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VIA E-MAIL AND FEDERAL EXPRESS

October 21, 2021

Dr. Rochelle P. Walensky, Director Centers for Disease Control and Prevention Royal Bldg. 21, Rm 12000 1600 Clifton Road Atlanta, GA 30333 aux7@cdc.gov Ms. Sandra Cashman, Executive Secretary Centers for Disease Control and Prevention Royal Bldg. 21, Rm 10230 1600 Clifton Road Atlanta, GA 30333 cdcexecsec@cdc.gov

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

<u>REPLY REGARDING CITIZEN PETITION TO LIFT RESTRICTIONS ON THE</u> <u>NATURALLY IMMUNE TO THE EXTENT LIFTED ON THE VACCINATED</u>

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 Network¹ ("**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

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,<u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012240/Weekly_Flu_and_COVID-19_report_w33.pdf</u> at 17-18.

⁵See https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Br iefing 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 counted 14,650 breakthrough infections of 25, 2021. See alone had as August 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) <u>https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm</u>.

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

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. <u>Reinfections v. Breakthrough Cases</u>

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<u>https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012240/Weekly_Flu_an_d_COVID-19_report_w33.pdf</u> at 17-18.

¹²https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Briefi ng_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 https://www.cdc.gov/vaccines/COVID-19/health-departments/breakthrough-cases.html. breakthrough cases; Notably. Louisiana alone had counted 14,650 breakthrough infections as of August 2021, 25. https://www.politico.com/news/2021/08/25/cdc-pandemic-limited-data-breakthroughs-506823.

¹³ <u>https://www.nytimes.com/article/covid-breakthrough-delta-variant.html</u>.

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

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

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

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) <u>https://pubmed.ncbi.nlm.nih.gov/33937733/</u>.

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

²⁰ <u>https://www.israelnationalnews.com/News/News.aspx/309762</u>.

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) <u>https://pubmed.ncbi.nlm.nih.gov/34289335/</u>.

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) <u>https://pubmed.ncbi.nlm.nih.gov/34401884/</u>.

²⁴ Id.

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

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

³⁰ Id.

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 <u>https://pubmed.ncbi.nlm.nih.gov/34612005/</u>.

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

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) <u>https://pubmed.ncbi.nlm.nih.gov/34401884/</u>.

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

II. <u>Sterilizing Immunity v. Non-Sterilizing Immunity</u>

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

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/).

³⁴Sara 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 <u>https://twitter.com/CNNSitRoom/status/1423422301882748929</u>.

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) <u>https://pubmed.ncbi.nlm.nih.gov/32722908/</u>. Van Doremalen N., *et al., ChAdOx1 nCoV-19 vaccination prevents SARS-CoV-2 pneumonia in rhesus macaques*, Nature (July 30, 2020) <u>https://pubmed.ncbi.nlm.nih.gov/32731258/</u>.

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

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) <u>https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733</u>.

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) <u>https://pubmed.ncbi.nlm.nih.gov/34596015/</u>.

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

⁴³https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012240/Weekly_Flu_and <u>COVID-19 report w33.pdf</u> at 17-18.

⁴⁴https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Briefi ng 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, counted 14.650 breakthrough infections Louisiana alone had 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-didthis-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 <u>https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html</u>.

⁴⁶ <u>https://www.cdc.gov/coronavirus/2019-ncov/your-health/reinfection.html</u> ("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/3315049/.

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:

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-strongerthan-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) <u>https://www.biorxiv.org/content/10.1101/2021.08.22.457114v1</u>.

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. <u>Serological Data</u>

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 <u>https://onedrive.live.com/?authkey=%21ADfHk3IuaBrEH34&cid=914431B73799994E&id=914431B73799994E%217673</u> 5&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) <u>https://www.biorxiv.org/content/10.1101/2021.07.29.454333v1</u>.

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

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

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) <u>https://pubmed.ncbi.nlm.nih.gov/34462761/</u>.

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

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

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) <u>https://pubmed.ncbi.nlm.nih.gov/34193870/</u>.

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

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

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
- 1. 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 "infectioninduced 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

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) <u>https://pubmed.ncbi.nlm.nih.gov/34250512/</u>.

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

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) <u>https://www.cell.com/action/showPdf?pii=S2211-1247%2821%2901287-0</u>.

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

- 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. <u>Hybrid Immunity</u>

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 reengineered 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

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

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

 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) <u>https://www.cdc.gov/mmwr/volumes/70/wr/mm7032e1.htm</u>.
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.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

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) <u>https://pubmed.ncbi.nlm.nih.gov/34246326/</u>.

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

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) <u>https://pubmed.ncbi.nlm.nih.gov/34390647/</u> (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) <u>https://www.biorxiv.org/content/10.1101/</u>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

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

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

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Peter McCollough, MD, MPH

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