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VIA E-MAIL AND FEDERAL EXPRESS

October 21, 2021

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

REPLY REGARDING CITIZEN PETITION TO LIFT RESTRICTIONS ON THE NATURALLY IMMUNE TO THE EXTENT LIFTED ON THE VACCINATED

Dear Dr. Walensky and Ms. Cashman,

Thank you for your response on September 17, 2021 to the petition filed on behalf of the Informed Consent Action Network[1] ("**Petitioner**"), dated July 6, 2021. A copy of the petition, and the addendum, are appended as **Appendix A** (the "**Petition**").[2] A copy of your response is appended as **Appendix B**.

While your response is appreciated, it does not address any of the over 50 studies cited in the Petition which reflect that those previously infected with COVID-19 (the "**naturally immune**") have superior protection from becoming infected with and transmitting SARS-CoV-2 than those vaccinated for COVID-19 (the "**vaccine immune**"). Critically:

1. Your response does not contest any of the studies cited and data which collectively reviewed hundreds of thousands of naturally immune versus vaccine immune individuals and found that the rate of infection among the naturally immune ("**reinfections**") is far lower than the rate among the vaccinated ("**breakthrough cases**"). (*Infra* § I.)

[1] Including, but not limited to, on behalf of its members, including those who work for Petitioner.

[2] The Petition shall include Appendix A as well as this letter and its contents.

2. Your response does not contest that, despite a world-wide hunt, there has never been a single documented case of reinfection resulting in further transmission, while, in contrast, there are numerous documented cases of breakthrough cases resulting in further transmission. (*Infra* § II.)

3. Your response does not contest any of the studies and data cited which reflect that, consistent with the foregoing real-word data, the naturally immune have more robust and durable T cell and B cell immunity. (*Infra* § III.)

These three facts alone should suffice to lift restrictions on those naturally immune at least to the same extent as those vaccine immune.

The failure to do so is causing an **incredible level of reputational harm to the CDC.** It is the primary reason that national news outlets, with distribution to a majority of Americans, have regularly described the CDC as anti-science, political hacks, and far worse.[3] That in turn causes a loss of confidence in the CDC's other important efforts that are unrelated to COVID-19.

This loss of confidence is especially true for the science literate who, for example, can easily review the UK's official government COVID-19 data from the past 7 months which reflects a probable reinfection rate of 0.025% (and a confirmed reinfection rate of 0.0026%)[4] but a breakthrough rate of 23% of all Delta cases.[5] It is also true for those who, if nothing else, watched Dr. Walensky on national television state that the vaccinated should wear masks because "**what [the COVID-19 vaccines] can't do anymore is prevent transmission**."[6] While admitting this fact, the CDC continues to pretend that the human immune system has nothing to offer in terms of protection from the virus without a vaccine.

As discussed in Section IV below, the sole study cited in your response involved a convoluted, highly confounded, small retrospective case control study of a few hundred individuals from Kentucky that the CDC itself published on August 13, 2021, months after being served with the instant Petition and directly before finally responding to same (the "**Kentucky study**").[7] This study is **irrelevant** as to whether it is appropriate for the CDC to lift restrictions on the naturally immune because **it did not compare naturally immune individuals with vaccinated individuals**. Instead, it compared the naturally immune *to* the naturally immune with

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[3] *See, e.g.*, Fox News, Breitbart, The Federalist, The Daily Caller, The Washington Times, Newsmax, The Epoch Times, and The New York Post.

[4] *See,https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012240/Weekly_Flu_and_COVID-19_report_w33.pdf* at 17-18.

[5] *See* https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Briefing_22_21_09_02.pdf at 21. Meanwhile, the CDC – which is only reporting breakthrough cases which lead to hospitalization and death and whose "surveillance relies on passive and voluntary reporting" and acknowledges that "data are not complete or representative" and "are an undercount of all SARS-CoV-2 infections among fully vaccinated persons – has reported 14,115 breakthrough cases; https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html. Notably, Louisiana alone had counted 14,650 breakthrough infections as of August 25, 2021. *See* https://www.politico.com/news/2021/08/25/cdc-pandemic-limited-data-breakthroughs-506823.

[6] https://twitter.com/CNNSitRoom/status/1423422301882748929.

[7] Alyson Cavanaugh, *et al.*, *Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021*, MMWR (August 13, 2021) https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm.

subsequent vaccination. **Putting aside the possibility that vaccinating the naturally immune may improve their immunity, if the CDC lifts restrictions on those with only vaccine-induced immunity, it is simply authoritarian to not lift restrictions on those with only natural immunity since it is at least as good, and in fact superior, to vaccine immunity**.

Moreover, this Kentucky study is unreliable for several reasons. First, it re-engineered the controls in this study and chose, after the fact, those who had not been re-infected. Second, it lists five critical limitations. Two of the most notable are that "reinfection was not confirmed through whole genome sequencing, which would be necessary to definitively prove that the reinfection was caused from a distinct virus relative to the first infection" and that "**persons who have been vaccinated are possibly less likely to get tested. Therefore, the association of reinfection and lack of vaccination might be overestimated**." The latter limitation completely undermines the study's conclusion on its own.

Third, it explains that its "findings cannot be used to infer causation" and therefore "[a]dditional prospective studies with larger populations are warranted to support these findings." But yet, as discussed in Section IV below, the CDC ignores large, credible, well-controlled studies with limited confounders that further evidence that your heavily confounded Kentucky study is plainly unreliable. For example, a population-based study involving 2.5 million Israelis in a single, centralized medical database found that the naturally immune were 99.74% protected from reinfection while the naturally immune with subsequent vaccination were 99.86% protected from reinfection.[8] Putting aside that reinfections in both groups were mostly asymptomatic, this difference is negligible and has no clinical relevance.

More concerning is that even the assumed benefits of vaccinating the naturally immune do not outweigh the known risks. According to data from the UK, for every 11 individuals with natural immunity that are vaccinated, one will have a clinically significant vaccine adverse event, with the most common adverse events being significant fever, fatigue, myalgia-arthralgia, and lymphadenopathy.[9] Since vaccinating 833 individuals is necessary to prevent one case of *asymptomatic* reinfection (with the number being even higher for *symptomatic* reinfection), the CDC's policy will cause over 75 cases of clinically significant adverse events (NNT/NNH = 833/11) for just one avoided case of asymptomatic reinfection.[10] This further highlights why the CDC's policy is illogical and unscientific.

In any event, your reliance on the Kentucky study ignores that the naturally immune already have sterilizing immunity and a negligible rate of reinfection, and no documented case of subsequent transmission exists. Natural immunity, alone, is superior to vaccine immunity which

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[8] Sivan Gazit, *et al*., *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, medRxiv (August 25, 2021) https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf.

[9] Rachael Kathleen Raw, *et al., Previous COVID-19 infection, but not Long-COVID, is associated with increased adverse events following BNT162b2/Pfizer vaccination,* The Journal of Infection (May 29, 2021) https://pubmed.ncbi.nlm.nih.gov/34062184/ .

[10] Sivan Gazit, *et al.*, (*supra*). Cf. "Model 3 - previously infected vs. vaccinated and previously infected individuals" in this study: 20/14,029 previously infected-vaccinated later tested positive (0.14% reinfection), or 99.86% immunity compared to 37/14,029 previously infected-unvaccinated (0.26% reinfection) or 99.74% immunity. Difference of 0.12% (17/14,029), with NNT 1/0.0012 = 833.

is not sterilizing, produces asymptomatic carriers, has a high breakthrough rate, and has many documented cases of subsequent transmission after breakthrough. It is simply irrational to apply limitations to those naturally immune but not those vaccine immune.

While your letter claims that the CDC "evaluates available evidence, the quality of available and pertinent evidence and studies, and the benefits and potential harms from the intervention," your letter does not address any of the studies and evidence provided. We therefore provide notice that this is a final opportunity to substantively respond to this Petition. Otherwise, pursuant to 5 U.S.C. § 553(e), we have been authorized to commence an action and intend to file same absent a response within 21 days of this demand that either (1) lifts restrictions on the naturally immune to the same extent as the vaccinated; or (2) addresses the studies provided in the Petition as well as provides studies which, on balance, show that vaccine immunity is more durable, sterilizing, and prevents more subsequent cases than does natural immunity.

For the avoidance of any doubt, unless the CDC lifts restrictions for the naturally immune as it does for the vaccine immune, we will be initiating a lawsuit. As part of our opening papers, we will be submitting declarations from numerous highly credentialed experts. An initial list of those experts is appended hereto. Your decision to continue to ignore the evidence is crushing the civil and individual rights of millions of Americans and we intend to hold the CDC accountable for same, no matter how many lawsuits it takes, unless it corrects course forthwith. Such lawsuits will include suits against the CDC, and other federal health and non-health agencies, by their own employees that have natural immunity; numerous such individuals have contacted our firm and we intend to commence suit absent the forthwith recognition by the CDC that natural immunity is at least as effective as vaccine immunity. It is, at this point, absurd that the CDC maintains otherwise.

I. Reinfections v. Breakthrough Cases

The unrebutted data reflects that reinfection is rare and occurs at a small fraction of the rate of breakthrough cases. UK's official government COVID-19 data shows a **probable reinfection rate** of **0.025%** through August 19, 2021 during Delta.[11] In contrast, this same data shows, through September 2, 2021, a **vaccine breakthrough rate** for Delta infections of **23%**.[12] **This is in line with Dr. Walensky's statement that, "A modest percentage of people who are fully vaccinated will still get COVID-19 if they are exposed to the virus that causes it."**[13]

[11] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012240/Weekly_Flu_and_COVID-19_report_w33.pdf at 17-18.

[12] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Briefing_22_21_09_02.pdf at 21. Meanwhile, the CDC – which is only reporting breakthrough cases which lead to hospitalization and death and whose "surveillance relies on passive and voluntary reporting" and acknowledges that "data are not complete or representative" and "are an undercount of all SARS-CoV-2 infections among fully vaccinated persons – has reported 14,115 breakthrough cases; https://www.cdc.gov/vaccines/COVID-19/health-departments/breakthrough-cases.html. Notably, Louisiana alone had counted 14,650 breakthrough infections as of August 25, 2021, https://www.politico.com/news/2021/08/25/cdc-pandemic-limited-data-breakthroughs-506823.

[13] https://www.nytimes.com/article/covid-breakthrough-delta-variant.html.

The studies cited in the Petition, which you do not rebut, are consistent with the UK data and confirm that reinfections are exceedingly rare as well as confirm the durability of natural immunity:

a. The Cleveland Clinic measured cumulative incidence of SARS-CoV-2 infection among 52,238 vaccinated and unvaccinated health care workers over a five-month period and found that none of the 1,359 previously infected who remained *unvaccinated* contracted SARS-CoV-2 over the course of the research despite a high background rate of COVID-19 in the hospital.[14]

b. Researchers from Ireland conducted a review of 11 cohort studies involving over 600,000 total recovered COVID-19 patients who were followed up with for over 10 months and found that that reinfection in all studies was "an uncommon event" and explained that there was "**no study reporting an increase in the risk of reinfection over time**."[15]

c. Researchers from Qatar analyzed the population-level risk of reinfection based on whole genome sequencing, tracking 43,044 individuals for up to 35 weeks, and found that just .02% experienced reinfection (an estimated risk of reinfection of 0.66 per 10,000 person-weeks). Notably, there was no evidence of waning immunity during the over seven-month follow-up period.[16]

On the other hand, the rate of breakthrough cases are multiple times higher than the rate of reinfections. The following studies, all of which your response fails to rebut, affirm that natural immunity provides greater protection:

a. A comparison of 42,000 naturally immune individuals with 62,000 fully vaccinated individuals found that the fully vaccinated individuals were **6 to 13 times more likely to get infected than the naturally immune**.[17] Additionally, **the risk of symptomatic COVID-19 was 27 times higher among those vaccinated than those previously infected** and the risk of hospitalization was 8 times higher.[18] The study concluded that, "natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 [Pfizer] two-dose vaccine-induced immunity."[19]

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[14] Nabin K. Shrestha, *et al.*, *Necessity of COVID-19 vaccination in previously infected individuals*, medRxiv (June 19, 2021) https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3.

[15] Eamon Murchu, *et al.*, *Quantifying the risk of SARS-CoV-2 reinfection over time*, Reviews of Medical Virology (May 27, 2201) https://pubmed.ncbi.nlm.nih.gov/34043841/.

[16] Laith J. Abu-Raddad, *et al.*, *SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy*, EClinical Medicine (April 28, 2021) https://pubmed.ncbi.nlm.nih.gov/33937733/.

[17] Sivan Gazit, *et al.*, *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, medRxiv (August 25, 2021) https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.

[18] *Id.*

[19] *Id.*

b. The Israeli Health Ministry found that the vaccinated had 6.72 times the rate of infection as compared to those that had contracted COVID-19:

> With a total of 835,792 Israelis known to have recovered from the virus, the 72 instances of reinfection amount to 0.0086% of people who were already infected with SARS-CoV-2.
>
> By contrast, Israelis who were vaccinated were 6.72 times more likely to get infected after the shot than after natural infection.[20]

c. A nation-wide study of over 6 million individuals in Israel found that vaccine immunity had an efficacy of 92.8% for documented infection, 94.2% for hospitalization, and 94.4% for severe illness, but that the naturally immune had a higher rate of protection in all three of these categories.[21]

d. An outbreak of SARS-CoV-2 infected 24/44 (55%) employees of a gold mine in French Guiana. The attack rate was 15/25 (60.0%) in fully vaccinated miners, 6/15 (40.0%) in those partially vaccinated or with a history of COVID-19 (none of the partially vaccinated with a history of COVD-19 were positive), and 3/4 (75%) in those not vaccinated. The attack rate was 0/6 among persons with a previous history of COVID-19 versus 63.2% among those with no previous history.[22]

Moreover, while the risk of reinfection has not increased over time (see studies cited above), the risk of breakthrough infections is increasing over time. This is because the protection from natural immunity remains stable whereas vaccine immunity is rapidly waning.

A Mayo Clinic study looked at the efficacy of COVID-19 vaccines from January to July 2021 during which either the Alpha or Delta variant was highly prevalent.[23] The results showed that, as of July, the efficacy of Moderna's vaccine had dropped to 76% and the efficacy of Pfizer's vaccine dropped to 42%.[24] This is consistent with Pfizer's data which demonstrates that the efficacy of its vaccine falls by about 6 percent every two months (with data only through "up to 6 months").[25] As Pfizer's CEO publicly acknowledged, the efficacy after "four to six months was

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[20] https://www.israelnationalnews.com/News/News.aspx/309762.

[21] Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel*, medRxiv (April 24, 2021) https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.

[22] Nicolas Vignier, *et al.*, *Breakthrough Infections of SARS-CoV-2 Gamma Variant in Fully Vaccinated Gold Miners, French Guiana, 2021*, Emerging Infectious Diseases (July 21, 2021) https://pubmed.ncbi.nlm.nih.gov/34289335/.

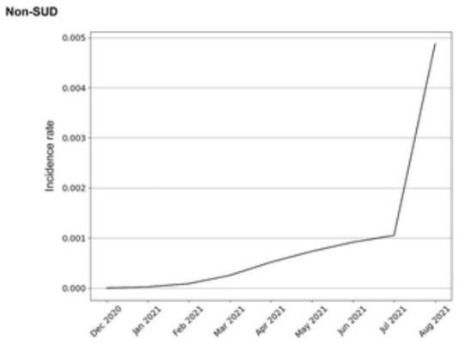
[23] Arjun Puranik, *et al.*, *Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence*, medRxiv (August 21, 2021) https://pubmed.ncbi.nlm.nih.gov/34401884/.

[24] *Id.*

[25] Stephen J. Thomas, *et al.*, *Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine*, medRxiv (July 28, 2021) https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf.

approximately 84%."[26] A drop of 6% per month means an efficacy of around 60% by one year and around 42% by 18 months, assuming the decline continues linearly rather than, as often happens, exponentially. This waning immunity is also apparent in Israel which has higher and earlier vaccination coverage and, as of August 10, 2021, "Health Ministry data showed that fully vaccinated individuals were responsible for most new cases and most of those hospitalized in moderate condition or worse."[27]

A recently published report from NIH and Case Western Reserve which reviewed the medical records of approximately 550,000 Americans found that from January through April 2021, when the vaccines are believed to be most effective, 1 in 28 fully vaccinated individuals was infected.[28] As immunity waned, as seen in the graph below, breakthrough cases increased *five-fold* from July through August:



The fact that natural immunity is more durable than vaccine immunity should not be surprising.[29] Vaccine immunity has never proven more durable than natural immunity for any vaccine.[30] Even directly after vaccination, natural immunity is plainly superior to vaccine immunity. Pfizer's interim clinical trial results, for example, demonstrate 95% effectiveness after two months in preventing symptomatic COVID-19 in those who have not been previously infected.[31] Moderna's interim clinical trial results demonstrate 94.1% effectiveness after two months in preventing symptomatic COVID-19 in those who have not been previously infected.[32] Even in these ideal, controlled situations, against the Alpha variant, the two mRNA vaccines have a significant gap in efficacy in preventing disease at any point in time, while the consistent and unrebutted data on natural immunity reflects greater than 99% efficacy against reinfection which

[26] https://www.cnbc.com/2021/07/28/pfizers-ceo-says-covid-vaccine-effectiveness-drops-to-84percent-after-six-months.html.

[27] https://www.timesofisrael.com/over-5000-new-coronavirus-cases-confirmed-monday-as-new-limits-mulled/.

[28] https://pubmed.ncbi.nlm.nih.gov/34612005/.

[29] *See, e.g.*, Plotkin's Vaccines, 7th Edition, at Section 2.

[30] *Id.*

[31] Sara E. Oliver, *et al.*, *The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine - United States, December 2020*, MMWR Morb Mortal Wkly Rep (December 18, 2020) https://pubmed.ncbi.nlm.nih.gov/33332292/.

[32] Arjun Puranik, *et al.*, *Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence*, medRxiv (August 21, 2021) https://pubmed.ncbi.nlm.nih.gov/34401884/.

has remained stable over time in all studies assessing same as reflected in studies cited *supra* and in Section III below.[33]

II. Sterilizing Immunity v. Non-Sterilizing Immunity

The data and studies also reflect that natural immunity provides sterilizing immunity while vaccination does not provide sterilizing immunity.

As you are aware, the clinical trial's primary endpoint for the COVID-19 vaccines is measuring effectiveness against disease – not against infection.[34] Once used in the real world, as Dr. Walensky has acknowledged, they do not "prevent transmission."[35] This is also confirmed by various studies, including:

1. COVID-19 vaccines could *not* fully block viral infection and replication in the nose of monkeys upon viral challenge.[36] In contrast, SARS-CoV-2 infection of monkeys completely prevented further re-infection at any site tested – by nasal, throat, and anal swabs.[37]

2. In Barnstable County, Massachusetts, which has a 69% vaccination coverage rate among its eligible residents, the CDC found that 74% of those infected in an outbreak were fully vaccinated for COVID-19 and that the vaccinated had on average more virus in their nasal cavity than the unvaccinated that were infected.[38]

3. A study of transmission among fully vaccinated health care workers in Vietnam found "transmission between the vaccinated people" and therefore concluded that

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[33] *See* studies cited in Section I *supra*. It is also noteworthy that 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, and the major antigen in SARS-CoV-2 is the nucleocapsid and this has greater than 90% homology to SARS-CoV-1. (Jiabao Xu, et al. *Systematic Comparison of Two Animal-to-Human Transmitted Human Coronaviruses: SARS-CoV-2 and SARS-CoV*, Viruses (February 22, 2020) https://pubmed.ncbi.nlm.nih.gov/32098422/.) 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. (Nina Le Bert, *et al., SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls*, Nature (July 15, 2020) https://pubmed.ncbi.nlm.nih.gov/32668444/; Jianmin Zuo, *et al., Robust SARS-CoV-2-specific T cell immunity is maintained at 6 months following primary infection*, Nat Immunol (March 5, 2021) https://pubmed.ncbi.nlm.nih.gov/33674800/).

[34] Sara E. Oliver, *et al., The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine - United States, December 2020* MMWR Morb Mortal Wkly Rep (December 18, 2020) https://pubmed.ncbi.nlm.nih.gov/33332292/.

[35] https://twitter.com/CNNSitRoom/status/1423422301882748929.

[36] Kizzmekia S. Corbett, Ph.D, *et al., Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates*, N Engl J Med (July 28, 2020) https://pubmed.ncbi.nlm.nih.gov/32722908/. Van Doremalen N., *et al., ChAdOx1 nCoV-19 vaccination prevents SARS-CoV-2 pneumonia in rhesus macaques*, Nature (July 30, 2020) https://pubmed.ncbi.nlm.nih.gov/32731258/.

[37] Wei Deng, *et al., Primary exposure to SARS-CoV-2 protects against reinfection in rhesus macaques*, Science (August 14, 2020) https://pubmed.ncbi.nlm.nih.gov/32616673/.

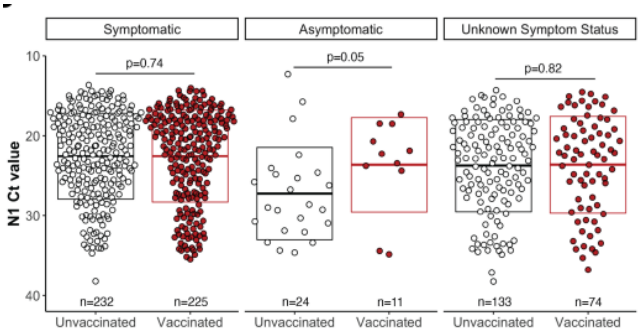
[38] Brown CM, *et al., Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts*, MMWR Morb Mortal Wkly Rep (August 6, 2021) https://pubmed.ncbi.nlm.nih.gov/34351882/.

"distancing measures remain critical to reduce SARS-CoV-2 Delta variant transmission" among the vaccinated.[39]

4. French researchers tested blood samples from health care workers who were COVID-19 naïve and received two doses of Pfizer's vaccine and compared them to those from health care workers who had a previous mild infection and a third group of patients who had serious cases of COVID-19. They found, "[n]o neutralization escape could be feared concerning the two variants of concern [Alpha and Beta] in" those previously infected.[40]

5. In a SARS-CoV-2 outbreak among 42 patients in a hospital setting, "39 were fully vaccinated," the "index case was a fully vaccinated [individual]," the "attack rate among exposed individuals reached 23.3% in patients and 10.3% in staff, with 96.2% vaccination rate among exposed individuals," "all transmission between patients and staff occurred between masked and vaccinated individuals, as experienced in an outbreak from Finland," and "[t]his nosocomial outbreak exemplifies the high transmissibility of the SARS-CoV-2 Delta variant among twice vaccinated and masked individuals."[41]

Notably, a study from researchers at the CDC and at Wisconsin's Department of Health Services evaluated the shedding of infectious SARS-CoV-2 in 36 counties in Wisconsin and observed high viral load in 68% of the fully vaccinated and in 63% of the unvaccinated.[42] This reflects that the vaccinated will shed virus and will do so at the same rate as the unvaccinated. On the other hand, **this study did not identify anyone with prior natural infection that had any viral load.** It is also noteworthy that among those who were asymptomatic, 29% of the unvaccinated had high viral load while 82% of the fully vaccinated had high viral load. This incredible finding was depicted in the following graph:



[39] Nguyen Chau, *Transmission of SARS-CoV-2 Delta variant among vaccinated healthcare workers, Vietnam*, Lancet (August 10, 2021) https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733.

[40] Claudia Gonzalez, *et al.*, *Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2*, Emerg Microbes Infect (June 28, 2021) https://pubmed.ncbi.nlm.nih.gov/34176436/.

[41] Pnina Shitrit *et al.*, *Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021*, Eurosuveillance (September 30, 2021) https://pubmed.ncbi.nlm.nih.gov/34596015/.

[42] https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v4.full.pdf.

That natural infection, unlike vaccine immunity, provides sterilizing immunity, is also reflected in the UK's official government COVID-19 data from the past 7 months while Delta was circulating which, as discussed above, reflects a probable reinfection rate of 0.025%[43] (and a confirmed reinfection rate of 0.0026%) but a breakthrough rate for Delta infections of 23%.[44]

These data comport with the observation that given approximately 120.2 million individuals had been infected in the United States as of May 2021,[45] if reinfection occurred in only 1% of individuals, the United States would have observed 1.2 million second and third cases, with many coming to clinical attention and/or requiring hospitalization. In fact, no such large volume of recurrent cases has been observed in any part of the United States.[46] In the 21 months since the SARS-CoV-2 virus first appeared in the United States, doctors and scientists have not documented a single case of a naturally immune individual that was re-infected with and transmitted the virus to anyone.[47]

Taken together, the data reflects that while the vaccinated when exposed to the virus can silently spread the virus to others, those naturally immune will not silently spread the virus. And when the rare instances of reinfection occur, there has never been a documented case of transmission from a reinfection. This is despite a world-wide hunt for such a case.

The findings in the dozens of studies cited above, none of which you have rebutted, are not surprising given that vaccines, by design, attempt to emulate the immunity created by a natural

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[43] *https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012240/Weekly_Flu_and_COVID-19_report_w33.pdf* at 17-18.

[44] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Briefing_22_21_09_02.pdf at 21. Meanwhile, the CDC – which is only reporting breakthrough cases which lead to hospitalization and death and whose "surveillance relies on passive and voluntary reporting" and acknowledges that "data are not complete or representative" and "are an undercount of all SARS-CoV-2 infections among fully vaccinated persons – has reported 14,115 breakthrough cases; https://www.cdc.gov/vaccines/COVID-19/health-departments/breakthrough-cases.html. Notably, Louisiana alone had counted 14,650 breakthrough infections as of August 25, 2021, https://www.politico.com/news/2021/08/25/cdc-pandemic-limited-data-breakthroughs-506823. Reflecting the sheer level of underreporting, Cornell University, despite a 95% vaccination rate for students and faculty, has more than five times the amount of confirmed positive cases during its first week of this academic year than it did during its first week of the 2020-21 academic year. https://www.thecollegefix.com/despite-95-vaccination-rate-cornell-today-has-five-times-more-covid-cases-than-it-did-this-time-last-year/. As of September 27, 2021, Harvard, despite boasting a rate of 96% faculty vaccinated and 95% students vaccinated, moved its business school remote due to "a 'steady rise' in breakthrough COVID-19 infection." https://www.bloomberg.com/news/articles/2021-09-27/harvard-moves-first-year-mba-students-online-amid-virus-outbreak.

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

[46] https://www.cdc.gov/coronavirus/2019-ncov/your-health/reinfection.html ("Cases of reinfection with COVID-19 have been reported, but remain rare" as of August 6, 2021).

[47] There is one case study published in Clinical Infections Diseases that told of a situation with a reinfection in one healthcare worker. Although the study states, "It seems likely that [the healthcare worker] played a role in the spread of this outbreak as she provides the only link between some of the patients," this is not definitive evidence of a proven case of reinfection and transmission. The study also states, "How transmission exactly occurred within this cluster of 4 individuals as well as its origin remain unclear." Additionally, were this a frequently occurring phenomenon, as stated above, there would be millions of cases of reinfection and evidence of transmission from same. *See* Selhorst P, *et al.*, *Symptomatic SARS-CoV-2 reinfection of a health care worker in a Belgian nosocomial outbreak despite primary neutralizing antibody response*, Clin Infect Dis. (December 14, 2020) https://pubmed.ncbi.nlm.nih.gov/33315049/.

infection.[48] Nonetheless, vaccines never achieve the same level of protection afforded by natural infection from a virus.[49] They universally confer inferior immunity to having had the actual virus and even the best vaccines do not confer immunity to all recipients.[50] In those who do obtain some immunity from vaccination, the immunity created often wanes over time.[51]

A recent article aptly explained why infection-induced immunity to SARS-CoV-2 is much deeper and broader than vaccine immunity:

> A natural infection induces hundreds upon hundreds of antibodies against all proteins of the virus, including the envelope, the membrane, the nucleocapsid, and the spike…Dozens upon dozens of these antibodies neutralize the virus when encountered again. Additionally, because of the immune system exposure to these numerous proteins (epitomes), our T cells mount a robust memory, as well. Our T cells are the 'marines' of the immune system and the first line of defense against pathogens. T cell memory to those infected with SARSCOV1 is at 17 years and running still….
>
> In vaccine-induced immunity…we mount an antibody response to only the spike and its constituent proteins … [and] this produces much fewer neutralizing antibodies, and as the virus preferentially mutates at the spike, these proteins are shaped differently and antibodies can no longer 'lock and key' bind to these new shapes.[52]

There is also apparently a high likelihood that the current COVID-19 vaccines will soon be rendered ineffective with regard to certain variants and Pfizer's CEO has admitted as much, saying a vaccine-resistant variant will likely emerge.[53] This is also confirmed by researchers as Osaka University which found that "the SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines."[54] Since vaccine-induced immunity does not prevent transmission or infection, this provides an opportunity for the virus to replicate in vaccinated individuals. In contrast, naturally immune individuals have sterilizing immunity, and in almost every case, do not become infected with and spread the virus upon coming into contact with the virus. They do not act as reservoirs for viral replication and transmission of new variants. As a professor of viral immunology at the University of Guelph recently explained:

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[48] *See* Plotkin's Vaccines, 7th Edition, at Section 2.

[49] *Id.*

[50] *Id.*

[51] *Id.*

[52] https://www.theblaze.com/op-ed/horowitz-israeli-government-data-shows-natural-immunity-from-infection-much-stronger-than-vaccine-induced-immunity#toggle-gdpr.

[53] https://www.insider.com/pfizer-ceo-vaccine-resistant-coronavius-variant-likely-2021-8.

[54] Yafei Liu, *et al.*, *The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines*, medRxiv (August 23, 2021) https://www.biorxiv.org/content/10.1101/2021.08.22.457114v1.

> Based on fundamental immunological principles, parenteral administration of these vaccines provides robust enough systemic antibody responses to allow these antibodies to spill over into the lower respiratory tract, which is a common point at which pathogens can enter systemic circulation due to the proximity of blood vessels to facilitate gas exchange. However, they do not provide adequate protection to the upper respiratory tract, like natural infection does, or like an intranasal or aerosolized vaccine likely would. As such, people whose immunity has been conferred by a vaccine only are often protected from the most severe forms of COVID-19 due to protection in the lower lungs, but they are also susceptible to proliferation of the virus in the upper airways, which causes them to shed equivalent quantities of SARS-CoV-2 as those who completely lack immunity. Dampened disease with equal shedding equals a phenotype that approaches that of a classic super-spreader.[55]

III. Serological Data

Reflecting the foregoing real-world data, the following studies, which you also fail to rebut, further evidence the superiority of natural immunity:

a. Researchers at the Chinese Center for Disease Control and Prevention studied those who had asymptomatic, mild, moderate, or severe disease during the prior one-year period and concluded that "SARS-CoV-2-specific cellular and humoral immunities are durable at least until one year after disease onset."[56]

b. Researchers at Yale found that "plasma from previously infected vaccinated individuals displayed overall better neutralization capacity when compared to plasma from uninfected individuals that also received two vaccine doses."[57]

c. Researchers at Rockefeller University concluded that memory B cells in those with prior infection "express increasingly broad and potent antibodies that are resistant to mutations found in variants of concern" and that "memory antibodies selected over time by natural infection have greater potency and breadth than antibodies elicited by vaccination."[58]

d. Researchers at the University of California concluded that "Natural infection induced expansion of larger CD8 T cell clones occupied distinct clusters, likely due

[55] https://onedrive.live.com/?authkey=%21ADfHk3IuaBrEH34&cid=914431B73799994E&id=914431B73799994E%2176735&parId=914431B73799994E%2173522&o=OneUp.

[56] https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab884/6381561.

[57] https://www.nature.com/articles/s41586-021-04085-y?source=techstories.org.

[58] Alice Cho, *et al.*, *Anti- SARS-CoV-2 Receptor Binding Domain Antibody Evolution after mRNA Vaccination*, medRxiv (August 23, 2021) https://www.biorxiv.org/content/10.1101/2021.07.29.454333v1.

to the recognition of a broader set of viral epitopes presented by the virus *not seen in the mRNA vaccine."*[59]

e. Researchers at the National Cancer Institute in Maryland and various Israeli institutions conducted a large-scale study of antibody titer decay following COVID-19 vaccine or SARS-CoV-2 infection. Aside from more robust T cell and memory B cell immunity, they found that antibodies wane slower among those who were previously infected. "In vaccinated subjects, antibody titers decreased by up to 40% each subsequent month while in convalescents they decreased by less than 5% per month."[60]

f. Researchers at Washington University School of Medicine found that, "People who recover [even] from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades."[61] Thus, prior COVID-19 infection creates memory B cells that "patrol the blood for reinfection, while bone marrow plasma cells (BMPCs) hide away in bones, trickling out antibodies for decades" as needed.[62]

g. Researchers at various Korean institutions found that the T cells of the naturally immune had "stem-cell like" qualities and that long-term "SARS-CoV-2-specific T cell memory is successfully maintained regardless of the severity of COVID-19."[63]

h. Researchers at the La Jolla Institute for Immunology found that that the immune systems of those who recovered from COVID-19 had durable memories of the virus for the eight-month duration of the study.[64]

i. Researchers at Washington University School of Medicine found that "SARS-CoV-2 infection induces a robust antigen-specific, long-lived humoral immune response in humans."[65]

j. Researchers at Emory University and the Fred Hutchinson Cancer Research Center found that recovered COVID-19 patients mount broad, durable immunity after

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[59] Suhas Sureshchandra *et al., Single cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine,* medRxiv (July 15, 2021) https://www.biorxiv.org/content/10.1101/2021.07.14.452381v1.

[60] Ariel Israel, *et al., Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection,* medRxiv (August 22, 2021) https://pubmed.ncbi.nlm.nih.gov/34462761/.

[61] Ewen Callaway, *Have COVID? You'll probably make antibodies for a lifetime,* Nature (August 22, 2021) https://pubmed.ncbi.nlm.nih.gov/34040250/.

[62] Jackson S. Turner, *et al., SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, Nature (May 24 2021) https://pubmed.ncbi.nlm.nih.gov/34030176/.

[63] Jung JH, *et al., SARS-CoV-2-specific T cell memory is sustained in COVID-19 convalescent patients for 10 months with successful development of stem cell-like memory T cells*, Nat Commun. (June 30, 2021) https://pubmed.ncbi.nlm.nih.gov/34193870/.

[64] Jennifer Dan, *et al., Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection,* Science (February 5, 2021) https://pubmed.ncbi.nlm.nih.gov/33408181/. *See also* https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-COVID-19.

[65] Jackson S. Turner, *et al., SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, Nature (May 24, 2021) https://pubmed.ncbi.nlm.nih.gov/34030176/ .

infection, and that "[t]he durable antibody responses in the COVID-19 recovery period are further substantiated by the ongoing rise in both the spike and RBD memory B cell responses after over 3–5 months before entering a plateau phase over 6–8 months. Persistence of RBD memory B cells has been noted."[66]

k. Researchers at Aarhus University Hospital in Denmark studied the immune response following SARS-CoV-2 infections and found that the vast majority of recovered individuals had detectable, functional SARS-CoV2 spike-specific adaptive immune responses, despite diverse disease severities, making vaccination post-COVID-19 for any of them redundant.[67]

l. Researchers from the UK Coronavirus Immunology Consortium (UK-CIC), Public Health England and Manchester University NHS Foundation Trust found that every naturally immune 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."[68]

m. Researchers from University of Minnesota Medical School found that "infection-induced primary MBCs [memory B cells] have better antigen-binding capacity and generate more plasmablasts and secondary MBCs of the classical and atypical subsets than vaccine-induced primary MBCs." As the authors state, "Our results suggest that infection induced primary MBCs have undergone more affinity maturation than vaccine-induced primary MBCs and produce more robust secondary responses."[69]

n. Researchers from NYU School of Medicine found that, "In COVID-19 patients, immune responses were characterized by a highly augmented interferon response which was largely absent in vaccine recipients. Increased interferon signaling likely contributed to the observed dramatic upregulation of cytotoxic genes in the peripheral T cells and innate-like lymphocytes in patients but not in immunized subjects." They also found that "Analysis of B and T cell receptor repertoires revealed that while the majority of clonal B and T cells in COVID-19 patients were effector cells, in vaccine recipients, clonally expanded cells were primarily circulating memory cells."[70]

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[66] Kristen W. Cohen, *et al., Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells*, Cell Rep Med. (July 14, 2021) https://pubmed.ncbi.nlm.nih.gov/34250512/.

[67] Stine Sf Nielsen, *et al*., *SARS-CoV-2 elicits robust adaptive immune responses regardless of disease severity*, EBioMedicine (June 4, 2021) https://pubmed.ncbi.nlm.nih.gov/34098342/.

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

[69] Kathryn A. Pape, *et al., High affinity memory B cells induced by SARS-CoV-2 infection produce more plasmablasts and atypical memory B cells than those primed by mRNA vaccines*, Cell Reports (September 20, 2021) https://www.cell.com/action/showPdf?pii=S2211-1247%2821%2901287-0.

[70] Ivanova EN, *et al., Discrete immune response signature to SARS-CoV-2 mRNA vaccination versus infection*, medRxiv (April 23, 2021) https://pubmed.ncbi.nlm.nih.gov/33907755/.

o. Researchers from the National Institutes of Health studied the likelihood of SARS-CoV-2 reinfection in people carrying antibodies against the virus, gathering data from more than 3.2 million people who had undergone SARS-CoV-2 antibody testing and found that those with SARS-CoV-2 antibodies became less likely to test positive for SARS-CoV-2 as time went on. The authors stated: "The data from this study suggest that people who have a positive result from a commercial antibody test appear to have substantial immunity to SARS-CoV-2, which means they may be at lower risk for future infection."[71]

p. Researchers from Swedish and UK institutions published a study which "shows that SARS-CoV-2 elicits broadly directed and functionally replete memory T cell responses, suggesting that natural exposure or infection may prevent recurrent episodes of severe COVID-19." This early finding of robust T cell memory has been supported by later studies as detailed above.[72]

IV. Hybrid Immunity

Given the unrebutted evidence that natural immunity is superior to vaccine immunity by every measure, the only retort in your Petition is to engage in an irrelevant comparison – one of naturally immune individuals *compared with* naturally immune individuals who were then vaccinated ("**hybrid immunity**"). Despite dozens of studies on hybrid immunity, you only cite a single small, self-conducted and highly confounded, retrospective study to claim that hybrid immunity is better than natural immunity. Even if correct, which is not supported by the balance of the data and studies, it is irrelevant. Natural immunity is *already* greater than 99% efficacious against COVID-19, regardless of variants, provides sterilizing immunity, and does not wane at nearly the rate vaccine-induced immunity wanes. Meaning, if you are going to lift restrictions on the vaccinated, it is authoritarian and prejudicial to not lift the same restrictions on the naturally immune.

In any event, as noted in the introduction above, your reliance on a single study, the Kentucky study, of a few hundred people is misplaced, including because the researchers re-engineered the controls in this study and chose, after the fact, those who had not been re-infected.[73] The study itself also lists five critical limitations, including that "reinfection was not confirmed through whole genome sequencing, which would be necessary to definitively prove that the reinfection was caused from a distinct virus relative to the first infection" and that "persons who have been vaccinated are possibly less likely to get tested. Therefore, the association of reinfection and lack of vaccination might be overestimated."[74]

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[71] https://pubmed.ncbi.nlm.nih.gov/33625463/; https://www.nih.gov/news-events/nih-research-matters/sars-cov-2-antibodies-protect-reinfection.

[72] Takuya Sekine, *et al., Robust T Cell Immunity in Convalescent Individuals with Asymptomatic or Mild COVID-19*, Cell (August 14, 2020) https://pubmed.ncbi.nlm.nih.gov/32979941/.

[73] Alyson Cavanaugh, *et al., Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021*, MMWR (August 13, 2021) https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm.

[74] *Id.*

Moreover, the Kentucky study explains that, "this is a retrospective study design using data from a single state during a 2-month period; therefore, these findings cannot be used to infer causation" and therefore "[a]dditional prospective studies with larger populations are warranted to support these findings."[75] Despite same, you simply ignore large, credible, well-controlled studies with limited confounders that reflect the finding in the heavily confounded Kentucky study is plainly unreliable. For example, the largest available population-based study involving 2.5 million Israelis in a single centralized-medical database (representing one of the four national health care funds in Israel) found the naturally immune were 99.74% protected from reinfection while the naturally immune with subsequent vaccination were 99.86% protection from reinfection.[76] Putting aside that reinfections in both groups were mostly asymptomatic, this difference is negligible and has no clinical relevance.

Worse is that even the assumed benefits of vaccinating the naturally immune do not outweigh the known risks. According to data from the UK, one of every 11 individuals with natural immunity that are vaccinated will have a clinically significant vaccine adverse event, with the most common adverse events being fever, fatigue, myalgia-arthralgia and lymphadenopathy.[77] Since, according to the Israeli study mentioned in the previous paragraph, vaccinating 833 naturally individuals is needed to prevent one case of *asymptomatic* reinfection (with the number being even higher for *symptomatic* reinfection), the CDC's policy will cause over 75 cases of clinically significant adverse events in order to prevent one asymptomatic reinfection (NNT/NNH = 833/11).[78]

You also ignore data that natural immunity is stunted by subsequent vaccination. Notably, U.S. researchers from Case Western Reserve University School of Medicine, Ragon Institute of MGH, MIT, and Harvard, and other institutes looked at humoral immunity from 2 weeks to 6 months post-vaccination in individuals both with and without pre-vaccination SARS-CoV-2 infection.[79] The authors noted that, "[a]ntispike, anti-RBD and neutralization levels dropped more than 84% over 6 months' time in all [vaccinated] groups *irrespective of prior SARS-CoV-2 infection*." In a previously infected individual with natural immunity who does not get vaccinated, these levels do not drop off. In fact, these levels persist and even grow.[80] The fact that they drop following vaccination is an indication that vaccination is having an adverse effect on naturally

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[75] *Id.*

[76] Sivan Gazit, *et al.*, *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, medRxiv (August 25, 2021) https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.

[77] Rachael Kathleen Raw, *et al., Previous COVID-19 infection, but not Long-COVID, is associated with increased adverse events following BNT162b2/Pfizer vaccination,* The Journal of Infection (May 29, 2021) https://pubmed.ncbi.nlm.nih.gov/34062184/.

[78] Sivan Gazit, *et al.*, (*supra*). Cf. "Model 3 - previously infected vs. vaccinated and previously infected individuals" in this study: 20/14,029 previously infected-vaccinated later tested positive (0.14% reinfection), or 99.86% immunity compared to 37/14,029 previously infected-unvaccinated (0.26% reinfection) or 99.74% immunity. Difference of 0.12% (17/14,029), with NNT 1/0.0012 = 833.

[79] David Canaday, *et al., Significant reduction in humoral immunity among healthcare workers and nursing home residents 6 months after COVID-19 BNT162b2 mRNA vaccination*, medRxiv (August 20, 2021) https://www.medrxiv.org/content/10.1101/2021.08.15.21262067v3.

[80] Moriyama S., *et al., Temporal maturation of neutralizing antibodies in COVID-19 convalescent individuals improves potency and breadth to circulating SARS-CoV-2 variants,* Immunity (July 2, 2021) https://pubmed.ncbi.nlm.nih.gov/34246326/.

induced immunity.[81] In other words, the normal, longstanding, robust immunity which does not typically show significant waning and, in fact shows increasing potency over time, in those recovered and subsequently vaccinated is dropping 84% over 6 months after vaccination.

Conclusion

The naturally immune have sterilizing immunity, a negligible rate of reinfection, and no documented cases of subsequent transmission exist for this population. The vaccine immune, in contrast, do not have sterilizing immunity, are frequent asymptomatic carriers, have a high breakthrough rate, and have many documented cases of subsequent transmission after breakthrough. **It is simply irrational, illogical, authoritarian, and punitive to apply limitations to the naturally immune that do not apply to the vaccinated.**

As noted in the introduction, while your letter claims that the CDC "evaluates available evidence, the quality of available and pertinent evidence and studies, and the benefits and potential harms from the intervention," your response did not evaluate any of the studies and evidence provided in the Petition. On behalf of ICAN, we therefore provide final notice. Pursuant to 5 U.S.C. § 553(e), we have been authorized to commence an action in federal court, as we have done on related matters, and intend to file same absent a response, within 21 days of this demand, that either (1) lifts restrictions on the naturally immune to the same extent as the vaccine immune or (2) addresses the science provided in the Petition and provides science which on-balance shows that vaccine immunity is more durable, sterilizing, and prevents more subsequent cases than does natural immunity.

Absent same, <u>we will be filing a lawsuit forthwith</u> to redress your actions which are crushing the civil and individual rights of those with natural immunity. We have also been authorized to seek and prosecute all available avenues to hold individuals at the CDC and the agency itself accountable for its disregard of these foundational rights. This will result in additional lawsuits because your edict regarding natural immunity is not merely a scientific stance but is the reason the federal government's vaccine mandates do not recognize natural immunity.

This means that every federal government employee that has natural immunity, including anyone that works for the CDC, FDA, NIH, or any other federal health agency, has standing under applicable law to sue its agency. Please be advised that employees of these and numerous other

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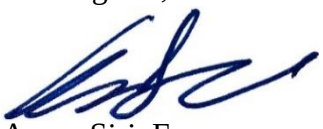
[81] Daniel Lozano-Ojalvo, *et al.*, *Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naive and COVID-19 recovered individuals*, Cell Rep (August 3, 2021) https://pubmed.ncbi.nlm.nih.gov/34390647/ (Researchers monitored a group of vaccinated people with and without prior infection and found that "in individuals with a pre-existing immunity against SARS-CoV-2, the second vaccine dose not only fail to boost humoral immunity but determines a contraction of the spike-specific T cell response." They also note that "the second vaccination does appears to exert a detrimental effect in the overall magnitude of the spike-specific humoral response in COVID-19 recovered individuals."); *see also* Jason Neidleman, *et al.*, *mRNA vaccine-induced SARS-CoV-2-specific T cells recognize B.1.1.7 and B.1.351 variants but differ in longevity and homing properties depending on prior infection status* (May 12, 2021) https://www.biorxiv.org/content/10.1101/2021.05.12.443888v1 (Researchers assessed those vaccinated who were naïve to COVID-19 and those vaccinated who had recovered (and did not assess those who recovered but were not vaccinated) concluded that, "[i]n infection-naïve individuals, the second dose boosted the quantity but not quality of the T cell response, while in convalescents the second dose helped neither. Spike-specific T cells from convalescent vaccinees differed strikingly from those of infection-naïve vaccinees, with phenotypic features suggesting superior long-term persistence and ability to home to the respiratory tract including the nasopharynx.").

federal agencies have reached out to our firm for precisely such representation. You can therefore be assured that we will be bringing lawsuits on behalf of these individuals, including directly against the CDC as an employer absent your forthwith treatment of those with natural immunity as having at least as good immunity as those with vaccine immunity.

This is your final warning.

Govern yourselves accordingly.

Best regards,



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

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

EXPERT WITNESS LIST

The below agree with the substance of the petition, dated October 21, 2021, titled *Reply Regarding Citizen Petition to Lift Restrictions on the Naturally Immune to the Extent Lifted on the Vaccinated* and will testify that the currently available studies and data support that SARS-CoV-2 infection acquired immunity is more durable and effective at preventing further infection than COVID-19 vaccine acquired immunity, and urge the CDC to lift restrictions on the naturally immune to the same extent that restrictions are lifted on the vaccinated.

Jay Battacharya, MD, PhD
Professor, Stanford University Medical School

Aditi Bhargava, PhD
Professor Emerita
Department of ObGyn and Reproductive Sciences
University of California San Francisco

Laszlo Boros, MD
Scientific Advisor
SIDMAP, LLC and the Deutenomics Science Institute

Andrew Bostom, MD, MS
Associate Professor of Family Medicine (Research)
The Warren Alpert Medical School of Brown University

Aaron Kheriaty, MD
Professor of Psychiatry, UCI School of Medicine
Director, Medical Ethics Program, UCI Health

Peter McCollough, MD, MPH
Chief Medical Advisor, Truth for Health Foundation, Tucson AZ

Linda Wastila, BSPharm, MSPH, PhD
Professor, Pharmaceutical Health Services Research
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Gabe Vorobiof, MD FACC FASE
Director, Adult Non-Invasive Cardiology Laboratories
UCLA Cardiovascular Center
Associate Clinical Professor of Medicine
David Geffen School of Medicine at UCLA

Note that the affiliations for each individual listed above are not intended to reflect an endorsement of this organization or its activities, and are listed for informational purposes only.

Appendix A

Siri | Glimstad

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PHOENIX | DETROIT

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VIA E-MAIL AND FEDERAL EXPRESS

July 6, 2021

Dr. Rochelle P. Walensky, Director
Centers for Disease Control and Prevention
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1600 Clifton Road
Atlanta, GA 30333
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[1] ("**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.

[1] Including, but not limited to, on behalf of its members, including those who work for Petitioner.

Exhibit A

Siri | Glimstad

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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

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 individuals who had been exposed to SARS-CoV-2 a year earlier and found that bone marrow

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

[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.

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.

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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[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.

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 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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[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* 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,

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.[1]

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*.[2] I have 40 peer-reviewed

[1] *See* http://www.cardiorenalsociety.org/.

[2] 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 has 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.[3] 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.[4]

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/.

[3] *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/.

[4] *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.[5] 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.[6] 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.[7] 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.[8] 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.

[5] *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.

[6] *See* Schwarzkopf S, Krawczyk A, Knop D, Klump H, Heinold A, Heinemann FM, Thümmler 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/.

[7] *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, Schwemmle 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+ 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/.

[8] *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.[9] 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.[10] 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.[11]

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.[12]

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 join 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.

[9] *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/.

[10] *See* https://www.worldometers.info/coronavirus/.

[11] *See* https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1.

[12] *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

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/.

Sincerely,

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

Siri | Glimstad

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VIA E-MAIL AND FEDERAL EXPRESS
September 15, 2021

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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[1] ("**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.

[1] 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

1. 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 February 22, 2020. doi:10.3390/v12020244 available at https://pubmed.ncbi.nlm.nih.gov/32098422/.

2. Van Doremalen N, Lambe T, Spencer A, Belij-Rammerstorfer S, Purushotham JN, Port JR, Avanzato V, Bushmaker T, Flaxman A, Ulaszewska M, Feldmann F, Allen ER, Sharpe H, Schulz J, Holbrook M, Okumura A, Meade-White K, Pérez-Pérez L, Bissett C, Gilbride C, Williamson BN, Rosenke R, Long D, Ishwarbhai A, Kailath R, Rose L, Morris S, Powers C, Lovaglio J, Hanley PW, Scott D, Saturday G, de Wit E, Gilbert SC, Munster VJ. ChAdOx1 nCoV-19 vaccination prevents SARS-CoV-2 pneumonia in rhesus macaques. bioRxiv [Preprint]. May 13, 2020:2020.05.13.093195. doi: 10.1101/2020.05.13.093195. https://pubmed.ncbi.nlm.nih.gov/32511340/.

3. Khan I, Hatiboglu MA. Can COVID-19 induce glioma tumorogenesis through binding cell receptors? Med Hypotheses. 2020 Nov;144:110009. doi: 10.1016/j.mehy.2020.110009. Epub 2020 Jun 19. PMID: 32758869; PMCID: PMC7303027; June 19, 2020; http://dx.doi.org/10.1016/j.mehy.2020.110009.

4. Singh N, Bharara Singh A. S2 subunit of SARS-nCoV-2 interacts with tumor suppressor protein p53 and BRCA: an in silico study. *Transl Oncol*. 2020;13(10):100814. doi:10.1016/j.tranon.June30,2020.100814; http://dx.doi.org/10.1016/j.tranon.2020.100814.

5. 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. August 2020;584(7821):457-462. doi: 10.1038/s41586-020-2550-z. Epub 2020 Jul 15. PMID: 32668444 available at https://pubmed.ncbi.nlm.nih.gov/32668444/; https://www.nature.com/articles/s41586-020-2550-z.

6. Iyer AS, Jones FK, Nodoushani A, Kelly M, Becker M, Slater D, Mills R, Teng E, Kamruzzaman M, Garcia-Beltran WF, Astudillo M, Yang D, Miller TE, Oliver E, Fischinger S, Atyeo C, Iafrate AJ, Calderwood SB, Lauer SA, Yu J, Li Z, Feldman J, Hauser BM, Caradonna TM, Branda JA, Turbett SE, LaRocque RC, Mellon G, Barouch DH, Schmidt AG, Azman AS, Alter G, Ryan ET, Harris JB, Charles RC. Dynamics and significance of the antibody response to SARS-CoV-2 infection. medRxiv [Preprint]. July 20, 2020.07.18.20155374. doi: 10.1101/2020.07.18.20155374. PMID: 32743600; PMCID: PMC7386524. https://pubmed.ncbi.nlm.nih.gov/32743600/.

7. Jun Wu, Boyun Liang, Cunrong Chen, Hua Wang, Yaohui Fang, Shu Shen, Xiaoli Yang, Baoju Wang, Liangkai Chen, Qi Chen, Yang Wu, Jia Liu, Xuecheng Yang, Wei Li, Bin Zhu, Wenqing Zhou, Huan Wang, Shumeng Li, Sihong Lu, Di Liu, Huadong Li, Adalbert Krawczyk, Mengji Lu, Dongliang Yang, Fei Deng, Ulf Dittmer, Mirko Trilling, Xin Zheng; SARS-CoV-2 infection induces sustained humoral immune responses in convalescent patients following symptomatic COVID-19; medRxiv 2020.07.21.20159178; doi: https://doi.org/10.1101/2020.07.21.20159178; July 21, 2020; https://www.medrxiv.org/content/10.1101/2020.07.21.20159178v1.

8. 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 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 August 7, 2020. 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, Ariel Israel, Yotam Shenhar, Ilan Green, Eugene Merzon, Avivit Golan-Cohen, Alejandro A Schäffer, Eytan Ruppin, Shlomo Vinker, Eli Magen; Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection; medRxiv August 19, 2020; 21262111; doi: https://doi.org/10.1101/2021.08.19.21262111; https://www.medrxiv.org/content/10.1101/2021.08.19.21262111v1.

9. Zhang, S., Liu, Y., Wang, X. *et al.* SARS-CoV-2 binds platelet ACE2 to enhance thrombosis in COVID-19. *J Hematol Oncol* 13, 120 (September 4, 2020). https://doi.org/10.1186/s13045-020-00954-7; http://dx.doi.org/10.1186/s13045-020-00954-7.

10. Yuichiro J. Suzuki, Sofia I. Nikolaienko, Vyacheslav A. Dibrova, Yulia V. Dibrova, Volodymyr M. Vasylyk, Mykhailo Y. Novikov, Nataliia V. Shults, Sergiy G. Gychka; SARS-CoV-2 spike protein-mediated cell signaling in lung vascular cells; bioRxiv 2020.10.12.335083; doi: https://doi.org/10.1101/2020.10.12.335083; Now published in *Vascular Pharmacology* doi: 10.1016/j.vph.2020.106823; October 12, 2020; http://dx.doi.org/10.1016/j.vph.2020.106823.

11. Schwarzkopf S, Krawczyk A, Knop D, Klump H, Heinold A, Heinemann FM, Thümmler 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. January 2021;27(1). doi: 10.3201/2701.203772. Epub October 15, 2020. PMID: 33058753 available at https://pubmed.ncbi.nlm.nih.gov/33058753/.

12. Corbett KS, Flynn B, Foulds KE, et al. Evaluation of the mRNA-1273 Vaccine against SARS-CoV-2 in Nonhuman Primates. *N Engl J Med*. 2020;383(16):1544-1555. doi:10.1056/NEJMoa2024671;October15,2020. https://www.nejm.org/doi/full/10.1056/NEJMoa2024671;

13. Alana F Ogata, Adam M Maley, Connie Wu, Tal Gilboa, Maia Norman, Roey Lazarovits, Chih-Ping Mao, Gail Newton, Matthew Chang, Katrina Nguyen, Maliwan Kamkaew, Quan Zhu, Travis E Gibson, Edward T Ryan, Richelle C Charles, Wayne A Marasco, David R Walt, Ultra-Sensitive Serial Profiling of SARS-CoV-2 Antigens and Antibodies in Plasma to Understand Disease Progression in COVID-19 Patients with Severe Disease, *Clinical Chemistry*, Volume 66, Issue 12, December 2020, Pages 1562–1572, https://doi.org/10.1093/clinchem/hvaa213; http://dx.doi.org/10.1093/clinchem/hvaa213.

14. Patra T, Meyer K, Geerling L, Isbell TS, Hoft DF, Brien J, Pinto AK, Ray RB, Ray R. SARS-CoV-2 spike protein promotes IL-6 trans-signaling by activation of angiotensin II receptor signaling in epithelial cells. PLoS Pathog. December 7, 2020;16(12):e1009128. doi:10.1371/journal.ppat.1009128.PMID:33284859;PMCID: PMC7746263.; http://dx.doi.org/10.1371/journal.ppat.1009128.

15. Rhea, E.M., Logsdon, A.F., Hansen, K.M. *et al.* The S1 protein of SARS-CoV-2 crosses the blood–brain barrier in mice. *Nat Neurosci* 24, 368–378 (2021). December 16, 2020. https://doi.org/10.1038/s41593-020-00771-8; http://dx.doi.org/10.1038/s41593-020-00771-8.

16. 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. December 30, 2020;21(4):517-530. doi:10.31083/j.rcm.2020.04.264.PMID:33387997_available_at https://pubmed.ncbi.nlm.nih.gov/33387997/.

17. Suresh SJ, Suzuki YJ. SARS-CoV-2 Spike Protein and Lung Vascular Cells. *Journal of Respiration*. 2021;1(1):40-48; December 31, 2020; https://doi.org/10.3390/jor1010004; https://www.mdpi.com/2673-527X/1/1/4.

18. 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, Schwemmle 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+ T cells. Nat Med. January 2021;27(1):78-85. doi: 10.1038/s41591-020-01143-2. Epub PMID: 33184509 available at https://pubmed.ncbi.nlm.nih.gov/33184509/.

19. Dan JM, Mateus J, Kato Y, Hastie KM, Yu ED, Faliti CE, Grifoni A, Ramirez SI, Haupt S, Frazier A, Nakao C, Rayaprolu V, Rawlings SA, Peters B, Krammer F, Simon V, Saphire EO, Smith DM, Weiskopf D, Sette A, Crotty S. Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. Science; 5;371(6529):eabf4063. doi: 10.1126/science.abf4063. Epub January 6, 2021. PMID: 33408181; PMCID: PMC7919858. https://pubmed.ncbi.nlm.nih.gov/33408181/.

20. Suzuki YJ, Gychka SG. SARS-CoV-2 Spike Protein Elicits Cell Signaling in Human Host Cells: Implications for Possible Consequences of COVID-19 Vaccines. *Vaccines*. 2021; 9(1):36. January 11, 2021; https://doi.org/10.3390/vaccines9010036; http://dx.doi.org/10.3390/vaccines9010036.

21. Florian Krammer, Komal Srivastava, the PARIS team, Viviana Simon; Robust spike antibody responses and increased reactogenicity in seropositive individuals after a single dose of SARS-CoV-2 mRNA vaccine; January 29, 2021; medRxiv 2021.01.29. 21250653; doi: https://doi.org/10.1101/2021.01.29.21250653.

22. Alexander G. Mathioudakis, Murad Ghrew, Andrew Ustianowski, Shazaad Ahmad, Ray Borrow, Lida Pieretta Papavasileiou, Dimitrios Petrakis, Nawar Diar Bakerly; Self-reported real-world safety and reactogenicity of COVID-19 vaccines: An international vaccine-recipient survey, February 26, 2021;medRxiv 2021.02.26.21252096; doi:https://doi.org/10.1101/2021.02.26.21252096; https://www.medrxiv.org/content/10.1101/2021.02.26.21252096v1.

23. 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. May 2021;22(5):620-626. doi: 10.1038/s41590-021-00902-8. Epub March 5, 2021. PMID: 33674800; PMCID: PMC7610739 available at https://www.nature.com/articles/s41590-021-00902-8.

24. Blumenthal KG, Robinson LB, Camargo CA, et al. Acute Allergic Reactions to mRNA COVID-19 Vaccines. *JAMA.* 2021;325(15):1562–1565. doi:10.1001/jama ; March 8, 2021.3976; https://jamanetwork.com/journals/jama/fullarticle/2777417.

25. Mathioudakis AG, Ghrew M, Ustianowski A, Ahmad S, Borrow R, Papavasileiou LP, Petrakis D, Bakerly ND. Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey. *Life*. March 17, 2021; 11(3):249. https://doi.org/10.3390/life11030249; https://www.mdpi.com/2075-1729/11/3/249.

26. Development of Syncytialized Placenta, Its Limited Homology to the SARS-CoV-2 Spike Protein and Arguments against Disturbing Narrative in the Context of COVID-19 Vaccination. Biology (Basel). March 19, 2021;10(3):238. doi: 10.3390/biology10030238. PMID: 33808658; PMCID: PMC8003504. http://dx.doi.org/10.3390/biology10030238.

27. Carmen Camara, Daniel Lozano-Ojalvo, Eduardo Lopez-Granados, Estela Paz-Artal, Marjorie Pion, Rafael Correa-Rocha, Alberto Ortiz, Marcos Lopez-Hoyos, Marta Erro Iribarren, Jose Portoles, Pilar Portoles, Mayte Perez-Olmeda, Jesus Oteo, Cecilia Berin, Ernesto Guccione, Antonio Bertoletti, Jordi Ochando ; Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naïve and COVID-19 recovered individuals;March 22, 2021; bioRxiv 2021.03.22.436441; doi: https://doi.org/10.1101/2021.03.22.436441.

28. Rachael K. Raw, Clive Kelly, Jon Rees, Caroline Wroe, David R. Chadwick; Previous COVID-19 infection but not Long-COVID is associated with increased adverse events following BNT162b2/Pfizer vaccination; April 15, 2021;medRxiv 2021.04.15.21252192; doi: https://doi.org/10.1101/2021.04.15.21252192; https://www.medrxiv.org/content/10.1101/2021.04.15.21252192v1.

29. Yair Goldberg, Micha Mandel, Yonatan Woodbridge, Ronen Fluss, Ilya Novikov, Rami Yaari, Arnona Ziv, Laurence Freedman, Amit Huppert ; Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel; April 20, 2021;medRxiv 2021.04.20.21255670; doi: https://doi.org/10.1101/2021.04.20.21255670; https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.

30. Ivanova EN, Devlin JC, Buus TB, et al. Discrete immune response signature to SARS-CoV-2, mRNA vaccination versus infection. Preprint. *medRxiv*. 2021;2021.04.20.21255677. Published April 21, 2021. doi:10.1101/2021.04.20.21255677; https://pubmed.ncbi.nlm.nih.gov/33907755/.

31. Laith J. Abu-Raddad, et al.; SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy; The Lancet; April 27, 2021; https://www.thelancet.com/journals/eclinm/article/PIIS2589-5370(21)00141-3/fulltext#%20.

32. Angeli F, Spanevello A, Reboldi G, Visca D, Verdecchia P. SARS-CoV-2 vaccines: Lights and shadows. *Eur J Intern Med*. 2021;88:1-8. April 29, 2021; doi:10.1016/j.ejim; http://dx.doi.org/10.1016/j.ejim.2021.04.019.

33. Lei Y, Zhang J, Schiavon CR, et al. SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2. *Circ Res*. April 30,2021; 128(9):1323-1326. doi:10.1161/CIRCRESAHA.121.318902; http://dx.doi.org/10.1161/CIRCRESAHA.121.318902.

34. Liguo Zhang, Alexsia Richards, M. Inmaculada Barrasa, Stephen H. Hughes, Richard A. Young, Rudolf Jaenisch; Reverse-transcribed SARS-CoV-2 RNA can integrate into the genome of cultured human cells and can be expressed in patient-derived tissues; ;Proceedings of the National Academy of Sciences; May 2021, 118 (21) e2105968118; DOI: 10.1073/pnas.2105968118; http://dx.doi.org/10.1073/pnas.2105968118.

35. Claudia Gonzalez, Carla Saade, Antonin Bal, Martine Valette, Kahina Saker, Bruno Lina, Laurence Josset, Mary-Anne Trabaud, Guillaume Thiery, Elisabeth Botelho-Nevers, Stéphane Paul, Paul Verhoeven, Thomas Bourlet, Sylvie Pillet, Florence Morfin, Sophie Trouillet-Assant, Bruno Pozzetto, Live virus neutralisation testing in convalescent patients and subjects vaccinated against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 isolates of SARS-CoV-2; May 11, 2021; medRxiv 2021.05.11.21256578; doi:https://doi.org/10.1101/2021.05.11.21256578; https://www.medrxiv.org/content/10.1101/2021.05.11.21256578v1.

36. Alana F Ogata, Chi-An Cheng, Michaël Desjardins, Yasmeen Senussi, Amy C Sherman, Megan Powell, Lewis Novack, Salena Von, Xiaofang Li, Lindsey R Baden, David R Walt, Circulating Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Vaccine Antigen Detected in the Plasma of mRNA-1273 Vaccine Recipients, *Clinical Infectious Diseases*, May 20, 2021, ciab465, https://doi.org/10.1093/cid/ciab465; https://academic.oup.com/cid/advance-article/doi/10.1093/cid/ciab465/6279075.

37. Idrees D, Kumar V. SARS-CoV-2 spike protein interactions with amyloidogenic proteins: Potential clues to neurodegeneration. *Biochem Biophys Res Commun*. 2021;554:94-98. May 21, 2021; doi:10.1016/j.bbrc.2021.03.100; http://dx.doi.org/10.1016/j.bbrc.2021.03.100.

38. Turner JS, Kim W, Kalaidina E, Goss CW, Rauseo AM, Schmitz AJ, Hansen L, Haile A, Klebert MK, Pusic I, O'Halloran JA, Presti RM, Ellebedy AH. SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans. Epub May 24, 2021; PMID: 34030176.https://pubmed.ncbi.nlm.nih.gov/34030176/;https://www.nature.com/articles/s41586-021-03647-4.

39. O Murchu E, Byrne P, Carty PG, De Gascun C, Keogan M, O'Neill M, Harrington P, Ryan M. Quantifying the risk of SARS-CoV-2 reinfection over time. Rev Med Virol. May 27, 2021:e2260. doi: 10.1002/rmv.2260. Epub ahead of print. PMID: 34043841; PMCID: PMC8209951.https://pubmed.ncbi.nlm.nih.gov/34043841/.

40. Nielsen SS, Vibholm LK, Monrad I, Olesen R, Frattari GS, Pahus MH, Højen JF, Gunst JD, Erikstrup C, Holleufer A, Hartmann R, Østergaard L, Søgaard OS, Schleimann MH, Tolstrup M. SARS-CoV-2 elicits robust adaptive immune responses regardless of disease severity. EBioMedicine. June 2021;68:103410. doi: 10.1016/j.ebiom.2021.103410. Epub June4,2021.PMID:34098342;PMCID:PMC8176920. https://pubmed.ncbi.nlm.nih.gov/34098342/; https://www.thelancet.com/journals/ebiom/article/PIIS2352-3964(21)00203-6/fulltext.

41. Amy S. Nowacki, Paul Terpeluk, Steven M. Gordonmed; Necessity of COVID-19 vaccination in previously infected individuals, Nabin K. Shrestha, Patrick C. Burke, ;June 6, 2021; Rxiv 2021.06.01.21258176; doi: https://doi.org/10.1101/2021.06.01.21258176; https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3.

42. Jung JH, Rha MS, Sa M, Choi HK, Jeon JH, Seok H, Park DW, Park SH, Jeong HW, Choi WS, Shin EC. SARS-CoV-2-specific T cell memory is sustained in COVID-19 convalescent patients for 10 months with successful development of stem cell-like memory T cells. Nat Commun. June 30, 2021;12(1):4043. doi: 10.1038/s41467-021-24377-1. PMID: 34193870; PMCID: PMC8245549. https://pubmed.ncbi.nlm.nih.gov/34193870/.

43. Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep 2021;70:1059-1062.DOI:http://dx.doi.org/10.15585/mmwr.mm7031e2; https://pubmed.ncbi.nlm.nih.gov/32616673/.

44. Moriyama S, Adachi Y, Sato T, Tonouchi K, Sun L, Fukushi S, Yamada S, Kinoshita H, Nojima K, Kanno T, Tobiume M, Ishijima K, Kuroda Y, Park ES, Onodera T, Matsumura T, Takano T, Terahara K, Isogawa M, Nishiyama A, Kawana-Tachikawa A, Shinkai M, Tachikawa N, Nakamura S, Okai T, Okuma K, Matano T, Fujimoto T, Maeda K, Ohnishi M, Wakita T, Suzuki T, Takahashi Y. Temporal maturation of neutralizing antibodies in COVID-19 convalescent individuals improves potency and breadth to circulating SARS-CoV-2 variants. Immunity. Epub July 2, 2021. PMID: 34246326; PMCID: PMC8249673; https://pubmed.ncbi.nlm.nih.gov/34246326/.

45. N Kojima, A Roshani, M Brobeck, A Baca, JD Klausner; Incidence of Severe Acute Respiratory Syndrome Coronavirus-2 infection among previously infected or vaccinated employees; July 3, 2021; medRxiv 2021.07.03.21259976; doi:https://doi.org/10.1101/2021.07.03.21259976; https://www.medrxiv.org/content/10.1101/2021.07.03.21259976v2.full-text.

46. Single cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine Suhas Sureshchandra, Sloan A. Lewis, Brianna Doratt, Allen Jankeel, Izabela Ibraim, Ilhem Messaoudi; July 14, 2021; bioRxiv 2021.07.14.452381; doi: https://doi.org/10.1101/2021.07.14.452381; https://www.biorxiv.org/content/10.1101/2021.07.14.452381v1.

47. Lopez Bernal J, Andrews N, Gower C, Gallagher E, Simmons R, Thelwall S, Stowe J, Tessier E, Groves N, Dabrera G, Myers R, Campbell CNJ, Amirthalingam G, Edmunds M, Zambon M, Brown KE, Hopkins S, Chand M, Ramsay M. Effectiveness of Covid-19 Vaccines against the B.1.617.2 (Delta) Variant. N Engl J Med. 2021 Aug 12;385(7):585-594. doi: 10.1056/NEJMoa2108891. Epub July 21, 2021. PMID: 34289274; PMCID: PMC8314739.https://pubmed.ncbi.nlm.nih.gov/34289274/; https://www.nejm.org/doi/10.1056/NEJMoa2108891.

48. Cohen KW, Linderman SL, Moodie Z, et al. Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells. *Cell Rep Med*. July 23, 2021;2(7):100354.

doi:10.1016/j.xcrm.2021.100354;https://doi.org/10.1016/j.xcrm.2021.100354; https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8253687/.

49. Stephen J. Thomas, Edson D. Moreira Jr., Nicholas Kitchin, Judith Absalon, Alejandra Gurtman, Stephen Lockhart, John L. Perez, Gonzalo Pérez Marc, Fernando P. Polack, Cristiano Zerbini, Ruth Bailey, Kena A. Swanson, Xia Xu, Satrajit Roychoudhury, Kenneth Koury, Salim Bouguermouh, Warren V. Kalina, David Cooper, Robert W. Frenck Jr., Laura L. Hammitt, Özlem Türeci, Haylene Nell, Axel Schaefer, Serhat Ünal, Qi Yang, Paul Liberator, Dina B. Tresnan, Susan Mather, Philip R. Dormitzer, Uğur Şahin, William C. Gruber, Kathrin U. Jansen; Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine; C4591001 Clinical Trial Group. medRxiv; July 28, 2021; 2021.07.28.21261159; https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf.

50. Alice Cho, Frauke Muecksch, Dennis Schaefer-Babajew, Zijun Wang, Shlomo Finkin, Christian Gaebler, Victor Ramos, Melissa Cipolla, Marianna Agudelo, Eva Bednarski, Justin DaSilva, Irina Shimeliovich, Juan Dizon, Mridushi Daga, Katrina Millard, Martina Turroja, Fabian Schmidt, Fengwen Zhang, Tarek Ben Tanfous, Mila Jankovic, Thiago Y. Oliveria, Anna Gazumyan, Marina Caskey, Paul D. Bieniasz, Theodora Hatziioannou, Michel C. Nussenzweig ; Anti- SARS-CoV-2 Receptor Binding Domain Antibody Evolution after mRNA Vaccination ;July 29, 2021; bioRxiv 2021.07.29.454333; doi: https://doi.org/10.1101/2021.07.29.454333; https://www.biorxiv.org/content/10.1101/2021.07.29.454333v1.

51. Arjun Puranik, Patrick J. Lenehan, Eli Silvert, Michiel J.M. Niesen, Juan Corchado-Garcia, John C. O'Horo, Abinash Virk, Melanie D. Swift, John Halamka, Andrew D. Badley, A.J. Venkatakrishnan, Venky Soundararajan; Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence; medRxiv 2021.08.06.21261707; August 6, 2021; doi: https://doi.org/10.1101/2021.08.06.21261707.

52. Impact of Delta on viral burden and vaccine effectiveness against new SARS-CoV-2 infections in the UK; Koen B. Pouwels, Emma Pritchard, Philippa C. Matthews, Nicole Stoesser, David W. Eyre, Karina-Doris Vihta, Thomas House, Jodie Hay, John I Bell, John N Newton, Jeremy Farrar, Derrick Crook, Duncan Cook, Emma Rourke, Ruth Studley, Tim Peto, Ian Diamond, A. Sarah Walker, the COVID-19 Infection Survey Team;August 19, 2021; medRxiv 2021.08.18.21262237; doi: https://doi.org/10.1101/2021.08.18.21262237; https://www.medrxiv.org/content/10.1101/2021.08.18.21262237v1.

53. Yafei Liu, Noriko Arase, Jun-ichi Kishikawa, Mika Hirose, Songling Li, Asa Tada, Sumiko Matsuoka, Akemi Arakawa, Kanako Akamatsu, Chikako Ono, Hui Jin, Kazuki Kishida, Wataru Nakai, Masako Kohyama, Atsushi Nakagawa, Yoshiaki Yamagishi, Hironori Nakagami, Atsushi Kumanogoh, Yoshiharu Matsuura, Daron M. Standley, Takayuki Kato, Masato Okada, Manabu Fujimoto, Hisashi Arase; The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines. bioRxiv

2021.08.22.457114;August 22, 2021; doi: https://doi.org/10.1101/2021.08.22.457114; https://www.biorxiv.org/content/10.1101/2021.08.22.457114v1.

54. Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon, Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections; August 24, 2021; medRxiv 2021.08.24.21262415; doi:https://doi.org/10.1101/2021.08.24.21262415; https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.

55. Peled Y, Ram E, Lavee J, et al. Third dose of the BNT162b2 vaccine in heart transplant recipients: immunogenicity and clinical experience [published online ahead of print, August 28, 2021]. *J Heart Lung Transplant*. 2021;doi:10.1016/j.healun.2021.08.010; https://pubmed.ncbi.nlm.nih.gov/32979941/.

56. Han M, Pandey D. ZMPSTE24 Regulates SARS-CoV-2 Spike Protein-enhanced Expression of Endothelial PAI-1. September 2021; Am J Respir Cell Mol Biol. 2021 Sep;65(3):300-308. doi: 10.1165/rcmb.2020-0544OC. PMID: 34003736.http://dx.doi.org/10.1165/rcmb.2020-0544OC.

Appendix B

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30329-4027

September 17, 2021

Aaron Siri, Esq.
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New York, New York 10166

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