21A244 in consolidation with 21A247

In the Supreme Court of the United States

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

v.

 $\begin{array}{c} \text{Occupational Safety and Health Administration, et al.,} \\ Respondents. \end{array}$

STATE OF OHIO, ET AL., Applicants,

υ.

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

AMENDED 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-

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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 81/2- by 11-inch paper rather than in

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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,

LEONARD E. IRELAND, JR. 18 N.W. 33RD COURT Gainesville, FL 32607 (352) 376-4694 lireland@clayton-johnston.com Counsel of Record SELDON J. CHILDERS 2135 40TH TERRACE, Suite B Gainesville, FL 32605 (352) 335-0400 Counsel for Movants-Amicus

January 2022.

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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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TABLE OF AUTHORITIES

Other Authorities

Aziz Sheikh, Steven Kerr, Mark Woolhouse, Jim McMenamin, and Chris Robertson, Severity of Omicron variant of concern and vaccine effectiveness against symptomatic disease: national cohort with nested test negative design study in Scotland, The University of Ediburgh (Dec. 22, 2021)
CBC News, Ontario pushes back school reopening to Jan. 5, restricts PCR testing to high-risk individuals (Dec. 30, 2021)25
CDC, Case Surveillance/United States COVID- 19 Cases and Deaths by State, https://data.cdc.gov/Case- Surveillance/United-States-COVID-19-Cases- and-Deaths-by-State-o/9mfq-cb36 (visited Jan. 4, 2022)
CDC, COVID Data Tracker, https://covid.cdc.gov/covid-data- tracker/#variant-proportions (visited Jan. 4, 2022)
CDC, Estimated flu-related illnesses, medical visits, hospitalizations, and deaths in the United States - 2017-2018 flu season (Sept. 30, 2021)
CDC, https://data.cdc.gov/resource/9bhg- hcku.csv?sex=All Sexes

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Christian Holm Hansen PhD, Astrid Blicher Schelde PhD, Ida Rask Moustsen-Helm PhD, Hanne-Dorthe Emborg PhD, Tyra Grove Krause PhD, Kåre Mølbak DMSc, Palle Valentiner Branth, Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two- dose or booster BNT162b2 or mRNA-1273 vaccination series: a Danish cohort study, medRxiv (Dec. 22, 2021)
Dep't: Health Republic of South Africa, Media Release: Cabinet Approves Changes to COVID-19 Regulations (Dec.30, 2021)11
Genomic Epidemiology of novel coronavirus – Global subsampling, https://nextstrain.org/ncov/gisaid/global?f_cou ntry=South%20Africa https://nextstrain.org/ncov/gisaid/global?f_cou ntry=South%20Africa (visited Jan. 4, 2022)6
Harry Moultrie (@hivepi), Twitter (Dec. 27, 2021, 3:29 AM), https://twitter.com/hivepi/status/14753834294 0348416310
LKS Faculty of Medicine, The University of Hong Kong, <i>HKUMed finds Omicron SARS-</i> <i>CoV-2 can infect faster and better than Delta</i> <i>in human bronchus but with less severe</i> <i>infection in the lung</i> (Dec. 15, 2021)

vii

Moderna, Moderna Announces Preliminary Booster Data and Updates Strategy to Address Omicron Variant (Dec. 20, 2021)
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)
Nicole A. Doria-Rose, Xiaoying Shen, Stephen D. Schmidt, Sijy O'Dell, , Charlene McDanal, Wenhong Feng, Jin Tong, Booster of mRNA- 1273 vaccine reduces SARS-CoV-2 Omicron Escape from Neutralizing Antibodies, medRxiv (Dec. 15, 2021)
Nicole Wolter, Waasila Jassat, Sibongile Walaza1, Richard Welch, Harry Moultrie, Michelle Groome, Daniel Gyamfi Amoako,Early assessment of the clinical severity of the SARS-CoV-2 Omicron variant in South Africa, medRxiv (Dec. 21, 2021)7
Oliver Barnes, John Burn-Murdoch, and Richard Milne, Omicron cases less likely to require hospital treatment, studies show, Ars Technica (Dec. 22, 2021)

viii

Ontario, All Ontario: Case numbers and spread, https://covid-19.ontario.ca/data/case- numbers-and-spread (visited Jan. 5, 2022)
Our World in Data, Coronavirus (COVID-19) Vaccinations, https://ourworldindata.org/covid-vaccinations (visited Jan. 4, 2022)
Our World in Data, <i>Moving-average case</i> fatality rate of COVID-19, https://ourworldindata.org/explorers/coronavi rus-data- explorer?zoomToSelection=true&time=2020- 03- 01latest&facet=none&pickerSort=asc&picke rMetric=location&Metric=Case+fatality+rate &Interval=7- day+rolling+average&Relative+to+Populatio n=true&Color+by+test+positivity=false&coun try=~ZAF (visited Jan. 4, 2022)17
Pfizer, Pfizer and BioNTech provide update on monicron variant (Dec. 8, 2021)
Pieter Streicher (@pieterstreicher), Twitter (Dec. 27, 2021, 12:56 PM), https://twitter.com/pieterstreicher/status/147 552590847583027816
Robert Koch Institut, Wochentlicher Lagebericht des RKI zur Coronavirus-Krankheit-2019 (COVID-19) (Dec. 30, 2021)

ix

Shabir A. Madhi, Gaurav Kwatra, Jonathan E. Myers, Waasila Jassat, Nisha Dhar, Christian K. Mukendi, Amit J. Nana, South African Population Immunity and Severe Covid-19 with Omicron variant, medRxiv (Dec. 21, 2021)11
Sivan Gazit, Roei Shlezinger, Galit Perez, Roni Lotan, Asaf Peretz, Amir Ben-Tov, Dani Cohen, Khitam Muhsen, Gabriel Chodick, Tal Patalon (2021) Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: reinfections versus breakthrough infections, medRxiv (Aug. 25, 2021)22
The White House, Press Briefing by White House COVID-19 Response Team and Public Health Officials (Dec. 29, 2021),
UK Health Security Agency, SARS-CoV-2 variants of conern and variants under investigation in England (Dec. 23, 2021)22

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INTEREST OF AMICUS CURIAE¹

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.

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.

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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.

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

		Hospital admission* n/N (96)	Adjusted odds ratio (95% Ci)	P-value
SARS-CoV-2 variant		No.11,495		-
	50.14	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 twothirds reduction in the risk of COVID-19 hospitalisation when compared to Delta."⁶

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-

	Unicron		\$5.	esk of stoppoling	A rower court	unmill tot. An	s lenite	octations.
	S Gene Status	N	Person Years	Hospital Admissions	Expected Admissions	Observed/ Expected	LCL	UCL
All cases	S Positive	119100	4375.1	856	856,9	21	0.93	1.07
linking into the EAVE	S Negative Weak S	22205	413.4	15	46.6	0.32	0,19	0.52
ll dataset	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

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

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-omicronsars-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

¹¹ https://www.medrxiv.org/con-

tent/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)
9-4 (n=1 381)	ED viel	3 69% (53)	21 01% (286)	Ped.	0.19 (0.14-0.25)
5~11 (n=1 307)	ED visit	3 80% (47)	12.62% (165)		9 29 (0 21-0 39)
12-17 (n≈1,244)	ED visit	2,09% (26)	13.10% (163)	leed.	0 10 (0 11-0.24)
18-64 (n=7,781)	ED visit	4 55% (353)	14.91% (1,157)	м	0 32 (0 27~0.34)
>=66 (n=2,173)	ED visit	7,38% (180)	13.94% (303)		0 53 (0 44~0 63)
0⊷4 (n=1,36 €)	Hospitalization	0,96% (13)	2,65% (36)	it	0.36 (0 19-0 68)
5-11 (n=£307)	Hospitalization	0.77% (10)	1:45% (19)		→ 0.53 (0.25-1.13)
t2-17 (n=1,244)	Hospitalization	1,21% (15)	1.83% (24)		
18-84 (n=7.761)	Hospitalization	1.20% (93)	3 78% (293)	⊢ =-\$	0.32 (0 25-0.40)
>=85 (n=2,173)	Hospitalization	6 29% (115)	9,87% (210)	+4	0 55 (0.44-0 68)
				0 0N 100	15 2

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

	Devalve With	"pes/Leatin	Quantu Without COVID	Deaths With COVID as Svot Age Group Deaths	Possess	Denns Wim (QHID) For \$00,000 Postuation	Wildruck CONEC Pre- 100,000 Put/withon	Age Graco (s of U.S.) Pollutetion	Age Grove hy of all Dearths with LOVID	Ape Group N of sti Ceadla Without COVID
0-17 years	578	58,254	85,556	1.25	74,128,215	0.51	88.44	22.2%	\$14	1.1%
TH 21 years	4.525	126,217	121,341	5,9%	54,277,335	\$ 13	223.41	16.2%	254	2.1%
50-35 yeart	14,614	184.876	170,262	2.9%	45,232,543	32 31	376.45	13.5%	1.6%	2.9%
40 49 yean	25,192	276,337	241, 147	22.7%	42,772,122	H 11	591.45	12.2%	4.3%	4.2%
50-64 years	151.598	1,121,572	970 151	25.5%	15,857,235	257.63	1524 07	19.0%	18.85	15.7%
55 years and over	607,972	4,845,695	4,237,723	12.5%	36,441,027	1077.18	7508.23	16 Ph	74.6%	75.0%
AN ARAL	HL4 HOS	8,520 916			354 501 458	243.59	1735 75	103.04	100.04	100.0%

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.

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 seroprevalencebased 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



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/coronavirusdata-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

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.

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



Time (days) since full vaccine protection (14 days post 2nd dose)

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

Detta
VE, W 195% CI
85,2;831;91.6
81.5 (77.7; 84.6
72.2 (70.4 24,0
65.0 (61.6 66 3

CI = confidence intervals; VE = vaccina affectiveness. VE estimates adjusted for IO-year age groups, soc and region five geographical regions). Vaccine protection was assumed 14 d ays post 2rd dose. Insufficient data to estimate mRNA-1273 booster VE against Omicron.

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



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

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

²⁴ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043807/technicalbriefing-33.pdf

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_Coronaviru s/Situationsberichte/Wochenbericht/Wochenbericht_2021-12-30.pdf?__blob=publicationFile



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

Ditter	Vaccine products	Days since latest dose	SABS-CuV-2 negative controls, n	Omicrim- positive cases, n	Vaccine effectiveness against Omleron (95% f.D	Dellas positive	Vaccine effectiveness against Delta (95% CI)
First 2 doors	23 mRNA visceine	2030	14.288	63 -	61(25, 30)	201	84 (81, 86)
		00-119	34,741	214	+13 1 (28, 8)	562	81 (79, \$2)
		120-179	282,977	2,257	-38 (-61, -16)	4,742	80 (29, 81)
		180-239	47:282	522	-12 (-69, -19)	635	74 (72, 76)
		2.240	10.285	46	-16 (-62, 17)	203	71 (66, 75)
Third dose	Any mRNA vaocine	9-0	10,200	50	2133.29	71	88 (85, 90)
		27	36.500	114	37 (19, 50)	136	93 (92, 94)
	BNT16262	0.0	8,461	-12	2 1.39, 301	64	87 (83, 90)
		27	30.269	106	84 (16. 49)	116	93 (91, 94)
	mRNA-1273	0-6	1,747	Я	5 (94. 54)	7	93 (86, 97)
		>7	6.231	8	59116 801	23	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

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

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

Cares in Decamber					Cases in December					
State	2021	2020	Difference	Fully Vaccinated	Sinte	2021	2020	Difference	Fully Veccinate	
Verminist	11.120	2,932	2701	77.4%	Ohle	201.694	279.317	1%	55.29	
Rhode Island	361.16	33,625	80%	78.55	West Virginia	30,723	37,433	132%	35.17	
Malor	25,029	12,225	100%		Resituctry	46,912	88,994	-25%	54.2%	
Contractions .	83,792	88,413	18%	74.5%	Meriana	8.049	19,337	-53%	51.05	
Massachusette	126.726	148.045	195	74 816	Oblahome	37 452	105.592	-55%	53:19	
New Yatk	645.471	332.116	941	71.83	South Caroline	47.804	97,2001	-85%	\$2.17	
New Jursey	242.649	100,001	52%	70,55	Missouri	82,558	111,450	25%	83.17*	
Maryland	113,292	29,064	43%	70.4%	Worth Oskota	10,403	13,315	-21%	52.6%	
Virginia	129,377	114,753	13%	38.4%	Indiacia	133734	472,732	31% 41%	52.05	
Waatdington	67,721	26.818	-12%	87 191	Tentuisee	87.CB3	211,296	-85%	51.47	
Dist. Columbia	25.133	7,433	2221	(行,419)	Arbanas	-28,713	67,779	-50%	31.22	
New Harryshire	35,4±2	23,034	54%	07.25	Osorgia	127,565	194,000	-25%	31.17	
Dregori	27,234	38,478	224	. 56.5%	Louistana	45,334	(花)(日)(-45%	90,35	
New Mexico	33.567	45.709	-27%	35.25	Mississippi	24.661	61.076	-59%	48.79	
Coloreda	80.861	105,744	-70%	16 25	Alabarta	43,257	111.711	-51%	47.65	
Californie	200.822	1.010,014	-70h		Wyoming	4,153	17,104	-62%	47.24	
Minnapota	103,065	06,533	7%	671.875	fellerboor	11.6:3	39,379	.71%	40.29	
MOST VACCINATED STATES			45%	10.2%	LEAST VACCINAT	LEAST VACCINATED STATES		-44%	\$1.65	

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

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

Respectfully submitted,

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