

January 19, 2022

**Via Federal eRulemaking Portal**

James S. Frederick,  
Acting Assistant Secretary of Labor  
Occupational Safety and Health  
Department of Labor  
200 Constitution Avenue NW  
Washington, DC 20210

**Re: EPPC Scholars Comment Opposing Interim Final Rule “COVID–19 Vaccination and Testing; Emergency Temporary Standard,” Docket No. OSHA–2021–0007, RIN: 1218-AD42**

Dear Acting Assistant Secretary Frederick:

We are scholars at the Ethics & Public Policy Center (EPPC) and write in opposition to the interim final rule “COVID–19 Vaccination and Testing; Emergency Temporary Standard” (“Rule”).<sup>1</sup> Roger Severino is the former Director for the Office for Civil Rights at the Department of Health and Human Services (2017–2021). Rachel Morrison is a former EEOC attorney. Dr. David Gortler is a former FDA medical officer who was appointed as senior advisor on drug safety to the FDA Commissioner. Dr. Aaron Kheriaty is a physician and bioethicist.

Based on our collective experience and expertise, we urge OSHA not to finalize the rule either as issued or in any other form that would mandate COVID-19 vaccination in workplaces. This Comment elaborates on comments EPPC scholars submitted to OSHA and OIRA as part of the Executive Order 12866 review before OSHA issued the ETS.<sup>2</sup>

**I. OSHA cannot finalize the ETS either as originally issued or with amendments.**

On October 18, 2021, two of the undersigned (Rachel Morrison and Roger Severino) presented the following arguments to OSHA and OMB under the EO 12866 process:

[V]accinations can be an important tool to combat pandemics. But the problem the rule should be addressing is not vaccination rates themselves, but the minimization of hospitalizations, serious illness, and death of employees due to workplace conduct or conditions. The status of being unvaccinated is the natural human condition. It is not workplace conduct or a workplace condition. There is nothing remotely unique about the dangers of “workplaces” (or workplaces of employers with 100 or more employees) when it comes to infectious diseases, because workplaces come in all shapes and sizes, including

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<sup>1</sup> 86 Fed. Reg. 61402.

<sup>2</sup> See <https://eppc.org/wp-content/uploads/2021/10/EPPC-Comments-for-EO-12866-Meeting-on-OSHA-COVID-Vaccine-Rule-1-1.pdf>.

work done in well-ventilated areas, outdoors, masked, remotely, seasonally, or in places that can be modified to adopt any of the above.

But under the proposed rule, the federal government is mandating a one-size-fits-all approach and forcing employers to coerce employees to undergo a medical intervention, potentially against the advice of a doctor or in violation of an employee's religious beliefs or conscience, or face intrusive weekly testing indefinitely (for those employees who would allow it) and concomitant stigmatization. Mandating vaccinations for all does not take into account the risk-benefits calculus for any individual person, and the attendant negative impacts on employees who will no longer work for covered employers and on the economy....

We all know that President Biden wants a national vaccine mandate and is only using OSHA because it is the closest thing he can get to lawful action. But it is still unlawful as there is not a grave danger in the workplace under the OSH Act justifying such a drastic action, most especially without public input.<sup>3</sup>

While OSHA and OMB ignored these arguments, the U.S. Supreme Court did not. On January 13, 2022, it held that OSHA acted without Congressional authority when it required the vaccination or testing of 84 million Americans, selected simply because they work for employers with more than 100 employees during the era of COVID. *Nat'l Federation of Indep. Business v. Dep't of Labor*, Slip op. at \*9 (U.S. Jan. 13, 2022). While Congress gave OSHA power to regulate occupational dangers, it did not give OSHA "power to regulate public health more broadly." *Id.* "[I]mposing a vaccine mandate on 84 million Americans in response to a worldwide pandemic is simply not 'part of what the agency was built for.'" *Id.* at \*7.

The Court rejected the argument that the risk of contracting COVID-19 qualifies as a "work-related danger." *Id.* It explained that while "COVID-19 is a risk that occurs in many workplaces, it is not an *occupational* hazard in most." *Id.* at \*6. "That kind of universal risk is no different from the day-to-day dangers that all face from crime, air pollution, or any number of communicable diseases." *Id.* at \*6-\*7. Because of the glaring legal deficiencies of the ETS, OSHA cannot finalize the ETS in its current form without it too being beyond the scope of authority Congress granted to OSHA. Although this wasn't a close question before the Supreme Court ruled, it certainly became a *closed* one after.

While OSHA may have "authority to regulate occupation-specific risks related to COVID-19," such as "where the virus poses a special danger because of the particular features of an employee's job or workplace," any such regulations must be "targeted" and the danger present in such workplaces must "differ[] in both degree and kind from the everyday risk of contracting COVID-19 that all face." *Id.* at \*7. Such a regulation would require so many significant substantive changes that it could not possibly be considered a logical outgrowth from the original ETS so that any attempt to finalize such a regulation would violate the Administrative Procedure Act.

OSHA has no other option but to promptly withdraw the ETS and abandon its efforts to issue a final rule (or modified final rule) based in any way on the ETS. If OSHA abandons its current course and seeks to issue a workplace COVID-19 vaccination mandate in the future, it must be exceedingly narrow,

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<sup>3</sup> *Id.*

issued under regular processes, and must address COVID risk *arising from* the workplace, not just *present in* the workplace. Even then, it would be a legally dubious proposition. Better, we advise, for OSHA to get out of the public health business altogether and stick to its original workplace health and safety mission.

## **II. The ETS was issued for political, not emergency reasons.**

The OSHA ETS was issued for political reasons. It is apparent President Biden wants a national vaccine mandate and was only using OSHA because he thought it was the closest thing he could get to lawful action. In President Biden's edict directing that OSHA "will" mandate employers to require their employees be vaccinated or subject to expensive and stigmatizing weekly testing, he explicitly said the OSHA mandate is merely a tool to "vaccinate the unvaccinated" across all sectors of the United States.<sup>4</sup> Biden pointed to nothing that distinguished the American workplace as being a COVID emergency danger zone. COVID-19 has been in the U.S. since January 2020. Vaccines, in response to President Trump's Operation Warp Speed, were approved in fall 2020 and it's been a year since President Biden took office. Large numbers of vaccinations continue to be administered every single day. There is no emergency requiring OSHA's intervention—only political power play. There was not an emergency when OSHA issued its ETS and there is not an emergency now permitting OSHA to issue another ETS. President Biden wants to be seen as being aggressive in keeping his campaign promise to "shut down" COVID. It's understandable that the President is facing huge political problems after he said in the October 22, 2020, presidential debate: "two hundred twenty thousand Americans dead.... Anyone who is responsible for that many deaths should not remain as President of the United States of America." Approximately 400,000 have died from or with COVID-19 under President Biden's watch.

Recall that the President initially said he had no authority to issue a national vaccine mandate only to see his Chief of Staff later tweet that the OSHA mandate was the "ultimate workaround." Chief Justice Roberts raised this point in oral argument when he asked the government's lawyer "I mean, this has been referred to the approach as a work-around. And I'm wondering what it is you're trying to work around?" The answer is obvious. The President ordered OSHA to issue a mandate (on an emergency basis no less) in order to address a massive political problem while having to "work around" the fact that the federal government has no authority whatsoever to issue national vaccine mandates. Any further attempts at reviving the original ETS is tainted by that political pall. Once an agency has lost credibility on an issue, it is near impossible to restore, at least not without deep acknowledgement of the error and even then, it likely takes a change of administration to eliminate the stain of politicization.

## **III. Any final or future rule must undergo a meaningful economic analysis.**

The ETS is a self-proclaimed economically significant rule, which requires meaningful economic analysis under EO 12866 and OMB Circular A-4. EO 12866 states:

In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among

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<sup>4</sup> <https://www.whitehouse.gov/covidplan/#vaccinate>.

alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

Issuing an ETS does not alleviate OSHA of responsibility to have reasoned decision-making. Rather it places an even higher bar on the agency to have sound analysis and the public is less a part of the process. The ETS falls far short of this requirement, which any final rule or future rule must remedy.

**Baseline.** In the ETS, OSHA used an incorrect baseline for analysis. Any potential benefits of the vaccine mandate cannot be attributed to the current vaccination rate (which is expected to continue) and all the voluntary and state-imposed employer-vaccination mandates. Any benefits of the rule can only be attributed to those who would get vaccinated *solely* because their employer required vaccination *solely* because of the OSHA rule. In calculating who would receive a health benefit from the mandate, the ETS attributes to itself benefits it cannot claim. This mistake cannot be repeated in any final or future rule.

**Alternatives.** Instead of a federal vaccination or testing mandate, the agency must consider alternatives and provide that analysis. Since the goal should be to prevent hospitalizations, serious illness, and death, some alternatives are: (a) tax incentives for employers or making COVID-related expenses tax deductible; (b) more focus on therapeutics to treat COVID-19; and (c) other methods to decrease transmission that have been employed throughout the pandemic such as testing, temperature taking, social distancing, masking, enhanced cleaning, working from home, etc. These alternatives were not adequately considered in the ETS. At a minimum, all of these alternatives and more must be explored by OSHA prior to issuing a final or future rule.

**Costs, benefits, transfers.** As part of its regulatory impact and economic analysis of the costs, benefits, and transfers, any OSHA vaccination or testing mandate must take into consideration the following key inputs (which EPPC scholars presented to OSHA and OIRA during an EO 12866 meeting on the ETS).

#### Economy

- The number of unvaccinated people currently employed by covered employers.
- The number of people who will quit or be terminated from their job because of the mandate.
- The number of jobs that will be lost due to the mandate.
- The financial and health impacts of job loss due to the mandate on those employees and their families.
- The number of people who will seek employment with employers not covered by the mandate.
- The impact on economy as a whole from loss of employees and jobs due to the mandate, including disruption to already suffering supply chains, including food chains.
- The impact on the availability of access to health care. There are already reports of shortages of health care personnel. One article discussed a rural Texas hospital CEO warning that a vaccine mandate could lead to the hospital closing, which would have vast negative health impacts in that community.<sup>5</sup> This hospital is not alone.
- The impact of the mandate in different industries and in different regions.

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<sup>5</sup> <https://www.lifesitenews.com/news/texas-hospital-ceo-warns-his-facility-might-have-to-close-because-of-bidens-vaccine-mandate/>.

- Projected compliance rates.
- The mandate's real-world effectiveness to solve the problem of infection, transmission, hospitalizations, serious illness, and death of employees, not the public at large.
- Costs to employers to create policies and systems for vaccine compliance and testing.
- The availability of tests and the cost of tests on the employee.
- The impact on unemployment benefits for those who are fired because of the mandate.
- Environmental costs from increased commutes for discharged employees who must find more distant work as a result of the mandate.
- The costs on taxpayers for OSHA to ensure enforcement.

### Health

- The number of increased adverse events due to vaccination as a result of the mandate. Presumably many of those who have not yet taken the vaccine have done so because they are at higher risk of adverse events.
- The health impact on younger employees without pre-existing conditions who are at minimal risk to COVID.
- The underreporting of adverse events to the VAERS database.
- The effectiveness of non-vaccine risk mitigation strategies, such as social distancing, masking, double-masking, increased cleaning, and telework that can help prevent transmission and illness.
- The effectiveness of early intervention and existing therapeutics to treat those with COVID to minimize or prevent serious illness, hospitalization, and death.
- The high vaccination rates and the voluntary employer mandates already are in place.
- The growing number of state vaccine mandates for employees and the impact of vaccine passports on vaccination rates.
- The number of unvaccinated employees who work from home, outdoors, or not in close contact with others.
- The waning effectiveness of the vaccines over time. As the CDC has found, vaccines do not prevent infection or transmission, and the vaccinated and unvaccinated can transmit the virus at the same rate and have the same viral load when infected.<sup>6</sup>
- The transmission and infection rates between the vaccinated and the unvaccinated, including the unvaccinated who already recovered from COVID and have natural (infection-induced) immunity.
- The number of unvaccinated who have already recovered from COVID and have natural immunity.
- The effectiveness of natural immunity compared to vaccination.
- The higher rates of vaccine adverse events for those who already have natural immunity.
- The effect of unvaccinated employees being more likely to have symptoms and thus more likely to stay home from work and avoid spreading, than vaccinated people who have fewer symptoms but can still transmit the virus.

### Civil rights

- The disparate impact perpetuating inequality on those in rural areas, on certain racial or ethnic minorities, on certain religious groups, or on certain people with disabilities, such as those who are medically unable to receive the vaccine.

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<sup>6</sup> <https://www.cdc.gov/mmwr/volumes/70/wr/mm7031e2.htm>.

- The impact of the mandate on conscience and religious rights in violation of First Amendment, RFRA, Title VII of the Civil Rights Act of 1964, as well as state laws.
- The alternative of excluding religious organizations from the mandate.
- Stigmatization or social ostracization of people who are not vaccinated and required to submit to weekly testing, constant pressure, and potential lost job advancement or retaliation.

*All* of these things, and more, must be taken into consideration, and quantified or estimated to the maximum extent possible for a sufficient analysis of impact, costs, benefits, and transfers. Any final or future rule must have sufficient legal and economic analysis that is rationale, reasoned, and scientific, not political, rushed, or prejudged.

Below we discuss in more detail the waning efficacy of the vaccines, the uncertain risks of the vaccine, studies related to natural immunity, and civil rights concerns.

#### **IV. Any final or future rule must address the waning efficacy of the COVID-19 vaccines.**

Despite official White House claims the vaccine is “highly effective,” the efficacy of the vaccines to prevent infection and transmission wanes over time and with the advent of new variants, especially Omicron. Some studies show that the gold standard Pfizer vaccine has plummeted to 33% effectiveness at preventing transmission<sup>7</sup> and will likely continue to fade on this score. This means that the vaccinated are also widely to transmit COVID in the workplace, and that vaccination is not sufficient to prevent COVID-19 infection or transmission. As Dr. Tony Fauci said in a January 11, 2022, interview: “Omicron, with its extraordinary, unprecedented degree of efficiency of transmissibility, will, ultimately, find just about everybody.... As Omicron goes up and comes down, I do hope that we will see a situation where there’ll be enough protection in community, enough drugs available, so that when someone does get infected and is in a high-risk group, it will be very easy to treat that person be that with Paxlovid or a monoclonal antibody or whatever the drugs are, that we have a combination of good, basic background immunity together with the ability to treat someone who is at risk. When we get there, there’s that transition. *Now, we may be on the threshold of that right now*, see. It’s entirely possible.”<sup>8</sup> If just about everybody is getting infected, we will hit herd immunity soon, and combined with better treatments, it’s “entirely possible” the conditions OSHA relied on to claim an emergency will have already passed by the time it gets to finalizing the rule.

COVID-19 is more complicated than many viruses we have dealt with historically because of its high number of spike proteins and their many mutations. Spike proteins are the “key” that allow the virus to fuse with human cells and propagate infection. For comparison, Ebola viruses have only one spike protein, the influenza virus has two, and herpes simplex virus has five. Depending on how many are expressed, each COVID-19 particle has 24–40 *different* spike proteins.<sup>9</sup>

America’s mRNA vaccines work strictly by transcribing spike proteins of the original version of the COVID-19 coronavirus. The shortcomings of mRNA vaccines are that it would only take a single mutation in a single spike protein to potentially circumvent them. According to electron microscopy and sequencing studies from December 2021, the Omicron variant has upwards of 50 overall mutation

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<sup>7</sup> <https://www.medrxiv.org/content/10.1101/2021.11.11.21266068v2>.

<sup>8</sup> <https://www.csis.org/analysis/fireside-chat-dr-anthony-fauci-pandemic-transition>.

<sup>9</sup> <https://www.nature.com/articles/d41586-021-02039-y>.

differences from the original COVID-19 strain, including at least 26—and as many as 43—known mutations on its different spike proteins.<sup>10</sup> The non-spike protein mutations could determine the biological properties of the virus as well as how quickly the virus can replicate.<sup>11</sup>

Because Omicron has so many different, mutated spike proteins, it should be expected that the vaccines could dramatically lose effectiveness against that variant. A study out of Columbia University found that the mRNA vaccines are generally ineffective against Omicron: “Omicron is markedly resistant to neutralization by serum not only from convalescent patients, but also from individuals vaccinated with one of the four widely used COVID-19 vaccines. Even serum from persons vaccinated and boosted with mRNA-based vaccines exhibited substantially diminished neutralizing activity against [Omicron].”<sup>12</sup> The report warned that, Omicron’s extensive mutations “raise the specter that current vaccines and therapeutic antibodies would be greatly compromised,” likely even invalidating them. Indeed, Pfizer’s CEO Albert Bourla recently admitted that “The two doses, they’re not enough for omicron.”<sup>13</sup>

It stands to reason that “boosters” of the same vaccine designed to address the *original* COVID spike protein profile would not be effective against the new spike protein mutations of the latest COVID-19 variant. The same would be true with any future variants with spike protein mutations. A recent study out of Israel confirms that a fourth COVID shot is “only partially effective in protecting against the Omicron strain,” with many who received even a fourth dose being infected.<sup>14</sup> In short, the vaccine for Omicron is “not good enough.”

For example, the most recent epidemiological spread of COVID in December alone has borne out the following truths about the vaccine, the booster, and the spread of the COVID after its many mutations:

- In early December, Reuters and MSN reported that most (79%) of the 43 COVID-19 cases caused by the Omicron variant identified in the United States so far were in people who were fully vaccinated, with a third having received a booster dose.<sup>15</sup>
- As of mid-December, according to statistics from the Oregon Health Authority, 622 fully vaccinated Oregon residents died of COVID-19.<sup>16</sup>
- In the week before Christmas, Massachusetts reported nearly 14,000 cases among fully vaccinated residents.<sup>17</sup>
- As of December 22, the most new COVID-19 cases in Denmark occur in people who are vaccinated or boosted—and that is true for both Omicron and earlier variants. More than 76

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<sup>10</sup> <https://www.biorxiv.org/content/10.1101/2021.12.14.472719v1.full.pdf>;  
<https://www.scmp.com/news/china/science/article/3157675/omicron-coronavirus-variant-has-more-double-mutations-delta>.

<sup>11</sup> <https://www.biorxiv.org/content/10.1101/2021.12.14.472622v1>.

<sup>12</sup> <https://www.biorxiv.org/content/10.1101/2021.12.14.472719v1.full.pdf>.

<sup>13</sup> <https://www.cnn.com/2022/01/10/pfizer-ceo-says-two-covid-vaccine-doses-arent-enough-for-omicron.html>

<sup>14</sup> <https://www.timesofisrael.com/israeli-trial-worlds-first-finds-4th-dose-not-good-enough-against-omicron/>.

<sup>15</sup> <https://news.yahoo.com/most-reported-u-omicron-cases-182642515.html> (As of December 10, most (79%) of the 43 COVID-19 cases caused by the Omicron variant identified in the United States so far were in people who were fully vaccinated, and a third of them had received a booster dose.).

<sup>16</sup> <https://www.ibtimes.com/622-fully-vaccinated-oregon-residents-died-covid-19-64-are-white-americans-3359388>.

<sup>17</sup> <https://www.masslive.com/coronavirus/2021/12/massachusetts-reports-13919-new-breakthrough-covid-cases-over-last-week-as-state-ramps-up-testing-deploys-national-guard-to-bolster-hospitals-and-ambulance-service.html>.

percent of non-Omicron COVID infections in Denmark are in vaccinated people, along with about 90 percent of Omicron infections.<sup>18</sup>

- On December 26th, 189,714 new cases of COVID-19 were reported in the U.S., with 54,828 (almost 30%) from New York City,<sup>19</sup> despite the city’s strict masking and vaccine passport requirements and 85 percent of residents having received at least one injection as of October 2021.<sup>20</sup>
- On December 29, new infection records were made in the highly vaccinated United Kingdom with 1 in 35 people now infected across the country and 1 in 20 infected in London.<sup>21</sup>
- On December 30, the U.S. set a world record of 489,267 new COVID cases in 24 hours.<sup>22</sup>
- On December 30, the Robert Koch Institute, a German federal government agency and research institute, reported 95.58% of Omicron cases in Germany are among fully vaccinated, 4% among unvaccinated.<sup>23</sup>
- Other epidemiological findings have shown that Omicron isn’t all that dangerous, with zero deaths confirmed from Omicron as of mid-December.<sup>24</sup>

While the CDC and others argue that vaccination remains important because it can limit severity of disease, thankfully, the data has shown that it’s not just “boostered” people that have mild symptoms, but most people with the Omicron variant seem to have milder symptoms than previous variants. A recent study conducted by Kaiser Permanente Southern California, looked at Omicron, which accounts for more than 99% of new cases. The data showed that the case fatality rate is 91% lower for Omicron compared to Delta, the ICU admission rate is 75% lower, the hospitalization rate is 53% lower, and hospitalization are 70% shorter. While Omicron is more infectious than Delta, overall mortality rates have fortunately remained much lower in this wave. The virus is evolving in precisely the direction that viruses typically evolve: more infectious but less fatal (evolutionarily, viruses “want” to propagate and this cannot be done if they kill their hosts).<sup>25</sup> It is also still the case that the most at risk are people out of the workforce (older retirees). The risk to those in the workforce of death or serious illness has dropped dramatically compared to Delta and before. This welcome development undercuts OSHA’s rationale for the mandate of keeping persons who choose to be unvaccinated safe from serious illness or death. OSHA’s predicted numbers of deaths it claims would have been averted by the mandate are now grossly overstating the true risk.

<sup>18</sup> <https://thebluestateconservative.com/2021/12/22/denmark-76-of-non-omicron-covid-infections-and-90-of-omicron-infections-are-vaccinated/>.

<sup>19</sup> <https://pjmedia.com/news-and-politics/matt-margolis/2021/12/27/nearly-30-of-new-covid-cases-in-america-came-from-one-city-n1544735>.

<sup>20</sup> <https://www.nbcnewyork.com/news/local/super-majority-85-of-adults-in-nyc-have-received-at-least-1st-dose-of-covid-vaccine/3322972/>.

<sup>21</sup> <https://www.msn.com/en-gb/news/world/covid-cases-uk-reports-record-183037-new-daily-infections-as-omicron-surge-continues/ar-AASfw6p>.

<sup>22</sup> <https://www.dailymail.co.uk/health/article-10355849/US-hits-record-nearly-500-000-Covid-cases-24-hours-Experts-says-viral-blizzard.html>.

<sup>23</sup> [https://www.rki.de/DE/Home/homepage\\_node.html](https://www.rki.de/DE/Home/homepage_node.html).

<sup>24</sup> <https://townhall.com/tipsheet/guybenson/2021/12/13/total-number-of-confirmed-omicron-deaths-zero-n2600477>;  
<https://www.newsweek.com/omicron-vaccine-covid-who-coronavirus-cases-1656108>;  
<https://www.theguardian.com/world/2021/dec/04/who-says-no-deaths-reported-from-omicron-yet-as-covid-variant-spreads>.

<sup>25</sup> Joseph A. Lewnard, Vennis X. Hong, Manish M. Patel, Rebecca Kahn, Marc Lipsitch, Sara Y. Tartof. *Clinical Outcomes Among Patients Infected with Omicron (B.1.1.529) SARS-CoV-2 Variant in Southern California*, MEDRxIV (Jan. 11, 2022), <https://doi.org/10.1101/2022.01.11.22269045>.



Even with more mild systems, it is clear that vaccinated and boosted people are testing positive for COVID-19, specifically Omicron, and transmitting it to others liberally. Again, as Fauci said, just about everyone is going to get it. This eviscerates OSHA's rationale that mandatory vaccination is required to prevent COVID infections and transmissions in the workplace, rendering any such mandate arbitrary and capricious. It is doubly irrational considering that the ETS requires unvaccinated persons to wear masks and test while vaccinated people, who can transmit Omicron others about as easily, are totally exempt from any mask or testing mandate.

**V. In any final or future rule, OSHA must consider the risks of vaccination.**

The ETS states that “[d]espite the proven safety and efficacy of the available COVID–19 vaccines, many workers remain unvaccinated and are currently exposed to a grave danger.” However, the danger from COVID-19 among unvaccinated workers varies enormously across different age groups and between those with compared to those without prior infection. Furthermore, the COVID-19 vaccines are not 100% safe or without risk. Unfortunately, the COVID-19 vaccines have led to adverse events in a significant number of cases. It is unclear, however, to what extent these adverse events are occurring because the FDA has so far refused to release its full COVID vaccine safety data. (For comparison, other FDA vaccine medical reviews, such as those for measles, mumps, rubella, chicken pox<sup>26</sup> influenza<sup>27</sup> or adenovirus,<sup>28</sup> were readily available for download immediately following FDA approval.) FDA's has delayed over 100 days from its August 23rd full approval of the Pfizer BioNTech Comirnaty vaccine to releasing the medical officer review detailing the FDA's assessment on its efficacy or safety. FDA's lack of transparency makes Americans wonder whether the adverse health effects being reported on VAERS today were foreshadowed in the still-unreleased data.

While the Biden administration is mandating vaccination, the FDA is delaying release of the original Pfizer application which contains the safety data used in assessing the novel mRNA vaccine, suggesting in response to a FOIA request that the public should not see the data until 2076! (A federal judge recently ordered the FDA to release this data over the next 8 months.<sup>29</sup>) This lack of transparency—especially in conjunction with the federal mandate—is simply unconscionable. To add insult to injury, before OSHA issued its vaccine mandate on a third of the American workforce, it lifted a requirement that employers track and report adverse health consequences of vaccination for their employees.<sup>30</sup> It is inexplicable that the federal agency charged with tracking workplace health and safety incidents would

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<sup>26</sup> <http://wayback.archive-it.org/7993/20170723150913/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM123800.pdf>.

<sup>27</sup> <http://wayback.archive-it.org/7993/20170723150034/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM341947.pdf>.

<sup>28</sup> <http://wayback.archive-it.org/7993/20170722071205/https://www.fda.gov/downloads/BiologicsBloodVaccines/Vaccines/ApprovedProducts/UCM564684.zip>.

<sup>29</sup> Cf. This update from the lawyer, Aaron Siri, who filed the FOIA request on behalf of a group of academic physicians and scientists: <https://aaron.siri.substack.com/p/instead-of-fdas-requested-500-pages>.

<sup>30</sup> <https://www.osha.gov/coronavirus/faqs#vaccine>. “OSHA does not wish to have any appearance of discouraging workers from receiving COVID-19 vaccination, and also does not wish to disincentivize employers’ vaccination efforts. As a result, OSHA will not enforce 29 CFR 1904’s recording requirements to require any employers to record worker side effects from COVID-19 vaccination at least through May 2022.”

simultaneously impose a vaccine mandate and eliminate a requirement to track the adverse consequences of the vaccine. OSHA should reverse this policy and require employers to report known-adverse events associated with employer-mandated or employer-administered vaccination.

If third-party reviews<sup>31</sup> of the FDA's Vaccine Adverse Event Reporting System (VAERS) database are accurate, it seems like the vaccine has not proven to be as safe as originally advertised. VAERS shows an alarming increase in the number of reported adverse events associated with the COVID-19 vaccines,<sup>32</sup> and adverse events are known to be significantly underreported to VAERS.<sup>33</sup> As of this writing, confirmed adverse events from COVID-19 vaccine administration listed in the FDA's VAERS database for the U.S. *alone* include: over 9,300 deaths, almost 3,000 cases of Bells' Palsy, nearly 4,900 heart attacks, over 4,600 cases of myocarditis, over 7,000 cases of shingles, over 1,500 miscarriages, over 28,000 cases of severe allergic reactions, and 11,600 cases of "permanent disability."<sup>34</sup> These numbers increase significantly with "nondomestic" VAERS reports.<sup>35</sup> Of course, reports do not prove causation, but according to the FDA only a small minority (approximately 1 to 10%<sup>36</sup>) cases of adverse events are actually reported, indicating that the *actual occurrences* of adverse events in the U.S. would be substantially higher, not to mention thousands to hundreds-of-thousands fold higher cases worldwide.

Myocarditis and pericarditis are rare conditions, but there has been a spike in cases over the last year. They are defined as inflammation of the heart muscle or layers of the pericardial sac, respectively. Both conditions cause easily recognizable ECG changes and have nonspecific symptoms that include shortness of breath and chest pain. They can easily be diagnosed clinically with echocardiograms and can easily typically be treated by pharmacology. If ignored or not warned, it could lead to heart attacks and death.

Although pericarditis or myocarditis, though rare, are most commonly caused by infectious diseases, the use of a brand-new mRNA COVID-19 vaccine and booster technology have now been directly related to myocarditis and pericarditis in a 42 million person study out of the UK.<sup>37</sup> The findings showed that myocarditis risk doubled after a single dose, which doubled again after a second dose and doubled yet again after a third booster dose.

The FDA had clear signals about cardiovascular vaccine safety on the day it received Pfizer's application for its Comirnaty vaccine. The FDA's medical officer review, which was the basis for approval of the Pfizer vaccine, noted that "clinically important serious adverse reactions [were] anaphylaxis and myocarditis/pericarditis."<sup>38</sup> The FDA medical reviewers go on to state: "Reporting rates for medical chart-confirmed myocarditis/pericarditis in VAERS have been higher among males under 40

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<sup>31</sup> <https://openvaers.com/covid-data>.

<sup>32</sup> *Id.*

<sup>33</sup> *See, e.g.,* <https://www.sirillp.com/wp-content/uploads/2021/10/Letter-Re-First-Hand-Account-of-Covid-19-Vaccine-Injuries-and-Underreporting-to-VAERS-1.pdf>.

<sup>34</sup> <https://openvaers.com/covid-data/cardiac>.

<sup>35</sup> *Id.*

<sup>36</sup> <https://digital.ahrq.gov/ahrq-funded-projects/electronic-support-public-health-vaccine-adverse-event-reporting-system>.

<sup>37</sup> <https://www.medrxiv.org/content/10.1101/2021.12.23.21268276v1.full.pdf>.

<sup>38</sup> <https://www.fda.gov/media/152256/download>.

years of age than among females and older males and have been highest in males 12-17 years of age.”<sup>39</sup> The review goes on to state that these myocarditis/pericarditis cases resulted in multiple fatalities. Yet many people do not realize these conditions warned about in the FDA medical review of the Pfizer application.

In other words, specific adverse events were predicated in the FDA review, particularly those involving cardiovascular risk and myocarditis and pericarditis. Myocarditis and pericarditis are now recognized side effects from COVID-19 vaccine administration, and ones which Americans should have been warned about from the very beginning. VAERS data had born out what was clearly warned about in the clinical trials and FDA review for the mRNA vaccines.

The FDA’s VAERS database does not capture all adverse event reports and the overall numbers reported may seem abstract. The following is a list of specific narratives, most involving young athletes in the prime of their careers, who had what appear to be cardiovascular events following vaccinations. Since these occurred outside the United States, they would have likely not been captured by VAERS. These are news reports that are not collected by clinical or regulatory experts and are missing extensive detail, but they are nonetheless compelling in their similarity. The following is a long list of seemingly healthy people worldwide who experienced sudden, unexpected heart attacks or death in just the last 45 days.<sup>40</sup> For example:

- December 1, 2021, Melbourne, Australia: Ben Madgen (age 36), a basketball player in hospital with pericarditis after 2nd Pfizer dose.<sup>41</sup>
- December 3, 2021, Australia: An unnamed Adelaide Crows football player went to hospital diagnosed with pericarditis two weeks after his first Pfizer dose.<sup>42</sup>
- December 10, 2021, Serbia: Ricardo Gomes (age 29) Cape Verde soccer player collapsed during training, 45 days after his COVID vaccination.<sup>43</sup>
- December 11, 2021, England: Victor Lindelof (age 27), Manchester United soccer player, collapsed clutching his chest and pointing to his heart, complained of chest pain and racing pulse. His wife confirmed they were both vaccinated.<sup>44</sup>
- December 13, 2021, England: Maxwell Harrison (age 21), an international ballroom dancer, developed pericarditis five days after his second Pfizer COVID-19 vaccine and was hospitalized.<sup>45</sup>
- December 17, 2021, Los Angeles: Donald Parham (age 24) Los Angeles Chargers (NFL) tight end player, collapsed in mid-air while taking a flying touchdown catch. He had received two COVID-19 vaccines and a booster. His arms were shaking as he was wheeled off. It appears that

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<sup>39</sup> *Id.*

<sup>40</sup> The full list is available here:

[https://www.americanthinker.com/blog/2022/01/fda\\_drug\\_safety\\_expert\\_dr\\_david\\_gortler\\_vaccine\\_manufacturers\\_fda\\_not\\_adequately\\_warnings\\_about\\_myocarditis\\_risks.html#ixzz7IRzkvWLM](https://www.americanthinker.com/blog/2022/01/fda_drug_safety_expert_dr_david_gortler_vaccine_manufacturers_fda_not_adequately_warnings_about_myocarditis_risks.html#ixzz7IRzkvWLM).

<sup>41</sup> <https://twitter.com/iMadgen01/status/1467245175864840196>.

<sup>42</sup> <https://www.fiveaa.com.au/show/rowey-s-sports-show/crows-top-up-player-diagnosed-with-heart-condition-after-covid-jab-reports-rowey/>.

<sup>43</sup> [https://nultatacka.rs/fudbaler-partizana-rikardo-gomes-koji-se-pre-tri-dana-srusio-na-treningu-pozirao-na-vakcinaciji-pre-mesec-ipo-dana-trener-stanojevic-situacija-je-ozbiljna/?\\_x\\_tr\\_sl&\\_x\\_tr\\_tl&\\_x\\_tr\\_hl](https://nultatacka.rs/fudbaler-partizana-rikardo-gomes-koji-se-pre-tri-dana-srusio-na-treningu-pozirao-na-vakcinaciji-pre-mesec-ipo-dana-trener-stanojevic-situacija-je-ozbiljna/?_x_tr_sl&_x_tr_tl&_x_tr_hl).

<sup>44</sup> <https://www.thesun.co.uk/sport/football/17012211/victor-lindelof-heart-scare-man-utd/>.

<sup>45</sup> <https://thecovidworld.com/maxwell-harrison-ballroom-dancer-develops-pericarditis-after-receiving-pfizer-vaccine-unable-to-dance-for-at-least-a-year/>.

his left arm locked up before his helmet hit the ground, which may be why he didn't handle the recovery well. The Chargers report he suffered a concussion, but the video tells a different story.<sup>46</sup>

- On January 6, 2022, New Jersey: Jack O'Drain (age 13), an otherwise healthy child, died following his second booster from "Unexplained Cardiac Arrest."<sup>47</sup>
- On January 4, 2022, Brazil: Rafael Silva, (age 36), a television reporter had a heart attack during a live news broadcast, followed by four more myocardial infarctions while being transported to the hospital. He had earlier tweeted in Portuguese: "My 3rd dose will give me a long life."<sup>48</sup>
- January 4, 2022, United States: Derek A. McIntosh (age 41) passed away unexpectedly, six days after receiving his COVID Vaccine. Derek had been vigorously opposed to taking the COVID vaccine, but his employer forced him to do so.<sup>49</sup>
- January 8, 2022: Fabienne Schlumpf, a 31-year-old triple vaccinated Swiss marathon record holder and Olympian was diagnosed with myocarditis and may never be able to compete again.<sup>50</sup>
- January 8, 2022: 29-year-old double-vaccinated Georgian tennis star Nikoloz Basilashvili was forced to drop out of the Sydney Cup in Australia due to breathing difficulties. Basilashvili stated: "every shot I'm out of breath" and then told medical staff that he was "struggling to breathe."<sup>51</sup>
- January 9, 2022, Argentina: Ámbar Suárez (age 3), died of a heart attack the day after receiving a COVID vaccine, a requirement for her to enter kindergarten. Her mother, Miryam Suárez said her daughter, had otherwise been healthy and "full of life."<sup>52</sup>

What this suggests is that there is a mysterious increase in seemingly healthy young individuals fainting, having heart attacks, and suffering deaths potentially related to cardiovascular adverse events following mRNA vaccines.

OSHA knows that potentially deadly cardiovascular adverse events may result from the COVID vaccine, as well as other adverse events that are trending upward in VAERS. Those who mandate vaccination, especially a federal government agency charged with workplace safety should halt further attempts at vaccine coercion until it conclusively determines the level of risk from the vaccine given the post approval data.

These are also just cardiovascular cases. According to Steve Kirsch, intracranial infection cases are up 60-fold since vaccines rolled out.<sup>53</sup> Additionally, there have been over four dozen cases of sudden onset of acute transverse myelitis following mRNA COVID-19 vaccination.<sup>54</sup>

In addition, a study of the Pfizer COVID-19 vaccine's safety discusses how the "Pfizer 6 month data shows that Pfizer's COVID-19 inoculations cause more illness than they prevent," as well as "an

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<sup>46</sup> <https://au.sports.yahoo.com/nfl-2021-america-shock-donald-parham-incident-024452881.html>.

<sup>47</sup> <https://www.infowars.com/posts/tragic-double-vaxxed-13-year-old-dies-from-unexplained-cardiac-arrest/>.

<sup>48</sup> <https://www.hollywoodlanews.com/rafael-silva-tv-presenter-brazil-heart-attack/>.

<sup>49</sup> <https://www.tributearchive.com/obituaries/23612603/derek-andrew-mcintosh/monticello/minnesota/peterson-grimsno-chapel>.

<sup>50</sup> <https://www.thegatewaypundit.com/2022/01/triple-vaccinated-swiss-olympic-athlete-fabienne-schlumpf-diagnose-myocarditis-may-never-able-compete/>.

<sup>51</sup> <https://www.rt.com/sport/545377-tennis-player-breathing-trouble-match-australia/>.

<sup>52</sup> <https://bigleaguepolitics.com/three-year-old-girl-dies-of-a-heart-attack-one-day-after-receiving-covid-19-jab/>.

<sup>53</sup> <https://stevekirsch.substack.com/p/intracranial-infection-cases-up->.

<sup>54</sup> <https://europepmc.org/article/PPR/PPR342408>.

overview of the Pfizer trial flaws in both design and execution.”<sup>55</sup> In a separate study out of Germany’s renowned Paul Ehrlich Institute (PEI), the COVID vaccine Death Rate was found to be 21 times higher than all other vaccines: “In the last eleven months, four times as many suspected adverse reaction reports and four times as many deaths in absolute numbers were reported for COVID vaccines alone than in the last 20 years for the totality of all vaccines used in Germany.”<sup>56</sup>

Americans should be informed about the vaccine’s risks and benefits. Americans cannot be expected to make any kind of informed or intelligent decision about whether or not to get the COVID-19 vaccine or mandate it for their employees without knowing what all the potential side effects are. Likewise, physicians and pharmacists should not be expected to blindly recommend and administer COVID-19 vaccines to their patients without first being able to personally review available efficacy and safety information. Yet OSHA is mandate vaccination for millions of American workers despite the FDA not having published the data supporting their findings.

A recent paper by dozens of doctors and epidemiologists from around the world argued that key clinical concerns should be addressed before any vaccine mandate is issued or continued<sup>57</sup>. We agree. These concerns include:

- The potentially hazardous mechanisms of action of the vaccine resulting in cell, tissue, and organ damage.
- The presence of potentially harmful spike protein in donated blood.
- Lack of genotoxicity, teratogenicity, and oncogenicity studies.
- The effects of bioaccumulation in women’s ovaries.<sup>58</sup>
- The potential for reduced fertility.<sup>59</sup>
- The lack of a data and safety monitoring board (DSMB) to oversee clinical trials and post-market surveillance.
- The lack of human ethics committee to oversee clinical trials.
- The lack of restrictions on exempted groups from randomized controlled trials (RCTs) such as pregnant women, women of childbearing potential, COVID survivors (previously immune)
- The lack of risk stratification for hospitalization and death in the clinical trials.
- The lack of Pfizer data transparency.
- The lack of public risk mitigation (early and at-home treatment options).

OSHA’s finding of “grave danger” for unvaccinated workers is based on the fact that COVID “can cause serious, long-lasting, and potentially permanent health effects” and serious cases “require hospitalization and dramatic medical interventions, and might leave employees with permanent and disabling health effects.” 86 Fed. Reg. at 61424. Based on the known-VAERS reports, the same could be

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<sup>55</sup> <https://www.canadiancovidcarealliance.org/media-resources/the-pfizer-inoculations-for-COVID-19-more-harm-than-good/>.

<sup>56</sup> <https://principia-scientific.com/covid-vax-death-rate-21-times-higher-than-all-other-vaxxes/>.

<sup>57</sup> <https://www.authorea.com/users/414448/articles/522499-sars-cov-2-mass-vaccination-urgent-questions-on-vaccine-safety-that-demand-answers-from-international-health-agencies-regulatory-authorities-governments-and-vaccine-developers>.

<sup>58</sup> “COVID-19 vaccination associated with a small, temporary increase in menstrual cycle length, suggests NIH-funded study.” <https://www.nih.gov/news-events/news-releases/covid-19-vaccination-associated-small-temporary-increase-menstrual-cycle-length-suggests-nih-funded-study>.

<sup>59</sup> *Id.*

said of the vaccines. The question is thus one of proportion. How many people will be helped versus harmed by forced vaccine administration given the fact that those most at risk of harm from COVID are already double or triple vaccinated? Without transparency of the safety and efficacy data of the vaccines, Americans cannot know the relative risk of COVID-19 versus the vaccine based on their personal medical situation, their age, and other relevant factors. And neither can OSHA. Yet in the ETS, OSHA did not consider or make any attempt to balance the known (and unknown) risks of the vaccine with the risks of COVID. It merely touts the political talking point that the vaccines are “safe and effective,” despite increasing evidence to the contrary. How safe? How effective? And for whom? The American public must have answers to these questions, especially from the government mandating vaccination.

Without safety and efficacy data transparency, the federal government cannot credibly mandate employers with over 100 employees to force their employees to be vaccinated, regardless of region, industry, current vaccination rates, potential for transmission, or existing risk of hospitalization, serious illness, and death, because it cannot make the proper comparison of expected health benefits of the mandate to expected health costs.

## **VI. Any final or future rule must recognize natural immunity.**

In response to the request for comment on prior COVID-19 infections, 86 Fed. Reg. at 61403, below is an in-depth analysis of relevant studies on natural immunity and vaccine immunity to COVID.

### ***A. Benefits and Risks of Vaccination for COVID-Recovered Individuals***

A population-based study involving 2.5 million Israelis in a single, centralized medical database (representing one of the four national health care funds in Israel) found that the naturally immune were 99.74% protected from reinfection while the naturally immune with subsequent vaccination were 99.86% protected from reinfection.<sup>60</sup> Putting aside that reinfections in both groups were mostly asymptomatic, this difference is negligible and has no clinical relevance. This miniscule difference included *asymptomatic* reinfections; numbers for *symptomatic* reinfections, hospitalizations, or deaths showed no improvement with vaccination. Numerous other large scale reliable studies have replicated these findings, as detailed below.

On the other hand, according to data from the U.K., every 11 individuals with natural immunity that are vaccinated will have a clinically significant vaccine adverse event, with the most common adverse events being significant fever, fatigue, myalgia-arthralgia, and lymphadenopathy.<sup>61</sup> Since vaccinating 833 individuals is necessary to prevent one case of *asymptomatic* reinfection according to the Israeli data (with the number being even higher for *symptomatic* reinfection), the CDC’s policy will cause over 75 cases of clinically significant adverse events (NNT/NNH = 833/11). This illustrates why the risks of Covid vaccines for me clearly outweigh any potential benefit.

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<sup>60</sup> Sivan Gazit, et al., *Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections Versus Breakthrough Infections*, MEDRXIV (Aug. 25, 2021), <https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1>.

<sup>61</sup> Rachael Kathleen Raw, et al., *Previous COVID-19 Infection, But Not Long-COVID, Is Associated with Increased Adverse Events Following BNT162b2/Pfizer Vaccination*, THE JOURNAL OF INFECTION (May 29, 2021), <https://pubmed.ncbi.nlm.nih.gov/34062184/>.

Furthermore, the naturally immune already have sterilizing immunity and a negligible rate of reinfection, and no documented case of subsequent transmission. This immunity alone is superior to vaccine immunity that is not sterilizing, produces asymptomatic carriers, has a high breakthrough rate, and has many documented cases of subsequent transmission after breakthrough.

### ***B. Reinfections v. Breakthrough Cases***

Reinfections are rare and occur at a small fraction of the rate of breakthrough cases. UK’s official government COVID-19 data shows a probable reinfection rate of 0.025% through August 19, 2021 during the Delta variant surge.<sup>62</sup> In contrast, this same data shows, through September 2, 2021, a vaccine breakthrough rate for Delta infections of 23%.<sup>63</sup> This is in line with the Director of the CDC’s statement that, “A modest percentage of people who are fully vaccinated will still get COVID-19 if they are exposed to the virus that causes it.”<sup>64</sup>

Other studies are consistent with the UK data and confirm that reinfections are exceedingly rare as well as confirm the durability of natural immunity:

- a. The Cleveland Clinic measured cumulative incidence of SARS-CoV-2 infection among 52,238 vaccinated and unvaccinated health care workers over a five-month period and found that none of the 1,359 previously infected who remained *unvaccinated* contracted SARS-CoV-2 over the course of the research despite a high background rate of COVID-19 in the hospital.<sup>65</sup>
- b. Researchers from Ireland conducted a review of 11 cohort studies involving over 600,000 total recovered COVID-19 patients who were followed up with for over 10 months and found that that reinfection in all studies was “an uncommon event” and explained that there was “no study reporting an increase in the risk of reinfection over time.”<sup>66</sup>
- c. Researchers from Qatar analyzed the population-level risk of reinfection based on whole genome sequencing, tracking 43,044 individuals for up to 35 weeks, and found that just .02% experienced reinfection (an estimated risk of reinfection of 0.66 per 10,000 person-weeks). Notably, there was no evidence of waning immunity during the over seven-month follow-up period.<sup>67</sup>

<sup>62</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1012240/Weekly\\_Flu\\_and\\_COVID-19\\_report\\_w33.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012240/Weekly_Flu_and_COVID-19_report_w33.pdf) at 17-18.

<sup>63</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1014926/Technical\\_Briefing\\_22\\_21\\_09\\_02.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Briefing_22_21_09_02.pdf) at 21. Meanwhile, the CDC—which is only reporting breakthrough cases which lead to hospitalization and death and whose “surveillance relies on passive and voluntary reporting” and acknowledges that “data are not complete or representative” and “are an undercount of all SARS-CoV-2 infections among fully vaccinated persons – has reported 14,115 breakthrough cases; <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html>. Notably, Louisiana alone had counted 14,650 breakthrough infections as of August 25, 2021, <https://www.politico.com/news/2021/08/25/cdc-pandemic-limited-data-breakthroughs-506823>.

<sup>64</sup> <https://www.nytimes.com/article/covid-breakthrough-delta-variant.html>.

<sup>65</sup> Nabin K. Shrestha, et al., *Necessity of COVID-19 Vaccination in Previously Infected Individuals*, MEDRXIV (June 19, 2021), <https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3>.

<sup>66</sup> Eamon Murchu, et al., *Quantifying the Risk of SARS-CoV-2 Reinfection Over Time*, REVIEWS OF MEDICAL VIROLOGY (May 27, 2021), <https://pubmed.ncbi.nlm.nih.gov/34043841/>.

<sup>67</sup> Laith J. Abu-Raddad, et al., *SARS-CoV-2 Antibody-Positivity Protects Against Reinfection for at Least Seven Months with 95% Efficacy*, ECLINICAL MEDICINE (April 28, 2021), <https://pubmed.ncbi.nlm.nih.gov/33937733/>.

On the other hand, the rate of breakthrough cases are multiple times higher than the rate of reinfections, and vaccine immunity is rapidly waning. The following studies affirm that natural immunity provides greater protection:

- a. A comparison of 42,000 naturally immune individuals with 62,000 fully vaccinated individuals found that the fully vaccinated individuals were 6 to 13 times more likely to get infected than the naturally immune.<sup>68</sup> Additionally, the risk of symptomatic COVID-19 was 27 times higher among those vaccinated than those previously infected and the risk of hospitalization was 8 times higher.<sup>69</sup> The study concluded that, “natural immunity confers longer lasting and stronger protection against infection, symptomatic disease and hospitalization caused by the Delta variant of SARS-CoV-2, compared to the BNT162b2 [Pfizer] two-dose vaccine-induced immunity.”<sup>70</sup>
- b. The Israeli Health Ministry found that the vaccinated had 6.72 times the rate of infection as compared to those that had contracted COVID-19:
  - i. With a total of 835,792 Israelis known to have recovered from the virus, the 72 instances of reinfection amount to 0.0086% of people who were already infected with COVID.
  - ii. By contrast, Israelis who were vaccinated were 6.72 times more likely to get infected after the shot than after natural infection.<sup>71</sup>
- c. A nationwide study of over 6 million individuals in Israel found that vaccine immunity had an efficacy of 92.8% for documented infection, 94.2% for hospitalization, and 94.4% for severe illness, but that the naturally immune had a higher rate of protection in all three of these categories.<sup>72</sup>
- d. An outbreak of SARS-CoV-2 infected 24/44 (55%) employees of a gold mine in French Guiana. The attack rate was 15/25 (60.0%) in fully vaccinated miners, 6/15 (40.0%) in those partially vaccinated or with a history of COVID-19 (none of the partially vaccinated with a history of COVID-19 were positive), and 3/4 (75%) in those not vaccinated. The attack rate was 0/6 among persons with a previous history of COVID-19 versus 63.2% among those with no previous history.<sup>73</sup>

Moreover, while the risk of reinfection has not increased over time (see studies cited above), the risk of breakthrough infections is increasing over time. This is because the protection from natural immunity remains stable whereas vaccine immunity is rapidly waning.

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<sup>68</sup> Sivan Gazit, et al., *Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections Versus Breakthrough Infections*, MEDRXIV (August 25, 2021) <https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1>.

<sup>69</sup> *Id.*

<sup>70</sup> *Id.*

<sup>71</sup> <https://www.israelnationalnews.com/News/News.aspx/309762>.

<sup>72</sup> Yair Goldberg, et al., *Protection of previous SARS-CoV-2 infection is similar to that of BNT162b2 vaccine protection: A three-month nationwide experience from Israel*, medRxiv (April 24, 2021) <https://www.medrxiv.org/content/10.1101/2021.04.20.21255670v1>.

<sup>73</sup> Nicolas Vignier, et al. *Breakthrough Infections of SARS-CoV-2 Gamma Variant in Fully Vaccinated Gold Miners, French Guiana, 2021*, Emerging Infectious Diseases (July 21, 2021) <https://pubmed.ncbi.nlm.nih.gov/34289335/>.



A Mayo Clinic study looked at the efficacy of COVID-19 vaccines from January to July 2021, during which either the Alpha or Delta variant was highly prevalent.<sup>74</sup> The results showed that as of July, the efficacy of Moderna’s vaccine had dropped to 76% and the efficacy of Pfizer’s vaccine dropped to 42%.<sup>75</sup> This is consistent with Pfizer’s data which demonstrates that the efficacy of its vaccine falls by about 6 percent every two months (with data only through “up to 6 months”).<sup>76</sup> As Pfizer’s CEO publicly acknowledged, the efficacy after “four to six months was approximately 84%.”<sup>77</sup> A drop of 6% per months means an efficacy of around 60% by one year and around 42% by 18 months, assuming the decline continues linearly rather than, as often happens, exponentially. This waning immunity is also apparent in Israel which has higher and earlier vaccination coverage and, as of August 10, 2021 “Health Ministry data ... showed that fully vaccinated individuals were responsible for most new cases and most of those hospitalized in moderate condition or worse.”<sup>78</sup>

That natural immunity is more durable than vaccine immunity is not surprising.<sup>79</sup> Vaccine immunity has never proven more durable than natural immunity for any vaccine.<sup>80</sup> Even directly after vaccination, natural immunity is plainly superior to vaccine immunity. Pfizer’s interim clinical trial results, for example, demonstrate 95% effectiveness after two months in preventing symptomatic COVID-19 in those who have not been previously infected.<sup>81</sup> Moderna’s interim clinical trial results demonstrate 94.1% effectiveness after two months in preventing symptomatic COVID-19 in those who have not been previously infected.<sup>82</sup> Even in these ideal, controlled situations, against the Alpha variant, the two mRNA vaccines have a significant gap in efficacy in preventing disease at any point in time, while the consistent data on natural immunity reflects greater than 99% efficacy against reinfection which has remained stable over time in all studies assessing same.<sup>83</sup>

<sup>74</sup> Arjun Puranik, et al., *Comparison of two highly-effective mRNA vaccines for COVID-19 during periods of Alpha and Delta variant prevalence*, medRxiv (August 21, 2021) <https://pubmed.ncbi.nlm.nih.gov/34401884/>.

<sup>75</sup> *Id.*

<sup>76</sup> Stephen J. Thomas, et al., *Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine*, medRxiv (July 28, 2021), <https://www.medrxiv.org/content/10.1101/2021.07.28.21261159v1.full.pdf>.

<sup>77</sup> <https://www.cnn.com/2021/07/28/pfizers-ceo-says-covid-vaccine-effectiveness-drops-to-84percent-after-six-months.html>.

<sup>78</sup> <https://www.timesofisrael.com/over-5000-new-coronavirus-cases-confirmed-monday-as-new-limits-mulled/>.

<sup>79</sup> See, e.g., Plotkin’s *Vaccines*, 7th Edition, at Section 2.

<sup>80</sup> *Id.*

<sup>81</sup> Sara E. Oliver, et al., *The Advisory Committee on Immunization Practices’ Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine—United States, December 2020*, MMWR MORB MORTAL WKL Y REP (Dec. 18, 2020), <https://pubmed.ncbi.nlm.nih.gov/33332292/>.

<sup>82</sup> Arjun Puranik, et al., *Comparison of Two Highly-Effective mRNA Vaccines for COVID-19 During Periods of Alpha and Delta Variant Prevalence*, MEDRXIV (Aug. 21, 2021), <https://pubmed.ncbi.nlm.nih.gov/34401884/>.

<sup>83</sup> See studies cited in Section I *supra*. It is also noteworthy that SARS-CoV-2 is at least 80% homologous to SARS-CoV-1 at the epitopes that would be recognized by host defenses that confer immunity, and the major antigen in SARS-CoV-2 is the nucleocapsid and this has greater than 90% homology to SARS-CoV-1. (Jiabao Xu, et al. *Systematic Comparison of Two Animal-to-Human Transmitted Human Coronaviruses: SARS-CoV-2 and SARS-CoV*, Viruses (February 22, 2020) <https://pubmed.ncbi.nlm.nih.gov/32098422/>.) The immunity to SARS-CoV-1 has been lifelong over the observation period thus far in humans which is 17 years reflecting the duration of immunity that is likely from SARS-CoV-2. (Nina Le Bert, et al., *SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls*, Nature (July 15, 2020) <https://pubmed.ncbi.nlm.nih.gov/32668444/>; Jianmin Zuo, et al., *Robust SARS-CoV-2-specific T cell immunity is maintained at 6 months following primary infection*, NAT IMMUNOL (Mar. 5, 2021), <https://pubmed.ncbi.nlm.nih.gov/33674800/>).

### ***C. Sterilizing Immunity v. Non-Sterilizing Immunity***

The data and studies also reflect that natural immunity provides sterilizing immunity while vaccination does not provide sterilizing immunity.

The clinical trial’s primary endpoint for the COVID-19 vaccines is measuring effectiveness against disease—not against infection.<sup>84</sup> Once used in the real-world, as Dr. Walensky has acknowledged, they do not “prevent infection or transmission.”<sup>85</sup> This is also confirmed by various studies, including:

1. Covid-19 vaccines could *not* fully block viral infection and replication in the nose of monkeys upon viral challenge.<sup>86</sup> In contrast, SARS-CoV-2 infection of monkeys completely prevented further re-infection at any site tested—by nasal, throat, and anal swabs.<sup>87</sup>
2. In Barnstable County, Massachusetts, which has a 69% vaccination coverage rate among its eligible residents, the CDC found that 74% of those infected in an outbreak were fully vaccinated for COVID-19 and that the vaccinated had on average more virus in their nose than the unvaccinated that were infected.<sup>88</sup>
3. A study of transmission among fully vaccinated health care workers in Vietnam found “transmission between the vaccinated people” and therefore concluded that “distancing measures remain critical to reduce SARS-CoV-2 Delta variant transmission” among the vaccinated.<sup>89</sup>
4. French researchers tested blood samples from health care workers who were COVID-19 naïve and received two doses of Pfizer’s vaccine and compared them to those from health care workers who had a previous mild infection and a third group of patients who had serious cases of COVID-19. They found, “No neutralization escape could be feared concerning the two variants of concern [Alpha and Beta] in” those previously infected.<sup>90</sup>

That natural infection, unlike vaccine immunity, provides sterilizing immunity, is also reflected in the UK’s official government COVID-19 data from the past 7 months while Delta was circulating which,

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<sup>84</sup>Sara E. Oliver, et al., *The Advisory Committee on Immunization Practices' Interim Recommendation for Use of Pfizer-BioNTech COVID-19 Vaccine—United States, December 2020* MMWR MORB MORTAL WKLY REP (Dec.18, 2020), <https://pubmed.ncbi.nlm.nih.gov/33332292/>.

<sup>85</sup> <https://twitter.com/CNNSitRoom/status/1423422301882748929>.

<sup>86</sup> Kizzmekia S. Corbett, Ph.D, et al., *Evaluation of the mRNA-1273 Vaccine Against SARS-CoV-2 in Nonhuman Primates*, N ENGL J MED (July 28, 2020), <https://pubmed.ncbi.nlm.nih.gov/32722908/>; Van Doremalen N. et al., *ChAdOx1 nCoV-19 Vaccination Prevents SARS-CoV-2 Pneumonia in Rhesus Macaques*, NATURE (July 30, 2020) <https://pubmed.ncbi.nlm.nih.gov/32731258/>.

<sup>87</sup>Wei Deng, et al., *Primary Exposure to SARS-CoV-2 Protects Against Reinfection in Rhesus Macaques*, SCIENCE (Aug. 14, 2020), <https://pubmed.ncbi.nlm.nih.gov/32616673/>.

<sup>88</sup> Brown CM, et al., *Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings—Barnstable County, Massachusetts*, MMWR MORB MORTAL WKLY REP (Aug. 6, 2021), <https://pubmed.ncbi.nlm.nih.gov/34351882/>.

<sup>89</sup> Nguyen Chau, *Transmission of SARS-CoV-2 Delta variant among vaccinated healthcare workers, Vietnam*, Lancet (August 10, 2021), [https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3897733](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3897733).

<sup>90</sup> Claudia Gonzalez, et al., *Live Virus Neutralisation Testing in Convalescent Patients and Subjects Vaccinated Against 19A, 20B, 20I/501Y.V1 and 20H/501Y.V2 Isolates of SARS-CoV-2*, EMERG MICROBES INFECT (June 28, 2021), <https://pubmed.ncbi.nlm.nih.gov/34176436/>.

as discussed above, reflects a probable reinfection rate of 0.025%<sup>91</sup> (and a confirmed reinfection rate of 0.0026%) but a breakthrough rate for Delta infections of 23%.<sup>92</sup>

These data comport with the observation that given approximately 120.2 million individuals have been infected in the United States,<sup>93</sup> if reinfection occurred in only 1% of individuals, the United States would have observed 1.2 million second and third cases, with many coming to clinical attention and/or requiring hospitalization. In fact, no such large volume of recurrent cases has been observed in any part of the United States.<sup>94</sup> In the 21 months since the COVID-19 virus first appeared in the United States, doctors and scientists have not documented a single case of a naturally immune individual that was reinfected with and transmitted the virus to anyone.<sup>95</sup>

Taken together, the data reflects that while the vaccinated when exposed to the virus can silently spread the virus to others, the naturally immune do not silently spread the virus. And when the rare instances of reinfections occur, as noted, there has never been a documented case of transmission from a reinfection. This is despite a world-wide hunt for such a case.

The findings in the dozens of studies cited above are not surprising given that vaccines, by design, attempt to emulate the immunity created by a natural infection.<sup>96</sup> Nonetheless, vaccines never

<sup>91</sup> See [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1012240/Weekly\\_Flu\\_and\\_COVID-19\\_report\\_w33.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1012240/Weekly_Flu_and_COVID-19_report_w33.pdf) at 17-18.

<sup>92</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/1014926/Technical\\_Briefing\\_22\\_21\\_09\\_02.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1014926/Technical_Briefing_22_21_09_02.pdf) at 21. Meanwhile, the CDC—which is only reporting breakthrough cases which lead to hospitalization and death and whose “surveillance relies on passive and voluntary reporting” and acknowledges that “data are not complete or representative” and “are an undercount of all SARS-CoV-2 infections among fully vaccinated persons—has reported 14,115 breakthrough cases; <https://www.cdc.gov/vaccines/covid-19/health-departments/breakthrough-cases.html>. Notably, Louisiana alone had counted 14,650 breakthrough infections as of August 25, 2021, <https://www.politico.com/news/2021/08/25/cdc-pandemic-limited-data-breakthroughs-506823>. Reflecting the sheer level of underreporting, Cornell University, despite a 95% vaccination rate for students and faculty, has more than five times the amount of confirmed positive cases during its first week of this academic year than it did during its first week of the 2020-21 academic year. <https://www.thecollegefix.com/despite-95-vaccination-rate-cornell-today-has-five-times-more-covid-cases-than-it-did-this-time-last-year/>. As of September 27, 2021, Harvard, despite boasting a rate of 96% faculty vaccinated and 95% students vaccinated, moved its business school remote due to “a ‘steady rise’ in breakthrough Covid-19 infection.” <https://www.bloomberg.com/news/articles/2021-09-27/harvard-moves-first-year-mba-students-online-amid-virus-outbreak>.

<sup>93</sup> See <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/burden.html>.

<sup>94</sup> <https://www.cdc.gov/coronavirus/2019-ncov/your-health/reinfection.html> (“Cases of reinfection with COVID-19 have been reported, but remain rare” as of August 6, 2021).

<sup>95</sup> There is one case study published in *Clinical Infectious Diseases* that told of a situation with a reinfection in one healthcare worker. Although the study states, “It seems likely that [the healthcare worker] played a role in the spread of this outbreak as she provides the only link between some of the patients,” this is not definitive evidence of a proven case of reinfection and transmission. The study also states, “How transmission exactly occurred within this cluster of 4 individuals as well as its origin remain unclear.” Additionally, were this a frequently occurring phenomenon, as stated above, there would be millions of cases of reinfection and evidence of transmission from same. See Selhorst P, et al., *Symptomatic SARS-CoV-2 reinfection of a health care worker in a Belgian nosocomial outbreak despite primary neutralizing antibody response*, *Clin Infect Dis.* (December 14, 2020) <https://pubmed.ncbi.nlm.nih.gov/33315049/>.

<sup>96</sup> See Plotkin’s *Vaccines*, 7th Edition, at Section 2.

achieve the same level of protection afforded by natural infection from a virus.<sup>97</sup> They universally confer inferior immunity to having had the actual virus and even the best vaccines do not confer immunity to all recipients.<sup>98</sup> In those who do obtain some immunity from vaccination, the immunity created often wanes over time.<sup>99</sup>

A recent article aptly explained why infection-induced immunity to SARS-CoV-2 is much deeper and broader than vaccine immunity:

A natural infection induces hundreds upon hundreds of antibodies against all proteins of the virus, including the envelope, the membrane, the nucleocapsid, and the spike... Dozens upon dozens of these antibodies neutralize the virus when encountered again. Additionally, because of the immune system exposure to these numerous proteins (epitomes), our T cells mount a robust memory, as well. Our T cells are the ‘marines’ of the immune system and the first line of defense against pathogens. T cell memory to those infected with SARS-CoV-1 is at 17 years and running still....

In vaccine-induced immunity ... we mount an antibody response to only the spike and its constituent proteins ... [and] this produces much fewer neutralizing antibodies, and as the virus preferentially mutates at the spike, these proteins are shaped differently and antibodies can no longer ‘lock and key’ bind to these new shapes.<sup>100</sup>

There is also apparently a high likelihood that the current Covid-19 vaccines will soon be rendered ineffective with regard to certain variants and Pfizer’s CEO has admitted as much, saying a vaccine-resistant variant will likely emerge.<sup>101</sup> This is also confirmed by researchers at Osaka University which found that “the SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines.”<sup>102</sup> Since vaccine-induced immunity does not prevent transmission or infection, this provides an opportunity for the virus to replicate in vaccinated individuals. In contrast, naturally immune individuals have sterilizing immunity, and in almost every case, do not become infected with and spread the virus upon coming into contact with the virus. They do not act as reservoirs for viral replication and transmission of new variants. As a professor of viral immunology recently explained:

Based on fundamental immunological principles, parenteral administration of these vaccines provides robust enough systemic antibody responses to allow these antibodies to spill over into the lower respiratory tract, which is a common point at which pathogens can enter systemic circulation due to the proximity of blood vessels to facilitate gas exchange. However, they do not provide adequate protection to the upper respiratory tract, like natural infection does, or like an intranasal or aerosolized vaccine likely would. As such, people whose immunity has been conferred by a vaccine only are often protected from the most severe forms of COVID-19 due to protection in the lower lungs, but they are also

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<sup>97</sup> *Id.*

<sup>98</sup> *Id.*

<sup>99</sup> *Id.*

<sup>100</sup> <https://onedrive.live.com/?authkey=%21ADfHk3IuaBrEH34&cid=914431B73799994E&id=914431B73799994E%2176735&parId=914431B73799994E%2173522&o=OneUp>.

<sup>101</sup> <https://www.insider.com/pfizer-ceo-vaccine-resistant-coronavirus-variant-likely-2021-8>.

<sup>102</sup> Yafei Liu, et al., *The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines*, medRxiv (August 23, 2021) <https://www.biorxiv.org/content/10.1101/2021.08.22.457114v1>.

susceptible to proliferation of the virus in the upper airways, which causes them to shed equivalent quantities of SARS-CoV-2 as those who completely lack immunity. Dampened disease with equal shedding equals a phenotype that approaches that of a classic super-spreader.<sup>103</sup>

***D. Serological Data on Natural Immunity***

Reflecting the foregoing real-world data, the following studies further evidence the superiority of natural immunity:

- a. Researchers at Rockefeller University concluded that memory B cells in those with prior infection “express increasingly broad and potent antibodies that are resistant to mutations found in variants of concern” and that “memory antibodies selected over time by natural infection have greater potency and breadth than antibodies elicited by vaccination.”<sup>104</sup>
- b. Researchers at the University of California concluded that “Natural infection induced expansion of larger CD8 T cell clones occupied distinct clusters, likely due to the recognition of a broader set of viral epitopes presented by the virus *not seen in the mRNA vaccine*.”<sup>105</sup>
- c. Researchers at the National Cancer Institute in Maryland and various Israeli institutions conducted a large-scale study of antibody titer decay following COVID-19 vaccine or SARS-CoV-2 infection. Aside from more robust T cell and memory B cell immunity, they found that antibodies wane slower among those who were previously infected. “In vaccinated subjects, antibody titers decreased by up to 40% each subsequent month while in convalescents they decreased by less than 5% per month.”<sup>106</sup>
- d. Researchers at Washington University School of Medicine found that, “People who recover [even] from mild COVID-19 have bone-marrow cells that can churn out antibodies for decades.”<sup>107</sup> Thus, prior COVID-19 infection creates memory B cells that “patrol the blood for reinfection, while bone marrow plasma cells (BMPCs) hide away in bones, trickling out antibodies for decades” as needed.<sup>108</sup>
- e. Researchers at various Korean institutions found that the T cells of the naturally immune had “stem-cell like” qualities and that long-term “SARS-CoV-2-specific T cell memory is successfully maintained regardless of the severity of COVID-19.”<sup>109</sup>

<sup>103</sup> <https://onedrive.live.com/?authkey=%21ADfHk3IuaBrEH34&cid=914431B73799994E&id=914431B73799994E%2176735&parId=914431B73799994E%2173522&o=OneUp>.

<sup>104</sup> Alice Cho, et al., *Anti-SARS-CoV-2 Receptor Binding Domain Antibody Evolution after mRNA Vaccination*, medRxiv (August 23, 2021) <https://www.biorxiv.org/content/10.1101/2021.07.29.454333v1>.

<sup>105</sup> Suhas Sureshchandra et al., *Single cell profiling of T and B cell repertoires following SARS-CoV-2 mRNA vaccine*, medRxiv (July 15, 2021) <https://www.biorxiv.org/content/10.1101/2021.07.14.452381v1>.

<sup>106</sup> Ariel Israel, et al., *Large-scale Study of Antibody Titer Decay Following BNT162b2 mRNA Vaccine or SARS-CoV-2 Infection*, MEDRxiv (Aug. 22, 2021), <https://pubmed.ncbi.nlm.nih.gov/34462761/>.

<sup>107</sup> Ewen Callaway, *Have COVID? You’ll Probably Make Antibodies for a Lifetime*, Nature (Aug. 22, 2021) <https://pubmed.ncbi.nlm.nih.gov/34040250/>.

<sup>108</sup> Jackson S. Turner, et al., *SARS-CoV-2 Infection Induces Long-Lived Bone Marrow Plasma Cells in Humans*, Nature (May 24 2021), <https://pubmed.ncbi.nlm.nih.gov/34030176/>.

<sup>109</sup> Jung JH, et al., *SARS-CoV-2-Specific T Cell Memory Is Sustained in COVID-19 Convalescent Patients for 10 Months with Successful Development of Stem Cell-Like Memory T Cells*, NAT COMMUN. (June 30, 2021) <https://pubmed.ncbi.nlm.nih.gov/34193870/>.

- f. Researchers at the La Jolla Institute for Immunology found that the immune systems of those who recovered from COVID-19 had durable memories of the virus for the eight-month duration of the study.<sup>110</sup>
- g. Researchers at Washington University School of Medicine found that “SARS-CoV-2 infection induces a robust antigen-specific, long-lived humoral immune response in humans.”<sup>111</sup>
- h. Researchers at Emory University and the Fred Hutchinson Cancer Research Center found that recovered COVID-19 patients mount broad, durable immunity after infection, and that “[t]he durable antibody responses in the COVID-19 recovery period are further substantiated by the ongoing rise in both the spike and RBD memory B cell responses after over 3–5 months before entering a plateau phase over 6–8 months. Persistence of RBD memory B cells has been noted.”<sup>112</sup>
- i. Researchers at Aarhus University Hospital in Denmark studied the immune response following SARS-CoV-2 infections and found that the vast majority of recovered individuals had detectable, functional SARS-CoV2 spike-specific adaptive immune responses, despite diverse disease severities, making vaccination post-COVID-19 for any of them redundant.<sup>113</sup>
- j. Researchers from the UK Coronavirus Immunology Consortium (UK-CIC), Public Health England and Manchester University NHS Foundation Trust found that every naturally immune person tested showed “robust T cell responses to SARS-CoV-2 virus peptides [six months after primary infection] in all participants” which included those with “asymptomatic or mild/moderate COVID-19 infection.”<sup>114</sup>
- k. Researchers from University of Minnesota Medical School found that “infection-induced primary MBCs [memory B cells] have better antigen-binding capacity and generate more plasmablasts and secondary MBCs of the classical and atypical subsets than vaccine-induced primary MBCs.” As the authors state, “Our results suggest that infection induced primary MBCs have undergone more affinity maturation than vaccine-induced primary MBCs and produce more robust secondary responses.”<sup>115</sup>
- l. Researchers from NYU School of Medicine found that, “In COVID-19 patients, immune responses were characterized by a highly augmented interferon response which was largely absent in vaccine recipients. Increased interferon signaling likely contributed to the observed dramatic upregulation of cytotoxic genes in the peripheral T cells and innate-like lymphocytes in patients but not in immunized subjects.” They also found that “Analysis of B and T cell receptor repertoires revealed that while the majority of clonal B and T cells in COVID-19 patients were

<sup>110</sup> Jennifer Dan, et al., *Immunological Memory to SARS-CoV-2 Assessed for Up to 8 Months After Infection*, SCIENCE (Feb. 5, 2021), <https://pubmed.ncbi.nlm.nih.gov/33408181/>; see also <https://www.nih.gov/news-events/nih-research-matters/lasting-immunity-found-after-recovery-covid-19>.

<sup>111</sup> Jackson S. Turner, et al., *SARS-CoV-2 Infection Induces Long-Lived Bone Marrow Plasma Cells in Humans*, NATURE (May 24, 2021), <https://pubmed.ncbi.nlm.nih.gov/34030176/>.

<sup>112</sup> Kristen W. Cohen, et al., *Longitudinal Analysis Shows Durable and Broad Immune Memory After SARS-CoV-2 Infection with Persisting Antibody Responses and Memory B and T Cells*, CELL REP MED. (July 14, 2021) <https://pubmed.ncbi.nlm.nih.gov/34250512/>.

<sup>113</sup> Stine Sf Nielsen, et al., *SARS-CoV-2 Elicits Robust Adaptive Immune Responses Regardless of Disease Severity*, EBIOMEDICINE (June 4, 2021), <https://pubmed.ncbi.nlm.nih.gov/34098342/>.

<sup>114</sup> <https://www.uk-cic.org/news/cellular-immunity-sars-cov-2-found-six-months-non-hospitalised-individuals>.

<sup>115</sup> Kathryn A. Pape, et al., *High Affinity Memory B Cells Induced by SARS-CoV-2 Infection Produce More Plasmablasts and Atypical Memory B Cells than those Primed by mRNA Vaccines*, CELL REPORTS (Sept. 20, 2021), <https://www.cell.com/action/showPdf?pii=S2211-1247%2821%2901287-0>.

effector cells, in vaccine recipients, clonally expanded cells were primarily circulating memory cells.”<sup>116</sup>

- m. Researchers from the National Institutes of Health studied the likelihood of SARS-CoV-2 reinfection in people carrying antibodies against the virus, gathering data from more than 3.2 million people who had undergone SARS-CoV-2 antibody testing and found that those with SARS-CoV-2 antibodies became less likely to test positive for COVID-19 as time went on. The authors stated: “The data from this study suggest that people who have a positive result from a commercial antibody test appear to have substantial immunity to SARS-CoV-2, which means they may be at lower risk for future infection.”<sup>117</sup>
- n. Researchers from Swedish and UK institutions published a study which “shows that SARS-CoV-2 elicits broadly directed and functionally replete memory T cell responses, suggesting that natural exposure or infection may prevent recurrent episodes of severe COVID-19.” This early finding of robust T cell memory has been supported by later studies as detailed above.<sup>118</sup>

***E. Hybrid Immunity (i.e., Vaccination Immunity plus Natural Immunity)***

Given the evidence that natural immunity is superior to vaccine immunity by every measure, the question can still be raised whether it is necessary to still vaccinate COVID-recovered/naturally immune individuals (“hybrid immunity”). Out of dozens of studies on hybrid immunity, all save one heavily confounded small study found that hybrid immunity is no better than natural immunity. Natural immunity is already greater than 99% efficacious against COVID-19, regardless of variants, provides sterilizing immunity, and does not wane at nearly the rate vaccine-induced immunity wanes.

The largest available population-based study involving 2.5 million Israelis in a single centralized-medical database (representing one of the four national health care funds in Israel) found the naturally immune were 99.74% protected from reinfection while the naturally immune with subsequent vaccination were 99.86% protection from reinfection.<sup>119</sup> Putting aside that reinfections in both groups were mostly asymptomatic, this difference is negligible and has no clinical relevance. Other large scale reliable studies have replicated these findings.

On the other hand, according to data from the U.K., every 11 individuals with natural immunity that are vaccinated will have a clinically significant vaccine adverse event, with the most common adverse events being fever, fatigue, myalgia-arthralgia and lymphadenopathy.<sup>120</sup> Since, according to the Israeli study mentioned in the previous paragraph, vaccinating 833 naturally individuals is needed to prevent one case of *asymptomatic* reinfection (with the number being even higher for *symptomatic*

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<sup>116</sup>Ivanova EN, et al., *Discrete Immune Response Signature to SARS-CoV-2 mRNA Vaccination Versus Infection*, MEDRXIV (April 23, 2021), <https://pubmed.ncbi.nlm.nih.gov/33907755/>.

<sup>117</sup><https://pubmed.ncbi.nlm.nih.gov/33625463/>; <https://www.nih.gov/news-events/nih-research-matters/sars-cov-2-antibodies-protect-reinfection>.

<sup>118</sup> Takuya Sekine, et al., *Robust T Cell Immunity in Convalescent Individuals with Asymptomatic or Mild COVID-19*, CELL (Aug. 14, 2020), <https://pubmed.ncbi.nlm.nih.gov/32979941/>.

<sup>119</sup> Sivan Gazit, et al., *Comparing SARS-CoV-2 Natural Immunity to Vaccine-Induced Immunity: Reinfections Versus Breakthrough Infections*, MEDRXIV (Aug. 25, 2021), <https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1>.

<sup>120</sup> Rachael Kathleen Raw, et al., *Previous COVID-19 Infection, but not Long-COVID, is Associated with Increased Adverse Events Following BNT162b2/Pfizer Vaccination*, THE JOURNAL OF INFECTION (May 29, 2021), <https://pubmed.ncbi.nlm.nih.gov/34062184/>.

reinfection), the CDC’s policy will cause over 75 cases of clinically significant adverse events (NNT/NNH = 833/11).<sup>121</sup>

There are several studies which suggest natural immunity is stunted by subsequent vaccination. Notably, U.S. researchers from Case Western Reserve University School of Medicine, Ragon Institute of MGH, MIT and Harvard, and other institutes looked at humoral immunity from 2 weeks to 6 months post-vaccination in individuals both with and without pre-vaccination SARS-CoV-2 infection. The authors noted that, “[a]ntispike, anti-RBD and neutralization levels dropped more than 84% over 6 months’ time in all [vaccinated] groups *irrespective of prior SARS-CoV-2 infection*.” In a previously infected individual with natural immunity who does not get vaccinated, these levels do not drop off. In fact, these levels persist and even grow.<sup>122</sup> The fact that they drop following vaccination is an indication that vaccination is having an adverse effect on naturally induced immunity.<sup>123</sup> In other words, the normal, longstanding, robust immunity which does not typically show significant waning and, in fact shows increasing potency over time, in those recovered is dropping 84% after vaccination.

#### F. Natural Immunity and Vaccine Immunity Against Omicron

As Omicron has become the latest dominant variant of the virus, accounting now for the vast majority of new cases, it is important to assess and compare vaccine immunity and natural immunity specifically against the new variant. As viruses almost invariably tend to do, the Omicron variant has evolved in the direction of becoming more contagious but less lethal. The reason is that, evolutionarily, viruses want to propagate (hence, more contagious) but without killing their host (less lethal), which interrupts transmission and propagation. Thus, the very good news is that the rates of hospitalization and death with the Omicron variant have declined precipitously as the virus moves closer to becoming endemic (i.e., a seasonal virus that almost everyone—vaccinated and unvaccinated—will eventually get exposed to).

<sup>121</sup> Sivan Gazit, et al., *supra*. Cf. “Model 3 - previously infected vs. vaccinated and previously infected individuals” in this study: 20/14,029 previously infected-vaccinated later tested positive (0.14% reinfection), or 99.86% immunity compared to 37/14,029 previously infected-unvaccinated (0.26% reinfection) or 99.74% immunity. Difference of 0.12% (17/14,029), with NNT 1/0.0012 = 833.

<sup>122</sup> Moriyama S., et al., *Temporal Maturation of Neutralizing Antibodies in COVID-19 Convalescent Individuals Improves Potency and Breadth to Circulating SARS-CoV-2 Variants*, IMMUNITY (July 2, 2021), <https://pubmed.ncbi.nlm.nih.gov/34246326/>.

<sup>123</sup> Daniel Lozano-Ojalvo, et al., *Differential effects of the second SARS-CoV-2 mRNA vaccine dose on T cell immunity in naive and COVID-19 recovered individuals*, Cell Rep (August 3, 2021) <https://pubmed.ncbi.nlm.nih.gov/34390647/> (Researchers monitored a group of vaccinated people with and without prior infection and found that “in individuals with a pre-existing immunity against SARS-CoV-2, the second vaccine dose not only fail to boost humoral immunity but determines a contraction of the spike-specific T cell response.” They also note that “the second vaccination does appears to exert a detrimental effect in the overall magnitude of the spike-specific humoral response in COVID-19 recovered individuals.”); *see also* Jason Neidleman, et al., mRNA vaccine-induced SARS-CoV-2-specific T cells recognize B.1.1.7 and B.1.351 variants but differ in longevity and homing properties depending on prior infection status (May 12, 2021), <https://www.biorxiv.org/content/10.1101/2021.05.12.443888v1> (Researchers assessed those vaccinated who were naïve to COVID-19 and those vaccinated who had recovered (and did not assess those who recovered but were not vaccinated) concluded that, “[i]n infection-naïve individuals, the second dose boosted the quantity but not quality of the T cell response, while in convalescents the second dose helped neither. Spike-specific T cells from convalescent vaccinees differed strikingly from those of infection-naïve vaccinees, with phenotypic features suggesting superior long-term persistence and ability to home to the respiratory tract including the nasopharynx.”).



There have been two recent robust Omicron studies available as preprints (the peer-review process takes several months), one on vaccine immunity and another on natural immunity, specifically examining this new variant. The study on vaccine immunity for Omicron<sup>124</sup> out of Ontario, Canada showed zero vaccine efficacy for the full two dose regimen of the mRNA vaccines (Pfizer or Moderna) against this variant, as the authors put it: “receipt of 2 doses of COVID-19 vaccines was not protective against Omicron.” After giving a third booster dose, the study found that vaccine efficacy against Omicron was way below the 50% efficacy threshold set by the FDA for vaccine approval: “Vaccine effectiveness against Omicron was 37% (95%CI, 19-50%)  $\geq 7$  days after receiving an mRNA vaccine for the third dose.” Consistent with this finding, the WHO recently announced that a strategy of repeated boosters is likely not feasible and will introduce ongoing repeated risks of vaccine adverse effects.

By contrast, another study<sup>125</sup> looking at natural immunity for Omicron found that while natural immunity’s protection against reinfection has declined with this new variant as compared to Delta, it remains strong—nearly twice as effective as vaccine immunity *with* boosters. The authors summarize their findings: “Protection afforded by prior infection in preventing symptomatic reinfection with Alpha, Beta, or Delta is robust, at about 90%. While such protection against reinfection with Omicron is lower, it is still considerable at nearly 60%. Prior-infection protection against hospitalization or death at reinfection appears robust, regardless of variant.” Of note, only two Omicron reinfection cases in those with natural immunity from a prior infection progressed to severe disease and no reinfections resulted in ICU cases or death.

While we do not yet have a single study that compares natural immunity and vaccine immunity for Omicron, a comparison of the findings of these two studies confirms the trend described above: vaccine immunity is declining sharply with new variants, to the point where two doses of mRNA vaccines show no protection against Omicron and a third booster shot provides minimal protection. On the other hand, the efficacy of natural immunity is declining much more modestly against new variants and remains very strong in terms of hospitalization, critical illness, and death.

### **G. Conclusion**

The naturally immune already have sterilizing immunity and a negligible rate of reinfection, and no documented cases of subsequent transmission exist. This immunity alone is superior to vaccine immunity which is not sterilizing, creates asymptomatic carriers, has a high breakthrough rate and has many documented cases of subsequent transmission after breakthrough. Thus, it is not necessary to vaccinate individuals like me who have natural immunity. Furthermore, several studies suggest that I am at elevated risk of vaccine adverse events after recovering from Covid infection.

Vaccination always involves some risk of adverse events, however small—including known risks of myocarditis, which are higher for young men. Of relevance, several studies suggest COVID recovered individuals are at elevated risk of vaccine adverse effects.<sup>126</sup> The notion that “you might not benefit but

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<sup>124</sup> Buchan SA, et al., *Effectiveness of COVID-19 Vaccines Against Omicron or Delta Infection*, MEDRXIV (Jan 1, 2022), <https://doi.org/10.1101/2021.12.30.21268565>.

<sup>125</sup> Altarawneh H., et al., *Protection Afforded by Prior Infection Against SARS-CoV-2 Reinfection with the Omicron Variant*, MEDRXIV (Jan 6, 2022), <https://doi.org/10.1101/2022.01.05.22268782>.

<sup>126</sup> Efrati, S., Catalogna, M., Abu Hamad, R. et al., *Safety and Humoral Responses to BNT162b2 mRNA Vaccination of SARS-CoV-2 Previously Infected and Naive Populations*, 11 SCI REP 16543 (2021),

should still get vaccinated for the sake of others” does not apply to Covid vaccines, because they do not prevent infection and transmission, but only lower the risk of severe symptoms. There are now countless documented cases of breakthrough infections in the vaccinated, and their likelihood of transmitting the virus is the same as the unvaccinated, as the Director of the CDC has acknowledged.<sup>127</sup> By contrast, there is *not a single reported case* of someone with natural immunity getting a reinfection and transmitting the virus to others: we are the safest people to be around.

The fact that the OSHA mandate does not account for natural immunity by itself renders the rule arbitrary and capricious. As shown above, people with natural immunity should not be treated as equivalent to unvaccinated persons when it comes to reinfection, transmission, and severity of illness from reinfection. In fact, naturally immune persons are not comparable to vaccinated persons because their immunity is in many respects *better* and longer lasting. It is thus irrational for the rule to mandate vaccination or masking and testing of people with natural immunity while exempting vaccinated persons who in several ways pose a greater risk to themselves and others by comparison.

## VII. EUA vaccines cannot and should not be mandated.

Most if not all of the Covid vaccines currently available in the U.S. are authorized under “Emergency Use Authorization” (EUA),<sup>128</sup> and are not the final approved version known as Comirnaty. For that reason alone, any vaccine mandate cannot stand and any such vaccination requirement must include the right to decline.

The EUA process is an emergency exception to the normal FDA approval process required of every drug and biologic to be proven safe and effective before its marketing, sale, and widespread distribution. It allows potentially dangerous vaccines without following the typical process because speed is deemed paramount. Under normal circumstances an employer could not require the use of an unapproved drug by employees or off-label use without the prescription of a doctor. Although the statute is worded a bit clumsily, the Act provides strong support for the right of people to, as it puts it, “refuse administration of the product.” *Id.*

The COVID-19 vaccines under the EUA are an unapproved biologic that were authorized for emergency use *only*. This explains why the use of the vaccine must, by statute, include “appropriate conditions designed to ensure that individuals to whom the product is administered are informed—(III) of the option to accept or refuse administration of the product, of the consequences, if any, of refusing administration of the product, and of the alternatives to the product that are available and of their benefits and risks.” *Id.*

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<https://doi.org/10.1038/s41598-021-96129-6>; Raw RK, et al., *Previous COVID-19 Infection but not Long-COVID is Associated with Increased Adverse Events Following BNT162b2/Pfizer Vaccination*, 83 J. OF INFECTION 381 (Sept. 2021), <https://doi.org/10.1101/2021.04.15.21252192>; Barda, N., et al., *Safety of the BNT162b2 mRNA COVID-19 Vaccine in a Nationwide Setting*, NEW ENGLAND J. OF MED. 385(12): 1078-1090 (2021); Menni C., 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 THE LANCET INFECTIOUS DISEASES 939 (July 1 2021), [https://doi.org/10.1016/S1473-3099\(21\)00224-3](https://doi.org/10.1016/S1473-3099(21)00224-3).

<sup>127</sup> <https://www.youtube.com/watch?v=FGvJYakwzI>; <https://www.nytimes.com/article/covid-breakthrough-delta-variant.html>.

<sup>128</sup> Pursuant to 21 U.S.C. § 360bbb-3(e)(1)(A)(ii)(III).

These required EUA conditions do not apply just to persons and institutions actually administering the vaccine. Rather they apply to any person “who carries out any activity for which the [emergency use] authorization is issued.” Any activity for which the authorization is issued clearly includes every process related to the vaccination, not merely its administration at the moment a needle hits an arm. For example, in a related context, an employer may *offer* wellness exams to employees but cannot *require* it without violating the Americans with Disabilities Act (ADA), which prohibits unnecessary medical exams of employees. It would be little comfort for only the doctor administering the exam to be bound not to discriminate against persons with disabilities in the administration of the exam when the harm is the coerced exam itself.

The EUA statute does not authorize the Secretary to negate the right to decline. In the middle of the EUA statute (literally at a point in between “shall” and “include”), the required conditions are modified with the phrase “as the Secretary finds necessary or appropriate to protect the public health.” This means that the Secretary can set the manner, required communicators, and specific wording for the advisements to patients of their right to decline the vaccine. It certainly does not authorize the Secretary to include *no* condition related to the right to decline. This is illustrated by the very next subsection of the statute, (e)(1)(B), which provides the Secretary “may,” as he finds necessary and appropriate, include certain additional conditions. Similarly, for emergency use of a product that is an unapproved use of an approved product (off-label use), the Secretary “shall” establish the same condition advising people of their right to decline the product for such off-label use. (e)(2)(A).

Since practically all of the COVID-19 vaccines currently available in the U.S. are under EUA, OSHA should not mandate vaccination.

### **VIII. Any final or future rule mandating vaccination or testing must comply with federal civil rights laws.**

#### ***A. Civil Rights Cannot Be Waived, Even During a Public Health Emergency***

The U.S. Department of Justice recognizes: “Civil rights protections and responsibilities still apply, even during emergencies. They cannot be waived.”<sup>129</sup> Likewise, HHS reminded “entities covered by civil rights authorities” that in light of the COVID-19 Public Health Emergency they should “keep in mind their obligations under laws and regulations that prohibit discrimination on the basis of race, color, national origin, disability, age, sex, and exercise of conscience and religion in HHS-funded programs.”<sup>130</sup>

The ETS rightly acknowledges the need for compliance with federal civil rights laws. Specifically, the ETS—premised on the existence of a “grave danger” in workplaces of employers with 100 or more employees—recognizes that employees “may be entitled to a reasonable accommodation.” 86 Fed. Reg. at 61,552. As such, consistent with the ADA and Title VII, the mandate’s vaccination requirement does not apply to employees “[w]ho are legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement.” *Id.* The ETS direct employers to consult

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<sup>129</sup> U.S. Dep’t of Just., *Civil Rights and COVID-19* (last updated May 12, 2021), [https://www.justice.gov/crt/Civil\\_Rights\\_and\\_COVID-19](https://www.justice.gov/crt/Civil_Rights_and_COVID-19).

<sup>130</sup> HHS Office for Civil Rights in Action, Bulletin: Civil Rights, HIPAA, and the Coronavirus Disease 2019 (COVID-19) 1 (Mar. 28, 2020), <https://www.hhs.gov/sites/default/files/ocr-bulletin-328-20.pdf>.

EEOC’s religion guidance and COVID-19 guidance for evaluating and responding to accommodation requests. *See* 86 Fed. Reg. at 61,522, 61,532, 61,552.

The Rule asks for comments on whether OSHA should “impose a strict vaccination mandate (i.e., all employers required to implement mandatory vaccination policies as defined in this ETS) with no alternative compliance option?” 86 Fed. Reg. at 61404. The Rule also asks for comments on the reasonable accommodation requests and what strategies employers have implemented to “address the accommodation and ensure worker safety (e.g., telework, working in isolation, regular testing and the use of face coverings).” 86 Fed. Reg. at 61404. But any final or future rule cannot violate federal civil rights laws, including an employer’s obligations under the ADA and Title VII to provide reasonable accommodations.

### ***B. Mandate Must Allow Reasonable Accommodations Under the ADA and Title VII***

Under the ADA, employers are required to provide “reasonable accommodations,” or adjustments or modifications, to qualified individuals with disabilities who are employees or applicants for employment, unless to do so would cause undue hardship, meaning significant difficulty or expense. 42 U.S.C. §§ 12101-12117, 12201-12213.

Similarly, under Title VII employers are affirmatively required to “reasonably accommodate” an employee’s religious beliefs, observances, and practices unless the accommodation would pose an “undue hardship on the conduct of the employer’s business.” 42 U.S.C. 2000e(j). Absent undue hardship, an employer’s failure to reasonably accommodate religious belief constitutes unlawful discrimination. In *Equal Employment Opportunity Commission v. Abercrombie and Fitch Stores, Inc.*, the Court held that “Title VII requires otherwise-neutral policies to give way to the need for an accommodation.” 575 U.S. 768, 775 (2015). The Court further explained, “Title VII does not demand mere neutrality with regard to religious practices—that they be treated no worse than other practices. Rather, it gives them favored treatment,” creating an affirmative obligation on the employer. *Id.*

An employee’s “sincerely held” religious objection to a workplace policy or job duty qualifies for a religious accommodation. EEOC Religion Guidance § 12-I-A-2 (2021)<sup>131</sup> (citing *United States v. Seeger*, 380 U.S. 163, 185 (1965)); *id.* § 12-IV; EEOC Religion Guidelines, 29 C.F.R. 1605.2. An employer is not required to provide an *un*-reasonable accommodation and is not necessarily required to provide the employee’s preferred accommodation. EEOC Religion Guidance § 12-IV-A-3 (citing *Ansonia Bd. of Educ. v. Philbrook*, 479 U.S. 60, 68 (1986)). An employer is required to provide a *reasonable* accommodation. *Id.* For an accommodation to be reasonable, it “must not discriminate against the employee or unnecessarily disadvantage the employee’s term’s conditions, or privileges of employment.” *Id.* (citing *Ansonia*, 479 U.S. at 70). An employer’s proposed religious accommodation is not reasonable if the employer provides a more favorable accommodation to other employees for non-religious reasons, including medical reasons. *Id.* (citing *Ansonia*, 479 U.S. at 70-71).

Likewise, a religious accommodation is not reasonable “if it requires the employee to accept a reduction in pay rate or some other loss of a benefit or privilege of employment” and there is another accommodation available that would not require such a harm. EEOC Religion Guidance § 12-IV-A-3. When there is more than one reasonable accommodation that does not pose an undue hardship, “the

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<sup>131</sup> <https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>.

employer ... must offer the alternative which least disadvantages the individual with respect to his or her employment opportunities.” EEOC Religion Guidelines, 29 C.F.R. 1605.2(c)(2)(ii). An employer “should thoroughly consider all possible reasonable accommodations,” which in the COVID-19 vaccine context could include periodic testing, masking, social distancing, modified shifts, tele-work, and—as a “last resort”—reassignment. EEOC COVID-19 Guidance at K.2, K.6, L.3.

Employees who need religious accommodations should generally be accommodated in their current positions unless there is no accommodation in that position that does not pose an undue hardship. EEOC Religion Guidance § 12-IV-C-3 (citing EEOC Religion Guidelines, 29 C.F.R. 1605.2(d)(iii)). Only when no such accommodation is possible, should the employer consider reassignment or a lateral transfer as an accommodation. *Id.* (citing EEOC Religion Guidelines, 29 C.F.R. 1605.2(d)(iii)). Similarly, an employer’s proposed accommodation that only partially eliminates the conflict is not reasonable, unless all reasonable accommodations that would eliminate the conflict would pose an undue hardship. *Id.* § 12-IV-A-3.

### ***C. Mandate Violates RFRA for Certain Religious Employers***

The ETS does not exempt religious employers from its mandate. For religious employers for whom the vaccination or testing mandate violates their sincerely held religious beliefs, the ETS would violate the Religious Freedom Restoration Act (RFRA). 42 U.S.C. § 2000bb et seq. A simple solution would be for religious organizations to be exempt from any such mandate. For any final or future rule, we urge OSHA to exempt religious employers.

### ***D. Testing Mandate Violates ADA***

The Americans with Disabilities Act prohibits discrimination against persons with disabilities in both private and public employment. The ADA provides that employers “shall not require a medical examination ... unless such examination or inquiry is shown to be job-related and consistent with business necessity.” 42 U.S. Code § 12112(d)(4)(A). Note, this prohibition is not limited to medical exams specifically related to disabilities or impacting persons with disabilities. It covers all medical exams for all employees. (ADA regulations confirm this fact, compare 29 CFR § 1630.14(b)(3) with (c)).

COVID-19 tests are clearly medical exams that are being mandated as a condition of employment, so the ADA protections apply. While OSHA may claim COVID-19 testing is a legitimate business need, it is too late because President Biden has already admitted that the vaccination or testing mandate’s actual purpose is bullying. Especially for employees who have already had COVID-19, and are much less unlikely than the vaccinated to be infected and pass it to others. According to the Director of the Centers for Disease Control and Prevention, the amount of virus in breakthrough infection cases in vaccinated people “is pretty similar to the amount of virus in [infected] unvaccinated people.”<sup>132</sup> To connect the dots, yes, people who have recovered from COVID-19 can in some cases get the virus, get reinfected and pass the virus, but we now know that the same holds true for vaccinated persons, yet only the first group of persons will be subject to bi-weekly medical exams. That’s irrational, unless, of course, the point is not infection control, but making the lives of every last unvaccinated person as miserable as possible. The lack of consistency and evidence of pretext makes the weekly testing requirement arbitrary and capricious.

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<sup>132</sup> <https://abcnews.go.com/Politics/cdc-mask-decision-stunning-findings-cape-cod-beach/story?id=79148102>.

*E. Mandate has a Disparate Impact on Minorities*

In addition, a vaccination or testing mandate would violate EO 13985 by disproportionately disadvantaging religious minorities for whom vaccination violates their sincerely held religious belief, observance, or practice, as well as unvaccinated persons who are “adversely afflicted by poverty” since they would have to bear the costs of weekly testing.

**IX. Conclusion**

In sum, vaccinations can be an important tool to combat pandemics. But the problem OSHA should be addressing is not vaccination rates themselves, but the minimization of hospitalizations, serious illness, and death of employees due to *workplace conduct or conditions*, which the Supreme Court has said does not include the universal risk of COVID-19.

OSHA should not mandate vaccination or testing. Employers should not be forced to coerce their employees to undergo a medical intervention, potentially against the advice of a doctor or in violation of an employee’s religious beliefs or conscience, or face intrusive weekly testing indefinitely (for those employees who would allow it) and concomitant stigmatization. Mandating vaccinations for all does not consider the risk-benefits calculus for any individual person, and the attendant negative impacts on employees who will no longer work for covered employers and on the economy.

We urge the Biden administration and OSHA to abandon its unlawful and unprecedented intrusion into intervention in the American economy and personal health decisions by immediately withdrawing the ETS, not issuing a final rule, and not issuing a future rule mandating workplace vaccination.

Sincerely,

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