UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF TEXAS

JAMES RODDEN, et al. *Plaintiffs,* v. ANTHONY FAUCI, Chief COVID Response Director of the National Institute of Allergy and Infectious Diseases, et al. *Defendants*.	Civil Action No._____

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. My curriculum vitae is attached to this declaration as Exhibit A.

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 the 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, or any personal or research funding from any pharmaceutical company. My participation here has been motivated solely by my commitment to public health, just as my participation in other cases has been.

7. I have no prior relationship with any of the plaintiffs.

8. I have been asked to provide my opinion on several matters related to the federal workers vaccine policy for its employees, including the following:

- Whether, based on the current medical and scientific knowledge, immunity after COVID recovery (sometimes referred to as 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 those who have recovered from COVID; and
- What those accommodations could look like in practice.

9. My opinions are partly summarized in a recent article I published and which I reaffirm here: "[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."[1]

10. 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 heightened risk of myocarditis and pericarditis after vaccination with the mRNA vaccines – especially for

[1] Kulldorff, M., & Bhattacharya, J. (2021, June 17). The ill-advised push to vaccinate the young. *The Hill.*

young men. It has also identified a heightened 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 scientific uncertainty about these heightened risks for some patients.

11. I also conclude that the federal government can safely accommodate COVID-recovered employees by exempting them from vaccine requirements since they possess better immunity via prior infection than a vaccinated worker who never had COVID possesses from vaccination. The federal government could also safely accommodate those employees who have not previously been infected with 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 government can require workers to conduct weekly PCR or antigen tests, though if it adopts this accommodation, it would be best practice to require it of both vaccinated and unvaccinated employees since both groups can spread the virus asymptomatically. If implemented, these accommodations would keep other workers as safe as possible from the risk of COVID infection, while preserving the employment of numerous government employees.

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.

12. 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.

13. 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 antibody levels 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.[2, 3] A Phase III trial showed 85% efficacy for the Johnson & Johnson adenovirus-based vaccine against severe disease.[4]

14. 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 cells[5], bone marrow plasma cells[6], spike-specific neutralizing

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[2] Baden, L. R., El Sahly, H. M., Essink, B., Kotloff, K., Frey, S., Novak, R., Diemert, D., Spector, S. A., Rouphael, N., Creech, C. B., McGettigan, J., Khetan, S., Segall, N., Solis, J., Brosz, A., Fierro, C., Schwartz, H., Neuzil, K., Corey, L., Zaks, T. for the COVE Study Group (2021). Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *The New England Journal of Medicine*, *384*(5), 403-416. doi: 10.1056/NEJMoa2035389

[3] Polack, F. P., Thomas, S. J., Kitchin, N., Absalon, J., Gurtman, A., Lockhart, S., Perez, J. L., Pérez Marc, G., Moreira, E. D., Zerbini, C., Bailey, R., Swanson, K. A., Roychoudhury, S., Koury, K., Li, P., Kalina, W. V., Cooper, D., Frenck, R. W. Jr., Hammitt, L. L., Gruber, W. C. (2020). Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *The New England Journal of Medicine*, *387*(27), 2603-2615. doi: 10.1056/NEJMoa2034577

[4] Sadoff, J., Gray, G., Vandebosch, A., Cárdenas, V., Shukarev, G., Grinsztejn, B., Goepfert, P. A., Truyers, C., Fennema, H., Spiessens, B., Offergeld, K., Scheper, G., Taylor, K. L., Robb, M. L., Treanor, J., Barouch, D. H., Stoddard, J., Ryser, M. F., Marovich, M. A., Douoguih, M. for the ENSEMBLE Study Group. (2021). Safety and Efficacy of Single-Dose Ad26.COV2.S Vaccine against Covid-19. *The New England Journal of Medicine*, *384*(23), 2187-2201. doi: 10.1056/NEJMoa2101544

[5] Dan, J. M., Mateus, J., Kato, Y., Hastie, K. M., Yu, E. D., Faliti, C. E., Grifoni, A., Ramirez, S. I., Haupt, S., Frazier, A., Nakao, C., Rayaprolu, V., Rawlings, S. A., Peters, B., Krammer, F., Simon, V., Saphire, E. O., Smith, D. M., Weiskopf, D., Crotty, S. (2021). Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection. *Science*, *371*, 1-13. doi: 10.1126/science.abf4063 (finding that memory T and B cells were present up to eight months after infection, noting that "durable immunity against secondary COVID-19 disease is a possibility in most individuals").

[6] Turner, J. S., Kim, W., Kalaidina, E., Goss, C. W., Rauseo, A. M., Schmitz, A. J., Hansen, L., Haile, A., Klebert, M. K., Pusic, I., O'Halloran, J. A., Presti, R. M. & Ellebedy, A. H. (2021). SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans. *Nature*, *595*(7867), 421-425. doi: 10.1038/s41586-021-03647-4 (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"); Callaway, E. (2021, May 26). Had COVID? You'll probably make antibodies for a lifetime. *Nature*. https://www.nature.com/articles/d41586-021-01442-

antibodies[7], and IgG+ memory B cells[8] following naturally acquired immunity.

15. 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).

16. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19[9] and show that the vast majority of reinfections are less severe than first-time

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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").

[7] Ripperger, T. J., Uhrlaub, J. E., Watanabe, M., Wong, R., Castaneda, Y., Pizzato, H. A., Thompson, M. R., Bradshaw, C., Weinkauf, C. C., Bime, C., Erickson, H. L., Knox, K., Bixby, B., Parthasarathy, S., Chaudhary, S., Natt, B., Cristan, E., El Aini, T., Rischard, F., Bhattacharya, D. (2020). Orthogonal SARS-CoV-2 serological assays enable surveillance of low-prevalence communities and reveal durable humor immunity. *Immunity*, *53*(5), 925-933. doi: 10.1016/j.immuni.2020.10.004 (study finding that spike and neutralizing antibodies remained detectable 5-7 months after recovering from infection).

[8] Cohen, K. W., Linderman, S. L., Moodie, Z., Czartoski, J., Lai, L., Mantus, G., Norwood, C., Nyhoff, L. E., Edara, V. V., Floyd, K., De Rosa, S. C., Ahmed, H., Whaley, R., Patel, S. N., Prigmore, B., Lemos, M. P., Davis, C. W., Furth, S., O'Keefe, J., McElrath, M. J. (2021). Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells. *medRxiv*, Preprint. (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").

[9] Shrestha, N. K., Burke, P. C., Nowacki, A. S., Terpeluk, P. & Gordon, S. M. (2021). Necessity of COVID-19 vaccination in previously infected individuals. *medRxiv*, Preprint. doi: 10.1101/2021.06.01.21258176 ("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 that those with natural immunity are "unlikely to benefit from COVID-19 vaccination"); Perez, G., Banon, T., Gazit, S., Moshe, S. B., Wortsman, J., Grupel, D., Peretz, A., Tov, A. B., Chodick, G., Mizrahi-Reuveni, M., & Patalon, T. (2021). A 1 to 1000 SARS-CoV-2 reinfection proportion in members of a large healthcare provider in Israel: A preliminary report. *medRxiv*, Preprint. doi: 10.1101/2021.03.06.21253051 (Israeli study finding that approximately 1/1000 of participants were reinfected); Bertollini, R., Chemaitelly, H., Yassine, H. M., Al-Thani, M. H., Al-Khal, A., & Abu-Raddad, L. J. (2021). Associations of vaccination and of prior infection with positive PCR test results for SARS-CoV-2 in airline passengers arriving in Qatar. *JAMA*, *326*(2), 185-188. doi: 10.1001/jama.2021.9970 (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); Pilz, S., Chakeri, A., Ioannidis, J. P. A., Richter, L., Theiler-Schwetz, V., Trummer, C., Krause, R., Allerberger, F. (2021). SARS-CoV-2 re-infection risk in Austria. *European Journal of Clinical Investigation*, *51*(4), 1-7. doi: 10.1111/eci.13520 (previous SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Breathnach, A. S., Duncan, C. J. A., El Bouzidi, K., Hanrath, A. T., Payne, B. A. I., Randell, P. A., Habibi, M. S., Riley, P. A., Planche, T. D., Busby, J. S., Sudhanva, M., Pallett, S. J. C. & Kelleher, W. P. (2021). Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies. *The Journal of Infection*, *83*(2), 237-279. doi: 10.1016/j.jinf.2021.05.024 (0.86% of previously infected population in

infections.[10] 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.[11] 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, found that only 0.31% of COVID-recovered patients experienced a reinfection within a year after the initial infection, despite the circulation of the Delta variant.[12] In summary, the overwhelming conclusion of the pertinent

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London became reinfected); Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total $CD4^+$ and $CD8^+$ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine 2*(7), 100355 (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).

[10] Abu-Raddad, L. J., Chemaitelly, H., Coyle, P., Malek, J. A., Ahmed, A. A., Mohamoud, Y. A., Younuskunju, S., Ayoub, H. H., Kanaani, Z. A., Kuwari, E. A., Butt, A. A., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Rahim, H. F. A., Nasrallah, G. K., Yassine, H. M., Al Kuwari, M. G., Al Romaihi, H. E., Al-Thani, M. H., Al Khal, A., Bertollini, R. (2021). SARS-CoV-2 antibody-positivity protects against reinfection for at least seven months with 95% efficacy. *EClinicalMedicine*, *35*, 1-12. doi: 10.1016/j.eclinm.2021.100861 (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); Hall, V. J., Foulkes, S., Charlett, A., Atti, A., Monk, E. J. M., Simmons, R., Wellington, E., Cole, M. J., Saei, A., Oguti, B., Munro, K., Wallace, S., Kirwan, P. D., Shroti, M., Vusirikala, A., Rokadiya, S., Kall, M., Zambon, M., Ramsay, M., Hopkins, S. (2021). SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: a large, multicentre, prospective cohort study. *The Lancet*, *397*(10283), 1459-1469. doi: 10.1016/S0140-6736(21)00675-9 (finding "a 93% lower risk of COVID-19 symptomatic infection… [which] show[s] equal or higher protection from natural infection, both for symptomatic and asymptomatic infection"); Hanrath, A. T., Payne, B., A., I., & Duncan, C. J. A. (2021). Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection. *The Journal of Infection*, *82*(4), e29-e30. doi: 10.1016/j.jinf.2020.12.023 (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).

[11] Goldberg, Y., Mandel, M., Woodbridge, Y., Fluss, R., Novikov, I., Yaari, R., Ziv, A., Freedman, L., & Huppert, A. (2021). Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2.vaccine protection: A three-month nationwide experience from Israel. *medRxiv*, Preprint. doi: 10.1101/2021.04.20.21255670

[12] Vitale, J., Mumoli, N., Clerici, P., de Paschale, M., Evangelista, I., Cei, M. & Mazzone, A. (2021). Assessment of SARS-CoV-2 reinfection 1 year after primary infection in a population in Lombardy, Italy. *JAMA Internal Medicine*, *181*(10), 1407-1409. doi: 10.1001/jamainternmed.2021.2959

scientific literature is that natural immunity is at least as effective against subsequent reinfection as even the most effective vaccines.

17. 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."[13]

18. 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.[14] 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.[15]

19. 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.

[13] Baraniuk, C. (2021). How long does covid-19 immunity last? *The British Medical Journal*, *373*, 1-3. doi: 10.1136/bmj.n1605 (emphasis added).

[14] Le Bert, N., Tan, A. T., Kunasegaran, K., Tham, C. Y. L., Hafezi, M., Chia, A., Chng, M. H. Y., Lin, M., Tan, N., Linster, M., Chia, W. N., Chen, M. I. C., Wang, L. F., Ooi, E. E., Kalimuddin, S., Tambyah, P. A., Low, J. G. H., Tan, Y. J. & Bertoletti, A. (2020). SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control. *Nature*, *584*, 457-462. doi: 10.1038/s41586-020-2550-z

[15] Yu, X., Tsibane, T., McGraw, P. A., House, F. S., Keefer, C. J., Hicar, M. D., Tumpey, T. M., Pappas, C., Perrone, L. A., Martinez, O., Stevens, J., Wilson, I. A., Aguilar, P. V., Altschuler, E. L., Basler, C. F., & Crowe Jr., J. E. (2008). Neutralizing antibodies derived from the B cells of 1918 influenza pandemic survivors. *Nature*, *455*, 532-536. doi: 10.1038/nature07231

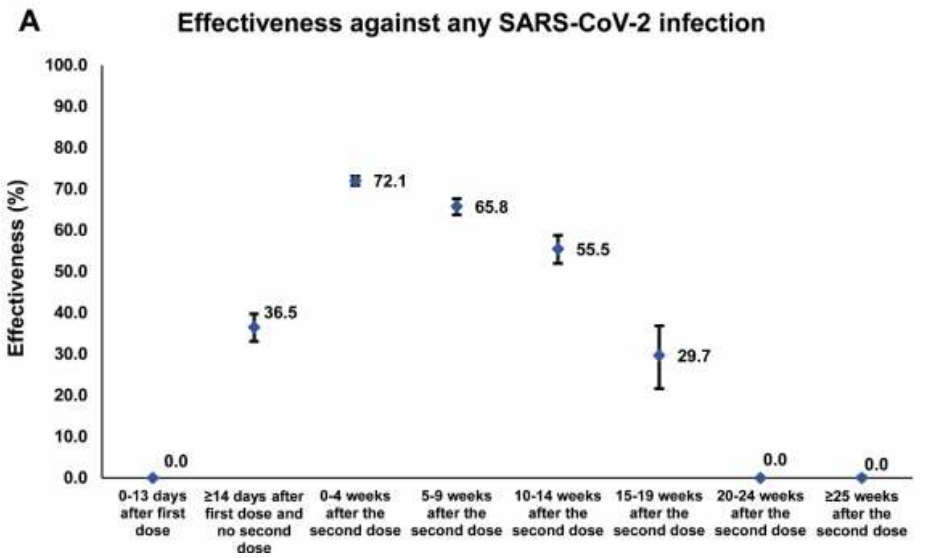
Notably, the researchers argue that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.[16]

20. A recent study from Qatar by Chemaitelly and colleagues, which tracked 927,321 individuals for six months after vaccination, concluded that the Pfizer vaccine's "induced protection against infection appears to wane rapidly after its peak right after the second dose, but it persists at a robust level against hospitalization and death for at least six months following the second dose."[17]

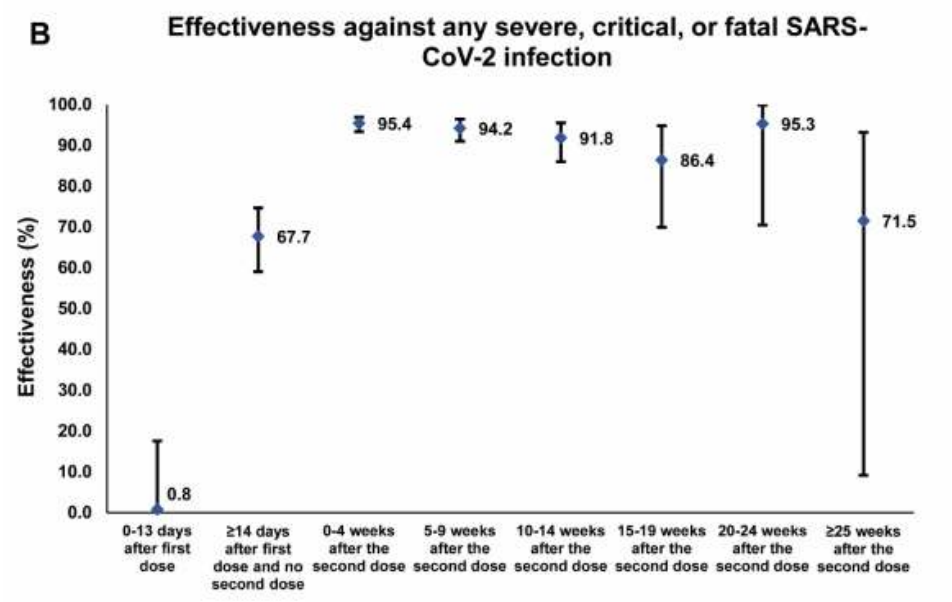
21. The key figures from the Qatari study are reproduced immediately below. Panel A shows that vaccine mediated protection against infection peaks at 72.1% zero to four weeks after the second dose, and then declines to 0%, 20 weeks after the second dose. According to this result, vaccines only protect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

[16] Ledford, H. (2021). Six months of COVID vaccines: What 1.7 billion doses have taught scientists. *Nature*, *594*(7862), 164-167. doi: 10.1038/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.").

[17] Chemaitelly, H., Tang, P., Hasan, M. R., Al Mukdad, S., Yassine, H. M., Benslimane, F. M., Khatib, H. A. A., Coyle, P., Ayoub, H. H., Kanaani, Z. A., Kuwari, E. A., Jeremijenko, A., Kaleeckal, A. H., Latif, A. N., Shaik, R. M., Rahim, H. F. A., Nasrallah, G. K., Kuwari, M. G. A., Romaihi, H. E. A., Abu-Raddad, L. J. (2021). Waning of BNT162b2 vaccine protection against SARS-CoV-2 infection in Qatar. *medRxiv*, Preprint. doi: 10.1101/2021.08.25.21262584



22. 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 is consistent with no decrease whatsoever even after 25 weeks.



23. The Qatari 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] Yet another study, conducted in Wisconsin, confirmed that vaccinated individuals can shed infectious SARS-CoV-2 viral particles.[19] 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 individuals infected with the Delta variant might transmit infection. Importantly, we show that infectious SARS-CoV-2 is frequently found even in vaccinated persons.

24. In summary, the evidence to date strong suggests that while vaccines—like natural immunity—provide protection against 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.

25. 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

[18] Eyre, D. W., Taylor, D., Purver, M., Chapman, D., Fowler, T., Pouwels, K. B., Walker, A. S. & Peto, T. E. A. (2021). The impact of SARS-CoV-2 vaccination on Alpha & Delta variant transmission. *medRxiv*, Preprint. doi: 10.1101/2021.09.28.21264260

[19] Riemersma, K. K., Grogan, B. E., Kita-Yarbro, A., Halfmann, P. J., Segaloff, H. E., Kocharian, A., Florek, K. R., Westergaard, R., Bateman, A., Jeppson, G. E., Kawaoka, Y., O'Connor, D. H., Friedrich, T. C., & Grande, K. M. (2021). Shedding of infectious SARS-CoV-2 despite vaccination. *medRxiv*, Preprint. doi: 10.1101/2021.07.31.21261387

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.

26. 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.[20] 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.[21] Finally, the CDC's vaccine safety committee has identified rare but deadly side effects, including a heightened risk of clotting abnormalities[22] in young women after the Johnson & Johnson (J&J) vaccination, elevated risks of myocarditis and pericarditis[23] in young people—but especially young men—after mRNA vaccination, and higher risk of Guillane-Barre Syndrome[24] 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.

[20] Centers for Disease Control and Prevention. (2021, September 30). *Possible side effects after getting a COVID-19 vaccine*. Retrieved October 1, 2021 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/expect/after.html

[21] Centers for Disease Control and Prevention. (2021, August 30). *What to do if you have an allergic reaction after getting a COVID-19 vaccine*. Retrieved October 1, 2021 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/allergic-reaction.html

[22] Kulldorff, M. (2021, April 17). The dangers of pausing the J&J vaccine. *The Hill*. https://thehill.com/opinion/healthcare/548817-the-dangers-of-pausing-the-jj-vaccine

[23] National Center for Immunization & Respiratory Diseases, Centers for Disease Control and Prevention. (2021, August 23). *Clinical considerations: Myocarditis and pericarditis after receipt of mRNA COVID-19 vaccines among adolescents and young adults*. Retrieved October 1, 2021 from https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html

[24] LaFraniere, S. & Weiland, N. (2021, July 12). FDA attaches warning of rare nerve syndrome to Johnson & Johnson vaccine. *The New York Times*. https://www.nytimes.com/2021/07/12/us/politics/fda-warning-johnson-johnson-vaccine-nerve-syndrome.html

27. Though the CDC[25] still recommends the vaccines for children 12 years old and up despite the evidence of elevated risk of myocarditis, other analysts[26] have objected to overly rosy assumptions made in the CDC analysis about vaccine side effects. Those analysts suggest that the CDC's recommendation is fragile to minor perturbation in their assumptions. The critical point for my 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.

28. 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."[27] 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 to polysorbate or PEG or to other non-COVID vaccines and injectable therapies. Patients with precautions are encouraged to consult

[25] Walensky, R. (2021, May 12). CDC director statement on Pfizer's use of COVID-19 vaccine in adolescents age 12 and older. *Center for Disease Control and Prevention*. Retrieved October 1, 2021 from https://www.cdc.gov/media/releases/2021/s0512-advisory-committee-signing.html

[26] Pegden, W. (2021, June 24). Weighing myocarditis cases, ACIP failed to balance the harms vs benefits of 2nd doses. *Medium.* https://medium.com/@wpegden?p=d7d6b3df7cfb

[27] National Center for Immunization & Respiratory Diseases, Centers for Disease Control and Prevention. (2021, September 27). *Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States*. Retrieved October 1, 2021 from https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

with an allergist or immunologist and to conduct an individualized risk assessment by the vaccination provider before getting the vaccine [28]

29. Some clinical evidence indicates that those who have recovered from COVID-19 could be at a *heightened* risk of adverse effects compared with those who have never had the virus.[29, 30] This may be because vaccine reactogenicity after the first dose is higher among those with prior immunity.[31] 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.

30. 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 particular clinical conditions. For instance, in a comprehensive discussion of the biology of immune responses to vaccination (including COVID-19 vaccination) for patients with Multiple

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[28] Centers for Disease Control and Prevention. (2021, September 27). *Interim clinical considerations for use of COVID-19 vaccines currently approved or authorized in the United States: Contraindications and precautions*. Retrieved Oct. 1, 2021 from 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

[29] Mathioudakis, A. G., Ghrew, M., Ustianowski, A., Ahmad, S., Borrow, R., Papavasileiou, L. P., Petrakis, D., & Bakerly, N. D. (2021). Self-reported real-world safety and reactogenicity of COVID-19 vaccines: A vaccine recipient survey. *Life*, *11*(3), 249. doi: 10.3390/life11030249

[30] Menni, C., Klaser, K., May, A., Polidori, L., Capdevila, J., Louca, P., Sudre, C. H., Nguyen, L. H., Drew, D. A., Merino, J., Hu, C., Selvachandran, S., Antonelli, M., Murray, B., Canas, L. S., Molteni, E., Graham, M. S., Modat, M., Joshi, A. D., Spector, T. D. (2021). 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. *The Lancet Infectious Diseases*, *21*(7), 939-949. doi: 10.1016/S1473-3099(21)00224-3 (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).").

[31] Krammer, F., Srivastava, K., the PARIS team & Simon, V. (2021). Robust spike antibody responses and increased reactogenitiy in seropositive individuals after a single dose of SARS-CoV-2 mRNA vaccine. *medRxiv*, Preprint. 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.").

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 MS patients should receive the COVID-19 vaccines. They and other authorities[32] emphasize the need for personalized decision making based on the clinical condition of the MS patient:[33]

> 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.

31. The paucity of data on the COVID-19 vaccine on patients with particular conditions is not limited to Multiple Sclerosis. Pregnant women were excluded from participating in the COVID-19 vaccination trials, consequently only limited randomized trial data are available about COVID-19 vaccine safety for that group.[34] Though the CDC and obstetrics focused specialty organizations nevertheless recommend COVID vaccination for pregnant women, many authors in peer reviewed journal articles have pointed to the lack of scientific data regarding vaccine safety in this group a problem for clinicians providing accurate advice to pregnant women.[35] Given this uncertainty, Nicola Volpe and her colleagues[36] writing in the *Journal of Perinatal Medicine*

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[32] Ciotti, J. R., Valtcheva, M. V. & Cross, A. H. (2020). Effects of MS disease-modifying therapies on responses to vaccinations: A review. *Multiple Sclerosis Related Disorders*, *45*, 1-11. doi: 10.1016/j.msard.2020.102439

[33] Coyle, P. K., Gocke, A., Vignos, M. & Newsome, S. D. (2021). Vaccine considerations for multiple sclerosis in the COVID-19 era. *Advances in Therapy*, *38*(7), 3550-3588. doi:10.1007/s12325-021-01761-3

[34] Rasmussen, S. A., Kelley, C. F., Horton, J. P., & Jamieson, D. J. (2021). Coronavirus disease 2019 (COVID-19) vaccines and pregnancy: What obstetricians need to know. *Obstetrics & Gynecology*, *137*(3), 408-414. doi: 10.1097/AOG.0000000000004290 Erratum in: *Obstetrics & Gynecology, 137*(5), 962. doi: 10.1097/AOG.0000000000004379

[35] Holness, N. A., Powell-Young, Y. M., Torres, E., DuBois, S., & Giger, J. N. (2021) Covid-19, pregnancy, and vaccinations. *Journal of National Black Nurses Association*, *32*(1), 1-9..

[36] Volpe, N., Luca Schera, G. B., Dall'Asta, A., Di Pasquo, E., & Ghi, T. (2021) COVID-19 in pregnancy: Where are we now? *Journal of Perinatal Medicine*, *49*(6), 637-642. doi: 10.1515/jpm-2021-0309.

explicitly recommend that "Women should discuss with healthcare professionals about the benefits and risks of having the vaccine, allowing an informed decision." In recent months some observational studies have shown reassuring results, including that pregnant woman face no greater risk of complications during pregnancy or delivery,[37] or of spontaneous abortion or miscarriage after vaccination.[38] Nevertheless, there is still an area of active research where safety signals may still emerge. A large French study of vaccine safety in pregnancy expects to report complete results in late 2022.[39] After a thorough review of mostly reassuring data on the safety of the vaccine for pregnant women, Lydia Shook and some of her colleagues at Massachusetts General Hospital write that – given the recent introduction of the vaccine into use by pregnant women – it may be some time before full safety data become available:[40]

> Complete pregnancy outcomes data from people vaccinated in the first and early second trimesters are not yet available as most of these pregnancies are ongoing. Durability of IgG in the blood of neonates born to vaccinated mothers has not yet been defined, nor has whether the anti-SARS-CoV-2 IgG generated influences the response to other childhood vaccines. Information on postnatal outcomes and offspring development will require long term follow-up of children born to individuals who received the vaccine during pregnancy.

32. There are also patients with particular genetic conditions where vaccine safety data are not adequate. 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

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[37] Theiler, R. N., Wick, M., Mehta, R., Weaver, A. L., Virk, A., & Swift, M. (2021). Pregnancy and birth outcomes after SARS-CoV-2 vaccination in pregnancy. *American Journal of Obstetrics & Gynecology MFM*, *3*(6), 100467. doi: 10.1016/j.ajogmf.2021.100467 Online ahead of print.

[38] Kharbanda, E. O., Haapala, J., DeSilva, M., Vazquez-Benitez, Vesco, K. K., Naleway, A. L., & Lipkind, H. S. (2021). Spontaneous abortion following COVID-19 vaccination during pregnancy. *JAMA*, e2115494. Online ahead of print. doi:10.1001/jama.2021.15494

[39] Cottin, J., Benevent, J., Khettar, S., & Lacroix, I. (2021). COVID-19 vaccines and pregnancy: What do we know? *Therapie*, *76*(4), 373-374. doi: 10.1016/j.therap.2021.05.011

[40] Shook, L. L., Fallah, P. N., Silberman, J. N., & Edlow, A. G. (2021) COVID-19 vaccination in pregnancy and lactation: Current research and gaps in understanding. *Frontiers in Cellular and Infection Microbiology*, *11*, 735394. doi: 10.3389/fcimb.2021.735394

the lungs— there are 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 prioritised 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."[41] The same can be said for other patients with many other 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.

33. In this section, I discuss the evidence regarding the asymptomatic transmission of disease. This is important because if asymptomatic disease spread is rare, the government can keep other workers safe from COVID disease spread by the simple expedient of requiring those who have not been 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 or class and get tested; returning to work only if the test is negative.

34. 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

[41] Yang, C. & Zhao, H. (2021) COVID-19 vaccination in patients with α1-antitrypsin deficiency. *The Lancet, Respiratory Medicine*, *9*(8), 818-820. doi:10.1016/S2213-2600(21)00271-X

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 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.[42]

35. There is some additional evidence on how frequently asymptomatic disease spread occurs. 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.[43] 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 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

[42] Madewell, Z. J., Yang, Y., Longini, I. M., Halloran, M. E. & Dean, N. E. (2020). Household transmission of SARS-CoV-2: A systematic review and meta-analysis. *JAMA Network Open*, *3*(12), 1-17. doi:10.1001/jamanetworkopen.2020.31756

[43] Cao, S., Gan, Y., Wang, C., Bachmann, M., Wei, S., Gong, J., Huang, Y., Wang, T., Li, L., Lu, K., Jiang, H., Gong, Y., Xu, H., Shen, X., Tian, Q., Lv, C., Song, F., Yin, X. & Lu, Z. (2020). Post-lockdown SARS-CoV-2 nucleic acid screening in nearly ten million residents of Wuhan, China. *Nature Communications*, *11*(1), 5917. doi: 10.1038/s41467-020-19802-w

symptomatic patients.[44]

36. 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.[45]

37. 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[46]), 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.

38. 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 from the likelihood of spread by an asymptomatic individual who never develops symptoms.[47] A primary finding of this study is that, while an asymptomatic individual who never develops symptoms is exceedingly unlikely to

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[44] Buitrago-Garcia, D., Egli-Gany, D., Counotte, M. J., Hossmann, S., Imeri, H., Ipekci, A. M., Salanti, G. & Low, N. (2020). Occurrence and transmission potential of asymptomatic and presymptomatic SARS-CoV-2 infections: A living systematic review and meta-analysis. *PLOS Medicine*, *17*(9), e1003346. doi: 10.1371/journal.pmed.1003346

[45] Cevik, M., Tate, M., Lloyd, O., Maraolo, A. E., Schafers, J. & Ho, A. (2021). 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*, *2*(1), e13-e22. doi: 10.1016/S2666-5247(20)30172-5

[46] Peirlinck, M., Linka, K., Costabal, F. S., Bhattacharya, J., Bendavid, E., Ioannidis, J. P. A. & 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), 113140. doi: 10.1016/j.cma.2020.113410

[47] Qiu, X., Nergiz, A. I., Maraolo, A. E., Bogoch, I. I., Low, N. & Cevik, M. (2021). The role of asymptomatic and pre-symptomatic infection in SARS-CoV-2 transmission-A living systematic review. *Clinical Microbiology and Infection*, *27*(4), 511-519. doi: 10.1016/j.cmi.2021.01.011

spread the disease, individuals who are not symptomatic now but will eventually develop symptoms are efficient at infecting others during their pre-symptomatic state.

39. 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.

40. 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 the working environment—is likely to be even less likely than in the household.

V. There Are Multiple Safe Alternatives to Indefinite Leave or Termination that Can Be Offered to Federal Employees.

41. Can the federal government keep employees safe if it does not mandate that all its employees (and students) be vaccinated? The answer is a definitive yes.

42. First and most obviously, the government could adopt a robust sick policy, requiring that those 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 PCR or antigen test result. This could be implemented, for instance, by requiring workers to complete a symptom self-check each day before coming to work. The government would provide employees and students with a supply of inexpensive 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.[48, 49] A large number of lateral flow antigen tests have received Emergency Use Authorization (EUA) by the US Food and Drug Administration.[50] Alternatively, the government could require that any unvaccinated members of its workforce obtain those tests themselves to keep its own costs down. Employees who report COVID-19 like symptoms would be asked to send a picture of their positive test result to their manager by phone or email to verify their result.[51] A system that required the few employees who seek the vaccine exemption to provide

[48] Surasi, K., Cummings, K. J., Hanson, C., Morris, M. K., Salas, M., Seftel, D., Ortiz, L., Thilakaratne, R., Stainken, C. & Wadford, D. A. (2021). Effectiveness of Abbott BinaxNOW rapid antigen test for detection of SARS-CoV-2 infections in outbreak among horse racetrack workers, California, USA. *Emerging Infectious Diseases*, *27*(11).

[49] Homza, M., Zelena, H., Janosek, J., Tomaskova, H., Jezo, E., Kloudova, A., Mrazek, J., Svagera, Z. & Pymula, R. (2021). Covid-19 antigen testing: Better than we know? A test accuracy study. *Infectious Diseases*, *53*(9), 661-668. doi: 10.1080/23744235.2021.1914857

[50] US FDA. (2021) In-Vitro Diagnostics EUA – Antigen Diagnostic Tests for SARS-CoV-2. Oct. 4, 2021. https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/in-vitro-diagnostics-euas-antigen-diagnostic-tests-sars-cov-2 Accessed Oct. 10, 2021

[51] Indeed, if United's goal is really to prevent the spread of COVID-19 as much as reasonably possible, symptom checking should be required of all workers, whether vaccinated or not, since the evidence shows that vaccination does not eliminate the possibility of infection and may provide less protection versus infection than immunity induced by prior COVID infection.

this information to their manager each day before coming to work would be inexpensive – no online reporting system would be necessary.

43. 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 will spread the disease is very low. And because the overwhelming majority of employees will themselves be vaccinated, they face even less risk from any of their asymptomatic, unvaccinated coworkers who receive an accommodation for religious or medical reasons (including on the basis of naturally acquired immunity) of developing severe COVID symptoms.

44. Second, the government could implement a program of weekly PCR or antigen testing as a condition of an employee's receiving an exemption. Many other organizations have implemented a testing regimen like this for all employees, including my home institution, Stanford University. Workers receiving an exemption could take the test in the workplace—there are versions of the test available that can be self-administered. Or workers could be required to purchase and take the test at home.[52]

45. Third, the government could simply exempt from its vaccine requirement all employees who legitimately claim an exemption and have recovered from COVID infection. The evidence provided in this declaration shows that such employees pose at 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.

[52] Indeed, the safest option would be for both vaccinated and unvaccinated workers to be required to provide a weekly test, since both can have asymptomatic SARS-CoV-2 infections.

46. While it is true that those who have recovered from COVID could incrementally reduce the infection risk they pose to other employees by *also* receiving the vaccine, it would make no sense to make this a requirement. For one thing, the incremental safety benefit of such a requirement would be vanishingly small. A study analyzing 738 patients in Kentucky and published in the CDC's journal (MMWR), estimated that the odds that COVID-recovered patients who are vaccinated are 2.34 [95% CI: 1.58-3.47] times lower for reinfection than COVID-recovered patients who are not vaccinated.[53] However, this reduction in the relative risk of reinfection represents a vanishingly small absolute risk reduction. Recall the study of Italian COVID-recovered patients that I cite above reported a reinfection rate of 0.3%, or 3 out of 1,000 after one year.[54] If the Kentucky study is right, vaccinating COVID recovered patients prevents on the order 2 infections out of a 1,000 people. This reduction can easily be replicated and improved upon without forced vaccination but with the symptom checking and regular testing solutions I suggest.

47. Moreover, the proper baseline for assessing the reasonableness of an exemption policy is not what kind of policy would produce the *maximum* reduction in risk, but rather what exemption options would reduce the risk posed by those receiving an exemption to a level below that posed by those complying with the government's vaccination requirement. After all, the government is willing to tolerate the risk of infection posed by those who have received the vaccine—a risk that increases substantially a few months after vaccination, or those who have received vaccines such as the Sinovac vaccine, for which no phase 3 randomized clinical trial study has been published (a

[53] Cavanaugh AM, Spicer KB, Thoroughman D, Glick C, Winter K. Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021. MMWR Morb Mortal Wkly Rep 2021;70:1081-1083. DOI: http://dx.doi.org/10.15585/mmwr.mm7032e1

[54] Vitale, J., Mumoli, N., Clerici, P., de Paschale, M., Evangelista, I., Cei, M. & Mazzone, A. (2021). Assessment of SARS-CoV-2 reinfection 1 year after primary infection in a population in Lombardy, Italy. *JAMA Internal Medicine*, *181*(10), 1407-1409. doi: 10.1001/jamainternmed.2021.2959

Sinovac randomized trial is due to be completed in February 2022.[55] If the objective were to reduce infection risk as much as humanly possible, the government would have to require its *vaccinated* employees to find a way to contract COVID (and stay home until they recover)—since the combination of a vaccination and a prior COVID reduces infection risk compared to either alone. But the government could not reasonably impose such a requirement, since an actual COVID infection would pose additional health risks to those who have been vaccinated. By the same risk/benefit logic—in light of the health risks posed by the vaccine itself—the government cannot reasonably require those seeking an exemption who have recovered from COVID to also be vaccinated.

VI. Variants Do Not Alter the Conclusion that Accommodations Can Be Allowed Without Risk to Public Safety.

48. 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.

49. For one thing, the first two accommodations discussed above would be equally effective against variants as they are against the original Wuhan version. That is because all variants to arise thus far produce symptoms that can be checked for, and can be identified through standard COVID testing. So regular symptom-checking and/or testing for those receiving medical or religious accommodations.

[55] US National Library of Medicine. Clinical Trials.gov. An Effectiveness Study of the Sinovac's Adsorbed COVID-19 (Inactivated) Vaccine (Projeto S). https://clinicaltrials.gov/ct2/show/NCT04747821. Accessed 10/18/2021

50. Variants likewise do not affect the reasonableness of the COVID-recovery alternative discussed above. The key point is that the mutant variants do not escape the immunity provided by prior infection with the wild-type virus or vaccination.[56, 57, 58] 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.[59] Although reinfection can occur, people who have been previously infected by the virus are 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 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

[56] Tarke, A., Sidney, J., Methot, N., Yu, E. D., Zhang, Y., Dan, J. M., Goodwin, B., Rubiro, P., Sutherland, A., Wang, E., Frazier, A., Ramirez, S. I., Rawlings, S. A., Smith, D. M., da Silva Antunes, R., Peters, B., Scheuermann, R. H., Weiskopf, D., Crotty, S., Grifoni, A. & Sette, A. (2021). Impact of SARS-CoV-2 variants on the total $CD4^+$ and $CD8^+$ T cell reactivity in infected or vaccinated individuals, *Cell Reports Medicine 2,* 100355.

[57] 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. (2021). mRNA-1273 vaccine induces neutralizing antibodies against spike mutants from global SARS-CoV-2 variants. *bioRxiv*, Preprint. doi: 10.1101/2021.01.25.427948

[58] Redd, A. D., Nardin, A., Kared, H., Bloch, E. M., Pekosz, A., Laeyendecker, O., Abel, B., Fehlings, M., Quinn, T.C. & Tobian, A. A. (2021). $CD8^+$ T-cell responses in COVID-19 convalescent individuals target conserved epitopes from multiple prominent SARS-CoV-2 circulating variants. *Open Forum Infectious Diseases 8*(7), ofab143.

[59] Gazit, S., Shlezinger, R., Perez, G., Lotan, R., Peretz, A., Ben-Tov, A., Cohen, D., Muhsen, K., Chodick, G. & Patalon, T. (2021). Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: Reinfections versus breakthrough infections. *medRxiv*, Preprint. doi: 10.1101/2021.08.24.21262415

provided to a large portion of the vulnerable elderly population and more, there have been "relatively few hospitalisations and deaths" in those countries.[60] 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.[61] 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.[62] A separate study with a more convincing longitudinal methodology, by contrast, concluded that only 2.3% of patients experienced such symptoms three months after recovery.[63] Patients who suffered a more severe acute course of COVID, including hospitalization, were more likely to report lingering symptoms

[60] Bhattacharya, J., Kulldorff, M. & Gupta, S. (2021, July 12). Sweden's lessons for the UK's third wave. *The Spectator*. https://www.spectator.co.uk/article/sweden-shows-that-the-uk-s-third-wave-won-t-sting

[61] Nalbandian, A., Sehgal, K., Gupta, A., Madhavan, M. V., McGroder, C., Stevens, J. S., Cook, J. R., Nordvig, A. S., Shalev, D., Sehrawat, T. S., Ahluwalia, N., Bikdeli, B., Dietz, D., Der-Nigoghossian, C., Liyanage-Don, N., Rosner, G. F., Bernstein, E. J., Mohan, S., Beckley, A. A. & Wan, E. Y. (2021). Post-acute COVID-19 syndrome. *Nature Medicine*, *27*(4), 601-615. doi: 10.1038/s41591-021-01283-z

[62] Logue, J. K., Franko, N. M., McCulloch, D. J., McDonald, D., Magedson, A., Wolf, C. R., & Chu, H. Y. (2021). Sequelae in adults at 6 months after COVID-19 infection. *JAMA Network Open, 4*(2), e210830. doi: 10.1001/jamanetworkopen.2021.0830

[63] Sudre, C. H., Murray, B., Varsavsky, T., Graham, M. S., Penfold, R. S., Bowyer, R. C., Pujol, J. C., Klaser, K., Antonelli, M., Canas, L. S., Molteni, E., Modat, M., Cardoso, M. J., May, A., Ganesh, S., Davies, R., Nguyen, L. H., Drew, D. A., Astley, C. M., Steves, C. J. (2021). Attributes and predictors of long COVID. *Nature Medicine*, *27*(4), 626-631. doi: 10.1038/s41591-021-01292-y

after recovery.[64] 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.[65] 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).[66]

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 now have 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 the Frequently Asked Questions (FAQ) section of its website encouraging vaccination, provides the following advice to previously recovered patients:[67]

> Yes, you should be vaccinated regardless of whether you already had COVID-

[64] Arnold, D. T., Hamilton, F. W., Milne, A., Morley, A. J., Viner, J., Attwood, M., Noel, A., Gunning, S., Hatrick, J., Hamilton, S., Elvers, K. T., Hyams, C., Bibby, A., Moran, E., Adamali, H. I., Dodd, J. W., Maskell, N. A., Barratt, S. L. (2021). Patient outcomes after hospitalisation with COVID-19 andimplications for follow-up: Results from a prospective UK cohort. *Thorax*, *76*, 399-401. doi: 10.1136/thoraxjnl-2020-216086

[65] Radtke, T., Ulyte, A., Puhan, M. A. & Kriemler, S. (2021). Long-term symptoms after SARS-CoV-2 infection in school children: Population-based cohort with 6-months follow-up. *JAMA*, *326*(9), 869-871. doi: 10.1001/jama.2021.11880

[66] Ballering, A., Olde Hartman, T. & Rosmalen, J. (2021). Long COVID-19, persistent somatic symptoms and social stigmatization. *Journal of Epidemiology and Community Health*, *75*, 603-604. doi: 10.1136/jech-2021-216643

[67] Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2019 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

> 19. That's because experts do not yet know how long you are protected from 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 natural immunity after recovery lasts, the immunological evidence to date suggests that protection against disease will last for years.[68] 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.[69] On the same CDC FAQ webpage I cite above,[70] 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.

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[68] Patel, N. V. (2021, January 6). *Covid-19 immunity likely lasts for years*. MIT Technology Review. https://www.technologyreview.com/2021/01/06/1015822/covid-19-immunity-likely-lasts-for-years/

[69] CDC COVID-19 Vaccine Breakthrough Case Investigations Team. (2021). COVID-19 Vaccine Breakthrough Infections Reported to CDC — United States, January 1–April 30, 2021. *Morbidity and Mortality Weekly Report (MMWR)*, *70*(21), 792-793. doi: http://dx.doi.org/10.15585/mmwr.mm7021e3

[70] Centers for Disease Control and Prevention. (2021, September 28). Frequently asked questions about COVID-19 vaccination. Retrieved October 1, 2021 from https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

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

IX. Conclusion

58. A fundamental ethical principle guiding the practice of medicine is that any medical intervention, whether surgical, pharmacological, or a vaccine, should be recommended and undertaken 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.

59. 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 (or more) as that acquired through 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 and who have sincere medical or religious objections 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.

60. In sum, based on my analysis of the existing medical and scientific literature, any exemption policy that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health.[71]

61. Indeed, now that every American adult and teenager has free access to the vaccines, the case for a vaccine mandate is weaker than it once was. There is no good public health case for the government to require proof of vaccination for employees who have recovered from COVID-19 and have a sincere medical or religious objection to vaccination. Since the successful vaccination campaign already protects the vulnerable population, the unvaccinated—especially recovered COVID patients—pose a vanishingly small threat to the vaccinated. They are protected by an effective vaccine that dramatically reduces the likelihood of hospitalization or death after infections to near zero. At the same time, natural immunity provides benefits that are at least as strong and may well be stronger than those from vaccines.

62. 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; and finally, that there exist inexpensive safe accommodations that the government can adopt which would protect both employees and customers against SARS-CoV-2 infection without terminating unvaccinated employees.

[71] Bhattacharya, J., Gupta, S. & Kulldorff, M. (2021, June 4). *The beauty of vaccines and natural immunity.* Smerconish Newsletter. https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity

63. 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 18th day of October 2021, at Stanford, California.

Respectfully submitted,

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