### UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

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Kate, et al.		
Plaintiffs,		
vs.		DECLARATION OF DR. JAYANTA BHATTACHARYA
de Blasio, et al. Defendants.		Civil Action No. 1:21-cv-07863
STATE OF CALIFORNIA	)	
COUNTY OF SANTA CLARA	) ss.: )	

### **DECLARATION OF DR. JAYANTA BHATTACHARYA SUPPORTING PLAINTIFFS**

- I, Dr. Jayanta Bhattacharya, declare as follows:
- 1. I am an adult of sound mind and make this statement voluntarily, based upon my own personal knowledge, education, and experience.
- 2. Based on my training and experience, I have formed an opinion on the reasonableness of the requested accommodations and on the possibility of other accommodations not listed to a reasonable degree of scientific certainty.

#### **EXPERIENCE & CREDENTIALS**

3. I am a former Professor of Medicine and current Professor of Health Policy at Stanford University School of Medicine and a research associate at the National Bureau of Economic Research. I am also Director of Stanford's Center for Demography and Economics of Health and Aging. I hold an M.D. and Ph.D. from Stanford University. I have published 154 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. My research has been cited in the peer-reviewed scientific literature more than 11,600 times.

- 4. I have dedicated my professional career to the analysis of health policy, including infectious disease epidemiology and policy, and the safety and efficacy of medical interventions. I have both studied extensively and commented publicly on the necessity and safety of vaccine requirements for those who have contracted and recovered from COVID-19 (individuals who have "natural immunity"). I am intimately familiar with the emergent scientific and medical literature on this topic and pertinent government policy responses to the issue both in the United States and abroad.
- 5. My assessment of vaccine immunity is based on studies related to the efficacy and safety of the one vaccine to receive full approval from the Food and Drug Administration (FDA) and two vaccines that the FDA has granted Emergency Use Authorization (EUA) for use in the United States. These include two mRNA-technology vaccines (manufactured by Pfizer-BioNTech and Moderna) and an adenovirus-vector vaccine technology (manufactured by Johnson & Johnson). Of those, the Pfizer vaccine, also known as Comirnaty, has full FDA approval.
- 6. I have not and will not receive any financial or other compensation to prepare this Declaration or to testify in this case. Nor have I received compensation for preparing declarations or reports or for testifying in *any* other case related to the Covid-19 pandemic. Nor have I ever received any personal or research funding from any pharmaceutical company. My participation here, just as my participation in other cases, has been motivated solely by my commitment to public health.
  - 7. I have no prior relationship with any of the plaintiffs.
- 8. I have been asked to provide my opinion on matters related to the mandatory vaccination policy for its New York City teachers and staff, including the following:
  - Whether people with religious or medical exemptions to vaccination pose a significant threat of substantial harm to their vaccinated co-workers and a largely unvaccinated student body

because of their vaccine status.

- Whether, based on the current medical and scientific knowledge, natural immunity is categorically inferior to vaccine immunity to prevent reinfection and transmission of the SARS-CoV-2 virus:
- Whether, based on the existing medical and scientific understanding of SARS- CoV-2 transmission and recovery, there is any categorical distinction between natural immunity and vaccine immunity;
- An assessment of the comparative safety to recipients of administering vaccines to those who
  have natural immunity relative to immunologically naïve recipients with no prior history of
  COVID infection;
- Whether vaccines pose any risks to individuals with certain medical conditions;
- The safety of providing accommodations to (1) those who have recovered from Covid and (2) those who have religious or medical reasons for declining to be vaccinated; and
- What those accommodations could look like in practice.
- 9. As a threshold matter, the protection provided by an individual being vaccinated to other people after the COVID-19 vaccination wanes within months after full vaccination. While the vaccines are each highly effective at mitigating severe disease, several studies show that vaccinated people are as infectious as unvaccinated people. Therefore, COVID-19 vaccination is primarily a matter of concern for the private health of an individual, rather than a matter of public health of concern to the public at large.
- 10. Vaccination remains a vital tool for personal protection, especially in higher risk groups. It has saved many lives during this pandemic. However, it is not necessary to require that everyone receive a vaccination given the lack of effectiveness in meaningfully mitigating transmission of disease. I provide the extensive scientific evidence on this point in Section I below.
- 11. My opinions are partly summarized in a recent article I published and which I reaffirm here: "the idea that everyone must be vaccinated against COVID-19 is as misguided as the anti-vax idea that no

one should. The former is more dangerous for public health." This is particularly true for those who have recovered from natural infection. "[R]ecovered COVID patients have strong, long-lasting protection against severe disease if reinfected, and evidence about protective immunity after natural infection is at least as good as from the vaccines. Hence, it makes no sense to require vaccines for recovered patients. For them, it simply adds a risk, however small, without any benefit."

12. I also offer my opinion that certain individuals may face heightened risk of vaccine side effects. Though the vaccines are safe for most patients, the FDA has identified a heighted risk of myocarditis and pericarditis after vaccination with the mRNA vaccines – especially for young men. It has also identified a heighted risk of clotting abnormalities in young women taking the adenovirus vector vaccine. Even more importantly, the vaccine has not been thoroughly tested for safety and efficacy in patients with certain chronic conditions such as Multiple Sclerosis, so there is still considerable uncertainty about these heightened risks for some patients.

13. I also conclude that the New York City Department of Education ("DOE") can safely accommodate COVID-recovered workers by exempting them from vaccine requirements since they possess better immunity versus reinfection than a vaccinated worker who never had COVID. The DOE could also safely accommodate those employees who have not recovered from Covid-19 but have religious or medical reasons for not wanting the vaccine by requiring daily symptom checking paired with rapid antigen tests to confirm if a worker is infectious. To reduce the risk from asymptomatically infected workers, the DOE can require workers to conduct weekly PCR tests, though if it adopts this accommodation, it should require it of both vaccinated and unvaccinated workers since both groups can spread the virus asymptomatically.

#### **OPINIONS**

I. Natural Immunity Provides Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected; COVID-19 Vaccines Provide Limited Protection Against Infection but Durable Protection Against Severe Outcomes if Infected.

<sup>&</sup>lt;sup>1</sup> Martin Kuldorff and Jay Bhattacharya, *The ill-advised push to vaccinate the young*, THEHILL.COM (June 17, 2021), https://thehill.com/opinion/healthcare/558757-the-ill-advised-push-to-vaccinate-the-young?rl=1.

- 14. Both vaccine-mediated immunity and natural immunity after recovery from COVID infection provide extensive protection against severe disease from subsequent SARS-CoV-2 infection. There is no reason to presume that vaccine immunity provides a higher level of protection than natural immunity. Since vaccines arrived one year after the disease, there is stronger evidence for long lasting immunity from natural infection than from the vaccines.
- 15. Both types are based on the same basic immunological mechanism—stimulating the immune system to generate an antibody response. In clinical trials, the efficacy of those vaccines was initially tested by comparing the antibodies level in the blood of vaccinated individuals to those who had natural immunity. Later Phase III studies of the vaccines established 94%+ clinical efficacy of the mRNA vaccines against severe COVID illness.<sup>2,3</sup> A Phase III trial showed 85% efficacy for the Johnson and Johnson adenovirus-based vaccine against severe disease.<sup>4</sup>
- 16. Immunologists have identified many immunological mechanisms of immune protection after recovery from infections. Studies have demonstrated prolonged immunity with respect to memory T and B

<sup>&</sup>lt;sup>2</sup> Baden LR, El Sahly HM, Essink B, Kotloff K, Frey S, Novak R, Diemert D, Spector SA, Rouphael N, Creech CB, McGettigan J, Khetan S, Segall N, Solis J, Brosz A, Fierro C, Schwartz H, Neuzil K, Corey L, Gilbert P, Janes H, Follmann D, Marovich M, Mascola J, Polakowski L, Ledgerwood J, Graham BS, Bennett H, Pajon R, Knightly C, Leav B, Deng W, Zhou H, Han S, Ivarsson M, Miller J, Zaks T., *COVE Study Group. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine*, N ENGL J MED. (Feb. 4, 2021).

<sup>&</sup>lt;sup>3</sup> Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, ZerbiniC, Bailey R, Swanson KA, Roychoudhury S, Koury K, Li P, Kalina WV, Cooper D, Frenck RW Jr, Hammitt LL, Türeci Ö, Nell H, Schaefer A, Ünal S, Tresnan DB, Mather S, Dormitzer PR, Şahin U, Jansen KU, Gruber WC, Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine, NENGL J MED. (Dec. 31, 2020).

<sup>&</sup>lt;sup>4</sup> Sadoff J, Gray G, Vandebosch A, Cárdenas V, Shukarev G, Grinsztejn B, Goepfert PA, Truyers C, Fennema H, Spiessens B, Offergeld K, Scheper G, Taylor KL, Robb ML, Treanor J, Barouch DH, Stoddard J, Ryser MF, Marovich MA, Neuzil KM, Corey L, Cauwenberghs N, Tanner T, Hardt K, Ruiz-Guiñazú J, Le Gars M, Schuitemaker H, Van Hoof J, Struyf F, Douoguih M, Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19, N ENGL J MED (June 10, 2021), 2187-2201.

cells<sup>5</sup>, bone marrow plasma cells<sup>6</sup>, spike-specific neutralizing antibodies<sup>7</sup>, and IgG+ memory B cells<sup>8</sup> following naturally acquired immunity.

17. Multiple extensive, peer-reviewed studies comparing natural and vaccine immunity have now been published. These studies overwhelmingly conclude that natural immunity provides equivalent or greater protection against severe infection than immunity generated by mRNA vaccines (Pfizer and Moderna).

<sup>&</sup>lt;sup>5</sup> Jennifer M. Dan, et al., *Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection*, SCIENCE(Feb. 5, 2021) (finding that memory T and B and B cells were present up to eight months after infection, noting that "durable immunity against secondary COVID-19 disease is a possibility for most individuals").

<sup>&</sup>lt;sup>6</sup> Jackson S. Turner, et al., *SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans*, NATURE (May 24, 2021) (study analyzing bone marrow plasma cells of recovered COVID-19 patients reported durable evidence of antibodies for at least 11 months after infection, describing "robust antigen-specific, long-lived humoral immune response in humans"); Ewen Callaway, Had COVID? You'll probably make antibodies for a lifetime, NATURE (May 26, 2021), https://www.nature.com/articles/d41586-021-01442-9#:~:text=Many%20people%20who%20have%20been,recovered%20from%20COVID%2D191 ("The study provides evidence that immunity triggered by SARS-CoV-2 infection will be extraordinarily long-lasting" and "people who recover from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades").

<sup>&</sup>lt;sup>7</sup> Tyler J. Ripperger, et al., *Orthogonal SARS-Cov-2 Serological Assays Enable Surveillance of Low-Prevalence Communities and Reveal Durable Humor Immunity*, 53 IMMUNITY, Issue 5, pp. 925-933 E4 (Nov. 17, 2020) (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

<sup>&</sup>lt;sup>8</sup> 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*, MEDRXIV (Apr. 27, 2021), https://www.medrxiv.org/content/10.1101/2021.04.19.21255739v1 (study of 254 recovered COVID patients over 8 months "found a predominant broad-based immune memory response" and "sustained IgG+ memory B cell response, which bodes well for rapid antibody response upon virus re-exposure." "Taken together, these results suggest that broad and effective immunity may persist long-term in recovered COVID-19 patients").

18. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19<sup>9</sup> and show that the vast majority of reinfections are less severe than first-time infections. <sup>10</sup> For example, an Israeli study of approximately 6.4 million individuals demonstrated that natural immunity provided equivalent if not better protection than vaccine immunity in preventing COVID-19 infection, morbidity, and mortality. <sup>11</sup> Of the 187,549 unvaccinated persons with natural immunity in the study, only 894 (0.48%) were reinfected; 38 (0.02%) were hospitalized, 16 (0.008%) were hospitalized with severe disease, and only one died, an individual over 80 years of age. Another study, analyzing data from Italy that only 0.31% of

<sup>&</sup>lt;sup>9</sup> Nabin K. Shrestha, et al., Necessity of COVID-19 vaccination in previously infected individuals, MEDRXIV (preprint), https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3 ("not one of the 1359 previously infected subjects who remained unvaccinated had a SARS-CoV-2 infection over the duration of the study "and concluded thatthose with natural immunity are "unlikely to benefit from covid-19 vaccination"); Galit Perez, et al., A 1 to 1000 SARS-CoV-2 reinfection proporation in members of a large healthcare provider in Israel: a preliminary report, MEDRXIV (Mar. 8, 2021), https://www.medrxiv.org/content/10.1101/2021.03.06.21253051v1 (Israeli study finding that approximately 1/1000 of participants were reinfected); Roberto Bertollini, et al., Associations of Vaccination and of Prior Infection With Positive PCR Test Results for SARS-CoV-2 in Airline Passengers Arriving in Qatar, JAMA (June 9, 2021), https://jamanetwork.com/journals/jama/fullarticle/2781112?resultClick=1 (study of international airline passengers arriving in Qatar found no statistically significant difference in risk of reinfection between those who had been vaccinated and those who had previously been infected); Stefan Pilz, et al., SARS-CoVre-infection risk EUR. CLIN. INVEST. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7988582/(previous SARS-CoV-2 infection reduced the odds of reinfection by 91% compared to first infection in the remaining generalpopulation); Aodhan Sean Breathnach, et al., Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies, 82 J. OF INFECTION e11e12 (2021) https://doi.org/10.1016/j.jinf.2021.05.024 (.0.86% of previously infected population in London became reinfected); Alison Tarke, Negligible impact of SARSOCoV-2 variants on CD4 and CD8 T cell reactivity in COVID-19 exposed and vaccines, https://www.biorxiv.org/content/10.1101/2021.02.27.433180v1 (an examination of the comparative efficacy of T cell responses to existing variants from patients with natural immunity compared to those who received an mRNA vaccine found that the T cell responses of both recovered Covid patients and vaccines were effective at neutralizing mutations found in SARS-CoV-2 variants).

<sup>&</sup>lt;sup>10</sup> Laith J. Abu-Raddad, et al., SARS-CoV-2 reinfection in a cohort of 43,000 antibody-positive individuals MEDRXIV followed 35 weeks, (Feb. https://www.medrxiv.org/content/10.1101/2021.01.15.21249731v2 (finding that of 129 reinfections from a cohort of 43,044, only one reinfection was severe, two were moderate, and none were critical or fatal); Victoria Jane Hall, et al., SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study, 397 LANCET: 1459-69 (Apr. 9, 2021), https://pubmed.ncbi.nlm.nih.gov/33844963/ (finding "a 93% lower risk of COVID-19 symptomatic infection... [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomaticinfection"); Aidan T. Hanrah, et al., Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection, 82 **JOURNAL** OF INFECTION, Issue E29-E30 (Apr. 1, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7832116/ (Apr. 1, 2021) (examined reinfection rates in a cohort of healthcare workers and found "no symptomatic reinfections" among those examined and that protection lasted for at least 6 months).

<sup>&</sup>lt;sup>11</sup> 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 (pre-print), https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1.

COVID-recovered patients experienced a reinfection within a year after the initial infection, despite the circulation of the delta variant.<sup>12</sup> In summary, the overwhelming conclusion of the pertinent scientific literature is that natural immunity is at least as effective against subsequent reinfection as even the most effective vaccines.

19. Based on such evidence, many scientists have concluded that natural protection against severe disease after COVID recovery is likely to be long-lasting. A survey article published on June 30, 2021, in the *British Medical Journal* concluded, "[t]here is reason to think that immunity could last for several months *or a couple of years*, at least, given what we know about other viruses and what we have seen so far in terms of antibodies in patients with COVID-19 and in people who have been vaccinated." <sup>13</sup>

20. These findings of highly durable natural immunity should not be surprising, as they hold for SARS-CoV-1 and other respiratory viruses. According to a paper published in *Nature* in August 2020, 23 patients who had recovered from SARS-CoV-1 still possess CD4 and CD8 T cells, 17 years after infection during the 2003 epidemic. <sup>14</sup> A *Nature* paper from 2008 found that 32 people born in 1915 or earlier still retained some level of immunity against the 1918 flu strain— some 90 years later. <sup>15</sup>

21. In contrast to the concrete findings regarding the robust durability of natural immunity, it is yet unclear in the scientific literature how long-lasting vaccine-induced immunity will be. Notably, the researchers argue that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.<sup>16</sup>

<sup>&</sup>lt;sup>12</sup> Vitale J, Mumoli N, Clerici P, et al. Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy. *JAMA Intern Med.* Published online May 28, 2021. doi:10.1001/jamainternmed.2021.2959

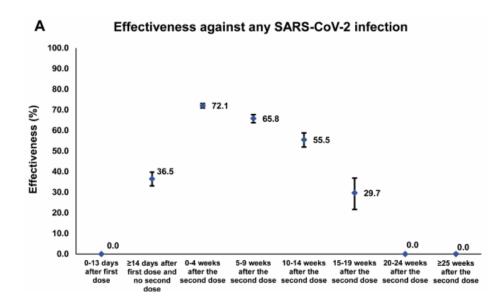
<sup>&</sup>lt;sup>13</sup> Chris Baranjuk, *How long does covid-19 immunity last?* 373 BMJ (2021) (emphasis added).

<sup>&</sup>lt;sup>14</sup> Nina Le Bert, *SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control*, NATURE (Aug. 2020).

<sup>&</sup>lt;sup>15</sup> Xiaocong Yu, et al., Neutralizing antibodies derived form the B cells of 1918 influenze pandemic survivors, NATURE (2008).

<sup>&</sup>lt;sup>16</sup> Heidi Ledford, *Six months of COVID vaccines: what 1.7 billion doses hove taught scientists*, 594 NATURE 164 (June 10, 2021), https://www.nature.com/articles/d41586-021-01505-x (study notes that "Six months is not much time to collect data on how durable vaccine responses will be.... In the meantime some researchers are looking to natural immunity as a guide.").

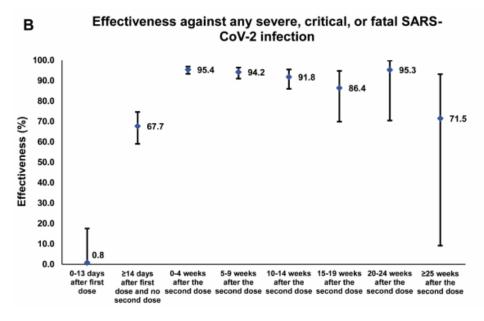
23. The key figures from the Qatari study are reproduced immediately below. Panel A shows that vaccine mediated protection against infection peaks at 72.1% zero to four weeks after the second dose, and then declines to 0%, 20 weeks after the second dose. According to this result, vaccines only protect against infection (and therefore disease spread) for a short period of time after the second dose of the mRNA vaccines.



24. On the other hand, Panel B shows that protection versus severe disease is long lasting after vaccination—even though the person will no longer be fully protected against infection and, presumably, disease spread. At 20-24 weeks after the second dose, the vaccine remains 95.3% efficacious versus severe disease. While it appears to dip after 25 weeks to 71.5% efficacy, the confidence interval is so wide that it

<sup>&</sup>lt;sup>17</sup> Hiam Chemaitelly et al., Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar, <a href="https://www.medrxiv.org/content/10.1101/2021.08.25.21262584v1.full.pdf">https://www.medrxiv.org/content/10.1101/2021.08.25.21262584v1.full.pdf</a>.

is consistent with no decrease whatsoever even after 25 weeks. The Qtari study is no outlier. Another recent study documented declining vaccine efficacy in the first three months after vaccination against disease



transmission in the era of the delta variant. 18

25. In July, the CDC conducted a study of an outbreak of COVID-19 in Barnstable, Massachusetts. 19 74% of the cases occurred in fully vaccinated individuals. Analysis of asymptomatic cases showed no significant difference in infectiousness between vaccinated and unvaccinated subjects, leading the CDC to update guidance to reflect that both vaccinated and unvaccinated people can infect others.

26. Yet another study, conducted in Wisconsin, confirmed that vaccinated individuals can shed infectious SARS-CoV-2 virus.<sup>20</sup> The authors analyzed nasopharyngeal samples to check whether patients showed evidence of infectious viral particles. They found that vaccinated individuals were at least as likely as unvaccinated individuals to be shedding live virus. They concluded:

Combined with other studies these data indicate that vaccinated and unvaccinated

<sup>&</sup>lt;sup>18</sup> David W Eyre, Donald Taylor, Mark Purver, et al. The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. medRxiv Sept. 29, 2021. medRxiv 2021.09.28.21264260; doi: https://doi.org/10.1101/2021.09.28.21264260

<sup>&</sup>lt;sup>19</sup> 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;

<sup>&</sup>lt;sup>20</sup> Kasen K. Riemersma, Brittany E. Grogan, Amanda Kita-Yarbro, et al. Shedding of Infectious SARS-CoV-2 Despite Vaccination medRxiv 2021.07.31.21261387; August 24, 2021, doi: https://doi.org/10.1101/2021.07.31.21261387

individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons...Vaccinated and unvaccinated persons should get tested when symptomatic or after close contact with someone with suspected or confirmed COVID-19.

27. In summary, the evidence to date strong suggests that, while vaccines—like natural immunity—provide protection versus severe disease, they, unlike natural immunity, provide only short-lasting protection against subsequent infection and disease spread. In short, there is no medical or scientific reason to believe that vaccine immunity will prove longer lasting than natural immunity, much less that all currently approved vaccines will be expected to prove more durable than natural immunity despite their different technological foundations and dosing protocols.

### II. Vaccine Side Effects, Though Rare, Do Occur and Can Be Deadly.

28. Though the COVID vaccines are safe by the standards of many other vaccines approved for use in the population, like all medical interventions, they have side effects. In summarizing the evidence on vaccine side effects, the CDC lists both common side effects, at least one of which occurs in over half of all people who receive the vaccines, as well as deadly side effects that occur rarely in demographic subsets of the vaccinated population.

29. The common side effects include pain and swelling at the vaccination site and fatigue, headache, muscle pain, fever, and nausea for a limited time after vaccination.<sup>21</sup> Less common but severe side effects also include severe and non-severe allergic (anaphylactic) reactions that can occur immediately after vaccination, which can typically be treated with an epinephrine injection if it occurs.<sup>22</sup> Finally, the CDC's vaccine safety committee has identified rare but deadly side effects, including a heightened risk of clotting abnormalities<sup>23</sup> in young women after the Johnson & Johnson (J&J) vaccination, elevated risks of

<sup>&</sup>lt;sup>21</sup> Centers for Disease Control, *Possible Side Effects After Getting a COVID-19 Vaccine* (June 24, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html.

<sup>&</sup>lt;sup>22</sup> Centers for Disease Control, *What to Do If You Have an Allergic Reaction after Getting a COVID-19 Vaccine* (June 24, 2021), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html.

<sup>&</sup>lt;sup>23</sup> Martin Kulldorff, *The Dangers of Pausing the J&J Vaccine*, THE HILL (April 17, 2021), https://thehill.com/opinion/healthcare/548817-the-dangers-of-pausing-the-jj-vaccine.

myocarditis and pericarditis<sup>24</sup> in young people—but especially young men—after mRNA vaccination, and higher risk of Guillane-Barre Syndrome<sup>25</sup> after the J&J vaccine. There is still the possibility of severe side effects that have yet to be identified as the vaccines have been in use in human populations for less than a year. Active investigation to check for safety problems is still ongoing.

30. Though the CDC<sup>26</sup> still recommends the vaccines for children 12 years old and up despite the evidence of elevated risk of myocarditis, other analysts<sup>27</sup> have objected to overly rosy assumptions made in the CDC analysis about vaccine side effects. They suggest that the recommendation is fragile to minor perturbation in their assumptions. The critical point for our analysis—undisputed in the scientific literature—is that the vaccines do have side effects, some of which are severe and not all of which are necessarily known now.

# III. The Risk Of Those Side Effects Is Heightened In Certain Groups & Clinical Data on Vaccine Safety and Efficacy are Not Available for Patients with Certain Chronic Diseases.

31. The CDC lists two primary contraindications to COVID vaccination: (1) "severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the Covid-19 vaccine"; and (2) "immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the COVID-19 vaccine." Among the inactive ingredients of the COVID vaccines, polyethylene glycol (PEG)—which is used in other drugs and vaccines—is most likely to induce an allergic reaction. In addition to contraindications, the CDC lists several precautions to vaccination, including known allergic reactions

<sup>&</sup>lt;sup>24</sup> Centers for Disease Control, *Myocarditis and Pericarditis after Receipt of mRNA COVID-19 Vaccines Among Adolescents and Young Adults* (May 28, 2021), https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html.

<sup>&</sup>lt;sup>25</sup> LaFranier and Weiland, *FDA Attaches Warning of Rare Nerve Syndrome to Johnson & Johnson Vaccine*, NEW YORK TIMES (July 12, 2021), https://www.nytimes.com/2021/07/12/us/politics/fda-warning-johnson-johnson-vaccine-nerve-syndrome.html.

<sup>&</sup>lt;sup>26</sup> Walensky, CDC Director Statement on Pfizer's Use of COVID-19 Vaccine in Adolescents Age 12 and Older (May 12, 2021), https://www.cdc.gov/media/releases/2021/s0512-advisory-committee-signing.html.

<sup>&</sup>lt;sup>27</sup> Pegden, Weighing myocarditis cases, ACIP failed to balance the harms vs benefits of 2nd doses (June 24, 2021), https://medium.com/@wpegden?p=d7d6b3df7cfb.

<sup>&</sup>lt;sup>28</sup> CDC, Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States, <a href="https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html">https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html</a>.

to polysorbate or to other non-COVID vaccines and injectable therapies. Patients with precautions are encouraged to consult with an allergist or immunologist before getting the vaccine.<sup>29</sup>

- 32. Some clinical evidence indicates that those who have recovered from COVID-19 could have a *heightened* risk of adverse effects compared with those who have never had the virus.<sup>30,31</sup> This may be because vaccine reactogenicity after the first dose is higher among those with prior immunity.<sup>32</sup> Despite this evidence, the CDC does not list prior immunity as a contraindication to vaccination, though it does recommend waiting 90 days after recovering before vaccination.
- 33. Though the CDC recommends the COVID vaccines for all adults, because they are novel—available for use in the population for only 9-10 months—there remain open questions about their use in special populations because they have not been tested in subgroups of patients with clinical conditions. For instance, in a comprehensive discussion of the biology of immune responses to vaccination (including COVID-19 vaccination) for patients with Multiple Sclerosis published in June 2021, Coyle et al. emphasize the lack of high-quality evidence available to guide recommendations for MS patients. They point out that three of six medical societies that focus on MS patients have failed to make a recommendation on whether

<sup>&</sup>lt;sup>29</sup> CDC. Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States. Contraindications and Precautions. Accessed Oct. 1, 2021. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-

us.html?CDC\_AA\_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html#Contraindications

<sup>&</sup>lt;sup>30</sup> Alexander G. Mathioudakis, et al., Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey, 11 LIFE 249 (Mar. 2021).

<sup>&</sup>lt;sup>31</sup> Cristina Menni, Vaccine side-effects and SARS-CoV-2 infection after vaccination in users of the COVID symptom study app in the UK: a prospective observational study, 21 LANCET INFECTIOUS DISEASES 939-49 (July 2021) (finding that "Systemic side-effects were more common (1.6 times after the first dose of ChAdOx1 nCoV-19 [i.e., AstraZeneca vaccine] and 2.9 times after the first dose of BNT162b2 [i.e., Pfizer/BioNTech vaccine]) among individuals with previous SARS-CoV-2 infection than among those without known past infection. Local effects were similarly higher in individuals previously infected than in those without known past infection (1.4 times after the first dose of ChAdOx1 nCoV-19 and 1.2 times after the first dose of BNT162b2).").

<sup>&</sup>lt;sup>32</sup> Florian Krammer, et al., *Robust spike antibody responses and increased reactogenitiy in seropositive individuals after a singe dose of SARS-CoV-2 mRNA vaccine*, MEDRXIV (Feb. 1, 2021), https://www.medrxiv.org/content/10.1101/2021.01.29.21250653v1 (concluding that "vaccine reactogenicity after the first dose is substantially more pronounced in individuals with pre-existing immunity." The authors note that "quantitative serological assays that measure antibodies to the spike protein could be used to screen individuals prior to vaccination," which would "limit the reactogenicity experienced by COVID-19 survivors.).

MS patients should receive the COVID-19 vaccines. They and other authorities<sup>33</sup> emphasize the need for personalized decision making based on the clinical condition of the MS patient:<sup>34</sup>

Currently, three COVID-19 vaccines have been granted emergency use authorization in the USA on the basis of promising interim findings of ongoing trials. Because analyses of these vaccines in people with MS are not available, decisions regarding COVID-19 vaccination and DMT choice should be informed by data and expert consensus, and personalized with considerations for disease burden, risk of infection, and other factors.

34. The paucity of data on the proper use of the COVID-19 vaccine on patients with particular conditions is not limited to Multiple Sclerosis. For instance, for patients with alpha-1 antitrypsin deficiency (AATD), an inherited disorder that predisposes a patient to enzymatic tissue injuries and inflammation—especially in the lungs—there is no clinical data whatsoever regarding the safety and efficacy of the COVID-19 vaccines. Writing in *Lancet Respiratory Medicine*, Yang and Zhao hypothesize "individuals with AATD might derive limited benefit from the current COVID-19 vaccines." They note that "even though vaccination has been prioritized to more vulnerable populations (such as people with AATD), individuals with AATD are usually not included in clinical trials (as reported in ClinicalTrials.gov), and thus the effectiveness and adverse event profile of vaccination in this population are unknown."<sup>35</sup> The same can be said for many other patients with chronic diseases, for whom the decision whether to vaccinate should be an individual decision made in consultation with their physicians, rather than coerced by a firm or the government.

#### IV. Asymptomatic Disease Spread is Rare.

35. In this section, I discuss the evidence regarding the asymptomatic transmission of disease. This is important because if asymptomatic disease spread is rare, the DOE can keep its employees and students safe from COVID disease spread by the simple expedient of requiring workers who have not been

<sup>&</sup>lt;sup>33</sup> Ciotti JR, Valtcheva MV, Cross AH. Effects of MS disease-modifying therapies on responses to vaccinations: A review. Mult Scler Relat Disord. 2020 Oct;45:102439. doi: 10.1016/j.msard.2020.102439. Epub 2020 Aug 1. PMID: 32769063; PMCID: PMC7395588.

<sup>&</sup>lt;sup>34</sup> Coyle PK, Gocke A, Vignos M, Newsome SD. Vaccine Considerations for Multiple Sclerosis in the COVID-19 Era. Adv Ther. 2021;38(7):3550-3588. doi:10.1007/s12325-021-01761-3

<sup>&</sup>lt;sup>35</sup> Yang C, Zhao H. COVID-19 vaccination in patients with  $\alpha$ 1-antitrypsin deficiency. Lancet Respir Med. 2021;9(8):818-820. doi:10.1016/S2213-2600(21)00271-X

vaccinated (and even those who have been) to report daily through an online app whether they are experiencing symptoms consistent with COVID-19. Those who are experiencing symptoms would be asked to stay at home from work and get tested; returning to work only if the test is negative.

36. The best evidence on how frequently asymptomatic disease spread occurs comes from a large meta-analysis of 54 studies from around the world of within-household spread of the virus—that is, from an infected person to someone else living in the same home (Madewell et al. 2020). This study represents the most comprehensive survey of the vast empirical literature on asymptomatic spread. At home, *of course*, none of the safeguards often recommended in public spaces outside of home (such as masking and social distancing) are typically applied. Because the study focuses on a single setting (household transmission), it is not subject to the same problems of that other studies on this topic might have. In particular, by focusing on a homogenous setting where few safeguards exist, the estimate represents an upper bound on the frequency that someone positive for the virus but with no symptoms (and hence either pre-symptomatic or asymptomatic) may spread the virus to close contacts. The primary result is that symptomatic patients passed on the disease to household members in 18% of instances. In comparison, those infected but without symptoms (asymptomatic and pre-symptomatic patients) passed on the infection to household members in only 0.7% of instances.<sup>36</sup>

37. There is some additional evidence. A large study of 10 million residents of Wuhan, China, all tested for the presence of the virus, found a total of 300 cases, all asymptomatic. A comprehensive contact tracing effort identified 1,174 close contacts of these patients, none of whom tested positive for the virus.<sup>37</sup> This is consistent with a vanishingly low level of asymptomatic spread of the disease. Given the late date of the study relative to the date of the large first wave of infections in Wuhan, it is likely that none of the

<sup>&</sup>lt;sup>36</sup> Madewell ZJ, Yang Y, Longini IM, Halloran ME, Dean NE. Household Transmission of SARS-CoV-2: A Systematic Review and Meta-analysis. *JAMA Netw Open.* 2020;3(12):e2031756. doi:10.1001/jamanetworkopen.2020.31756

<sup>&</sup>lt;sup>37</sup> Cao, S., Gan, Y., Wang, C. et al. Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China. *Nat Commun* 11, 5917 (2020). https://doi.org/10.1038/s41467-020-19802-w

300 asymptomatic cases were likely ever to develop symptoms. A separate, smaller meta-analysis similarly found that asymptomatic patients are much less likely to infect others than symptomatic patients.<sup>38</sup>

38. By contrast with asymptomatic patients, symptomatic patients are very likely to infect others with the virus during extended interactions, especially in the initial period after they develop symptoms. A careful review of 79 studies on the infectivity of COVID-19 patients found that even symptomatic patients are infectious for only the first eight days after symptom onset, with no evidence of live virus detected beyond day nine of illness.<sup>39</sup>

39. Much of the support for the idea that asymptomatic disease spread is common comes from theoretical modeling work from earlier in the epidemic (including some of my own published research<sup>40</sup>), predicting some level of asymptomatic disease spread. However, this sort of modeling work does not represent actual evidence that asymptomatic spread is common in the real world, since they rely on many modeling assumptions that are impossible to check.

40. There is at least one prominent real-world study that some have used to argue that asymptomatic disease spread is common. A meta-analytic study by Qiu et al. (2021) distinguishes the likelihood of disease spread by a pre-symptomatic individual the likelihood of spread by an asymptomatic individual who never develops symptoms.<sup>41</sup> A primary finding of this study is that, while an asymptomatic individual who never develops symptoms is exceedingly unlikely to spread the disease, individuals who are not symptomatic now but will eventually develop symptoms are efficient at infecting others during their pre-symptomatic state. One problematic interpretation of this result is that the relative efficiency of disease

<sup>&</sup>lt;sup>38</sup> Buitrago-Garcia D, Egli-Gany D, Counotte MJ, Hossmann S, Imeri H, Ipekci AM, Salanti G, Low N. Occurrence and transmission potential of asymptomatic and presymptomatic SARS-CoV-2 infections: A living systematic review and meta-analysis. PLoS Med. 2020 Sep 22;17(9):e1003346. doi: 10.1371/journal.pmed.1003346. PMID: 32960881; PMCID: PMC7508369.

<sup>&</sup>lt;sup>39</sup> Cevik M, Tate M, Lloyd O et al. SARS-CoV-2, SARS-CoV, and MERS-CoV viral load dynamics, duration of viral shedding, and infectiousness: a systematic review and meta-analysis. The Lancet Microbe. Nov. 19, 2020. DOI:https://doi.org/10.1016/S2666-5247(20)30172-5

<sup>&</sup>lt;sup>40</sup> Peirlinck M, Linka K, Costabal FS, Bhattacharya J, Bendavid E, Ioannidis J, Kuhl E (2020), "Visualizing the Invisible: The Effect of Asymptotic Transmission on the Outbreak Dynamics of COVID-19" Computer Methods in Applied Mechanics and Engineering. 372: 1 Dec. 2020, 113410. https://doi.org/10.1016/j.cma.2020.113410.

<sup>&</sup>lt;sup>41</sup> Qiu X, Nergiz AI, Maraolo AE, Bogoch II, Low N, Cevik M. The role of asymptomatic and pre-symptomatic infection in SARS-CoV-2 transmission-a living systematic review. Clin Microbiol Infect. 2021 Apr;27(4):511-519. doi: 10.1016/j.cmi.2021.01.011. Epub 2021 Jan 21. PMID: 33484843; PMCID: PMC7825872.

spread by pre-symptomatic individuals militates in favor of lockdown policies and mass asymptomatic testing. This interpretation is incorrect.

- 41. Distinguishing between an infected individual who will eventually develop symptoms and an infected individual who will never develop symptoms is difficult without the passage of time. Infected individuals who will develop symptoms tend to do so within a very short interval (two to three days) after first becoming infected. Meanwhile, infected individuals who never develop symptoms may test positive with the PCR test for the virus for an extended period. These two groups of observationally identical individuals are mixed in the population in some unknown frequency that may change over time. Given this information constraint, from a policy point of view, the relevant question is how likely it is that an infected individual without symptoms (whether pre-symptomatic or purely asymptomatic) will spread the disease to close contacts. The Madewell et al. (2020) study provides an answer (less than 0.7% secondary attack rate in household settings), while the Qiu et al. (2021) study does not. Additionally, unlike the Madewell et al. (2020) study, the Qiu et al. (2021) study does not concentrate its focus on a homogenous environment (households), which makes the results it reports harder to interpret.
- 42. In summary, asymptomatic individuals are an order of magnitude less likely to infect others than symptomatic individuals, even in intimate settings such as people living in the same household where people are much less likely to follow social distancing and masking practices that they follow outside the household. Spread of the disease in less intimate settings by asymptomatic individuals—including in the context of schools—is likely to be even less likely than in the household.

## V. There Are Multiple Safe Alternatives to Indefinite Leave That Can Be Offered to DOE teachers and staff

- 43. Can the DOE keep its employees and students safe if it does not mandate that all its employees be vaccinated? The answer is a definitive yes.
- 44. First, and most obviously, the DOE could exempt all employees who have recovered from COVID infection from a vaccine requirement. The evidence provided in this declaration shows that such

employees pose as least as little—and likely less—risk of spreading the SARS-CoV-2 virus than fully vaccinated workers who are not among the set of COVID-recovered patients.

45. Second, the DOE could adopt a robust sick policy, requiring that workers who have not been vaccinated and who show symptoms consistent with COVID-19 infection stay at home from work, returning to work only once they have had a negative COVID-19 antigen test result. This could be implemented for instance, by requiring workers to complete an online symptom self-check each day before coming to work. The DOE would provide workers with a supply of rapid antigen tests, which are easy to self-administer at home, provide results within 30 minutes, and are highly accurate for detecting whether a patient is infectious. 42, 43 Alternatively, the DOE could require that any unvaccinated workers obtain those tests themselves to keep its own costs down. If the DOE's goal is to prevent the spread of Covid-19, symptom checking should be required of all employees, whether vaccinated or not, since the evidence shows that vaccination does not eliminate the probability of infection or transmission and may provide less protection versus infection than immunity induced by prior COVID infection.

46. For this symptom checking policy to be effective in reducing the risk of disease spread, it must be the case that symptomatic workers are substantially more likely to infect others than workers who are infected (that is, have evidence of the virus in the nasopharynx), but who have no symptoms. Fortunately, as we have seen in the previous section, the best empirical evidence shows that the probability that an asymptomatic individual spreading the disease is rare.

47. Third, the DOE could implement a program of weekly PCR testing of asymptomatic workers to guard against the risk (admittedly low) of a worker coming to work with an asymptomatic infection. Many other organizations have implemented a testing regimen like this, including my home institution, Stanford University. Workers could take the test in the workplace – there are versions of the test available

<sup>&</sup>lt;sup>42</sup> Surasi K, Cummings KJ, Hanson C, Morris MK, Salas M, Seftel D, et al. Effectiveness of Abbott BinaxNOW rapid antigen test for detection of SARS-CoV-2 infections in outbreak among horse racetrack workers, California, USA. Emerg Infect Dis. 2021 Nov [date cited]. https://doi.org/10.3201/eid2711.211449

<sup>&</sup>lt;sup>43</sup> Homza M, Zelena H, Janosek J, et al. Covid-19 antigen testing: better than we know? A test accuracy study. *Infect Dis (Lond)*. 2021;53(9):661-668. doi:10.1080/23744235.2021.1914857

that can be self-administered. One key detail: if implemented, both vaccinated and unvaccinated workers should be required to provide a weekly test, since both can have asymptomatic SARS-CoV-2 infections.

48. In sum, as a general matter, there are multiple risk mitigation strategies short of a mandate or leave without pay that can be implemented to accommodate religious and medical exemptions safely.

## VI. <u>Variants Do Not Alter the Conclusion that Accommodations Can Be Allowed Without Risk to Public Safety.</u>

49. Since its spread through the human population, the SARS-CoV-2 virus—an RNA virus—has been mutating, including some forms that are likely more transmissible than the original wild-type virus that emerged from Wuhan, China, in 2019. As of the date of this declaration, the delta variant is the dominant form of the SARS-CoV-2 virus worldwide. The virus will continue to mutate as it continues to spread. However, the possibility of such a mutation does not alter the conclusion that accommodations can be allowed without risk to public safety.

50. The key point is that the mutant variants do not escape the immunity provided by prior infection with the wild-type virus or vaccination. 44,45,46 This is true of the delta variant as well. In a study of a large population of patients in Israel, vaccinated people who had not been previously infected were 13 times more likely to experience a breakthrough infection with the delta variant than patients who had recovered from COVID. 47 Although reinfection can occur, people who have been previously infected by the virus are

<sup>&</sup>lt;sup>44</sup> Alison Tarke, A., Sidney, J., Methot, N., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., da Silva Antunes, R., Frazier, A., Rawlings, S. A., Smith, D. M., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A., & Sette, A., *Negligible impact of SARS-CoV-2 variants on CD4 + and CD8 + T cell reactivity in COVID-19 exposed donors and vaccinees*, BioRxiv, 2021.02.27.433180 (2021), https://doi.org/10.1101/2021.02.27.433180.

<sup>&</sup>lt;sup>45</sup> Wu, K., Werner, A. P., Moliva, J. I., Koch, M., Choi, A., Stewart-Jones, G. B. E., Bennett, H., Boyoglu-Barnum, S., Shi, W., Graham, B. S., Carfi, A., Corbett, K. S., Seder, R. A., & Edwards, D. K., *mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants*, BIORXIV: THE PREPRINT SERVER FOR BIOLOGY, 2021.01.25.427948 (2021), https://doi.org/10.1101/2021.01.25.427948.

<sup>&</sup>lt;sup>46</sup> Redd, A. D., Nardin, A., Kared, H., Bloch, E. M., Pekosz, A., Laeyendecker, O., Abel, B., Fehlings, M., Quinn, T.C., & Tobian, A. A., *CD8+ T cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants*, MEDRXIV: THE PREPRINT SERVER FOR HEALTH SCIENCES, 2021.02.11.21251585 (2021), https://doi.org/10.1101/2021.02.11.21251585.

<sup>&</sup>lt;sup>47</sup> Sivan Gazit, Roei Shlezinger, Galit Perez, et al. Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections. medRxiv. August 25, 2021. doi: https://doi.org/10.1101/2021.08.24.21262415

unlikely to have a severe outcome (hospitalization or death) after exposure to a variant virus (see section I above for citations). A variant circulating in the population thus poses little additional risk of hospital overcrowding or excess mortality due to viral infection.

51. The dissemination of vaccines that protect against hospitalizations and deaths upon COVID-19 infection throughout the older population in the United States has partially decoupled the growth in COVID-19 cases from COVID-19 mortality. Vaccinated people can still be infected but much less commonly have severe symptoms in response to infection. Throughout last year, a rise in cases was inevitably accompanied by an increase in deaths with a two-to-three-week lag. However, during this most recent wave, in Sweden and the U.K., where vaccines have been provided to a large portion of the vulnerable elderly population and more, there have been "relatively few hospitalisations and deaths" in those countries. Because of the success of the American vaccination effort among the vulnerable elderly, COVID-19 cases and COVID-19 deaths are at least partially decoupled, so the public danger from the continuing spread of COVID-19 disease is less than it was last year when the vaccine was not available.

# VII. The Presence of Lingering Post-Viral Infection Symptoms in a Subset of Recovered COVID Patients ("Long COVID") Does Not Alter the Conclusion that Accommodations Pose No Threat to Public Safety.

52. Some analysts and politicians have used the possibility that a fraction of patients who recover from COVID infection will experience lingering symptoms to justify unyielding vaccine mandates. Long COVID, as this phenomenon is called, includes a complex set of clinical outcomes with a poorly understood link to acute COVID infection.<sup>49</sup> One cross-sectional study found that about 30% of recovered COVID patients reported at least one symptom months after recovery, with fatigue and anosmia (loss of sense of smell) by far the most common.<sup>50</sup> A separate study with a more convincing longitudinal methodology, by

<sup>&</sup>lt;sup>48</sup> Jay Bhattacharya, Martin Kulldorff, and Sunetra Gupta, *Sweden's Lessons for the UK's Third Wave*, THE SPECTATOR (July 12, 2021), https://www.spectator.co.uk/article/sweden-shows-that-the-uk-s-third-wave-won-t-sting.

<sup>&</sup>lt;sup>49</sup> Nalbandian, A., Sehgal, K., Gupta, A. et al., *Post-acute COVID-19 syndrome*, NAT MED 27, 601–615 (2021), https://doi.org/10.1038/s41591-021-01283-z.

<sup>&</sup>lt;sup>50</sup> Logue JK, Franko NM, McCulloch DJ, et al., *Sequelae in Adults at 6 Months After COVID-19 Infection*, JAMA NETW OPEN (2021);4(2):e210830, doi:10.1001/jamanetworkopen.2021.0830.

contrast, concluded that 2.3% of patients experienced such symptoms three months after recovery.<sup>51</sup> Patients who suffered a more severe acute course of COVID, including hospitalization, were more likely to report lingering symptoms after recovery.<sup>52</sup> A study of children who recovered from COVID found the same rate of long COVID symptoms as a control group of children who had no serological evidence of prior COVID infection.<sup>53</sup> Some analysts have noted the similarity between "long COVID" symptoms and other functional somatic syndromes that sometimes occur after other viral infections and other triggers (and sometimes with no identifiable etiology).<sup>54</sup>

53. To summarize, as with other viruses, long COVID symptoms occur in a minority of patients who recover from COVID and pose a real burden on patients who suffer from it. However, this fact does not alter the logic of my point about accommodations. On the contrary. After suffering through a COVID infection, with or without long COVID, such individuals should not be forced to also endure common, but mild, vaccine adverse reactions or risk rare—but serious—adverse reactions. Moreover, the successful vaccine rollout in the United States—where every teenager and adult has free access to the vaccines—addresses the problem of long COVID, just as it addresses COVID-associated mortality.

# VIII. The CDC's Recommendation for Vaccination of Recovered COVID Patients Applies with Equal Force to Those Who Have Been Previously Vaccinated, Whose Protection Against Infection Wanes Within a Few Months After Vaccination.

54. The CDC, in a FAQ section of a website encouraging vaccination, provides the following advice to previously recovered patients:<sup>55</sup>

Yes, you should be vaccinated regardless of whether you already had COVID-19. That's because experts do not yet know how long you are protected from

<sup>&</sup>lt;sup>51</sup> Sudre, C.H., Murray, B., Varsavsky, T. et al., *Attributes and predictors of long COVID*, NAT MED 27, 626–631 (2021), https://doi.org/10.1038/s41591-021-01292-y.

<sup>&</sup>lt;sup>52</sup> Arnold DT, Hamilton FW, Milne A, et al., *Patient outcomes after hospitalisation with COVID-19 and implications for follow-up: results from a prospective UK cohort*, THORAX, 76:399-401 (2021).

<sup>&</sup>lt;sup>53</sup> Thomas Radtke, Agne Ulyte, Milo A Puhan, Susi Kriemler, *Long-term symptoms after SARS-CoV-2 infection in school children: population-based cohort with 6-months follow-up*, MEDRXIV (2021), https://doi.org/10.1101/2021.05.16.21257255.

<sup>&</sup>lt;sup>54</sup> Ballering A, Olde Hartman T, Rosmalen J, *Long COVID-19*, persistent somatic symptoms and social stigmatization, J EPIDEMIOL COMMUNITY HEALTH (2021).

<sup>&</sup>lt;sup>55</sup> US Centers for Disease Control (2021), Frequently Asked Questions About COVID-19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.

getting sick again after recovering from COVID-19. Even if you have already recovered from COVID-19, it is possible—although rare—that you could be infected with the virus that causes COVID-19 again. Studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19. Learn more about why getting vaccinated is a safer way to build protection than getting infected.

55. The text of this advice by the CDC does not address any of the scientific evidence included here about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that I do not know how long-lasting natural immunity after recovery lasts, the immunological evidence to date suggests that protection against disease will last for years. <sup>56</sup> Uncertainty over the longevity of immunity after recovery is a specious reason for not exempting COVID-recovered patients from vaccination mandates, since the same can be said about vaccine mediated immunity. I do not know how long it will last either, and there is no reason to believe it provides longer lasting or more complete immunity than recovery from COVID.

56. Similarly, just as reinfections are possible though rare after COVID recovery, breakthrough infections are possible after vaccination, as the CDC's team investigating vaccine breakthrough infections itself recognizes.<sup>57</sup> On the same CDC FAQ webpage I cite above,<sup>58</sup> the CDC writes about vaccine mediated immunity, "We don't know how long protection lasts for those who are vaccinated."

57. The CDC's main concern in this FAQ seems to be to help people understand that it is safer to attain immunity against SARS-CoV-2 infection via vaccination rather than via infection. This is a point not in dispute. Rather, the question is whether someone who *already* has been infected and recovered will benefit on net from the additional protection provided by vaccination. On this point, the CDC's statement in the FAQ is non-responsive and ignores the scientific evidence. Here again, the possibility of reinfection

<sup>&</sup>lt;sup>56</sup> Patel N (2021) Covid-19 Immunity Likely Lasts for Years. MIT Technology Review. January 6, 2021. https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/.

<sup>&</sup>lt;sup>57</sup> CDC COVID-19 Vaccine Breakthrough Case Investigations Team (2021) COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. May 28, 2021. https://www.cdc.gov/mmwr/volumes/70/wr/mm7021e3.htm.

<sup>&</sup>lt;sup>58</sup> US Centers for Disease Control (2021) Frequently Asked Questions About COVID-19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html.

does not alter the conclusion that, especially for those who have already recovered from COVID, accommodations can be allowed without threatening public safety.

## IX. <u>Fetal Cell Lines Were Used to Develop the Johnson & Johnson Vaccine and Were</u> Used to Test the Two mRNA Vaccines.

58. Many people of religious faith have a deeply held objection to benefitting from abortion of a human fetus. At the same time, much modern biological research, development, and production employs fetal cell lines that are derived from an abortion that occurred decades ago. The fetal tissue used in biological work is not the actual tissue from the aborted baby—it is a clone of cells sampled from that tissue. Nevertheless, many religious people object to the personal use of any product that involved the use of these fetal tissue cell lines. In the context of the COVID-19 vaccines, fetal tissue lines were used in the research and testing of both the mRNA vaccines (Pfizer and Moderna) and the adenovector vaccine (Johnson & Johnson).

59. While aborted fetal tissue is not used in the production of the mRNA vaccines, they are used in the production of the Johnson & Johnson vaccine.<sup>59</sup> While some religious authorities have stated that the cell lines used in the development, production, and testing of these vaccines are remote enough from the act of abortion that it is permissible for faithful people to be vaccinated with these vaccines,<sup>60</sup> other religious authorities disagree<sup>61</sup> reflecting longstanding objections to vaccines derived using aborted tissue lines.<sup>62</sup> Ultimately, it is a matter of individual conscience for each person to decide whether the benefits derived from the vaccines in terms of protection against severe COVID disease should be eschewed in light of sincere moral qualms about deriving that benefit as the ultimate fruit of an action that the faithful person deems sinful. Science cannot resolve this question as a matter of law.

<sup>&</sup>lt;sup>59</sup> Zimmerman RK. Helping patients with ethical concerns about COVID-19 vaccines in light of fetal cell lines used in some COVID-19 vaccines. *Vaccine*. 2021;39(31):4242-4244. doi:10.1016/j.vaccine.2021.06.027

<sup>&</sup>lt;sup>60</sup> Giangrave C and Jenkins J. As US Bishops Reject Exemptions, Pope Francis Dubs COVID-19 Vaccine 'Act of Love'. Religious News Service. August 18, 2021. https://religionnews.com/2021/08/18/pope-francis-declaresgetting-a-covid-19-vaccine-an-act-of-love/

<sup>&</sup>lt;sup>61</sup> John Piper. Can I Take a Vaccine Made from Aborted Babies? Desiring God. January 4, 2021. https://www.desiringgod.org/interviews/can-i-take-a-vaccine-made-from-aborted-babies

<sup>&</sup>lt;sup>62</sup> Pelčić G, Karačić S, Mikirtichan GL, et al. Religious exception for vaccination or religious excuses for avoiding vaccination. *Croat Med J.* 2016;57(5):516-521. doi:10.3325/cmj.2016.57.516

### X. Conclusion

60. A fundamental ethical principle guiding the practice of medicine is that any medicalintervention, whether surgical, pharmacological, or a vaccine, should be recommended only if it is deemed medically necessary. Any medical procedure, including vaccination, involves risk. No medical procedure is 100% safe, especially those involving a new vaccine, which by definition has not been studied for long-term adverse side effects. For this reason, it is a fundamental principle of medical ethics that the risks of the procedure be balanced against the potential benefits.

61. As I established earlier, based on the scientific evidence to date, those who have recovered from a SARS-CoV-2 infection possess immunity as robust and durable as that acquiredthrough vaccination. The existing clinical literature overwhelmingly indicates that the protection afforded to the individual and community from natural immunity is as effective and durable as the efficacy levels of the most effective vaccines to date. There is no good reason for those who have such protection to be vaccinated. At the very least, the decision should be left to them, in conjunction with their doctors, and without coercion from their employers.

- 62. In sum, based on my analysis of the existing medical and scientific literature, any policy mandating vaccinations that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health.<sup>63</sup>
- 63. In this context, addition factors counsel against a finding that the exemptions will create a significant risk of substantial harm to co-workers and students.
- 64. The students, who constitute the majority of the population, are largely unvaccinated. Even if herd immunity were conceivable through vaccination against SARS-CoV-2, and all staff were vaccinated against SARS-CoV-2, the majority of the school population, the students, are unvaccinated, rendering herd immunity impossible in that setting. The reservoir of unvaccinated students already constitutes too large a

<sup>&</sup>lt;sup>63</sup> Jay Bhattacharya, Sunetra Gupta, & Martin Kulldorff, *The Beauty of Vaccines and Natural Immunity*, SMERCONISH NEWSLETTER (June 4, 2021), https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity.

percent of the population to stop the spread of disease in the school community regardless of how many teachers and staff are immune.

- 65. But Children, luckily, are at very low risk of severe disease. If they are infected, either in the school or outside of school, they are not at substantial risk of developing severe symptoms. Similarly, an unvaccinated DOE employee poses little danger to co-workers, the overwhelming majority of whom are vaccinated and thus protected from severe symptoms if they have are infected.
- 66. Now that every American adult and teenager has free access to the vaccines, the case for a vaccine mandate is even weaker than it once was. There is no good public health case for DOE to require proof of vaccination for employees who have recovered from Covid-19. Since the successful vaccination campaign already protects the vulnerable adult population in schools, the unvaccinated—especially recovered COVID patients—pose a vanishingly small threat to their vaccinated coworkers. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero and natural immunity, which provides benefits that are at least as strong and may well be stronger.
- 67. In conclusion, the emerging evidence from the medical literature finds that COVID-recovered patients have robust and long lasting immunity against SARS-CoV-2 reinfection; that this immunity against infection is better than vaccinated patients who have never had COVID; that the vaccines—though safe for most people—do sometimes cause known severe side effects; that for patients with particular chronic conditions, including Multiple Sclerosis, the data on the safety and efficacy of the vaccine is still uncertain; that the development of the mRNA vaccines and the production of the adenovirus vector vaccines both involved the use of fetal tissue cell lines, to which some people have sincere religious objections; and finally that there exist inexpensive safe accommodations that the DOE can adopt which would protect both employees and customers against SARS-CoV-2 infection without terminating unvaccinated employees.
- 68. I declare under penalty of perjury under the laws of the United States of America that, to the best of my knowledge, the foregoing is true and correct this 3<sup>rd</sup> day of October, 2021, Stanford, California.

Respectfully submitted,

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