21A242, 21A243, 21A244, 21A245, 21A246, 21A247, 21A248, 21A249, 21A250, 21A251, 21A252, 21A258, 21A259, 21A260, and 21A267

In the Supreme Court of the United States

NATIONAL FEDERATION OF INDEPENDENT BUSINESS, ET AL.,
Applicants,

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL.,
Respondents.

STATE OF OHIO, ET AL.,
Applicants,

v.

DEPT. OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMIN., ET AL.,
Respondents.

On Applications for Stay of Administrative Action and Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF OF AMERICAN COMMITMENT FOUNDATION, INC. AS *AMICUS CURIAE* SUPPORTING APPLICANTS, A STAY OF AGENCY STANDARD, AND CERTIORARI BEFORE JUDGMENT

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MOTION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

Amicus American Commitment Foundation, Inc. respectfully moves for leave **(1)** to file the attached *amicus curiae* brief in opposition to the eleven Emergency Applications, filed on December 17– 20, 2021, seeking a stay or injunction pending certiorari review of the Sixth Circuit's decision granting a motion to dissolve a stay of the Occupational Safety and Health Administration (OSHA) Emergency Temporary Standard on COVID-19 vaccination and testing (ETS), which was issued by the Fifth Circuit before being transferred to the Sixth Circuit, and **(2)** to file the enclosed brief without 10 days' advance notice to the parties of *amicus'* intent to file.

Amicus provided notice to all parties of their intent to file an *amicus* brief in opposition to the emergency applications by email on January 4, 2022. Counsel for the petitioners-applicants in 7 of the 15 applications—Nos. 21A242, 21A243, 21A244, 21A246, 21A247, 21A248, 21A249, 21A250, 21A251, 21A252, 21A258, 21A259, 21A260 and 21A267—stated that they consent or do not object to the filing.

American Commitment Foundation is a 501(c)(3) charitable foundation organized to educate the general public about concepts that advance economic freedom and constitutionally limited government, led by its president Phil Kerpen. The Foundation was ad-

vised in the preparation of this brief by epidemiologists Jay Bhattacharya of Stanford University and Andrew Bostom of Brown University.

Specifically, the scientific and technical landscape related to the Covid-19 pandemic is, like the virus itself, ever evolving. *Amicus* seek to file this brief to inform the Court of the latest developing scientific and technical information related to the dominant viral variant, referred to as "Omicron." *Amicus* are confident that this information will inform and assist the Court as it considers the weighty legal matters related to this dispute.

Given the expedited consideration of this matter of significant national interest, *amicus* respectfully request leave to file the enclosed brief without 10 days' advance notice to the parties of intent to file. The Sixth Circuit granted the government's motion to dissolve the stay imposed by the Fifth Circuit on the evening of December 17, 2021, and the applications for a stay were filed in this Court on December 17, 18, and 20. The Court set a deadline of December 30 for respondent's brief. Counsel for *amicus* provided notice to all parties on January 4, 2022. Because of the rapid schedule and because no party has opposed the filing, *amicus* request that the Court grant leave to file the attached *amicus* brief without 10 days' advance notice to the parties.

To the extent that leave is required, the proposed *amicus* respectfully moves for leave to file the attached brief on 8½- by 11-inch paper rather than in

booklet form, given the expedited briefing. Should the Clerk's Office or the Court so require, the proposed *amicus* commit to re-filing expeditiously in booklet format. See S. Ct. Rule 21.2(c).

CONCLUSION

For the foregoing reasons, *amicus* American Commitment Foundation respectfully requests that the Court grant this motion to file the attached proposed *amicus* brief and accept it in the format and at the time submitted.

Respectfully submitted,

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January 2022.

QUESTIONS PRESENTED

1. Whether the Court should stay the emergency temporary standard that the Occupational Safety and Health Administration issued, which exceeded its statutory authority and violates the United States Constitution.

2. Whether the Court should grant certiorari before judgment so that it can review the ETS before the cases become moot.

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INTEREST OF *AMICUS CURIAE*[1]

The American Commitment Foundation is a 501(c)(3) charitable foundation organized to educate the general public about concepts that advance economic freedom and constitutionally limited government, led by its president Phil Kerpen. The Foundation was advised in the preparation of this brief by epidemiologists Jay Bhattacharya of Stanford University and Andrew Bostom of Brown University.

Jay Bhattacharya is a Professor of Health Policy at Stanford University School of Medicine, a research associate at the National Bureau of Economic Research, and the Director of Stanford's Center for Demography and Economics of Health and Aging. Dr. Bhattacharya holds an M.D. and Ph.D. from Stanford University. He has published 155 scholarly articles in peer-reviewed journals in the fields of medicine, economics, health policy, epidemiology, statistics, law, and public health, among others. His research has been cited in the peer-reviewed scientific literature more than 12,500 times.

Dr. Bhattacharya has testified as an expert in numerous lawsuits related to the Covid-19 pandemic generally and vaccine mandates in particular, and has devoted substantial time in research and writing on the subject.

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[1] *Amicus* have moved for leave to file this brief. No party's counsel authored the brief in whole or in part, and no party or party's counsel, nor anyone other than *amicus* or their counsel, contributed money intended to fund its preparation or submission.

Andrew Bostom is currently affiliated with the Brown University Center For Primary Care and Prevention, and was an Associate Professor of Medicine and Family Medicine at The Warren Alpert Medical School of Brown University from 1997 until June, 2021. A clinical trialist and epidemiologist, Dr. Bostom designed and completed the largest randomized, controlled trial ever conducted in chronic kidney transplant recipients.

Dr. Bostom has 114 scholarly, peer-reviewed publications focused on epidemiology and clinical trials. He has testified as an expert witness in lawsuits pertaining to the Covid-19 pandemic—specifically on vaccine and mask mandates—while researching and writing extensively on those subjects.

INTRODUCTION & SUMMARY OF ARGUMENT

Substantial new factual developments related to the Omicron variant, arising after the filing, briefing, and arguing of the original cases, substantially undermine the government's justification for the ETS standard. The Omicron variant is — or will shortly be — the dominant viral strain in the United States, accounting for nearly all new SARS-CoV2 infections.

This significant change in circumstances negates the factual basis for the OSHA order in two ways: it dramatically reduces the risk of severe illness or death, and it renders the existing vaccines ineffective at reducing transmissions — thereby negating any possible societal benefit from mandating their use. The Court should completely disregard any fact evidence developed prior to the rise of Omicron, including the original vaccine trials, which showed efficacy against the original "wild type" virus which is no longer in circulation.

Presently available vaccines may confer a *personal benefit* against severe disease from the Omicron variant, but do not confer any demonstrable societal benefit, because they do not effectively reduce infections or transmission. They simply cannot protect workers from the spread of SARS-CoV-2 in the workplace.

With the Omicron variant now dominant, vaccine mandates cannot possibly stop viral *transmission*. Therefore, they amount to a personal health mandate, akin to a requirement to eat broccoli, exercise, or any

number of personal health measures that the Court has previously rejected as beyond the scope of legitimate federal power.

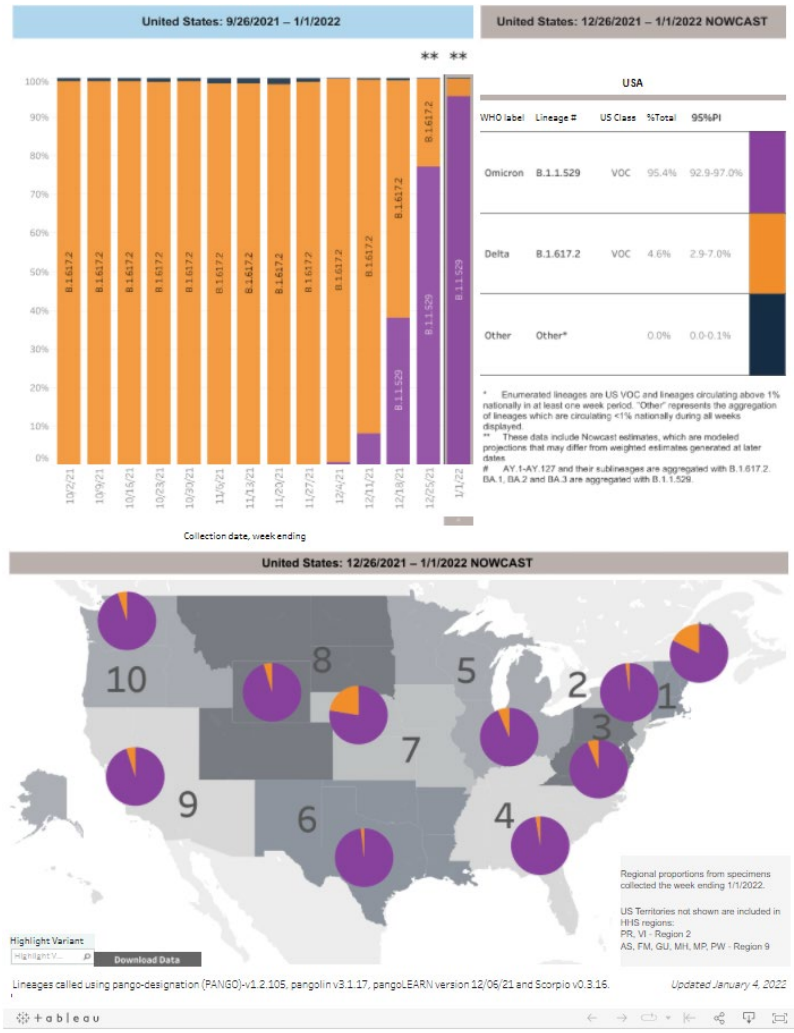
ARGUMENT

I. OMICRON IS NOW THE DOMINANT VARIANT

The Omicron variant now accounts for the majority of new SARS-COV2 infections in the United States, and is expected to represent substantially all new infections within weeks.

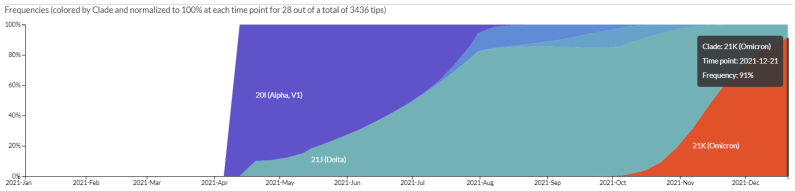
Below is the CDC official variant projection, called "NOWCAST," which shows Omicron represented 95.4% of new cases for the week ending January 1 — and is still rising:[2]

[2] CDC, *COVID Data Tracker,* https://covid.cdc.gov/covid-data-tracker/#variant-proportions (visited Jan. 4, 2022).



This follows the trajectory in South Africa, where the Omicron variant was discovered in the Gauteng

province on November 22, 2020.[3] In South Africa, Omicron rose to 91% dominance by December 21.[4]



Given the Omicron trajectory in the United States and the unprecedented steep rise in cases nationally, driven by Omicron, it is likely that by the time the Court decides whether to grant a stay, Omicron will represent substantially all of the SARS-CoV2 infections in the United States. That fact renders nearly all of the fact evidence in the record obsolete.

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[3] National Institute for Communicable Diseases, *Frequently asked questions for the B.1.1.529 mutated SARS-COV-2 lineage in South Africa*, https://www.nicd.ac.za/frequently-asked-questions-for-the-b-1-1-529-mutated-sars-cov-2-lineage-in-south-africa/ (visited Jan.4, 2022).

[4] https://nextstrain.org/ncov/gisaid/global?f_country=South%20Africa

II. OMICRON DOES NOT PRESENT A GRAVE DANGER

A recent analysis from the South African government's National Institute for Communicable Diseases provides some reason for optimism: S-Gene Target Failure (presumptive Omicron) cases are 80% less likely to be hospitalized.[5]

Table 1. Multivariable logistic regression analysis evaluating the association between S gene target failure (SGTF) infection, compared to non-SGTF infection, and hospitalisation, South Africa, 1 October – 30 November 2021[a] (N=11,255)

		Hospital admission[b] n/N (%)	Adjusted odds ratio (95% CI)	P-value
SARS-CoV-2 variant		N=11,495		
	SGTF	256/10,547 (2)	0.2 (0.1-0.3)	**<0.001**
	Non-SGTF	121/948 (13)	Ref	-

The latest data from Scotland also strongly suggests the same optimistic conclusion: "early national data suggest that Omicron is associated with a two-thirds reduction in the risk of COVID-19 hospitalisation when compared to Delta."[6]

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[5] https://www.medrxiv.org/content/10.1101/2021.12.21.21268116v1.full.pdf

[6] https://www.research.ed.ac.uk/en/publications/severity-of-omicron-variant-of-concern-and-vaccine-effectiveness-

Table 3: Observed vs expected analysis for risk of hospital admission by S gene status

Omicron

Risk of hosp 68% lower controlling for vax, reinfections)

	S Gene Status	N	Person Years	Hospital Admissions	Expected Admissions	Observed/ Expected	LCL	UCL
All cases linking into the EAVE II dataset	S Positive	119100	4375.1	856	856.9	1	0.93	1.07
	S Negative	22205	413.4	15	46.6	0.32	0.19	0.52
	Weak S Positive	2199	57.3	7	6.9	1.02	0.45	2
	Other	990	33.8	*	*	0.79	0.26	1.88
	Unknown	1647	58.2	14	14.8	0.94	0.54	1.54

Denmark's data shows Omicron cases were three times less likely to end up with hospital admissions than the previous dominant variant, Delta.[7]

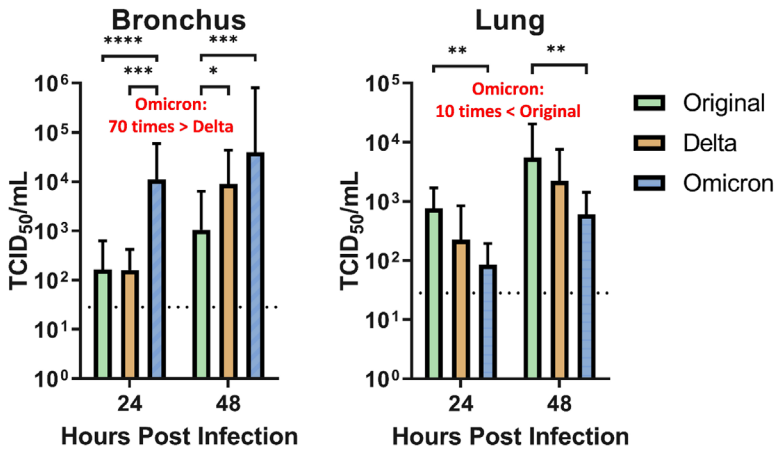
The United States has not published any comparable data. But, NIAID Director Dr. Anthony Fauci noted the global evidence of reduced severity at a December 29, 2021 White House briefing and indicated unpublished U.S. data show the same trend:

> In the United States, we are getting accumulation of data. The spike in cases is out of proportion to the increase in hospitalization. So, if one looks at 14-day averages, the data, as of last night, indicate a plus 126 percent increase in cases [but only] an 11 percent increase in hospitalizations. Now, we must remember that hospitalizations and deaths are lagging indicators. However, the pattern and disparity between cases and hospitalization strongly suggest that there will be a lower hospitalization-

[7] https://arstechnica.com/science/2021/12/omicron-cases-less-likely-to-require-hospital-treatment-studies-show/

to-case ratio when the situation becomes more clear.[8]

Hong Kong University researchers pointed to the likely reason, or mechanism, for Omicron's increased infectiousness but reduced virulence: it replicates far more efficiently in the bronchus and upper respiratory tract than Delta, but less efficiently in the lungs:[9]

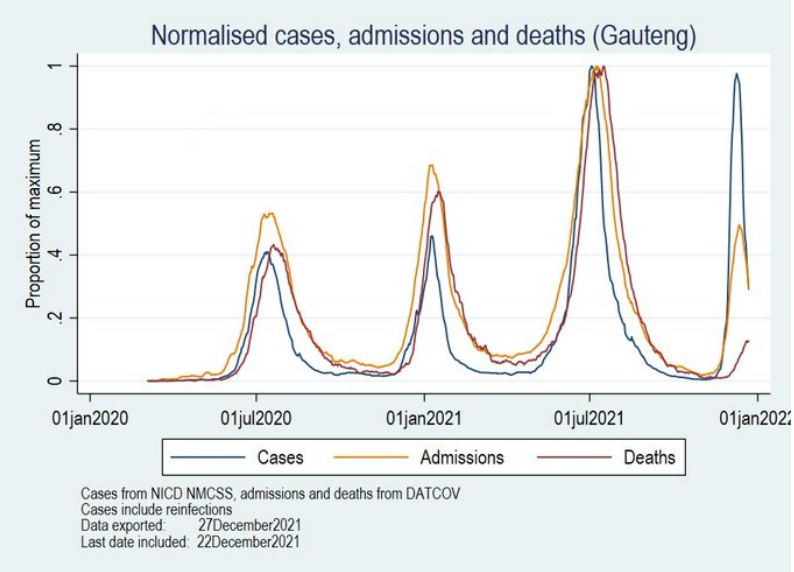


But the most compelling evidence of Omicron ending any grave danger from SARS-CoV2 comes from

[8] https://www.whitehouse.gov/briefing-room/press-briefings/2021/12/29/press-briefing-by-white-house-covid-19-response-team-and-public-health-officials-76/

[9] http://www.med.hku.hk/en/news/press/20211215-omicron-sars-cov-2-infection

South Africa, particularly the Gauteng province (population 18 million) where the first recognized Omicron wave occurred. According to Dr. Harry Moultrie of the South African government's National Institute for Communicable Diseases, Gauteng cases peaked on December 9 at 97 percent of the delta wave. Even more reassuringly, deaths were only 13 percent of the delta peak:[10]



A recently published working paper by a South African team of scientists who were conducting a sero-

[10] https://twitter.com/hivepi/status/1475383429403484163

epidemiological survey in the Gautang Province confirms the conclusion that Omicron infection is substantially less likely to require hospitalization or induce mortality than infection with other strains. While cases may rise sharply as a wave of Omicron sweeps through a region, hospitalizations and deaths do not follow. The authors conclude:[11]

> We demonstrate widespread underlying SARS-CoV-2 seropositivity in Gauteng Province prior to the current Omicron-dominant wave, with epidemiological data showing an uncoupling of hospitalization and death rates from infection rate during Omicron circulation.

Based on their Omicron experience, some South African scientists have effectively declared the pandemic over, stating:[12]

> All indicators suggest the country may have passed the peak of the fourth wave at a national level… While the Omicron variant is highly transmissible, there has been lower rates of hospitalisation than in previous waves. This means that the country has a spare capacity for

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[11] https://www.medrxiv.org/content/10.1101/2021.12.20.21268096v1

[12] https://sacoronavirus.co.za/2021/12/30/media-release-cabinet-approves-changes-to-covid-19-regulations/

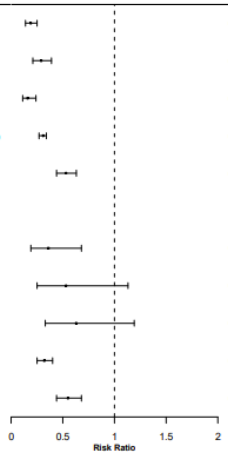
admission of patients even for routine health services.

In other words, the first country to experience an Omicron wave has unambiguously concluded that the dominant variant presents no grave danger.

Early U.S. data is available in a preprint from a team at Case Western Reserve University, which used propensity matched-cohort analysis to find markedly reduced disease severity during the period from December 14 to December 24, 2021. On an age and risk-matched basis, they found ER visits were 70% lower than earlier cohorts, hospitalizations were 56% lower, ICU admissions were 67% lower, and ventilation were 84% lower.

Age−stratified comparison of 3−day acute outcomes in matched patients with SARS−CoV−2 infections Emergent Omicron cohort (12/15−12/24) vs. Delta cohort (9/1−11/15)

Age group	Outcome	Emergent Omicron cohort	Delta cohort	RR (95% CI)
0−4 (n=1,361)	ED visit	3.89% (53)	21.01% (286)	0.19 (0.14−0.25)
5−11 (n=1,307)	ED visit	3.60% (47)	12.62% (165)	0.29 (0.21−0.39)
12−17 (n=1,244)	ED visit	2.09% (26)	13.10% (163)	0.16 (0.11−0.24)
18−64 (n=7,761)	ED visit	4.55% (353)	14.91% (1,157)	0.32 (0.27−0.34)
>=65 (n=2,173)	ED visit	7.36% (160)	13.94% (303)	0.53 (0.44−0.63)
0−4 (n=1,361)	Hospitalization	0.96% (13)	2.65% (36)	0.36 (0.19−0.68)
5−11 (n=1,307)	Hospitalization	0.77% (10)	1.45% (19)	0.53 (0.25−1.13)
12−17 (n=1,244)	Hospitalization	1.21% (15)	1.93% (24)	0.63 (0.33−1.19)
18−64 (n=7,761)	Hospitalization	1.20% (93)	3.78% (293)	0.32 (0.25−0.40)
>=65 (n=2,173)	Hospitalization	5.29% (115)	9.67% (210)	0.55 (0.44−0.68)



As good as they appear, these reductions substantially *understate* the reduction of risk represented by Omicron, because this cohort included a non-negligible number of Delta infections. According to the authors:

> The estimated prevalence of the Omicron variant during 12/15-12/24 was only 22.5-58.6%, suggesting that the outcomes for the Omicron variant may be found to be even milder than what we report here as the prevalence of the Omicron variant increases.

Adding to the lack of any grave danger, there is also strong early evidence that Omicron infection offers robust protection against the Delta variant. This means that even if the Delta variant still presented a grave danger, it would be *counterproductive* to stop or slow the spreading of the presently dominant Omicron variant.

Research at the Africa health Research Institute found:

> Importantly, there was an enhancement of Delta virus neutralization, which increased 4.4-fold. The increase in Delta variant neutralization in individuals infected with Omicron may result in decreased ability of Delta to re-infect those individuals. Along with emerging data indicating that Omicron, at this time in the pandemic, is less pathogenic

> than Delta, such an outcome may have positive implications in terms of decreasing the Covid-19 burden of severe disease.

This substantial reduction of severe disease risk must be applied to a contextualized understanding of the already low-risk to working-age individuals.

Since the start of the pandemic, there have been 206,156 COVID-associated deaths among the working age 18 to 64 population – overwhelmingly in those above age 50 with pre-existing health conditions – according to the preliminary death count at the CDC's National Center for Health Statistics:[13]

	Deaths With COVID	Total Deaths	Deaths Without COVID	Deaths With COVID as % of Age Group Deaths	Population	Deaths With COVID Per 100,000 Population	Deaths Without COVID Per 100,000 Population	Age Group % of U.S. Population	Age Group % of all Deaths with COVID	Age Group % of all Deaths Without COVID
0-17 years	678	66,234	65,556	1.0%	74,128,216	0.91	88.44	22.2%	0.1%	1.1%
18-29 years	4,956	126,217	121,261	3.9%	54,277,315	9.13	223.41	16.2%	0.6%	2.1%
30-39 years	14,614	184,876	170,262	7.9%	45,227,543	32.31	376.46	13.5%	1.8%	2.9%
40-49 years	35,190	276,337	241,147	12.7%	40,772,122	86.31	591.45	12.2%	4.3%	4.2%
50-64 years	151,396	1,121,577	970,181	13.5%	63,657,235	237.83	1524.07	19.0%	18.6%	16.7%
65 years and over	607,972	4,845,695	4,237,723	12.5%	56,441,027	1077.18	7508.23	16.9%	74.6%	73.0%
All Ages	814,806	6,620,936	5,806,130	12.3%	334,503,458	243.59	1735.75	100.0%	100.0%	100.0%

CDC NVSS Deaths, Wonder Population Estimates. From January 1, 2020 to December 25, 2021 as of December 29, 2021.

Given substantial improvements in treatments, including therapeutics that can reduce the risk of hospitalization of death by more than 50 percent, we would expect that even if the virus had not attenuated deaths in this age group, and even in the absence of vaccination, deaths would be 50,000 or less per year going forward.

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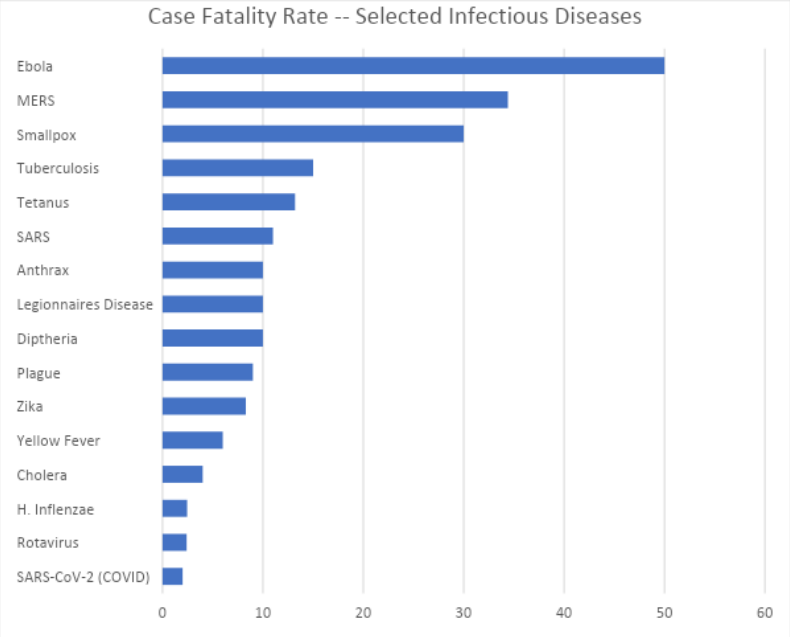
[13] https://data.cdc.gov/resource/9bhg-hcku.csv?sex=All Sexes

Case fatality rates might be an even better way to conceptualize the risk than other common measures. As Dr. Jay Bhattacharya of Stanford notes:

> It is helpful to provide some context for how large the mortality risk is posed by COVID infection relative to the risk posed by other infectious diseases. Since seroprevalence-based mortality estimates are not readily available for every disease, in the figure immediately below, I plot case fatality rates, defined as the number of deaths due to the disease divided by the number of identified or diagnosed cases of that disease. The case fatality rate for SARS-CoV-2 is ~2% (though that number has decreased with the availability of vaccines and effective treatments). By contrast, the case fatality rate for SARS is over five times higher than that, and for MERS, it is 16 times higher than that.



But the case fatality rate appears to be falling even more sharply than that. In South Africa, the case fatality rate plunged dramatically when Omicron became dominant. Pieter Streicher of the University of Johannesburg projects that for Gauteng Province: "C-19 deaths are expected to total 640 for this wave, 25x lower compared to Delta (15,400)."[14]

The graph below tracks a 7-day moving average of the case fatality rate of COVID infection from September 1, 2020 to January 1, 2022 in South Africa with

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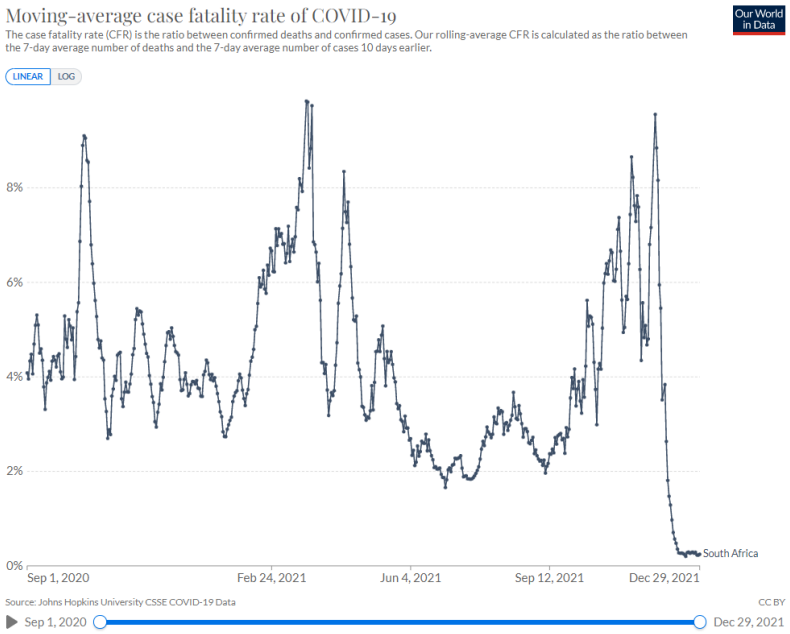
[14] https://twitter.com/pieterstreicher/status/1475525908475830278

data from a well-known COVID data provider, Our World in Data.[15] It confirms the collapse in the case fatality rate of COVID in South Africa as Omicron became the dominant strain.



[15] Our World in Data, *Moving-average case fatality rate of COVID-19*, https://ourworldindata.org/explorers/coronavirus-data-explorer?zoomToSelection=true&time=2020-03-01..latest&facet=none&pickerSort=asc&pickerMetric=location&Metric=Case+fatality+rate&Interval=7-day+rolling+average&Relative+to+Population=true&Color+by+test+positivity=false&country=~ZAF (visited Jan. 4, 2022)

With Omicron's observed decline in severity, expected working-age deaths fall into a range comparable to — or even lower than — the CDC's modeled 8,000 influenza deaths in 2017-18.[16] Quite simply, the Omicron variant is now a *normal respiratory virus,* not an unusual, extraordinary, or grave danger. There is no evidence in the record specific to Omicron to support a grave danger finding.

III. VACCINES ARE INEFFECTIVE AT PREVENTING OMICRON INFECTIONS

Pfizer and BioNTech are the manufacturers of the current leading vaccine. They recently admitted that the existing vaccine does not provide robust protection against Omicron, saying:

> Sera from individuals who received two doses of the current COVID-19 vaccine did exhibit, on average, more than a 25-fold reduction in neutralization titers against the Omicron variant compared to wild-type, indicating that two doses of BNT162b2 may not be sufficient to protect against infection with the Omicron variant.[17]

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[16] https://www.cdc.gov/flu/about/burden/2017-2018.htm

[17] https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-provide-update-omicron-variant

Moderna, the second-leading manufacturer, similarly admitted that its vaccine does not provide acceptable efficacy against Omicron, stating:

> All groups had low neutralizing antibody levels in the Omicron PsVNT assay prior to boosting.[18]

Similarly, NIH-funded researchers at Duke university found in vitro that: "neutralizing titers to Omicron are 49-84 times lower than neutralization titers to D614G [wild-type SARS-CoV2] after 2 doses of mRNA-1273 [Moderna], which could lead to an increased risk of symptomatic breakthrough infections."[19]

Real-world evidence from at least four countries with significant experience with Omicron — Denmark, the United Kingdom, Germany, and Canada, all of which provide more detailed and transparent data than has been made available in the United States — evidences that these vaccines have *substantially zero efficacy* at preventing Omicron transmission, undermining the central rationale for mandating them in the workplace.

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[18] https://investors.modernatx.com/news/news-details/2021/Moderna-Announces-Preliminary-Booster-Data-and-Updates-Strategy-to-Address-Omicron-Variant/default.aspx

[19] https://www.medrxiv.org/content/10.1101/2021.12.15.21267805v1.full-text

The Statens Serum Institut in Copenhagen, Denmark analyzed Danish data and found vaccine efficacy turned *negative* after 91 days following the second dose was administered. In other words, vaccinated Danes were *even more likely* than unvaccinated Danes to be infected with Omicron after 3 months:[20]

[20] https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v2.full.pdf

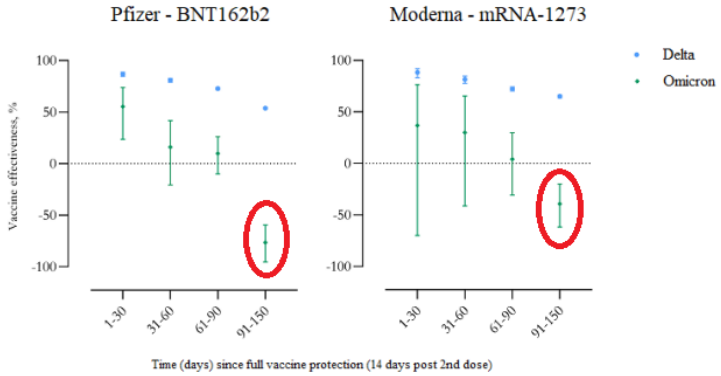

Figure Vaccine effectiveness against SARS-CoV-2 infection with the Delta and Omicron variants, shown separately for the BNT162b2 and mRNA-1273 vaccines. Vertical bars indicate 95% confidence intervals.

Table Estimated vaccine effectiveness for BNT162b2 and mRNA-1273 against infection with the SARS-CoV-2 Omicron and Delta variants during November 20 – December 12, 2021, Denmark.

	Pfizer – BNT162b2				Moderna - mRNA-1273			
	Omicron		Delta		Omicron		Delta	
Time since vaccine protection	Cases	VE, % |95% CI|	Cases	VE, % |95% CI|	Cases	VE, % |95% CI|	Cases	VE, % |95% CI|
1-30 days	14	55.2 |23.5; 73.7|	171	86.7 |84.6; 88.6|	4	36.7 |-69.9; 76.4|	29	88.2 |83.1; 91.8|
31-60 days	32	16.1 |-20.8; 41.7|	454	80.9 |79.0; 82.6|	8	30.0 |-41.3; 65.4|	116	81.5 |77.7; 84.6|
61-90 days	145	9.8 |-10.0; 26.1|	3,177	72.8 |71.7; 73.8|	48	4.2 |-30.8; 29.8|	1,037	72.2 |70.4; 74.0|
91-150 days	2,851	-76.5 |-95.3;-59.5|	34,947	53.8 |52.9; 54.6|	393	-39.3 |-61.6;-20.0|	3459	65.0 |63.6; 66.3|
1-30 days after booster vaccination protection	29	54.6 |30.4; 70.4|	453	81.2 |79.2; 82.9|	-	-	5	82.8 |58.8; 92.9|

CI = confidence intervals; VE = vaccine effectiveness. VE estimates adjusted for 10-year age groups, sex and region (five geographical regions). Vaccine protection was assumed 14 days post 2nd dose. Insufficient data to estimate mRNA-1273 booster VE against Omicron.

This may be because unvaccinated, COVID-recovered patients have better protection versus Omicron than vaccinated patients who never previously had COVID.[21]

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[21] Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon (2021) *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus*

In Germany, the most recent detailed report from the Robert Koch Institute (the German equivalent of the CDC) found that 78.6 percent (4,020 of 5,117) of sequenced Omicron cases were in *vaccinated* Germans,[22] despite a population vaccination rate of just 70 percent.[23]

In the United Kingdom, the UK Health Security Agency calculated preliminary vaccine effectiveness estimates remarkably like the Danish findings, with *near-zero vaccine efficacy* for both Pfizer-BioNTech and Moderna vaccines after 20 weeks following the second dose:[24]

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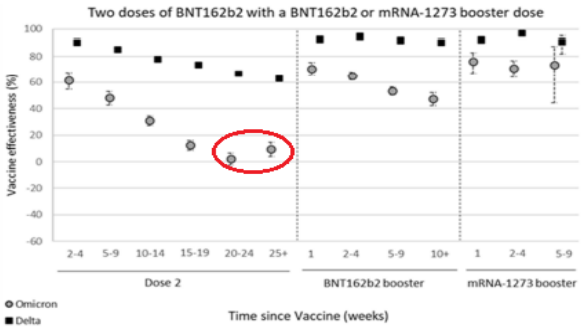
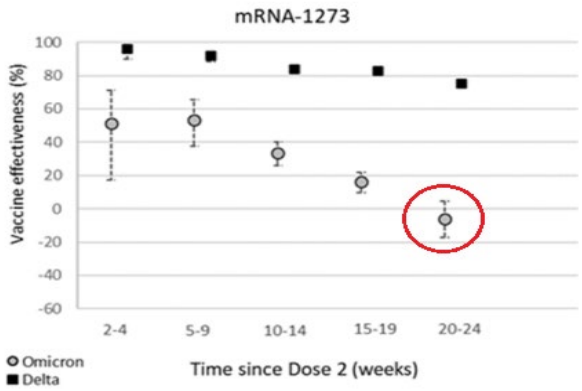
breakthrough infections, medRxiv (Aug. 25, 2021) https://doi.org/10.1101/2021.08.24.21262415

[22] https://www.rki.de/DE/Content/InfAZ/N/Neuartiges_Coronavirus/Situationsberichte/Wochenbericht/Wochenbericht_2021-12-30.pdf?__blob=publicationFile

[23] https://ourworldindata.org/covid-vaccinations

[24] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043807/technical-briefing-33.pdf

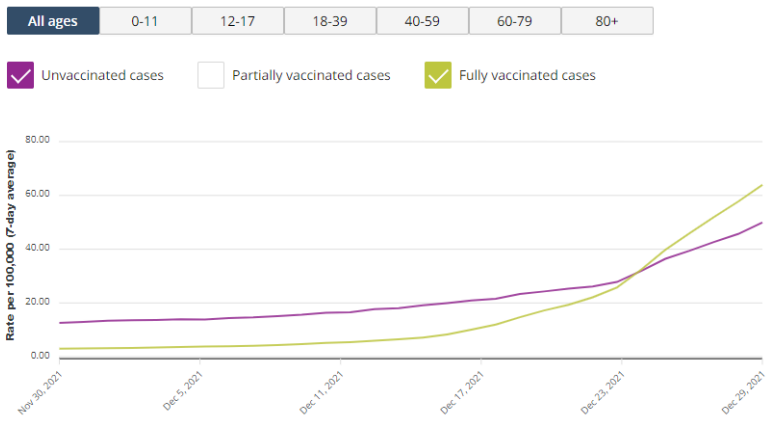




Although the UK Health Security Agency clarifies "[t]hese results should be interpreted with caution due to the low counts and the possible biases related to the populations with highest exposure to Omicron (including travellers and their close contacts) which cannot fully be accounted for," these results are consistent with the epidemiological patterns we are seeing in the United States and globally.

In Ontario, Canada, the case rate per 100,000 fully *vaccinated* Ontarians has risen sharply above the case

rate per 100,000 unvaccinated Ontarians, again suggesting *negative vaccine efficacy*:[25]



A test-negative control analysis of Ontario test data by researchers from Public Health Ontario and leading Canadian universities found: "observed *negative* VE against Omicron among those who had received 2 doses compared to unvaccinated individuals" (emphasis added).

As the following table shows, the Ontario researchers found that after day 60 following the second dose, vaccine effectiveness was *negative*, meaning a vaccinated person was *more likely* to be infected than an unvaccinated person:

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[25] https://covid-19.ontario.ca/data/case-numbers-and-spread

Table 2. Vaccine effectiveness against infection by Omicron or Delta among adults aged ≥18 years by time since latest dose

Doses	Vaccine products	Days since latest dose	SARS-CoV-2 negative controls, n	Omicron-positive cases, n	Vaccine effectiveness against Omicron (95% CI)	Delta-positive cases, n	Vaccine effectiveness against Delta (95% CI)
First 2 doses	≥1 mRNA vaccine	7-59	14,288	63	6 (-25, 30)	204	84 (81, 86)
		60-119	34,741	214	-13 (-38, 8)	562	81 (79, 82)
		120-179	282,977	2,257	-38 (-61, -18)	4,342	80 (79, 81)
		180-239	47,282	522	-42 (-69, -19)	635	74 (72, 76)
		≥240	10,285	46	-16 (-62, 17)	203	71 (66, 75)
Third dose	Any mRNA vaccine	0-6	10,208	50	2 (-35, 29)	71	88 (85, 90)
		≥7	36,500	114	37 (19, 50)	138	93 (92, 94)
	BNT162b2	0-6	8,461	42	2 (-39, 30)	64	87 (83, 90)
		≥7	30,269	106	34 (16, 49)	116	93 (91, 94)
	mRNA-1273	0-6	1,747	8	5 (-94, 54)	7	93 (86, 97)
		≥7	6,231	8	59 (16, 80)	22	93 (90, 96)

Contemporaneous with this development, Ontario announced a major shift in strategy *away from* mass testing. On December 20, 2021, Ontario's health officer Kieran Moore said:

> We have to pivot, we know there's ongoing community activity, we know we'll have transmission risk, that data has to focus to screen those who need treatment and to protect those in high-risk settings.[26]

In the United States, studies and data from last summer showing higher viral transmission in less vaccinated southern states is now completely obsolete. As the following CDC table demonstrates, in the Omicron wave there is no observable reduction in case rates based on vaccination rates:[27]

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[26] https://www.cbc.ca/news/canada/toronto/covid-19-ontario-dec-30-2021-testing-guidelines-cases-1.6300425

[27] https://data.cdc.gov/Case-Surveillance/United-States-COVID-19-Cases-and-Deaths-by-State-o/9mfq-cb36
https://covid.cdc.gov/covid-data-tracker/COVIDData/getAjaxData?id=vaccination_data

Difference in Cases in the Month of December: Most Vaccinated States Compared to Least Vaccinated

State	Cases in December 2021	2020	Difference	Fully Vaccinated
Vermont	11,120	2,932	279%	77.4%
Rhode Island	34,434	32,625	6%	76.5%
Maine	25,029	12,225	105%	75.8%
Connecticut	80,792	68,413	18%	74.6%
Massachusetts	176,728	149,046	19%	74.6%
New York	645,476	332,116	94%	71.8%
New Jersey	242,649	160,001	52%	70.5%
Maryland	113,299	79,084	43%	70.4%
Virginia	129,377	114,703	13%	68.0%
Washington	67,731	76,819	-12%	67.9%
Dist. Columbia	25,133	7,431	238%	67.6%
New Hampshire	35,412	23,034	54%	67.2%
Oregon	27,234	38,478	-29%	66.5%
New Mexico	33,567	45,769	-27%	66.2%
Colorado	80,691	100,744	-20%	66.2%
California	308,923	1,018,584	-70%	66.1%
Minnesota	103,065	96,539	7%	65.4%
MOST VACCINATED STATES			**45%**	**70.2%**

State	Cases in December 2021	2020	Difference	Fully Vaccinated
Ohio	281,594	279,317	1%	55.2%
West Virginia	30,720	37,492	-18%	55.1%
Kentucky	66,912	88,994	-25%	54.2%
Montana	6,049	19,357	-69%	54.0%
Oklahoma	37,452	105,592	-65%	53.5%
South Carolina	47,894	97,200	-51%	53.1%
Missouri	88,356	111,450	-21%	53.0%
North Dakota	10,403	13,115	-21%	52.6%
Indiana	133,734	172,712	-23%	52.0%
Tennessee	82,063	211,266	-61%	51.4%
Arkansas	28,713	67,779	-58%	51.2%
Georgia	127,565	194,889	-35%	51.1%
Louisiana	45,334	82,861	-45%	50.3%
Mississippi	24,681	63,076	-61%	48.1%
Alabama	43,257	111,713	-61%	47.6%
Wyoming	4,153	11,104	-63%	47.5%
Idaho	11,613	39,379	-71%	46.2%
LEAST VACCINATED STATES			**-44%**	**51.5%**

CONCLUSION

The situation is, as they say, highly fluid. Substantial new factual developments related to the Omicron variant, which arose subsequent to the filing, briefing, and arguing of the original cases, substantially undermine any possible justification for the government's ETS.

Even if SARS-CoV-2 did present a grave danger justifying the ETS at the time it was published — a highly controversial assertion in its own right — at this time, the Omicron virus that presently dominates the field does not even arguably present a grave danger. Nor could its transmission be substantially reduced through mandatory vaccination even if it did present a grave danger. Therefore, the OSHA order

should be stayed, and the Court should grant certiorari before judgment.

Respectfully submitted,

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