society of America, an organization dedicated to bringing together cardiologists and nephrologists and engage in research, improved quality of care, and community outreach to patients with both heart and kidney disease.<sup>1</sup>

9. I am the current President of the Cardiorenal Society of America, a professional organization dedicated to advancing research and clinical care for patients who have combined heart and kidney disease. I am the Editor-in-Chief of *Cardiorenal Medicine*, a primary research journal listed by the National Library of Medicine which is the only publication with a primary focus on research concerning patients with combined heart and kidney disease. Finally, I am the Editor-in-Chief of *Reviews in Cardiovascular Medicine*, a widely read journal that publishes reviews on contemporary topics in cardiology and is also listed by the National Library of Medicine.

10. My appended *curriculum vitae* further demonstrates my academic and scientific achievements and provides a list of publications authored by me in the past 30 years.

11. Since the outset of the pandemic, I have been a leader in the medical response to the COVID-19 disaster and have published “Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection,” the first synthesis of sequenced multidrug treatment of ambulatory patients infected with SARS-CoV-2 in the *American Journal of Medicine* and updated in *Reviews in Cardiovascular Medicine*.<sup>2</sup> I have 40 peer-reviewed

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<sup>1</sup> See <http://www.cardiorenalsociety.org/>.

<sup>2</sup> McCullough PA, Kelly RJ, Ruocco G, Lerma E, Tumlin J, Wheelan KR, Katz N, Lepor NE, Vijay K, Carter H, Singh B, McCullough SP, Bhambi BK, Palazzuoli A, De Ferrari GM, Milligan GP, Safder T, Tecson KM, Wang

publications on the COVID-19 infection cited in the National Library of Medicine. Through a window to public policymakers, I have contributed extensively on issues surrounding the COVID-19 crisis in a series of OPED's for *The Hill*. I testified on the SARS-CoV-2 outbreak in the U.S. Senate Committee on Homeland Security and Governmental Affairs on November 19, 2020. I testified on lessons learned from the pandemic response in the Texas Senate Committee on Health and Human Services on March 10, 2021, and on early treatment of COVID-19 the Colorado General Assembly on March 31, 2021. Additionally, I testified in the New Hampshire Senate on legislation concerning the investigational COVID-19 vaccine on April 14, 2020. My expertise on the SARS-CoV-2 infection and COVID-19 syndrome, like that of infectious disease specialists, is approximately 18 months old. I have formed my opinions based on my direct clinical experience with acute and convalescent COVID-19 cases as well as closely following the preprint and published literature on the outbreak. I have specifically reviewed all the key published rare cases and reports concerning possible recurrence of SARS-CoV-2.

### **Opinion**

12. It is my opinion that SARS-CoV-2 causes an infection in humans that results in robust, complete, and durable immunity. It is also my opinion that that natural immunity is superior to vaccination-induced immunity for the reasons explained below, including because the CDC has recorded >10,000 breakthrough cases in fully vaccinated individuals. I have reviewed the available preprint and published medical literature on the topic and have formed my opinions based on these reports.

13. SARS-CoV-2 is at least 80% homologous to SARS-CoV-1 at the epitopes that would be recognized by host defenses that confer immunity.<sup>3</sup> The major antigen in SARS-CoV-2 is the nucleocapsid and this has >90% homology to SARS-CoV-1. The immunity to SARS-CoV-1 has been lifelong over the observation period thus far in humans which is 17 years reflecting the duration of immunity that is likely from SARS-CoV-2.<sup>4</sup>

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DD, McKinnon JE, O'Neill WW, Zervos M, Risch HA. Pathophysiological Basis and Rationale for Early Outpatient Treatment of SARS-CoV-2 (COVID-19) Infection. *Am J Med.* 2021 Jan;134(1):16-22. doi: 10.1016/j.amjmed.2020.07.003. Epub 2020 Aug 7. PMID: 32771461; PMCID: PMC7410805 available at <https://pubmed.ncbi.nlm.nih.gov/32771461/>; McCullough PA, Alexander PE, Armstrong R, Arvinte C, Bain AF, Bartlett RP, Berkowitz RL, Berry AC, Borody TJ, Brewer JH, Brufsky AM, Clarke T, Derwand R, Eck A, Eck J, Eisner RA, Fareed GC, Farella A, Fonseca SNS, Geyer CE Jr, Gonnering RS, Graves KE, Gross KBV, Hazan S, Held KS, Hight HT, Immanuel S, Jacobs MM, Ladapo JA, Lee LH, Littell J, Lozano I, Mangat HS, Marble B, McKinnon JE, Merritt LD, Orient JM, Oskoui R, Pompan DC, Procter BC, Prodromos C, Rajter JC, Rajter JJ, Ram CVS, Rios SS, Risch HA, Robb MJA, Rutherford M, Scholz M, Singleton MM, Tumlin JA, Tyson BM, Urso RG, Victory K, Vliet EL, Wax CM, Wolkoff AG, Wooll V, Zelenko V. Multifaceted highly targeted sequential multidrug treatment of early ambulatory high-risk SARS-CoV-2 infection (COVID-19). *Rev Cardiovasc Med.* 2020 Dec 30;21(4):517-530. doi: 10.31083/j.rcm.2020.04.264. PMID: 33387997 available at <https://pubmed.ncbi.nlm.nih.gov/33387997/>.

<sup>3</sup> See Xu J, Zhao S, Teng T, et al. Systematic Comparison of Two Animal-to-Human Transmitted Human Coronaviruses: SARS-CoV-2 and SARS-CoV. *Viruses.* 2020;12(2):244. Published 2020 Feb 22. doi:10.3390/v12020244 available at <https://pubmed.ncbi.nlm.nih.gov/32098422/>.

<sup>4</sup> See Le Bert N, Tan AT, Kunasegaran K, Tham CYL, Hafezi M, Chia A, Chng MHY, Lin M, Tan N, Linster M, Chia WN, Chen MI, Wang LF, Ooi EE, Kalimuddin S, Tambyah PA, Low JG, Tan YJ, Bertoletti A. SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls. *Nature.* 2020 Aug;584(7821):457-462. doi: 10.1038/s41586-020-2550-z. Epub 2020 Jul 15. PMID: 32668444 available at

14. Natural immunity that develops after infection with SARS-CoV-2 is conferred by antibodies to the nucleocapsid and to the spike protein, as well as T-helper cells, natural killer cells, B-cells, and innate immunity.<sup>5</sup> This robust host defense system is far more extensive than the limited library of antibodies to the spike protein that are generated in response to the currently available COVID-19 investigational vaccines which have demonstrated immunity lasting only a few months at this time. This results in more protective immunity for those who have had a natural infection as compared to those who have been vaccinated.

15. After the natural SARS-CoV-2 infection, even in cases where antibody responses have not meet the threshold for being “reactive” in the ~100 commercial assays, there is scientific evidence that cellular based immunity is present.<sup>6</sup> Thus, there is ample evidence to suggest the clinical infection alone, without either antibody or cellular based testing afterwards, is sufficient to identify an individual who is no longer susceptible to COVID-19.<sup>7</sup> Specifically, in such an individual, there is no evidence that SARS-CoV-2 can be acquired, carried, or transmitted to another individual.

16. There are no published, credible reports of reinfection with SARS-CoV-2 in humans. In the case published by Zucman and colleagues, a patient is described as having a positive nasal PCR test for SARS-CoV-2 but no symptoms and then months later having COVID-19 syndrome requiring hospitalization. It is my interpretation that rare cases such as this, in the absence of antigen and whole genome sequencing, represent a false positive nasal PCR test on one occasion and a single COVID-19 syndrome on a separate occasion.<sup>8</sup> Similarly,

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<https://pubmed.ncbi.nlm.nih.gov/32668444/>; Zuo J, Dowell AC, Pearce H, Verma K, Long HM, Begum J, Aiano F, Amin-Chowdhury Z, Hallis B, Stapley L, Borrow R, Linley E, Ahmad S, Parker B, Horsley A, Amirthalingam G, Brown K, Ramsay ME, Ladhani S, Moss P. Robust SARS-CoV-2-specific T cell immunity is maintained at 6 months following primary infection. *Nat Immunol.* 2021 May;22(5):620-626. doi: 10.1038/s41590-021-00902-8. Epub 2021 Mar 5. PMID: 33674800; PMCID: PMC7610739 available at <https://www.nature.com/articles/s41590-021-00902-8>.

<sup>5</sup> See Zuo J, Dowell AC, Pearce H, Verma K, Long HM, Begum J, Aiano F, Amin-Chowdhury Z, Hallis B, Stapley L, Borrow R, Linley E, Ahmad S, Parker B, Horsley A, Amirthalingam G, Brown K, Ramsay ME, Ladhani S, Moss P. Robust SARS-CoV-2-specific T cell immunity is maintained at 6 months following primary infection. *Nat Immunol.* 2021 May;22(5):620-626. doi: 10.1038/s41590-021-00902-8. Epub 2021 Mar 5. PMID: 33674800; PMCID: PMC7610739 available at <https://www.nature.com/articles/s41590-021-00902-8>.

<sup>6</sup> See Schwarzkopf S, Krawczyk A, Knop D, Klump H, Heinold A, Heinemann FM, Thümmeler L, Temme C, Breyer M, Witzke O, Dittmer U, Lenz V, Horn PA, Lindemann M. Cellular Immunity in COVID-19 Convalescents with PCR-Confirmed Infection but with Undetectable SARS-CoV-2-Specific IgG. *Emerg Infect Dis.* 2021 Jan;27(1). doi: 10.3201/2701.203772. Epub 2020 Oct 15. PMID: 33058753 available at <https://pubmed.ncbi.nlm.nih.gov/33058753/>.

<sup>7</sup> See Schulien I, Kemming J, Oberhardt V, Wild K, Seidel LM, Killmer S, Sagar, Daul F, Salvat Lago M, Decker A, Luxenburger H, Binder B, Bettinger D, Sogukpinar O, Rieg S, Panning M, Huzly D, Schwemmler M, Kochs G, Waller CF, Nieters A, Duerschmied D, Emmerich F, Mei HE, Schulz AR, Llewellyn-Lacey S, Price DA, Boettler T, Bengsch B, Thimme R, Hofmann M, Neumann-Haefelin C. Characterization of pre-existing and induced SARS-CoV-2-specific CD8<sup>+</sup> T cells. *Nat Med.* 2021 Jan;27(1):78-85. doi: 10.1038/s41591-020-01143-2. Epub 2020 Nov 12. PMID: 33184509 available at <https://pubmed.ncbi.nlm.nih.gov/33184509/>.

<sup>8</sup> See Zucman N, Uhel F, Descamps D, Roux D, Ricard JD. Severe reinfection with South African SARS-CoV-2 variant 501Y.V2: A case report. *Clin Infect Dis.* 2021 Feb 10:ciab129. doi: 10.1093/cid/ciab129. Epub ahead of

Severaj et al. have reported 1 case of their own and 34 others in the literature with a similar profile with misinterpretation of a false positive PCR leading doctors to believe a second infection was possible.<sup>9</sup> None of these cases of “reinfection” was confirmed by antigen and whole genome sequencing to confirm the actual presence of the SARS-CoV-2 in the setting of a clinical infection on two or more occasions in the same patient.

17. At the current number of estimate cases in the world being 164 million, if reinfection was possible in 1% of individuals, the world would have observed 1.6 million second and third cases with many requiring hospitalization and coming to clinical attention.<sup>10</sup> In fact, no such large volume of recurrent cases has come to clinical attention in any region of the world.

18. Raw et al. reported that in 974 individuals who received the BNT162b2/Pfizer vaccine, those with a prior history of SARS-CoV-2 or those who had positive antibodies at baseline, had a higher rate of vaccine reactions than those who were COVID-19 naive.<sup>11</sup>

19. Mathioudakis et al. reported that in 2002 patients who underwent vaccination with either mRNA-based, or vector-based COVID-19 vaccines, COVID-recovered patients who were needlessly vaccinated had higher rates of vaccine reactions.<sup>12</sup>

20. Krammer et al. reported on 231 volunteers for COVID-19 vaccination, 83 of whom had positive SARS-CoV-2 antibodies at the time of immunization. The authors found: “Vaccine recipients with preexisting immunity experience systemic side effects with a significantly higher frequency than antibody naïve vaccines (e.g., fatigue, headache, chills, fever, muscle or joint pains, in order of decreasing frequency,  $P < 0.001$  for all listed symptoms, Fisher’s exact test, two-sided).” (<https://doi.org/10.1101/2021.01.29.21250653>).

21. To my knowledge, there are no studies demonstrating clinical benefit of COVID-19 vaccination in COVID-19 survivors or those who have laboratory evidence of prior infection.

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print. PMID: 33566076; PMCID: PMC7929064 available at <https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab129/6132402>.

<sup>9</sup> See Selvaraj V, Herman K, Dapaah-Afriyie K. Severe, Symptomatic Reinfection in a Patient with COVID-19. *R I Med J* (2013). 2020 Nov 9;103(10):24-26. PMID: 33172223 available at <https://pubmed.ncbi.nlm.nih.gov/33172223/>.

<sup>10</sup> See <https://www.worldometers.info/coronavirus/>.

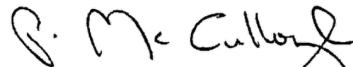
<sup>11</sup> See <https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1>.

<sup>12</sup> See <https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1>.

22. In sum, it is my opinion that SARS-CoV-2 causes an infection in humans that results in robust, complete, and durable immunity, and is superior to vaccine immunity. There are no studies demonstrating clinical benefit of COVID-19 vaccination in COVID-19 survivors and there are three studies demonstrating harm in such individuals. Thus, it is my opinion that the COVID-19 vaccination is contraindicated in COVID-19 survivors.

I DECLARE UNDER THE PENALTY OF PERJURY UNDER THE LAWS OF THE UNITED STATES OF AMERICA THAT THE FOREGOING INFORMATION CONTAINED IN THIS DECLARATION IS TRUE AND CORRECT.

May 28, 2021



28-MAY-2021

Peter A. McCullough, MD, MPH

# **Exhibit B**

## Elizabeth Brehm

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**From:** CDCExecSec (CDC) <CDCExecSec@cdc.gov>  
**Sent:** Tuesday, June 22, 2021 9:53 AM  
**To:** Aaron Siri  
**Cc:** Elizabeth Brehm; Caroline Tucker; Jessica Wallace  
**Subject:** Acknowledgment of your letter re CDC recommendations regarding the fully vaccinated

Dear Mr. Siri:

Thank you for your letter on behalf of your client and your interest in 2019 Coronavirus Disease (COVID-19). Please see the latest information on the COVID-19 pandemic and fully vaccinated guidance at [www.cdc.gov/COVID-19/](http://www.cdc.gov/COVID-19/).

Sincerely,

Sandra Cashman, MS  
Executive Secretary  
Office of the Chief of Staff  
Centers for Disease Control and Prevention (CDC)



200 Park Avenue, 17th Floor, New York, NY 10166  
sirillp.com | P: (212) 532-1091 | F: (646) 417-5967

## VIA E-MAIL AND FEDERAL EXPRESS

September 15, 2021

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](mailto:Aux7@cdc.gov)


### UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES AND THE CENTERS FOR DISEASE CONTROL AND PREVENTION

#### **SUPPLEMENTAL EXHIBIT TO CITIZEN PETITION FOR THE ISSUANCE OF A RULE REGARDING FREEDOMS FOR THE CONVALESCED FOLLOWING COVID- 19 DISEASE**

This petition for administrative action was submitted on behalf of Informed Consent Action Network<sup>1</sup> (“**Petitioner**”) on July 6, 2021 pursuant to 5 U.S.C. § 553(e) to request 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. The petition attached, as Exhibit A, a letter submitted on May 28, 2021 regarding same and, as Exhibit B, the CDC’s June 21, 2021 response.

Petitioner, to date, has not received a response to the petition and respectfully submits the attached list of recent relevant studies regarding the topic at issue in the petition, as Exhibit C. If we do not receive a substantive response to this request within 21 days, we have been directed by Petitioner to file an action in federal court.

Best regards,



Aaron Siri, Esq.  
Elizabeth A. Brehm, Esq.  
Caroline Tucker, Esq.  
Jessica Wallace, Esq.

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<sup>1</sup> Including, but not limited to, on behalf of its members, including those who work for Petitioner.

## EXHIBIT C

### **SUPPLEMENTAL EXHIBIT TO CITIZEN PETITION FOR THE ISSUANCE OF A RULE REGARDING FREEDOMS FOR THE CONVALESCED FOLLOWING COVID- 19 DISEASE**

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