ATTACHMENT C

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

ERIC MCARTHUR and JENNY MCARTHUR, Proceeding on their own behalf and on Behalf of their minor child, M.M., *Plaintifs,* v. SCOTT BRABRAND, *et. al.,* *Defendants,*	Civil Action No.: _____

Joint Declaration of Dr. Jayanta Bhattacharya and Dr. Martin Kulldoff

We, Drs. Jayanta ("Jay") Bhattacharya and Martin Kulldorff provide the following Joint Declaration and hereby declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct:

Background

1. Dr. Jay Bhattacharya is a Professor of Medicine at Stanford University and a research associate at the National Bureau of Economic Research. He is also Director of Stanford's Center for Demography and Economics of Health and Aging. He holds an M.D. and Ph.D. from Stanford University. He has published 152 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. His research has been cited in the peer-reviewed scientific literature more than 11,000 times.

2. Dr. Martin Kulldorff is a Professor of Medicine at Harvard Medical School, and he is a biostatistician and epidemiologist at Brigham and Women's Hospital. He holds a Ph.D. from Cornell University. He is the author of 237 published articles in leading medical, epidemiological, statistics, and science journals, cited over 25,000 times in peer-reviewed scientific journals. Dr. Kulldorff is recognized internationally for his foundational research on the detection and monitoring of disease outbreaks and on the monitoring and evaluation of vaccine safety issues. His epidemiological methods are routinely used by the Centers for Disease Control and Prevention ("CDC"), the Food and Drug Administration ("FDA") and other public health agencies around the world.

3. Both of us have dedicated our professional careers to the analysis of public health data, including infectious disease epidemiology and policy, and the efficacy and safety of medical interventions.

4. We 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"). We are 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. Our assessment of vaccine immunity is based on studies related to the efficacy and safety of the three vaccines that have received Emergency Use Authorization ("EUA") from the Food and Drug Administration (FDA) 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).

6. Neither of us has received any financial or other compensation to prepare this Declaration. Nor have we ever received any personal or research funding from any pharmaceutical company. In writing this, we are motivated solely by our commitment to public health.

7. Neither of us has an existing doctor-patient relationship with Jeanna Norris.

8. We have been asked to provide our opinion on several matters related to Michigan State University ("MSU" or "University") vaccine policy for faculty and staff (the "mandatory vaccination" directive), including the following:

a. 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;

b. 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; and

c. 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.

9. Our opinions are summarized in a recent article we published and which we 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 stronger than the evidence from the vaccines. Hence, it makes no sense to require vaccines for recovered COVID patients. For them, it simply adds a risk, however small."[1]

[1] 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.

Mortality Risk from COVID-19 Infection and Corresponding Marginal Benefit From Vaccination Varies By Orders of Magnitude Based on Age

10. The mortality risk posed by COVID infection is a basic parameter necessary to understand the public health benefits from vaccines. The best evidence on the infection fatality rate from SARS-CoV-2 infection (that is, the fraction of infected people who die due to the infection) comes from seroprevalence studies. The definition of seroprevalence of COVID-19 is the fraction of people within a population who have specific antibodies against SARS-CoV-2 in their bloodstream. Seroprevalence studies provide better evidence on the total number of people who have been infected than do case reports or a positive reverse transcriptase-polymerase chain reaction (RT-PCR) test counts; these both miss infected people who are not identified by the public health authorities or do not volunteer for RT-PCR testing. Because they ignore unreported cases in the denominator, fatality rate estimates based on case reports or positive test counts are substantially biased upwards. According to a meta-analysis (published by the World Health Organization) by Dr. John Ioannidis of every seroprevalence study conducted with a supporting scientific paper (74 estimates from 61 studies and 51 different localities worldwide), the median infection survival rate from COVID-19 infection is 99.77%. For COVID-19 patients under 70, the meta-analysis finds an infection survival rate of 99.95%.[2] A newly released meta-analysis by scientists independent of Dr. Ioannidis' group reaches qualitatively similar conclusions.[3]

11. The mortality risk for those infected with SARS-CoV-2 is not the same for all patients. Older patients are at higher risk of death if infected, while younger patients face a

[2] Ioannidis JPA, *Infection fatality rate of COVID-19 inferred from seroprevalence data*, BULL WORLD HEALTH ORGAN (Jan 1, 2021).
[3] Andrew T. Levin, et al., *Assessing the Age Specificity of Infection Fatality Rates for COVID-19: Meta-Analysis & Public Policy Implications*, MEDRXIV (Aug. 14, 2020), https://bit.ly/3gpIoIV.

vanishingly small risk.[4] The same is true for hospitalization risk, which is similarly age-dependent. The best evidence on age-specific infection fatality rates comes again from seroprevalence studies.

12. The CDC's best estimate of the infection fatality ratio for people ages 0-19 years is 0.00002, meaning infected children have a 99.998% infection survivability rate.[5] The CDC's best estimate of the infection fatality rate for people ages 20-49 years is 0.0005, meaning that young adults have a 99.95% survivability rate. The CDC's best estimate of the infection fatality rate for people age 50-64 years is 0.006, meaning this age group has a 99.4% survivability rate. The CDC's best estimate of the infection fatality rate for people ages 65+ years is .09, meaning seniors have a 91.0% survivability rate.

13. A study of the seroprevalence of COVID-19 in Geneva, Switzerland (published in the *Lancet*)[6] provides a detailed age breakdown of the infection survival rate in a preprint companion paper[7]: 99.9984% for patients 5 to 9 years old; 99.99968% for patients 10 to 19 years old; 99.991% for patients 20 to 49 years old; 99.86% for patients 50 to 64 years old; and 94.6% for patients above 65 years old.

14. In summary, the mortality risk posed by COVID infection in the young is vanishingly small, while the threat posed to the elderly is orders of magnitude higher. One direct corollary of this point is that the corresponding personal benefit from vaccination, at least as far as mortality risk is concerned, is orders of magnitude lower for the young relative to the elderly.

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[4] Kulldorff M., *COVID-19 Counter Measures Should Be Age-Specific*, LINKEDIN (Apr. 10, 2020), https://www.linkedin.com/pulse/covid-19-counter-measures-should-age-specific-martin-kulldorff/.

[5] Centers for Disease Control and Prevention, *COVID-19 Pandemic Planning Scenarios*, https://www.cdc.gov/coronavirus/2019-ncov/hcp/planning-scenarios.html.

[6] Silvia Stringhini, et al., *Seroprevalence of Anti-SARS-CoV-2 IgG Antibodies in Geneva, Switzerland (SEROCoV-POP): A Population Based Study*,THE LANCET (June 11, 2020), https://bit.ly/3l87S13.

[7] Francisco Perez-Saez, et al., *Serology-Informed Estimates of SARS-COV-2 Infection Fatality Risk in Geneva, Switzerland*, OSF PREPRINTS (June 15, 2020), https://osf.io/wdbpe/.

Another corollary is that the community benefit from vaccines mandates is orders of magnitude lower for a university compared to say a nursing home, whee the average age is much higher.

Both Vaccine Immunity and Natural Immunity Provide Durable Protection Against Reinfection and Against Severe Outcomes If Reinfected

15. 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 has never been a reason to presume that vaccine immunity provides a higher level of protection than natural immunity, and there is now evidence that natual immunity is stronger than vaccine immunity. Since vaccines arrived one year after the disease, there is also stronger evidence for long lasting immunity from natural infection than from the vaccines.

16. 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.[8,9] A Phase III trial showed 85% efficacy for the Johnson and Johnson adenovirus-based vaccine against severe disease.[10]

[8] 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).

[9] Polack FP, Thomas SJ, Kitchin N, Absalon J, Gurtman A, Lockhart S, Perez JL, Pérez Marc G, Moreira ED, Zerbini C, 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*, N ENGL J MED. (Dec. 31, 2020).

[10] 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.

17. 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[11], bone marrow plasma cells[12], spike-specific neutralizing antibodies [13], and IgG+ memory B cells[14] following naturally acquired immunity.

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

19. Specifically, studies confirm the efficacy of natural immunity against reinfection of COVID-19[15] and show that the vast majority of reinfections are less severe than first-time

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[11] 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").

[12] 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").

[13] 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).

[14] 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").

[15] 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 that those 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-CoV-2 re-infection risk in Austria*, EUR. J. CLIN. INVEST. (2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7988582/(previous

infections.[16] For example, an Israeli study of approximately 6.4 million individuals demonstrated that natural immunity provided excellent protection in preventing COVID-19 infection, morbidity, and mortality.[17] 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.

20. A more recent study from Israel directly compare natual immunity with vaccine immunity.[18] The study compares previously infected and recovered individuals who did not receive a vaccine after their recovery against individuals who received the Pfizer vaccine without having had the disease. The study considered four primary endpoints: a positive COVID test (a surrogate endpoint of limited value); symptomatic COVID-19 disease, hospitalization for COVID-

SARS-CoV-2 infection reduced the odds of re-infection by 91% compared to first infection in the remaining general population); Aodhan Sean Breathnach, et al., *Prior COVID-19 protects against reinfection, even in the absence of detectable antibodies*, 82 J. OF INFECTION e11-e12 (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 SARS0CoV-2 variants on CD4 and CD8 T cell reactivity in COVID-19 exposed donors and vaccines*, BIORXIV (Mar. 1, 2021), 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).

[16] Laith J. Abu-Raddad, et al., *SARS-CoV-2 reinfection in a cohort of 43,000 antibody-positive individuals followed for up to 35 weeks*, MEDRXIV (Feb. 8, 2021), 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 asymptomatic infection"); Aidan T. Hanrah, et al., *Prior SARS-CoV-2 infection is associated with protection against symptomatic reinfection*, 82 JOURNAL OF INFECTION, Issue 4, 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).

[17] 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.

[18] Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon (2021) 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.

19 disease, and COVID-19 associated mortality (all recorded in the months after recovery or vaccination). The study adjusts for age, demographic variables, patient comorbidities, and the timing of the disease/vaccine. The primary findings are that vaccinated individuals had 13.1 times higher risk of testing positive [95% CI: 8.08-21.1], 27 times higher risk of symptomatic disease [95% CI: 12.7-57.5], ~8.1 times higher risk of COVID-related hospitalization [95% CI: 1.01-64.55]. None of the patients in the study died due to COVID-related mortality. The vaccinated individuals were also at higher risk compared to those that had COVID diseas before the vaccines became available. The authors concluded:

> This study demonstrated that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 two-dose vaccine-induced immunity.

21. Based on such evidence, many scientists have concluded that natural protection against severe disease after COVID recovery is likely to be long-lasting.[19]

22. 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.[20] 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.[21]

[19] Chris Baranjuk, *How long does covid-19 immunity last?* 373 BMJ (2021) (emphasis added).
[20] Nina Le Bert, *SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected control*, NATURE (Aug. 2020).
[21] Xiaocong Yu, et al., *Neutralizing antibodies derived form the B cells of 1918 influenze pandemic survivors*, NATURE (2008).

23. 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, researchers have argued that they can best surmise the predicted durability of vaccine immunity by looking at the expected durability of natural immunity.[22]

24. In short, there is no medical or scientific reason to believe that vaccine immunity is superior to or 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.

Vaccine Side Effects Do Occur, Including Rare But Deadly Side Effects

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 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.[23] Less common but severe side effects also include severe and non-severe allergic (anaphylactic) reactions that can occur within 30 minutes after vaccination, which can typically be treated with an epinephrine injection if it occurs.[24] Finally, the CDC's vaccine safety committee has identified

[22] 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] 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.
[24] 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.

rare but deadly side effects, including a heightened risk of clotting abnormalities[25] in young women after the Johnson & Johnson (J&J) vaccination, elevated risks of myocarditis and pericarditis[26] in young people — but especially young men — after mRNA vaccination, and higher risk of Guillane-Barre Syndrome[27] 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.

27. Though the CDC[28] still recommends the vaccines for children 12 years old and up despite the evidence of elevated risk of myocarditis, other analysts[29] 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 at this point in time.

28. While uncertain, some clinical evidence indicates that those who have recovered from COVID-19 could potentially have a *heightened* risk of adverse effects compared with those

[25] 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.
[26] 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.
[27] 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.
[28] 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.
[29] Pegden, *Weighing myocarditis cases, ACIP failed to balance the harms vs benefits of 2nd doses* (June 24, 2021), https://medium.com/@wpegden?p=d7d6b3df7cfb.

who have never had the virus.[30] [31] This may be because vaccine reactogenicity after the first dose is higher among those with prior natural immunity.[32]

Variants Do Not Alter the Conclusion that Vaccine Mandates Are Unwarranted

29. 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. The virus will continue to mutate as it continues to spread. However, the possibility of such a mutation does not alter the conclusion that a vaccine mandate is unwarranted.

30. First, the mutant variants do not escape the immunity provided by prior infection with the wild-type virus or vaccination.[33,34,35] Although reinfection can occur, people who have been previously infected by the wild-type (non-variant) virus are unlikely to have a severe outcome

[30] 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).
[31] 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).").
[32] 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.).
[33] 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.
[34] 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.
[35] 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.

(hospitalization or death) after exposure to a variant virus. A variant circulating in the population thus poses little additional risk of hospital overcrowding or excess mortality due to viral infection.

31. Second, theoretical work suggests that lockdowns place selective pressure that promotes the development and establishment of more deadly variants. This, in part, may explain why the most concerning variants have emerged in places like the U.K., South Africa, and California, where severe lockdowns have been imposed for extended periods.[36] While this hypothesis awaits a definitive empirical test, it is consistent with the *prima facie* evidence on mutant variants' development.

32. Third, the variants have been widely spreading in many countries these past months, even as cases have dropped. This is true, for instance, in Florida, where the U.K. variant B.1.1.7 was widespread this past winter[37], but cases fell sharply over the same period that the variant has been spreading. That variants with an infectivity advantage – but no more lethality – make up a larger fraction of a smaller number of cases is an interesting scientific observation but not crucial for public health policy.

33. Fourth, the dissemination of vaccines that protect against hospitalizations and deaths upon COVID-19 infection throughout the older population in the United States has decoupled the growth in COVID-19 cases from COVID-19 mortality. Vaccinated people can still perhaps be infected but rarely 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, there has been little rise in daily deaths to accompany the rise in cases because of the deployment of the vaccine in the vulnerable older population in the

[36] Moran J., *Mutant variations and the danger of lockdowns*, THE CRITIC MAGAZINE (March 2, 2021), https://thecritic.co.uk/mutant-variations-and-the-danger-of-lockdowns/.
[37] US Centers for Disease Control, *US COVID-19 Cases Caused by Variants* (2021), https://www.cdc.gov/coronavirus/2019-ncov/transmission/variant-cases.html.

United States. The same is true in Sweden and the U.K., where vaccines have been provided to the entirety of the vulnerable elderly population and more.[38] Because of the success of the American vaccination effort among the vulnerable elderly, COVID-19 cases and COVID-19 deaths are now effectively decoupled.

The Presence of Lingering Post-Viral Infection Symptoms in a Subset of Recovered COVID patients ("Long COVID") Does Not Alter The Conclusion that Vaccine Mandates Are Unwarranted

34. Some analysts and politicians have used the possibility that a fraction of patients who recover from COVID infection will experience lingering symptoms to justify vaccine mandates and lockdown measures. Long COVID, as this phenomenon is called, includes a complex set of clinical outcomes with a poorly understood link to acute COVID infection.[39] 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.[40] A separate study with a more convincing longitudinal methodology, by contrast, concluded that 2.3% of patients experienced such symptoms three months after recovery.[41] Patients who suffered a more severe acute course of COVID, including hospitalization, were more likely to report lingering symptoms after recovery.[42] A study of children who recovered from

[38]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.
[39] 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.
[40] 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.
[41] 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.
[42] 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).

COVID found the same rate of long COVID symptoms as a control group of children who had no serological evidence of prior COVID infection.[43] 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).[44]

35. 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 our argument. On the countrary. After suffering through COVID, with or without long COVID, such individuals should not be forces 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.

CDC Recommendation for Vaccination of Recovered COVID Patients Applies With Equal Force to Previously Vaccinated

36. Written before the Israel study, the CDC, in a frequently asked questions section of a website encouraging vaccination, provided the following advice to previously recovered patients in July 2021:[45]

> 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 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

[43] 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.
[44] Ballering A, Olde Hartman T, Rosmalen J Long COVID-19, *persistent somatic symptoms and social stigmatization,* J EPIDEMIOL COMMUNITY HEALTH (2021).
[45] US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (accessed July 30, 2021)

more about why getting vaccinated is a safer way to build protection than getting infected.

37. The last sentence is true but irrelevant for people with natural immunity. The statement on CDC's website that "studies have shown that vaccination provides a strong boost in protection in people who have recovered from COVID-19," is incorrect. As one would expect, people with prior COVID-19 disease have increased levels of antibodies after receiving the vaccine, leading to fewer positive tests, just as if they are re-exposed to the disease. This does not mean that the vaccine increases protection against symptomatic disease, hospitalizations or deaths. In an update to the website[46] on August 19, 2021, the CDC links to a single study from Kentucky.[47] That study showed fewer positive tests among those who had both natural immunity and a vaccine, but the study did not evaluate the relevant outcomes of symptomatic disease, hospitalizations, deaths or transmission. Like the Kentucky study, the Israel study also found that those with both natural immunity and a vaccine were less likely to test positive compared with those with natural immunity but no vaccine. The Israel study also evaluated other outcomes, and did not find any statistically significant difference with respect to symptomatic disease, hospitalizations or deaths, all of which were very low in both groups (e.g. no deaths in either group).

38. The text of this advice by the CDC also does not address any of the scientific evidence we have provided in our declaration, herein, about the lack of necessity for recovered COVID patients to be vaccinated. While it is true that we do not know how long natural immunity

[46] US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (accessed August 26, 2021)
[47] 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

after recovery lasts, in terms of 5, 10, or 20 years from now, the immunological evidence to date suggests that protection against disease will last for years.[48]

39. That is because, with exceedingly few reinfections among millions of recovered COVID-19 patients, we know that there is excellent protection for at least 18 months, and that protection is not suddenly going to disappear after exactly 18 months.

40. Uncertainty over the longevity of immunity after recovery is a specious reason for not exempting COVID recovered patients from vaccination mandates, since the same is true to an even highe degree about vaccine mediated immunity. We 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.

41. 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.[49] On the same CDC FAQ webpage we cite above[50], the CDC writes about vaccine mediated immunity, "We don't know how long protection lasts for those who are vaccinated."

42. 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.

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[48] 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/

[49] 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

[50] US Centers for Disease Control (2021) Frequently Asked Questions About COVI19 Vaccination. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html

On this point, the CDC's statement in the FAQ is non-responsive, and ignores the scientific evidence.

Conclusion

43. 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.

44. As we 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 acquired through vaccination. In Jeanna Norris' case, there is no doubt that, based on recent measures of her antibody levels, she is protected by natural immunity (Dr. Bhattacharya has examined the results from Ms. Norris' laboratory tests). The results indicate the presence of both spike-protein and nucleocapsid protein antibodies; the latter is a reliable sign of previous natural infection (the former turns positive after either previous natural infection or 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. From the point of view of Ms. Norris' personal health, there is no good reason that she should be vaccinated. At the very least, the decision should be left to Ms. Norris and her doctors without coercion applied by the University.

45. There is also no community health reason for the University to mandate vaccinations since she already has stonge immunity than those that ae vaccinated, and the vaccine is available to all teens and adults who want it. Indeed, based on our 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.[51]

46. As we wrote in the *Wall Street Journal* this spring, "[t]he idea that everybody needs to be vaccinated is as scientifically baseless as the idea that nobody does. Covid vaccines are essential for older, high-risk people and their caretakers and advisable for many others. But those who've been infected are already immune . . . .If authorities mandate vaccination of those who don't need it, the public will start questioning vaccines in general . . . . Coercive vaccination policies would erode trust even further."[52]

47. We criticized those pushing for and implementing vaccine mandates as "undermining public trust in vaccines. In this sense, they are more dangerous than the small group of so-called anti-vaxxers have ever been."

48. It is unethical to coerce low-risk Americans to take the vaccine, such as low-risk students and those with natual immunity, while older high-risk individuals in Asia, Africa and Latin America are dying from COVID19 because there are not enough vaccines available in those countries.

49. Now that every American adult and teenager has free access to the vaccines, the case for a vaccine mandate is even weaker than it was in the spring when we wrote that *Wall Street*

[51] Jay Bhattacharya, Sunetra Gupta, and 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.

[52] Martin Kulldorff and Jay Bhattacharya, *Vaccine Passports Prolong Lockdowns*, WALL STREET JOURNAL (Apr. 6, 2021), https://www.wsj.com/articles/vaccine-passports-prolong-lockdowns-11617726629.

Journal piece. There is no good public health case for MSU to require proof of vaccination for employees and students to participate in University activities that do not involve care for high-risk patients. And, since those recovered from COVID19 has better protection than vaccinated individuals, there are no public health reasons to impose different mask requirements for the two groups.

50. Since the successful vaccination campaign already protects the vulnerable population, even the unvaccinated who have not had COVID disease –pose a vanishingly small threat to the vaccinated o those with natual immunity. They are protected by an effective vaccine, that dramatically reduces the likelihood of hospitalization or death after infections to near zero, o by natural immunity.

51. With widespread vaccination of the vulnerable, asymptomatic people pose even less risk to the vulnerable than before the vaccine became available. At the same time, the requirement for a vaccine passport or other type of proof of vaccine undermines trust in public health because of its coercive nature. While vaccines are an excellent tool for protecting the vulnerable, COVID does not justify ignoring principles of good public health practice that caution against warrantless discrimination against segments of the population (in this case, the unvaccinated).

52. We recently observed that "[u]niversities used to be bastions of enlightenment. Now many of them ignore basic benefit-risk analyses, a staple of the toolbox of scientists; they deny immunity from natural infection; they abandon the global international perspective for narrow nationalism; and they replace trust with coercion and authoritarianism. Mandating the COVID-19 vaccine thus threatens not only public health but also the future of science."[53]

[53] 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.

53. Universities can be leaders in developing sensible policies grounded in sound scientific evidence and abide by the fundamental principles of medical ethics. Individuals who have recovered from COVID-19 should be exempt from any vaccine mandates and treated as in an identical position to those who have been vaccinated.

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