No. 22-1200

United States Court Of Appeals For The Sixth Circuit

JEANNA NORRIS, ET AL.,

PLAINTIFFS-APPELLANTS,

v.

SAMUEL STANLEY, ET AL.,

DEFENDANTS-APPELLEES

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MICHIGAN

BRIEF OF *AMICI CURIAE* PROFESSOR TODD ZYWICKI AND JEFFREY SINGER, M.D., IN SUPPORT OF APPELLANTS AND REVERSAL

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INTEREST OF *AMICI CURIAE*[1]

Todd Zywicki is the George Mason University Foundation Professor of Law at George Mason University's Antonin Scalia Law School. Jeffrey A. Singer, M.D., is president emeritus/founder of Valley Surgical Clinics, Ltd., the largest and oldest group private surgical practice in Arizona.

Professor Zywicki and Dr. Singer each contributed to the submission of a Comment on the Occupational Health & Safety Administration's proposed vaccine mandate prior to its withdrawal. The Comment addressed the overwhelming scientific evidence showing that natural immunity is at least as effective as any of the available vaccines at preventing infection, transmission, and sickness from SARS-CoV-2, the virus that causes COVID-19, and highlighted the irrationality of OSHA's decision not to consider previous infection on par with vaccination. *See* Attach. A. *Amici* submit this brief to explain why Michigan State University's ("MSU") application of its vaccine mandate to employees and students with natural immunity from COVID-19 does not provide them additional protection from infection, reduce transmission to others, or decrease the risk of adverse effects on reinfection.

[1] This brief is filed with the consent of all parties. No party or person other than *amici* and their counsel authored this brief in whole or in part or contributed money for its preparation or submission.

SUMMARY OF ARGUMENT

Amici do not dispute that vaccines are generally an effective and vital tool in addressing the ongoing COVID-19 pandemic. To withstand constitutional scrutiny, however, MSU must base any policy to address the pandemic on the best available evidence and scientific findings.

Here, that means it must account for natural immunity. The most up-to-date, scientific literature confirms that, once people contract COVID-19, they develop natural immunity to the disease that protects against infection and transmission at least as effectively as vaccination. In light of these benefits and the limited efficacy of vaccines, there is no scientific basis to penalize employees or students with natural immunity, simply because they have not received a vaccine.

Nevertheless, MSU claims for itself the broad power to force all employees and students—including those with natural immunity like the plaintiffs in this action—to undergo forced vaccination or face discipline, up to and including termination of employment. MSU claims this sweeping mandate is necessary to further its interests in protecting the health of its population.

As applied to naturally immune employees, however, MSU's vaccine mandate does not serve this interest. It does not further prevent the spread of the disease because naturally immunity is just as effective at preventing infection and transmission as vaccination, if not more so. In fact, if anything, vaccination of

naturally immune employees *harms* MSU's interest in protecting employee health because the vaccines' adverse effects are more severe for previously infected people. Thus, to survive any level of scrutiny, any vaccine mandate must exempt COVID-recovered individuals. MSU's mandate does not do so.

ARGUMENT

I. Accepted Biological Principles Indicate that Natural Immunity Is More Effective than Vaccination.

Like any respiratory virus, the virus responsible for the COVID-19 pandemic—SARS-CoV-2—enters the body through a mucus-lined surface like the nose, mouth, or eyes.[2] It then "latches its spiky surface proteins [i.e., the 'spike protein'] to receptors on healthy cells."[3] Once attached, the virus replicates its genome and uses the host cell to make structural proteins critical to form new copies of itself that will soon escape the host cell and infect the rest of the body.[4]

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[2] Melinda Ratini, *Coronavirus: What Happens When You Get Infected?* WEBMD MEDICAL REFERENCE (Jan. 21, 2022), https://wb.md/38eZSJT; U.S. Centers for Disease Control and Prevention ("CDC"), *How COVID-19 Spreads* (July 14, 2021), https://bit.ly/3iQ7vZb.

[3] Ratini, *supra* n.2; *see also* Megan Scudellari, *How the coronavirus infects cells — and why Delta is so dangerous*, NATURE (July 28, 2021), https://go.nature.com/3Do2pNa ("SARS-CoV-2 spike proteins attach to a familiar protein . . . which adorns the outside of most human throat and lung cells.").

[4] Johns Hopkins Medicine, *How Coronaviruses Work*, https://bit.ly/3JX5XIH (July 22, 2020).

In response to infection, the body produces "IgA antibodies," which are specific to the mucosal surfaces where the virus first enters the body.[5] These antibodies recognize a broad array of proteins carried by the virus.[6] As a result, even if the virus's proteins mutate so as to partially escape vaccine protection, natural immunity can still recognize the virus to a substantial degree.[7]

The IgA antibodies also reduce transmission, neutralizing the virus more than other antibodies during the time when an infected person is most infectious.[8] Finally, these antibodies evolve over time, developing greater "potency and breadth" and greater capacity to respond to future variants and mutations.[9]

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[5] *See* Claude Matuchansky, *Mucosal immunity to SARS-CoV-2: a clinically relevant key to deciphering natural and vaccine-induced defences*, 27(12) CLIN. MICROBIL. INFECT. 1724, 1724 (2021), https://bit.ly/3JVzlzc ("Natural SARS-CoV-2 infection does induce mucosal . . . S-IgA as well as systemic IgG antibody responses.").

[6] *See* Ian Martiszus, *SARS-CoV-2 Vaccines*, *Breakthrough Infections and Lasting Natural Immunity*, CURE-HUB (Aug. 22, 2021), https://bit.ly/3q9iWQl (observing "the broad antibody repertoire generated after a natural infection").

[7] *Id.* ("Antibodies against [the virus's N protein] offer an additional layer of protection for naturally immune individuals. The N protein is reported to have a slower mutation rate than S, which further reduces susceptibility to SARS-CoV-2 variants.").

[8] Delphine Sterlin, *et al.*, *IgA dominates the early neutralizing antibody response to SARS-CoV-2*, SCI. TRANSL. MED., Jan. 2021, at 1, https://bit.ly/3JWyGgO ("IgA contributed to virus neutralization to a greater extent compared with [other antibodies].").

[9] Alice Cho, *et al.*, *Anti-SARS-CoV-2 receptor binding domain antibody evolution after mRNA vaccination*, 600 NATURE 517, 521 (2021), https://go.nature.com/3iNnPdc.

Current COVID-19 vaccines, by contrast, target only the spike protein, are administered through the muscles rather than mucosal surfaces, and thus do "not generate [the] mucosal IgA" antibodies necessary to provide robust protection.[10] As such, vaccination does not prevent "the nasal cavity [from becoming] a reservoir for [SARS-CoV-2] . . . placing patients at risk for reinfection or spread of disease."[11]

From a conceptual standpoint then, because of these biological mechanisms, those who recover from the disease should be *at least* equally resistant to reinfection and transmission as those who receive the vaccine, and likely more so.

II. The Scientific Evidence Overwhelmingly Confirms What Biological Principles Suggest: Natural Immunity Is At Least As Effective As Vaccination When It Comes To Sars-Cov-2.

Scientific testing bears out these expectations. The most recent studies establish that natural immunity provides an efficacy equal or superior to vaccination, against both the original virus and variants.

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[10] Eva Piano Mortari, *et al.*, *Highly-specific memory B cells generation after the 2nd dose of BNT162b2 vaccine compensate for the decline of serum antibodies and absence of mucosal IgA*, MEDRXIV [preprint] (June. 09, 2021) https://bit.ly/3JT2T0H; *see also* CDC, *mRNA Vaccines* (Jan. 4, 2022), https://bit.ly/3uFpd79.

[11] Uday S. Kumar, *et al.*, *Gold-Nanostar-Chitosan-Mediated Delivery of SARS-CoV-2 DNA Vaccine for Respiratory Mucosal Immunization: Development and Proof-of-Principle*, 15 ACS NANO 17582 (2021), https://bit.ly/3K00fG7.

A. Naturally Immune People Exhibit Rates of Infection Comparable to or Lower than Vaccinated People over Longer Periods.

First, contrary to MSU's assertion below, vaccination provides "additional protection" to previously infected individuals, Appellants' Br. at 10–11 (citing record), numerous studies now conclude that natural immunity produces protection against infection comparable to or greater than vaccines. As of October 2021, at least 150 studies affirmed the presence of robust, naturally acquired immunity to COVID-19.[12] Meta-analyses of these studies have shown that natural immunity reduces the risk of infection by 90% or more for upwards of ten months after the original infection, reflecting the full time periods for which data was available.[13]

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[12] *See* Paul Elias Alexander, *150 Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted*, BROWNSTONE.ORG (Oct. 17, 2021), https://bit.ly/3qPwpwy (collecting studies).

[13] CDC, *Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity* (Oct. 29, 2021), https://bit.ly/3wQ0Zdb ("SARS-CoV-2 infection decreased risk of subsequent infection by 80-93% for at least 6-9 months."); N. Kojima, N. K. Shrestha, J. D. Klausner, *A Systematic Review of the Protective Effect of Prior SARS-CoV-2 Infection on Repeat Infection*, 44(4) EVALUATION AND THE HEALTH PROFESSIONS 327, 327 (2021), https://bit.ly/3NzXD48 (finding 90.4% reduction in risk against reinfection); Tawanda Chivese, *et al.*, *The prevalence of adaptive immunity to COVID-19 and reinfection after recovery—a comprehensive systematic review and meta-analysis*, MEDRXIV [preprint] (Dec. 11, 2021), https://bit.ly/3qXFpyQ (finding that "around 90% of people previously infected with SARS-CoV-2 had evidence of immunological memory . . . which was sustained for at least 6-8 months after recovery" and a prevalence of reinfection of 0.2%); Eamon O. Murchu, *et al.*, *Quantifying the risk of SARS-CoV-2 reinfection over time*, 2021 REV. MED. VIROL., May 2021, at 1, https://bit.ly/3iT0tmB (finding that "reinfection was an uncommon event (absolute rate 0%-1.1%) with no study reporting an increase in the risk of reinfection over time" and that "naturally

Another study, completed before the Delta variant became dominant, found that the odds of *any* SARS-CoV-2 infection were 13 times higher for vaccinated individuals than for those with natural immunity.[14] The same study found that vaccinated individuals were 27 times more likely to have a *symptomatic* infection and eight times more likely to be hospitalized than those with natural immunity.[15]

In terms of the duration of the protections, studies have shown that the relative protection against reinfection for the naturally immune stood at 85% at 3–15 months and remained 73% effective after 15 months.[16] Other studies have shown that natural immunity provides robust protection from 6 to 11 months after initial infection, some showing reduced risk of infection by 80–93% for at least 6 to 9 months.[17] Still other studies have shown that the risk of reinfection "remain[s]

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acquired SARS-CoV-2 immunity does not wane for at least 10 months post-infection").

[14] Sivan Gazit, *et al.*, *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, MEDRXIV [preprint] (Aug. 25, 2021), https://bit.ly/3q9isK1.

[15] *Id.*

[16] Victoria Hall, *et al.*, *Effectiveness and durability of protection against future SARS-CoV-2 infection conferred by COVID-19 vaccination and previous infection; findings from the UK SIREN prospective cohort study of healthcare workers March 2020 to September 2021*, MEDRXIV [preprint] at 24 (Dec. 01, 2021), https://bit.ly/3zAz9B7 ("Adjusted Absolute protection against infection" column of Table 3).

[17] CDC, *supra* n.13; Dana Wollins, *COVID-19 Clinician Call*, IDSA (July 17, 2021), https://bit.ly/3f8Lov2 ("Immune responses to SARSCoV2 following natural infection can persist for months (maximum follow-time is ~11 months.");

low for up to *20 months*."[18] The data also suggest that the protection from natural immunity *increases* over time.[19]

By contrast, it is well-understood that the efficacy of protection from current vaccines wanes substantially in a relatively short period of time compared to natural immunity.[20] One study, for example, showed that the Pfizer vaccine's

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World Health Organization, *COVID-19 natural immunity*, WORLD HEALTH ORG. SCIENTIFIC BRIEF (May 10, 2021), https://bit.ly/3n8AmdU (finding that "in most people, immune responses remain robust and protective against reinfection for at least 6-8 months after infection"—8 months being the longest follow up study at that point—and that "robust immunity [persisted] at 6 months post-infection in 95% of subjects under study").

[18] Peter Nordstrom, *Risk of SARS-CoV-2 reinfection and COVID-19 hospitalisation in individuals with natural and hybrid immunity: a retrospective, total population cohort study in Sweden*, The Lancet (March 31, 2022), https://bit.ly/3yQklzE (emphasis added).

[19] Megan M. Sheehan, *et al.*, *Reinfection Rates among Patients who Previously Tested Positive for COVID-19: A Retrospective Cohort Study*, CLIN. INFECT. DIS. (Mar. 15, 2021), https://bit.ly/3fkb5cx ("Protection offered from prior infection was 81.8% . . . and against symptomatic infection was 84.5%. *This protection increased over time*.") (emphasis added).

[20] *See, e.g.*, Hiam Chemaitelly, *et al.*, *Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar*, N. ENGL. J. MED., Dec. 2021, at e83(5), https://bit.ly/3NxTiy9 ("[Vaccine]-induced protection against infection builds rapidly after the first dose, peaks in the first month after the second dose, and then gradually wanes in subsequent months."); Peter Nordström, Marcel Ballin, Anna Nordström, *Effectiveness of Covid-19 Vaccination Against Risk of Symptomatic Infection, Hospitalization, and Death Up to 9 Months: A Swedish Total-Population Cohort Study*, SSRN [preprint] (Oct. 25, 2021), https://bit.ly/3f2IR5F ("Vaccine effectiveness of BNT162b2 against infection waned progressively from 92% . . . at day 15-30 to 47% . . . at day 121-180, and from day 211 and onwards no effectiveness could be detected. . . . The

protection dropped from a peak of 81% at days 14–73 after vaccination to just 65% for days 74 to 144 and a mere 43% after 193 days.[21] This study thus demonstrates that natural immunity provides better protection against infection at the 3–9 month marks than vaccination does at the 2-week to 2.5-month marks. Natural immunity even provides better protection after 15 months than the Pfizer vaccine does from months 2.5 to 4.5. Additional studies reveal similar results.[22]

B. Natural Immunity More Effectively Combats Variants than Vaccination.

Second, natural immunity more effectively guards against COVID-19 variants than vaccination. Recent research into the Omicron variant indicates that

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effectiveness waned slightly slower for mRNA-1273, being estimated to 59% . . . from day 181 and onwards.").

[21] Hall, *supra* n.16, at 22 ("aVE (1-HR)" column of Table 2, "Vaccinated 2 doses" section, rows for days 14–73, 74–133, and >193).

[22] *See, e.g.*, Yair Goldberg, *et al.*, *Protection and waning of natural and hybrid COVID-19 immunity*, MEDRXIV [preprint] (Dec. 05, 2021), https://bit.ly/34lHflp ("Protection from reinfection decreases with time since previous infection, but is, nevertheless, higher than that conferred by vaccination with two doses at a similar time since the last immunity-conferring event."); Ariel Israel *et al.*, *Large-scale study of antibody titer decay following BNT162b2 mRNA vaccine or SARS-CoV-2 infection*, MEDRXIV [preprint] (Aug. 22, 2021), https://bit.ly/3G8pJix ("In vaccinated subjects, antibody titers decreased by up to 40% each subsequent month while in [COVID-recovered individuals] they decreased by less than 5% per month.").

full vaccination—one dose of the Johnson & Johnson vaccine or two doses of Pfizer or Moderna—provides minimal protection against infection.[23]

As such, vaccine efficacy has waned as Omicron became the dominant strand. In fact, one study shows that the Pfizer and Moderna vaccines prove only 6% effective at preventing infection against Omicron for the first two months, their efficacy dropping to -13% for months 2–4, -39% at 4 months, and -42% at 6 months.[24] Another study put those numbers as low as -76.5% for Pfizer and -39.3% for Moderna.[25] These negative efficacies mean vaccination makes people more susceptible to Omicron infection. In other words, vaccinated individuals are *more likely* to be infected than unvaccinated individuals. And once infected, vaccinated

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[23] *See* Sandile Cele, *et al.*, *SARS-CoV-2 omicron has extensive but incomplete escape of Pfizer BNT162b2 elicited neutralization and requires ACE2 for infection*, MEDRXIV [preprint] (Dec. 09, 2021), https://bit.ly/3qZBFNl ("[B]ased on the large number of mutations in the spike protein and elsewhere on the virus . . . [the Omicron] variant will have considerable escape from vaccine elicited immunity. . . . The results we present here with Omicron show much more extensive escape."); *see also* Nicola Davis, Hannah Devlin, and Ian Sample, *Two jabs offer little protection against Omicron infection, UK data shows*, THE GUARDIAN (Dec. 20, 2021), https://bit.ly/3zEOUqB ("Having two doses of a Covid vaccine offers less defence against symptomatic infection from the Omicron variant than with Delta.").

[24] Sarah A. Buchan, *et al.*, *Effectiveness of COVID-19 vaccines against Omicron or Delta infection*, MEDRXIV [preprint] (Jan. 1, 2022), https://bit.ly/3GvDpUZ (Table 2).

[25] Christian Holm Hansen, *et al.*, *Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT 162b2 or mRNA-1273 vaccination series: a Danish cohort study*, MEDRXIV [preprint] (Dec. 23, 2021), https://bit.ly/3Kom4jo (Table).

people "seem to have the same transmission capacity [as] non-vaccinated people."[26] In this way, vaccination provides no reduction in transmission versus Omicron.

The findings on the ineffectiveness of the vaccines in preventing both infection and transmission of Omicron are consistent with the public statements of the Pfizer and Moderna CEOs. Both executives have publicly conceded that two doses of their vaccines do not provide protection against Omicron infection.[27]

By contrast, the protection provided from a previous infection remains robust against Omicron. One study found that the protection for those with natural immunity remained at 61.9% despite the rise in that variant.[28] And interestingly, the same research also showed that protection fell for naturally immune persons

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[26] Javier Del Aguila-Mejia *et al.*, *Secondary Attack Rates, Transmission, Incubation and Serial Interval Periods of first SARS-CoV-2 Omicron variant cases in a northern region of Spain*, RESEARCH SQUARE (Jan. 20, 2022), https://bit.ly/3tQqk4T.

[27] Spencer Kimball, *Pfizer CEO says two Covid vaccine doses aren't 'enough for Omicron'*, CNBC: Health & Science (Jan. 10, 2022), https://www.cnbc.com/2022/01/10/pfizer-ceo-says-two-covid-vaccine-doses-arent-enough-for-omicron.html; Tom Westbrook & Kim Coghill, *Moderna CEO says vaccines likely less effective against Omicron – FT*, Reuters: Healthcare & Pharmaceuticals (Nov. 30, 2021), https://reut.rs/3ITsepH.

[28] Heba Altarawneh, *et al.*, *Protection afforded by prior infection against SARS-CoV-2 reinfection with the Omicron variant*, MEDRXIV [preprint] (Jan. 6, 2022), https://bit.ly/3GvDA2B (Table 3).

who were subsequently vaccinated.[29] This research indicates that vaccination increases the risk of infection for people who have recovered from COVID-19, suggesting the vaccines' negative efficacy affected not just for those that vaccinate but have never been infected but also the recovered and then vaccinated.

Natural immunity has proven more effective than vaccinations against the Delta variant as well. The CDC, for example, has found that "after emergence of the Delta variant and over the course of time, incidence increased sharply in [vaccinated persons without a previous COVID-19 diagnosis], but only slightly among both vaccinated and unvaccinated persons with previously diagnosed COVID-19."[30] This finding is consistent with "early declining of vaccine-induced immunity in many persons."[31] It is also consistent with "recent international studies," which "have also demonstrated increased protection in persons with previous infection, with or without vaccination, relative to vaccination alone."[32]

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[29] *Id*. (Table 3).

[30] Tomás M. León *et al.*, *COVID-19 Cases and Hospitalizations by COVID-19 Vaccination Status and Previous COVID-19 Diagnosis — California and New York, May–November 2021*, CDC, 71 Morbidity and Mortality Weekly Report 4 at 126–27, 130 (Jan. 28, 2022), https://bit.ly/3iWp5ut.

[31] *Id.* at 130.

[32] *Id.*

C. Natural Immunity More Effectively Combats Transmission on Reinfection.

Finally, vaccinated individuals who nevertheless experience a "breakthrough infection" of COVID-19 are more likely to contract the disease again in the future and transmit it to others than naturally immune people who suffer reinfection. Multiple studies have confirmed, for example, that when a vaccinated person contracts COVID-19, the infectiousness of his disease is comparable to that of an unvaccinated individual who has never contracted the disease.[33]

In addition, vaccinated individuals who suffer breakthrough infections are much more likely to be infected with and transmit variants than unvaccinated individuals who have never contracted COVID-19.[34] This increased vulnerability

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[33] *See, e.g.*, Karen K. Riemersma, *et al.*, *Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2-Delta variant*, MEDRXIV [preprint] (Nov. 06, 2021), https://bit.ly/3JVsndK ("[I]nfectious SARS-CoV-2 is found at similar titers in vaccinated and unvaccinated persons when specimen Ct values are low.") (full text); Charlotte B. Acharya, *et al.*, *No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups When Infected with SARS-CoV-2 Delta Variant*, MEDRXIV [preprint] (Oct. 05, 2021), https://bit.ly/3K4dear ("In our study, mean viral loads [a proxy for infectiousness] as measured by Ct-value were similar for large numbers of asymptomatic and symptomatic individuals infected with SARS-Cov-2 during the Delta surge, regardless of vaccine status, age, or gender.").

[34] Venice Servellita, *et al.*, *Predominance of antibody-resistant SARS-CoV-2 variants in vaccine breakthrough cases from the San Francisco Bay Area, Calif.*, NATURE MICROBIOLOGY (Jan. 10, 2022), https://bit.ly/3nsdupZ ("[V]accine breakthrough infections are overrepresented by immunity-evading variants as compared with unvaccinated infections."); Rui Wang, Jiahui Chen, Guo-Wei Wei, *Mechanisms of SARS-CoV-2 Evolution Revealing Vaccine-Resistant Mutations in*

from the vaccines may explain the Delta variant's rise to dominance in the summer of 2021 following widespread vaccinations.

In short, vaccinated individuals are both more likely to contract COVID-19 and to transmit it to others than naturally immune individuals. Indeed, one study showed that naturally immune individuals are as much as *four times* less likely to transmit the disease than vaccinated individuals who contract the disease.[35] And as of January 2022, the CDC did not have a single documented case of reinfection of a naturally immune person transmitting SARS-CoV-2 to another person.[36]

Where reinfections do occur, moreover, they are overwhelmingly asymptomatic, and any symptoms that do manifest are rarely severe.[37]

Europe and America, 12(49) J. PHYS. CHEM. LETT. 11850, 11854-55 (2021), https://bit.ly/3tRR1WK ("[V]accine-resistant mutations correlate strongly with the vaccination rates in Europe and America."); Debra Van Egeren *et al.*, *Risk of rapid evolutionary escape from biomedical interventions targeting SARS-CoV-2 spike protein*, PLOS ONE (April 28, 2021), https://bit.ly/3F6WwDA ("SARS-CoV-2 mutants . . . are expected to exist in high numbers due to neutral genetic variation, and consequently resistance to vaccines or other prophylactics that rely on one or two antibodies for protection can develop quickly.").

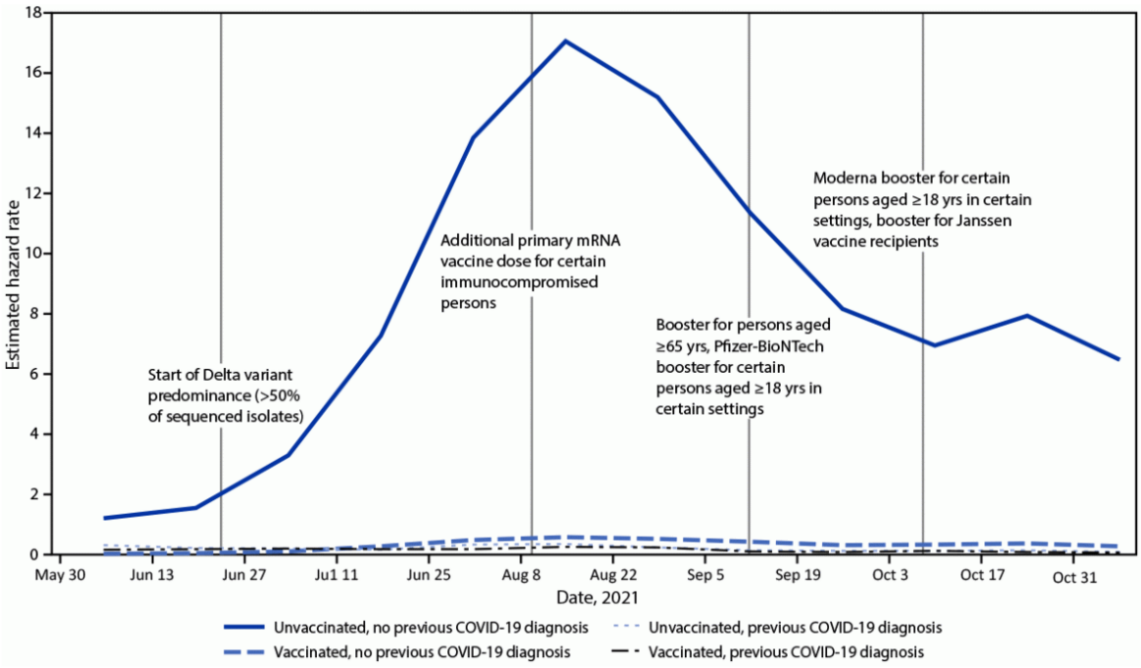
[35] Laith J. Abu-Raddad, *et al.*, *Effect of vaccination and of prior infection on infectiousness of vaccine breakthrough infections and reinfections*, MEDRXIV [preprint] (July 30, 2021), https://bit.ly/33grFXD ("The Ct value was 1.3 . . . cycles higher for [Pfizer] breakthrough infections, 3.2 . . . cycles higher for [Moderna] breakthrough infections, and 4.0 . . . cycles higher for reinfections in unvaccinated individuals.")

[36] Letter of Department of Health and Human Services to Elizabeth Brehm (Nov. 5, 2021), https://bit.ly/3qfHwPD.

[37] CDC, *Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity* (Oct. 29, 2021), https://bit.ly/3Gojis5 ("[A] large proportion of the

The CDC recently released data to this effect:[38]

FIGURE. Incident laboratory-confirmed COVID-19-associated hospitalizations among immunologic cohorts defined by vaccination and previous diagnosis histories — California, May 30–November 13, 2021*,†



CONCLUSION

The district court's order dismissing Plaintiffs' First Amended Complaint should be reversed.

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reinfections reported across the studies were asymptomatic infections"); Megan M. Sheehan, *supra* n.18, at 1883, https://bit.ly/3LyHcDn ("Prior infection in patients with COVID-19 was highly protective against reinfection and symptomatic disease.").

[38] León *et al.*, supra n.29, at 129 (link to "Figure").

Dated: July 12, 2022

Respectfully submitted,

s/ Frederick R. Yarger

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CERTIFICATE OF COMPLIANCE WITH RULE 32(A)

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Dated: July 12, 2022

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on July 12, 2022 a true and correct copy of Brief of Amici Curiae Professor Todd Zywicki and Jeffrey Singer, M.D., in Support of Appellants and Reversal was filed with the Clerk of Court for the United States Court of Appeals for the Sixth Circuit using the CM/ECF filing system and that service upon counsel for the parties will be accomplished using the CM/ECF system.

s/ Frederick R. Yarger
Frederick R. Yarger

APPENDIX A

Cato Institute Comment on COVID-19 Vaccination & Testing ETS (OSHA-2021-0007)

January 17, 2022

Todd Zywicki, Jeffrey A. Singer, and Ilya Shapiro*

The arguments for why this emergency temporary standard (ETS) goes beyond OSHA's statutory authority, violates the major questions and nondelegation doctrines, and has other defects of administrative and constitutional law, have been spelled out *ad nauseum* elsewhere—and indeed are the focus of ongoing litigation that has already reached the Supreme Court.[1] This comment focuses on how arbitrary and capricious the ETS is in ignoring natural immunity and the effects of vaccination on Covid-recovered individuals, as well as on the weakness of the communitarian argument for mandatory vaccination and OSHA's testing-regime alternative.

Universal vaccine mandates are irrational and arbitrary in ignoring naturally acquired immunity from infection and recovery, which has come to be referred to as "natural immunity" in public discussion. This single-minded focus on vaccination as the exclusive means to acquiring some degree of immunity from infection is largely novel. Contrary to conventional belief, states typically do not have "vaccine" requirements for children to attend school or any other purpose; they require evidence of *immunity* to certain viruses, whether acquired by natural infection or vaccination, whether through serological testing that evidences the presence of relevant protective antibodies or evidence of prior history "diagnosed or verified by a health care provider."[2] Virtually all countries in the Western world that impose some form of vaccine passport or mandate recognize natural immunity to Covid as qualifying under the passport program for at least six months post-recovery.[3]

The administrative record in support of the various mandates provide no evidentiary basis for ignoring natural immunity as a suitable exception to any vaccine mandates. As Judge Terry Doughty noted in his decision regarding CMS's conclusory rejection of natural immunity as an exception to its vaccine mandate for health-care workers, "The 'evidence' CMS relied upon in rejecting that alternative is not provided."[4] And Judge Matthew Schelp noted that CMS rejected

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[1] *See, e.g.*, Ilya Shapiro, SCOTUS Correctly Blocks OSHA Vax Mandate, CATO AT LIBERTY (Jan. 13, 2022), https://bit.ly/3FuvndK; Ilya Somin, *Supreme Court Covid Vaccine Mandate Hearing Exposes Biden Administration Overreach*, NBCNEWS.COM (Jan. 7, 2022), https://nbcnews.to/3JQW3sA; Ed Whelan, *Federal Vaccine-Mandate Wars at the Supreme Court*, NATIONAL REVIEW (Jan. 5, 2022), https://bit.ly/3HJWwej; Walter Olson, *Where Does Biden Get the Authority to Mandate Vaccination?*, REASON (Sept. 10, 2021), https://bit.ly/3tapjVk.

[2] The Commonwealth of Virginia, for example, requires a showing of immunity, either by vaccination or natural immunity, not a requirement of vaccination as the only means of establishing immunity. *See* 12 Va. Admin. Code § 5-110-80B (recognizing exception to state vaccine requirement if a student can "demonstrate[]" "by means of a serological testing method appropriate for measuring antibodies against mumps, measles, rubella, or varicella" and for chicken pox, "reliable history of chickenpox disease diagnosed or verified by a health care provider.")

[3] *See* Jennifer Block, *Vaccinating People Who Have Had Covid-19: Why Doesn't Natural Immunity Count in the US?*, 374(8307) BRIT. MED. J. 390, 392 (2021).

[4] *Louisiana v. Becerra*, No. 3:21-CV-03970, 2021 U.S. Dist. LEXIS 229949, at *25 (W.D. La. Nov. 30, 2021).

mandate alternatives for those with natural immunity, "But, elsewhere, [CMS] plainly contradicts itself regarding the value of natural immunity."[5] He further observed, "Such contradictions are tell-tale signs of unlawful agency actions."[6] In characterizing the OSHA mandate as "staggeringly overbroad," the Fifth Circuit noted "a naturally immune unvaccinated worker is presumably at less risk than an unvaccinated worker who has never had the virus."[7] As that court concluded citing this and other examples, "The list goes on, but one constant remains—the Mandate fails almost completely to address, or even respond to, much of this reality and common sense."[8]

If OSHA had reviewed the medical and scientific literature regarding the relative protective efficacy of natural immunity compared to vaccination, it is unlikely that the agency would be successful in establishing a factual basis for forced vaccination of Covid-recovered individuals. A review of the literature indicates the following conclusions regarding natural immunity: (1) it provides protection against infection that is at least equal to and in some instances clearly superior to that provided by some vaccines covered by the OSHA rule, (2) it provides protection against emergent variants that is at least equal to or superior to that of vaccination, (3) it provides protection against transmission that is at least equal to or superior to that of vaccination when "breakthrough" infections arise, (4) although some research suggests that in some instances some Covid-recovered individuals may receive some very small temporary benefit from receiving a partial course of vaccination (one dose), no scientific or medical evidence exists that shows that those with natural immunity receive any benefit at all from a full course of vaccination (*i.e.*, two doses of mRNA vaccine), and (5) the risk of adverse effects, including those that require hospitalization or emergency room treatment, are substantially higher for those with natural immunity than for naïve recipients of vaccination.

Given the trivial—if any—benefit to either the individual or the public from compelled vaccination of Covid-recovered individuals, that evidence of elevated adverse effects requires an especially high standard of proof by regulators to overcome. As the Supreme Court noted in *Washington v. Harper*, in light of the Constitution's elevated protection for the protection of bodily autonomy, any compelled medical treatment must not only be necessary to protect the public but "in the [individual's] medical interest."[9] This admonition was echoed in *Sell v. United States*, where in a case involving forced administration of antipsychotic drugs to enable a criminal defendant to be competent to stand trial, the Court held that a treatment may be compelled if it is "medically appropriate, is unlikely to have side effects that may undermine the fairness of the trial and, taking account of less intrusive alternatives, is necessary to further important governmental trial-related interests."[10] In light of the clear equivalence (or superiority) of natural immunity compared to vaccination in protection against infection and transmission,

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[5] *Missouri v. Biden*, No. 4:21-cv-01329-MTS, 2021 U.S. Dist. LEXIS 227410, at *23 (E.D. Mo. Nov. 29, 2021). The court observed this blithe rejection of the protective efficacy of natural immunity came "despite an intense public debate and a trove of scientific data on the strength and durability of natural immunity from COVID-19—alone and compared to vaccine-induced immunity." *Id.* at *23 n.20.

[6] *Id.*

[7] *BST Holdings v. OSHA*, No. 21-60845, 2021 U.S. App. LEXIS 33698, at *16 (5th Cir. Nov. 12, 2021).

[8] *Id.*

[9] *Washington v. Harper*, 494 U.S. 210, 222 (1990).

[10] *Sell v. United States*, 539 U.S. 166, 179 (2003).

the lack of any demonstrable benefit to Covid-recovered individuals from a full course of vaccination, and the well-established evidence of higher elevated adverse effects for vaccination of Covid-recovered individuals, any failure to recognize natural immunity as qualifying under any vaccine-mandate regulation would render that rule arbitrary and unconstitutional.

I. Natural Immunity Provides an Efficacy Equal to Or Superior to Vaccination

It is now beyond doubt that natural immunity provides robust and durable protection against future SARS-CoV-2 infection that is at least equivalent to and in some instances unquestionably superior to that of some vaccines recognized under the OSHA rule. The evidence is ample; only a few representative studies and evidence will be discussed here.

At their peak level of protection immediately following full vaccination and against the original SARS-CoV-2 variant, the mRNA vaccines available in the United States were observed to provide strong protection for a few months against infection with the SARS-CoV-2 variant.

However, this initial protection is not uniform. The OSHA rule also recognizes the one-dose Janssen/Johnson & Johnson vaccine as qualifying under its vaccine mandate rule. But *even at the outset* in approved clinical trial, that vaccine was reported to have an efficacy against infection of only 66.3%,far below *any* estimates of protection provided by natural immunity.[11] There is not a single reported study or any evidence that indicates that the one-dose Johnson & Johnson vaccine provides protection against infection and transmission that is superior to natural immunity. This classification, therefore, is completely lacking in any factual basis and contrary to all extant evidence—which alone suffices to render the OSHA rule arbitrary and unfounded.

According to a survey by Dr. Paul Alexander, as of October 2021 there were at least 140 studies that affirmed the presence of robust naturally acquired immunity to Covid-19, including studies drawn from around the world and multiple different contexts.[12] At least three major meta-analyses of studies have been published that affirm the conclusion that natural immunity provides a level of protection at least equivalent to that of the best vaccinations. In a meta-analysis that included over 10 million total participants, Kojima and Klausner found that natural immunity provided 90.4% risk reduction against reinfection for at least 10 months.[13] Another meta-analysis by Chivese, et al., that surveyed evidence involving 12 million individuals found a "low risk of reinfection," that "around 90% of people previously infected with SARS-CoV-2 had evidence of immunological memory . . . which was sustained for at least 6-8 months after recovery," and prevalence of reinfection was 0.2%.[14] Another meta-analysis by Murchu, et al., of studies involving 615,000 individuals concluded that "reinfection was an uncommon event (absolute rate 0%-1.1%) with no study reporting an increased in the risk of reinfection over

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[11] *Johnson & Johnson's Janssen COVID-19 Vaccine Overview and Safety*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Dec. 28, 2021), https://bit.ly/3n7rbum.

[12] *See* Paul Elias Alexander, *140 Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted*, BROWNSTONE.ORG (Oct. 17, 2021), https://bit.ly/3f2EaZB.

[13] N. Kojima, N. K. Shrestha, J. D. Klausner, *A Systematic Review of the Protective Effect of Prior SARS-CoV-2 Infection on Repeat Infection*, 44(4) EVALUATION AND THE HEALTH PROFESSIONS 327, 327 (2021).

[14] Tawanda Chivese, et al., *The Prevalence of Adaptive Immunity to COVID-19 and Reinfection after Recovery—A Comprehensive Systematic Review and Meta-Analysis*, MEDRXIV [preprint] (Dec. 11, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3qXFpyQ.

time."[15] The Murchu meta-study concluded that "naturally acquired SAWS-CoV-2 immunity does not wane for at least 10 months post-infection."[16]

Notably, all of these meta-analyses are conditioned by the recurrent phrase "at least," which reflects the simple limits of the fact that studies at that point only had followup periods that reflected that duration; subsequent studies involving longer followup periods have demonstrated that natural immunity remains robust and durable for a period of time well beyond that time, having now been documented for periods extending beyond one year. For example, a recent UK study by Hall, et al., of UK healthcare workers that included some who had been vaccinated to those who had natural immunity found that while the protection provided by the Pfizer vaccine declined rapidly from a peak of 81% VE protection for days 14-73, to 65% at days 74-133, and a mere 43% VE beyond 193 days, the relative protection against reinfection for those with natural immunity who remained unvaccinated stood at 85% at *3-9 months* and remained 73% effect at *greater than 15 months*.[17] In short, the protection provided by natural immunity after *3-9 months exceeded* that of vaccination at days 14-73 and the protection provided by natural immunity at 15 months following original infection was found to exceed that of the protection provided by a full course of Pfizer vaccination at 74-133 days (approximately 2-1/2 to 4-1/2 months).

A recent paper by Goldberg, et al., using Israeli data, also found significantly higher waning of protection from infection for those vaccinated compared to those with natural immunity.[18] Using a metric of "person days" the authors found that for naïve vaccinated individuals, protection against infection waned rapidly from 21.1 per 100,000 person days for persons vaccinated in the fist two months to 88.9 for those vaccinated more than six months ago. For those with natural immunity (who remained unvaccinated) they reported 10.5 risk-days for those previously infected *4-6 months ago* to 30.2 for those previously infected *over a year ago*. In short, the protection against subsequent infection provided by natural immunity at 12+ months was reported to be approximately equivalent to that of vaccination at approximately 3 months.

OSHA's refusal to address this compelling evidence of the protective effect of natural immunity is especially striking in light of the fact that this evidence is well-known to qualified health officials within the government itself. For example, in a CDC/IDSA clinician call conducted on July 17, 2021, Dana Wollins, Vice President of IDSA, reported that as of that early date there were already several studies that showed that immune responses to SARS-CoV-2 persisted for at least 11 months (the maximum follow-up time at that point).[19] A scientific brief by the World Health Organization published on May 10, 2021, similarly concluded that "in most

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[15] Eamon O Murchu, et al., *Quantifying the Risk of SARS-CoV-2 Reinfection Over Time*, 2021 REV. MED. VIROL., May 2021, at 1.

[16] *Id.* at 7.

[17] Victoria Hall, et al., *Effectiveness and Durability of Protection against Future SARS-CoV-2 Infection Conferred by COVID-19 Vaccination and Previous Infection; Findings from the UK SIREN Prospective Cohort Study of Healthcare Workers March 2020 to September 2021*, MEDRXIV [preprint] (Dec. 01, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3zAz9B7. This study is considered particularly important because of high level of exposure and monitoring of healthcare workers.

[18] Yair Goldberg, et al., *Protection and Waning of Natural and Hybrid COVID-19 Immunity*, MEDRXIV [preprint] (Dec. 05, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/34lHflp.

[19] Dana Wollins, *COVID-19 Clinician Call*, IDSA (July 17, 2021), https://bit.ly/3f8Lov2.

people immune responses remain robust and protection against reinfection for at least 6-8 months after infection" (8 months being the longest follow up study at that point) and that robust cellular immunity was found in 95% of subjects for at least six months following infection.[20]

Of particular relevance, in an October "Science Brief" this year, the CDC surveyed existing research on the protective efficacy of natural immunity.[21] The CDC survey concluded that the evidence at that time reported that prior SARS-CoV-2 infection "decreased risk of subsequent infection by 80-93% for at least 6-9 months."[22] For those with demonstrated evidence of seroconversion of anti-N and anti-S antibodies following infection the protective effect was even higher (89-93%). The studies had a follow-up period of a mean or median 7 months up to 12 months post-infection. Three studies that included sub-analysis to assess whether protection waned over time, "none of these found a decline in protection within the follow-up period." Overall, the CDC reported, "SARS-CoV-2 infection induces a robust humoral and cellular immune response."[23] In fact, some studies have found that protection from natural immunity actually *increases* over time.[24]

In contrast to this record, it is now well-understood that the efficacy of protection from the current generation of vaccines wanes substantially in a relatively short period of time compared to natural immunity.[25] One study of antibodies decay found that in vaccinated individuals, antibodies titers decreased by up to 40% each month following initial vaccination while antibodies declined by less than 5% per month for those with natural immunity.[26] It has been well-established in multiple clinical studies, including those mentioned above, that although protection against severe disease persists for some time for those vaccinated, that protection, especially against asymptomatic infection, wanes dramatically within a few months. A study from Sweden even *before* the spread of the Omicron variant suggested that by approximately eight months following vaccination, vaccine efficacy may actually turn negative relative to all unvaccinated individuals.[27] This waning effect appears to be especially pronounced among the one-dose Janssen/Johnson & Johnson vaccine.[28] This rapid waning of vaccine effectiveness against infection is the foundation of the recent recommendation for booster shots within 6 months of initial vaccination. As Judge Doughty noted, it is difficult to simultaneously assert that

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[20] *COVID-19 Natural Immunity*, WORLD HEALTH ORG. SCIENTIFIC BRIEF (May 10, 2021), https://bit.ly/3n8AmdU.

[21] *Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Oct. 29, 2021), https://bit.ly/3q4AQUg.

[22] *Id.*

[23] *Id.*

[24] *See* Megan M. Sheehan, et al., *Reinfection Rates among Patients who Previously Tested Positive for COVID-19: A Retrospective Cohort Study*, CLIN. INFECT. DIS. (Mar. 15, 2021), https://bit.ly/3fkb5cx.

[25] Hiam Chemaitelly, et al., *Waning of BNT162b2 Vaccine Protection against SARS-CoV-2 Infection in Qatar*, N ENGL J MED, Dec. 2021, at e83(5) (reporting VE of about 20% by around five months after vaccination).

[26] Ariel Israel et al., *Large-scale Study of Antibody Titer Decay following BNT162b2 mRNA Vaccine or SARS-CoV-2 Infection*, MEDRXIV [preprint] (Aug. 22, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3G8pJix.

[27] Peter Nordström, Marcel Ballin, Anna Nordström, *Effectiveness of Covid-19 Vaccination Against Risk of Symptomatic Infection, Hospitalization, and Death Up to 9 Months: A Swedish Total-Population Cohort Study*, SSRN [preprint] (Oct. 25, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3f2IR5F.

[28] Barbara A. Cohn, et al., *SARS-CoV-2 Vaccine Protection and Deaths among US Veterans during 2021* SCIENCE (Nov. 4, 2021), https://bit.ly/3eZSxy1.

vaccination provides protection against infection while simultaneously recommending booster just six months after being "fully vaccinated."[29]

An important article from last summer by Gaziz, et al., compared the relative protection provided by natural immunity versus vaccination after the Delta variant became dominant.[30] The authors found that the odds ratio of any infection was 13 times higher for vaccination than natural immunity, the odds of symptomatic infection was 27 times higher, and the odds of hospitalization was 8 times higher.

Moreover, intramuscular vaccination fails to produce mucosal IgA antibodies that are necessary to provide robust and durable protection against infection.[31] This absence of mucosal immunity produced by vaccination means "the nasal cavity may become a reservoir for SC2 in the absence of mucosal immunity, placing patients at risk for reinfection or spread of disease to others."[32] To the extent that vaccination produces neutralizing IgA antibodies, evidence shows those decline rapidly following vaccination.[33] In addition to providing important protection against initial infection, the presence of mucosal immunity is important in subsequent transmission because research finds that in the first week after symptom onset—when the patient is most infectious—the presence of IgA antibodies is more correlated with neutralization of SARS-CoV-2 than circulating IgM or IgG antibodies.[34] Naturally acquired immunity, by contrast, produces robust and durable IgA mucosal immunity.[35]

II. Natural Immunity Provides at Least Equivalent Protection Against Variants

Natural immunity also provides protection against variants that is at least equivalent or superior to that of current generation vaccines. Recent research with respect to the efficacy of the vaccines in providing protection against the omicron variant indicates that the current definition

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[29] *Louisiana*, 2021 U.S. Dist. LEXIS 229949, at *26.

[30] Sivan Gazit, et al., *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections*, MEDRXIV [preprint] (Aug. 25, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3q9isK1.

[31] Eva Piano Mortari, et al., *Highly-Specific Memory B Cells Generation after the 2nd Dose of BNT162b2 Vaccine Compensate for the Decline of Serum Antibodies and Absence of Mucosal IgA*, MEDRXIV [preprint] (June. 09, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3JT2T0H ("Most importantly, the vaccine triggers a serological IgA response, but does not generate mucosal IgA. The lack of specific IgA strategically located at the virus site of entrance explains why the vaccine does not induce sterilizing immunity.").

[32] Uday S Kumar, et al., *Gold-Nanostar-Chitosan-Mediated Delivery of SARS-DoV-2 DNA Vaccine for Respieratory Mucosal Immunication:Development and Proof-of-Principle*, 15 ACS NANO 17582–17601 (2021), https://bit.ly/32YP9ks.

[33] Adam V. Wisnewski, et al., *Humoan IgG and IgA responses to COVID-19 mRNA Vaccines*, PLOS ONE (June 16, 2021), https://bit.ly/3zDf39b.

[34] Delphine Sterlin, et al., *IgA dominates the early neutralizing antibody response to SARS-CoV-2*, SCI. TRANSL. MED., Jan. 2021, at 1.

[35] Claude Matuchansky, *Mucosal Immunity to SARS-CoV-2: A Clinically Relevant Key to Deciphering Natural and Vaccine-Induced Defences*, 27(12) CLIN. MICROBIL. INFECT. 1724, 1724 (2021), ("Natural SARS-CoV-2 infection does induce mucosal (e.g., in saliva, nasal swab/wash or BAL fluid) S-IgA as well as systemic IgG antibody responses."); Mangalakumari Jeyanathan, et al., *Immunological Considerations for COVD-19 Vaccine Strategies*, NAT. REV. IMMUNOL., Sept. 2020, at 5 (noting that the "parenternal vaccination" approach of current vaccines "is unable to effectively induce mucosal IgA antibodies").

of "fully vaccinated" provided by the OSHA rule (one dose of J&J or two doses of Pfizer or Moderna) provides minimal protection against infection from the omicron variant.[36] This suggests that the current OSHA rule that is under consideration—which refers to an existing understanding of "fully vaccinated"—is *already obsolete* in light of changes in the evolutionary trajectory of the virus. There is no rational basis for issuing a rule that requires a medical treatment that would be ineffective against the very pathogen toward which the rule is directed.

Indeed, evidence to date strongly indicates that not only is the two-dose regime mandated by the OSHA rule ineffective, but that it actually provides *negative* vaccine efficacy against the Omicron variant. According to a clinical study in Toronto, two doses of the Pfizer or Moderna vaccines provides only 6% efficacy against Omicron in the first two months, far below the minimum level necessary for FDA approval.[37] Protection falls to -13% efficacy at 2-4 months, -39% at 4 months, and -42% at 6 months after full vaccination as defined by the rule. (Those are all *negative* efficacies, meaning vaccination makes people *more susceptible* to Omicron. Similarly, a study from Denmark found that vaccine efficacy after three months was an extraordinary -76.5% for Pfizer and -39.3% for Moderna.[38]

In contrast to this complete collapse of protection from two doses of the vaccines, the protection afforded by naturally acquired immunity has held up substantially better. Research by Altarawneh, et al., estimated the efficacy of protection from naturally acquired immunity as 61.9%, which *fell* to 55.9% among those who were subsequently vaccinated—indicating that even among those with natural immunity the vaccines provided negative protection.[39] The Omicron outbreak, for which natural immunity continues to provide effective protection while vaccination manifestly do not, illustrates the irrationality of the government's regulatory posture.

Although the long-term efficacy of natural immunity in providing protection against Omicron and future variants relative to vaccination is unknown, evidence with respect to earlier variants makes clear that natural immunity provides protection at least equivalent if not superior to vaccination. This is not surprising. Unlike the vaccines, which are designed to narrowly target the spike protein of the now-extinct original wild-type variant, natural immunity recognizes the full array of proteins carried by the virus. As a result, even if the spike protein mutates so as to partially escape vaccine protection, natural immunity can still recognize the virus to a substantial effect.[40] Moreover, while vaccines by design produce only spike-protein antibodies and do not

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[36] Sandile Cele, et al., *SARS-CoV-2 Omicron Has Extensive but Incomplete Escape of Pfizer BNT162b2 Elicited Neutralization and Requires ACE2 for Infection*, MEDRXIV [preprint] (Dec. 09, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3qZBFNl; *see also* Nicola Davis, Hannah Devlin, and Ian Sample, *Two Jabs Offer Little Protection Against Omicron Infection, UK Data Shows*, THE GUARDIAN (Dec. 20, 2021), https://bit.ly/3zEOUqB.

[37] Sarah A. Buchan, et al., *Effectiveness of COVID-19 vaccines against Omicron or Delta infection*, MEDRXIV [preprint] (Jan. 1, 2022) [accessed Jan. 11, 2022], *available at* https://bit.ly/3GvDpUZ.

[38] Christian Holm Hansen, et al., *Vaccine Effectiveness against SARS-CoV-2 Infection with the Omicron or Delta Variants Following a Two-Dose or Booster BNT 162b2 or mRNA-1273 Vaccination Series: A Danish Cohort Study*, MEDRXIV [preprint] (Dec. 23, 2021) [accessed Jan. 11, 2022], *available at* https://bit.ly/3Kom4jo.

[39] Heba Altarawneh, et al., *Protection Afforded by Prior Infection against SARS-CoV-2 Reinfection with the Omicron Variant*, MEDRXIV [preprint] (Jan. 6, 2022) [accessed Jan. 11, 2022], *available at* https://bit.ly/3GvDA2B. Moreover, the estimated level of protection provided by natural immunity also exceeded the level of protection provided by vaccines immediately following their third dose, as found in the Toronto and Denmark studies.

[40] Ian Martiszus, *SARS-CoV-2 Vaccines, Breakthrough Infections and Lasting Natural Immunity*, CURE-HUB (Aug. 22, 2021), https://bit.ly/3q9iWQl.

produce nucleocapsid antibodies, a substantial majority of those who experience natural infection do produce detectable anti-nucleocapsid antibodies following natural infection.[41]

In addition, once produced in response to an infection, antibodies produced by natural infection continue to evolve over time, thereby developing greater "potency and breadth" over time, building greater capacity to respond to future variants and mutations.[42] Antibodies produced by vaccination, by contrast, reach their full potential soon after the second shot, but thereafter remain static with respect to their breadth and potency, then decline rapidly in quantity, as discussed above.

This theoretical model has been confirmed in clinical studies, which have found that compared to the alpha variant, natural immunity showed no reduction in protection against the Delta variant as compared to vaccination which found a 1.9-times increased odds of infection.[43]

III. Vaccine-Breakthrough Infections Are More Infectious than Natural-Immunity Reinfections

In addition to the broad, durable protection against infection that natural immunity provides, reinfections have been established to be much less infectious than vaccine-breakthrough infections.

Significant evidence has confirmed that, contingent on infection, vaccine-breakthrough infections carry a viral load (a proxy for infectiousness) that is comparable to that of an unvaccinated, unimmune individual. The high viral load associated with vaccine breakthrough infections has been understood since the large outbreak among vaccinated individuals in Barstable, Massachusetts this summer.[44] Subsequent studies have confirmed this finding.[45] Shedding of virus is also comparable, or even slightly higher, among vaccinated individuals who suffer breakthrough infections when compared to unvaccinated, unimmune individuals.[46]

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[41] Niamh Allen, et al., *Serological Markers of SARS-CoV-2 Infection; Anti-Nucleocapsid Antibody Positivity May Not be the Ideal Marker of Natural Infection in Vaccinated Individuals*, 83(4) J. INFECT. e9, e9 (2021). Notably, seroconversion of anti-Nucleocapsid antibodies following vaccine breakthrough infections was much smaller than for natural infection. *Id.*

[42] Alice Cho, et al., *Anti-SARS-CoV-2 Receptor Binding Domain Antibody Evolution after mRNA Vaccination*, 600 NATURE 517, 521 (2021).

[43] Stijn P. Andeweg, et al., *Increased Risk of Infection with SARS-CoV-2 Beta, Gamma, and Delta Variant Compared to Alpha Variant in Vaccinated Individuals*, MEDRXIV [preprint] (Nov. 24, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3JSnYrZ. The study also examined protective efficacy against the Beta and Gamma variants and also found greater protection from previous infection relative to full vaccination.

[44] Catherine M. Brown, et al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with large Public Gatherings, Barnstable County Massachusetts,* 70(31) MMWR MORB. MORTAL WKLY REP 1059, 1059–61 (2021).

[45] *See generally* Karen K. Riemersma, et al., *Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2-delta variant*, MEDRXIV [preprint] (Nov. 06, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3JVsndK; Charlotte B. Acharya, et al., *No Significant Difference in Viral Load Between Vaccinated and Unvaccinated, Asymptomatic and Symptomatic Groups When Infected with SARS-CoV-2 Delta Variant*, MEDRXIV [preprint] (Oct. 05, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3K4dear.

[46] Kasen K. Riemersma, et al., *Shedding of Infection SARS-CoV-2 Virus Despite Vaccination*, MEDRXIV [preprint] (Nov. 06, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3nazntB.

In addition, vaccinated individuals who suffer breakthrough infections are much more likely to be infected with and transmit antibody-resistant viral variants (such as the Delta variant) than unvaccinated, unimmune individuals. Thus, while vaccinated and unvaccinated, unimmune individuals transit comparable viral loads when infected with the same variant, the *average* viral load associated with a vaccine-breakthrough infection was found to be higher than unvaccinated, unimmune individuals as a result of the tendency for vaccinated individuals to contract and transmit variants that carried higher viral load.[47] As a result, it appears that widespread vaccine-breakthrough infections during a period of mass vaccination in an ongoing pandemic were predominantly responsible for the rapid rise to dominance of the Delta variant in the United States and abroad last spring and summer.[48] This period of multiple and rapid emergent mutations and variants contrast to the first 11 months of the pandemic, which have been characterized as a period of "relative evolutionary stasis" that was destabilized by the "changing immune profile of the human population" following the introduction of vaccines.[49]

In contrast to these findings of high viral load and shedding by vaccinated individuals who suffer breakthrough infections, natural-immunity reinfections (when they occur) carry significantly lower viral load than primary infections or breakthrough infections of vaccinated individuals. According to a study by Abu-Raddad, while infectiousness associated with vaccine-breakthrough infections for the Pfizer vaccine was comparable to that of unvaccinated, unimmune individuals, the infectiousness of breakthrough infections for individuals with naturally acquired immunity was almost four times lower, as measured by Ct value.[50] When reinfection cases occur they are overwhelmingly asymptomatic and even when symptoms occur they are rarely severe.[51] According to the response of the Department of Health and Human Services to a FOIA request, the CDC does not have a single documented case of a reinfection of a naturally immune person producing transmission of SARS-CoV-2 to another person.[52]

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[47] *See* Venice Servellita, et al., *Predominance of Antibody-Resistant SARS-CoV-2 Variants in Vaccine Breakthrough Cases from the San Francisco Bay Area, Calif.*, NATURE MICROBIOLOGY (Jan. 10, 2022), https://bit.ly/3nsdupZ.

[48] Rui Wang, Jiahui Chen, Guo-Wei Wei, *Mechanisms of SARS-CoV-2 Evolution Revealing Vaccine-Resistant Mutations in Europe and America*, 12(49) J. PHYS. CHEM. LETT. 11850, 11854-55 (2021); *See also* Debra Van Egeren et al., *Risk of Rapid Evolutionary Escape from Biomedical Interventions Targeting SARS-CoV-2 Spike Protein*, PLOS ONE (April 28, 2021), https://bit.ly/3F6WwDA.

[49] William T. Harvey, et al., *SARS-CoV-2 Variants, Spike Mutations and Immune Escape*, 19 NATURAL REVIEW MICROBIOLOGY 409, 409 (2021).

[50] Laith J. Abu-Raddad, et al., *Effect of Vaccination and of Prior Infection on Infectiousness of Vaccine Breakthrough Infections and Reinfections*, MEDRXIV [preprint] (July 30, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/33grFXD.

[51] *Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity*, CENTERS FOR DISEASE CONTROL AND PREVENTION (Oct. 29, 2021), https://bit.ly/3Gojis5 ("a large proportion of the reinfections reported across the studies were asymptomatic infections"); Megan M. Sheehan, et al., *Reinfection Rates Among Patients Who Previously Tested Positive for Coronavirus Disease 2019: A Retrospective Cohort*, 73(10) CLINICAL INFECTIOUS DISEASES 1882, 1883 (2021).

[52] Letter of Department of Health and Human Services to Elizabeth Brehm (Nov. 5, 2021), *available at* https://bit.ly/3qfHwPD.

IV. Full Vaccination of Covid-Recovered Individuals Imposes Elevated Risk of Adverse Side Effects and Is Medically Unnecessary

Vaccination of Covid-recovered individuals "represent a unique population segment with distinct risk/benefit considerations and a narrower therapeutic window than their COVID-naïve counterparts."[53] This unique tradeoff reflects several considerations: (1) the small incremental benefit provided to Covid-recovered individuals from vaccination on top of natural immunity, (2) elevated risk of adverse side-effects, including serious adverse effects, and (3) a complete absence of evidence to support a full course of vaccination (i.e., two doses of vaccination) as opposed to a potential benefit from one dose. It is especially important that OSHA consider this clinical evidence as part of its rulemaking, because Covid-recovered individuals were specifically excluded from the vaccine's clinical trials. Accordingly, no evidence was produced with respect to the safety or efficacy of vaccination on this population.

A peer-reviewed meta-analysis of studies by Shenai, et al., investigating the potential benefits of vaccination for COVID-recovered individuals concluded that "while there may be some incremental protection to vaccination in COVID-recovered individuals, the absolute magnitude of that protection is dramatically lower compared to that experienced by COVID-naïve individuals."[54] This minimal absolute benefit stems from the high baseline degree of protection afforded by natural immunity, so that even a positive odds ratio might reflect an extremely high level of protection under either scenario. The authors estimated that it would require injection of 218 individuals with natural immunity to prevent one SARS-CoV-2 infection of any type (including asymptomatic infection), compared to 6.5 COVID-naïve individuals, a 33.5-fold difference.

Vaccination not only provides minimal benefit to individuals with natural immunity, it is accompanied by a significantly higher rate of adverse events—including serious adverse effects—for Covid-recovered individuals compared to the population at large. For example, a study published in *Nature Scientific Reports* in August found that 6.8% of Covid-recovered individuals who received a dose of mRNA vaccine suffered severe side-effect that required medical attention such as hospitalization or emergency room treatment, compared to only 0.6% of Covid-naïve individuals after the first shot and zero after the second shot.[55] A study published in *JAMA Internal Medicine* reported 4.59-fold higher risk of adverse effects associated with the first shot for Covid-recovered individuals compared to Covid-naïve population and an addition 0.60-fold increased risk from the second shot.[56] Mathioudakis, et al., reported not only increased risk of any side effect from vaccination of Covid-recovered individuals, but a 1.56-fold increased risk of side effects leading to hospital care.[57] Multiple other studies have uniformly found

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[53] Mahesh B Shenai, et al., *Equivalency of Protection From Natural Immunity in COVID-19 Recovered Versus Fully Vaccinated Persons: A Systematic Review and Pooled Analysis*, CUREUS J. OF MED. SCI., Oct. 2021, at 15.

[54] *Id.*

[55] Shai Efrat, et al., *Safety and Humoral Responses to BNT162b2 mRNA Vaccination for SARS-CoV-2 Previously Infected and Naïve populations*, NATURE SCIENTIFIC REPORTS, Aug. 2021, at 1–2, 5.

[56] Amanda K. Debes, et al., *Association of Vaccine Type and Prior SARS-CoV-2Infection With Symptoms and Antibody Measurements Following Vaccination Among Health Care Workers*, 181(12) JAMA INTERNAL MED. 1660, 1661 (2021).

[57] Alexander G. Mathioudakis, et al., *Self-Reported Real-World Safety and Reactogenicity of COVID-19 Vaccines: A Vaccine Recipient Survey*, LIFE, March 2021, at 3.

evidence of higher elevated risk of adverse events from vaccination of Covid-recovered individuals compared to the baseline risk of those without prior infection.[58] We have located no studies that find no relative difference in the frequency of adverse events for vaccination of Covid-recovered individuals versus Covid-naïve.

In addition, the OSHA rule requires all employees to be "fully vaccinated," meaning one dose of the Johnson & Johnson vaccine or two doses of mRNA vaccines (Pfizer/Moderna), regardless of prior immunity status. There appears to be no valid medical basis for requiring any Covid-recovered individual to receive a full course of Covid vaccination. Indeed, throughout Europe, Israel, and elsewhere, while Covid-naïve individuals are considered "fully vaccinated" only after receiving two doses of vaccine, those with natural immunity have been required to receive only one shot. This reflects both the elevated protection provided by natural immunity as well as the elevated risk of side effects associated with vaccinating Covid-recovered individuals. Some studies have found some potential benefit to some Covid-recovered individuals under some circumstances from receipt of one dose of vaccine, but no study that we have located has found any additional benefit is provided by requiring a *second* shot of vaccine for a Covid-recovered individual.[59] Given the absence of any evidence to support full vaccination of Covid-recovered individuals, and ample evidence that a second shot provides no discernible benefit but still carries risk of side-effects, it is irrational for OSHA to mandate full vaccination of Covid-recovered individuals without taking into account the relative risks and benefits of doing so.

V. The Relevance of Natural Immunity in Protection Against Infection and Transmission Has Been Recognized by Several Courts Outside the Context of Vaccine Mandates

The importance of natural immunity in protecting against Covid reinfection has been noted by courts outside the specific context of the challenges to the Biden Administration mandates. For example, several courts have recognized the protective effect of natural immunity in the context of petitions for early "compassionate release" from prison by inmates who are potentially elevated risk from serious symptoms or death if they contract Covid.[60] Most recently,

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[58] *See* Rajneesh K. Joshi, *Higher Incidence of Reported Adverse Events Following Immunisation (AEFI) after First Dose of COVID-19 Vaccine Among Previously Infected Health Care Workers*, 77 MED. J. ARMED FORCES INDIA S505, S505–07 (2021); Florian Krammer, et al., *Antibody Responses in Seropositive Persons after a Single Dose of SARS-CoV-2 mRNA Vaccine*, 384(14) N. ENGL J. MED 1372, 1372–74 (2021); Rachael Kathleen Raw, et al., *Previous COVID-19infection, but not Long-COVID, Is Associated with Increased Adverse Events Following BNT162b2/Pfizer Vaccination*, 83 J. INFECT. 401, 401–03 (2021); Marie Tré-Hardy, et al., *Reactogenicity, Safety and Antibody Response, after One and Two Doses of mRNA-1273 in Seronegative and Seropositive Healthcare Workers*, 83(2) J. INFECT. 254, 254 (2021); Cristina Menni, et al., *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(7) LANCET INFECT. DIS. 939, 943–46 (2021).

[59] *See* Daniel Lozano-Ojalvo, et al., *Differential Effects of the Second SARS-CoV-2 mRNAvaccine Dose on T Cell Immunity in Naive and COVID-19 Recovered Individuals*, CELL REPORTS, Aug. 2021, at 2; Shai Efrati, et al., *Safety and Humoral Responses to BNT162b2 mRNA Vaccination of SARS-CoV-2 Previously Infected and Naive Populations*, SCIENTIFIC REPORTS, Aug. 2021, at 4–5; Krammer, et al., *supra* n. 58, at 137–74; Tré-Hardy, et al., *supra* n. 58, at 254.

[60] *See United States v. Tuitele*, No. 13-00593 JMS, 2021 U.S. Dist. LEXIS 1753, at *10–11 (D. Haw., Jan. 6, 2021) ("In short, it is beyond question that Defendant's age coupled with his pre-existing medical conditions places him at a greatly increased risk of serious injury, or death, should he contract COVID-19. But Defendant has contracted COVID-19 and recovered, a fact that counsels heavily against a finding of extraordinary or compelling reasons to

the Third Circuit rejected one such petition, noting that the petitioner in that case filed records showing that he already had contracted and recovered from Covid in December 2020, and thus his risk of getting sick is "no longer 'imminent'—it has already occurred."[61] Because he therefore is protected by natural immunity, he could not show "that continued exposure to COVID-19 still puts him at imminent risk of serious physical injury."

VI. The Communitarian Argument for Mandatory Vaccination Breaks Down

If vaccine efficacy against COVID-19 was suboptimal before, the vaccines are even less efficacious with the advent of the Omicron variant, now replacing Delta as the dominant pandemic variant.[62] The data suggest the 2-dose regimen of the mRNA vaccines provide only 30-40 precent protection against symptomatic illness.[63] A booster may raise such protection to 70 percent.[64] Lab results indicate the neutralizing antibodies in fully vaccinated individuals are less effective against the Omicron variant.[65] Recent evidence suggests the Johnson & Johnson vaccine provides "virtually no protection" against the Omicron variant.[66] On December 16, 2021 the Centers for Disease Control and Prevention updated its vaccine recommendations in accordance with the new evidence of the lack of efficacy the Johnson & Johnson vaccine. The CDC recommended individuals get vaccinated with the mRNA vaccine, but that the Johnson & Johnson vaccine remain available for those who are "unable or unwilling to receive an mRNA vaccine."[67] (OSHA accepts receiving a single dose of the Johnson & Johnson vaccine as complying with its rule despite this new evidence.)

Even before the emergence of the Omicron variant, leading public health authorities were recognizing the irrationality of categorically distinguishing between vaccinated and unvaccinated individuals in terms of their relative risk of infection and transmission of Covid. The evidence is

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warrant release…. Taking into account Defendant's age, risk factors, and that he has already contracted COVID-19, the court concludes that she has failed to demonstrate that extraordinary and compelling reasons warrant compassionate release."); *United States v. Carter*, No. 15-228-1, 2021 U.S. Dist. LEXIS 23229, at *2–*3 (E.D. Pa. Feb. 8, 2021) ("Unfortunately, Mr. Carter contracted COVID in late September of 2020 after this motion was filed…. The available scientific evidence suggests that there is a protective development of antibodies among recovered COVID patients, lowering future risk."); *United States v. Saunders*, 2:07-cr-00294, 2021 U.S. Dist. LEXIS 118649, at *13 –*22 (W.D. Pa. June 23, 2021) (noting evidence that, while recovery from Covid provides protection against future reinfection, defendant's unique circumstances of elevated risk from active cancer chemotherapy treatment and congregate setting created uncertainty about strength of protection against reinfection).

[61] *Garrett v. Murphy*, Nos. 20-2719 & 21-2810, 2021 U.S. App. LEXIS 32385, at *22–*23 (3rd Cir. Oct. 29, 2021).

[62] *COVID Data Tracker, Variant Proportions*, CENTERS FOR DISEASE CONTROL AND PREVENTION (last visited Dec. 28, 2021), https://bit.ly/3n8CF0y.

[63] Amanda D'Ambrosio, *Early U.K. Data: Two Vax Doses Don't Cut It Against Omicron—But Booster Bumps Effectiveness to More than 70%, Technical Briefing Finds*, MEDPAGE TODAY (Dec. 13, 2021), https://bit.ly/3qSooGk.

[64] *Pfizer and BioNTech Provide Update on Omicron Variant*, PFIZER (Dec. 8, 2021), https://bit.ly/34xlNKu.

[65] Ewen Callaway, *Omicron Likely to Weaken COVID Vaccine Protection*, 600 NATURE 367, 367– 68 (2021); *see also* Nick Andrews, et al., *Effectiveness of COVID-19 Vaccines against the Omicron (B.1.1.529) Variant of Concern*, MEDRXIV [preprint] (Dec. 14, 2021) [accessed Jan. 5, 2022], *available at* https://bit.ly/3n7yD8O.

[66] *J&J, Sinovac Shots Less Effective Against Omicron Covid*, KHN (Dec. 15, 2021), https://bit.ly/31GAlq6.

[67] Media Statement, Centers for Disease Control and Prevention, CDC Endorses ACIP's Updated COVID-19 Vaccine Recommendations (Dec. 16, 2021), https://bit.ly/3q4HeuK.

summarized in a recent article in *The Lancet*, "The epidemiological relevance of the COVID-19-vaccnated population is increasing" by Dr. Gunter Kampf.[68] Even at that time, Kumpf notes, evidence from around the world, including the UK, Germany, and elsewhere, demonstrated the declining efficacy of current vaccines in preventing infection and transmission. As he summarized the findings, "Many decisionmakers assume that the vaccinated can be excluded as a source of transmission. It appears to be grossly negligent to ignore the vaccinated population as a possible and relevant source of transmission when deciding about public health control measures." Peer-reviewed research by Subramanian and Kumar in the *European Journal of Epidemiology* confirmed this observation, finding no relationship between the level of vaccination and increases in COVID-19 rates at the country level or at the level of United States counties.[69] In fact, at the country level they found a marginally positive association between vaccination rates and COVID-19 cases during the period under examination.

Therefore, the argument that compulsory vaccination protects the community from contracting and/or transmitting the virus does not hold water. The only argument for vaccination is that it provides an individual a certain degree of personal protection against infection. It is well-known that the risk of serious consequences from COVID-19 infection is highly risk-stratified, varying greatly by age and overall health condition, including obesity and other comorbidities. Thus, the benefits of this treatment will vary greatly among different individuals. Securing that therapeutic benefit also comes at some risk and that risk too will vary according to the unique circumstances and medical history of each individual, often inversely to the risk of serious consequences from contracting COVID-19—as may be the case for incidence of myocarditis in some young people, especially healthy males. Decisions about personal protection are personal. OSHA may not impose normative judgments on individual workers.

VII. OSHA's Rule on Testing Ignores the Evidence and Is Applied Arbitrarily

Recognizing the potential of vaccinated individuals to contract and spread the COVID-19 virus, the advent of the more contagious Omicron variant caused the CDC to issue updated guidelines for international travelers.[70] These new guidelines went into effect on December 6, 2021. They require all travelers to the United States—including those considered "fully vaccinated"—to test negative for COVID by a test taken no longer than one day prior to scheduled departure.

Yet the OSHA rule only requires testing of employees who choose to not get vaccinated. The exclusion of vaccinated employees from any testing requirement may result in a significant number of vaccinated workers carrying and spreading the virus in the workplace. This ignores the evidence and arbitrarily exempts a segment of workplace participants from testing for COVID infection.

Frequent testing is especially important for asymptomatic infections, which present an elevated risk of unconscious spread. As noted, vaccine-induced immunity is not sterilizing and

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[68] Gunter Kampf, *The Epidemiological Relevance of the COVID-19-Vaccinated Population Is Increasing*, THE LANCET REGIONAL HEALTH-EUROPE, Nov. 2021, at 1–2.

[69] S.V. Subramanian and Akhil Kumar, *Increases in COVID-19 Are Unrelated to Levels of Vaccination Across 68 Countries and 2947 Counties in the United States*, 36 EUROPEAN J. OF EPIDEMIOLOGY 1237, 1237–38 (2021).

[70] Press Release, Centers for Disease Control and Prevention, CDC Tightens Testing Requirement for International Travel to the US to One Day (Dec. 2, 2021), https://bit.ly/3JSi0rj.

does not provide mucosal immune protection, as a result the benefit of vaccination in reducing asymptomatic infection, is unclear. The extent to which vaccination reduces the frequency of asymptomatic infection, as opposed to preventing serious disease, is also unclear, but several studies conclude that the rate of asymptomatic infection is equivalent.[71] But some experts have warned that by protecting the carrier against symptoms that might warn of an active infection, "Vaccinated asymptomatic viral carriers may be more relevant for transmission because they do not even know or suspect that they may spread SARS-CoV-2."[72] Given evidence of comparable rates of asymptomatic infection and viral load upon infection, it is not obvious that unvaccinated, unimmune individuals should be tested more frequently than vaccinated individuals.

Furthermore, weekly testing is too infrequent to detect infection in pre-symptomatic or asymptomatic people.[73] For that reason, the CDC revised the testing guidelines for international travelers, requiring that tests be taken within one day of departure. Previously it had required test be taken within three days of departure.

Thus, by excluding vaccinated workers from weekly testing, and requiring only weekly testing of unvaccinated workers, the OSHA rule does nothing to prevent the spread of the COVID-19 virus among individuals in the workplace.

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In sum, even beyond its infirmities of constitutional and structural administrative law, the ETS again and again ignores the evidence, is applied arbitrarily, and is scientifically irrational. With respect to natural immunity, community spread, testing regimes, and other aspects of public health, it is arbitrary and capricious, and should be withdrawn.

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[71] *See* Gunter Kampf, *COVID-19 Vaccinated Individuals Can be a Source of SARS-CoV-2 Transmission—A Systematic Review*, 1(1) HYGIENE 1, 8–9 (2021); Anika Singanayagam, et al., *Community Transmission and Viral Load Kinetics of the SARS-CoV-2 Delta (B.1.617.2) Variant in Vaccinated and Unvaccinated Individuals in the UK: A Prospective, Longitudinal, Cohort Ctudy*, THE LANCET INFECTIOUS DISEASES, Oct. 2021, at 1.

[72] Kampf, *supra* n. 71, at 8.

[73] Robert Schooley and Natasha Martin, *Weekly Coronavirus Tests Are a terrible Substitute for Vaccination*, WASHINGTON POST (Sept. 28, 2021), https://wapo.st/3qZCBRR.