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IN THE UNITED STATES COURT OF APPEALS FOR THE SIXTH CIRCUIT

IN RE: OSHA RULE ON COVID-19
VACCINATION AND TESTING, 86 FED. REG. 61,402

On Petitions for Review

BRIEF OF THE AMERICAN MEDICAL ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF RESPONDENTS' EMERGENCY MOTION TO DISSOLVE STAY

Rachel L. Fried

Counsel of Record

Jessica Anne Morton

Jeffrey B. Dubner

JoAnn Kintz*

DEMOCRACY FORWARD FOUNDATION

P.O. Box 34553

Washington, DC 20043

Counsel for Proposed Amicus Curiae American Medical Association

*Not admitted in the District of Columbia; practicing under the supervision of Democracy Forward lawyers

CORPORATE DISCLOSURE STATEMENT

The American Medical Association ("AMA") is a non-profit entity and has no parent corporation. No publicly owned corporation owns 10% or more of the stocks of the AMA.

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INTEREST OF AMICUS CURIAE

The American Medical Association ("AMA") is the largest professional association of physicians, residents, and medical students in the United States. Additionally, through state and specialty medical societies and other physician groups seated in its House of Delegates, substantially all physicians, residents, and medical students in the United States are represented in the AMA's policy-making process. The AMA was founded in 1847 to promote the art and science of medicine and the betterment of public health, and these remain its core purposes. AMA members practice in every medical specialty and in every state. The AMA has an interest in providing evidence-based guidance on public health issues and working to reduce the spread of contagious illnesses.

INTRODUCTION

The United States is in an unprecedented and ongoing public health crisis. SARS-CoV-2, the causative agent of COVID-19, has wreaked havoc in communities across the country, taxed hospitals to the point of rationing care, upended the lives of countless families, and killed

¹ *Amicus* certifies that no party's counsel authored this brief in whole or in part, no party or party's counsel contributed money intended to fund this brief, and no person other than *amicus*, its members, and their counsel contributed money intended to fund this brief.

over 769,000 Americans. Widespread vaccination is essential to ending the COVID-19 pandemic and preventing thousands more needless deaths.

For nearly two years, the AMA has monitored the COVID-19 pandemic and advocated for evidence-based public health measures to end it. Many COVID-19 outbreaks have occurred in workplaces. The AMA's extensive review of the medical literature demonstrates that COVID-19 vaccines authorized or approved by FDA are safe and effective, and the widespread use of those vaccines is the best way to keep COVID-19 from spreading within workplaces. The Fifth Circuit did not address these public health issues in evaluating whether a stay of OSHA's Emergency Temporary Standard was in the public interest.² The AMA respectfully submits that maintaining that stay would severely and irreparably harm the public interest.

ARGUMENT

I. COVID-19 poses a grave danger to public health.

COVID-19 presents a severe risk to public health. Although most people infected with the virus will experience mild to moderate

 $^{^2}$ See BST Holdings, L.L.C. v. Occupational Safety & Health Admin., Case No. 21-60845, 2021 WL 5279381, at *8 (5th Cir. Nov. 12, 2021).

symptoms, individuals with COVID-19 can become seriously ill or die at any age. As of November 19, 2021, there have been over forty-seven million confirmed cases of COVID-19 in the United States, leading to more than 3,330,000 hospitalizations.³

Even those who recover may experience post-COVID conditions with debilitating symptoms several months after the acute phase of infection. A systematic review of forty-five studies including 9,751 participants found that 73% of infected individuals experienced at least one long-term symptom.⁴ Over half of previously hospitalized patients continue to experience cardiopulmonary symptoms and abnormalities six months later.⁵ And over 769,000 people in the United States have died from COVID-19—more than twenty-four times the number of people in the United States who die from influenza in the average year.⁶

³ COVID Data Tracker Weekly Review: This is Their Shot, Centers for Disease Control and Prevention ("CDC") (Nov. 19. 2021), https://bit.ly/3EYAdAb.

⁴ Tahmina Nasserie et al., Assessment of the Frequency and Variety of Persistent Symptoms: A Systematic Review, JAMA Netw. Open (2021), https://bit.ly/3qocFkk.

⁵ M.P. Cassar et al., Symptom Persistence Despite Improvement in Cardiopulmonary Health – Insights from longitudinal CMR, CPET and lung function testing post-COVID-19, EClinicalMedicine (2021), https://bit.ly/3H7AeDB.

 $^{^6}$ $Disease\ Burden\ of\ Flu,\ CDC$ (Oct. 4, 2021), https://bit.ly/3ocAuZA.

SARS-CoV-2 is highly transmissible. The original strain was more contagious than the flu, and the Delta variant of SARS-CoV-2, now the leading strain, is more than twice as contagious as the original. Crucially, over 50% of the spread of the virus may be from individuals who have no symptoms at the time of transmission.

Workplace transmission has been a major factor in the spread of COVID-19. COVID-19 outbreaks have occurred among workers in numerous industries, including service and sales, education, hospitality, construction, domestic work, meat-processing, transportation, prison, and of course healthcare industries. Studies found widespread COVID-19 outbreaks in meat- and poultry-processing facilities and "identified high proportions of asymptomatic or presymptomatic infections." 10

⁷ Delta Variant: What We Know About the Science, CDC (Aug. 26, 2021), https://bit.ly/3plAmcy; Apoorva Mandavilli, C.D.C. Internal Report Calls Delta Variant as Contagious as Chickenpox, N.Y. Times (Jul. 30, 2021), https://nyti.ms/3wxXaHB.

⁸ Use of Cloth Masks to Control the Spread of SARS-CoV-2, CDC (May 7, 2021), https://bit.ly/30inWYx.

⁹ Update 64—COVID-19 Prevention at the Workplace, World Health Organization (Jul. 28, 2021), https://bit.ly/307J1V6; Investigating and Responding to COVID-19 Cases in Non-Healthcare Work Settings, CDC (Oct. 25, 2021), https://bit.ly/3qC74XN.

¹⁰ Michelle A. Waltenburg et al., Coronavirus Disease among Workers in Food Processing, Food Manufacturing, and Agriculture Workplaces, 27 Emerging Infectious Diseases 243 (2021), https://bit.ly/3kp3Lip.

Forty-five percent more people reported missing work for medical reasons during 2020 than the previous twenty-year average. ¹¹ Another study found that adults who tested positive for SARS-CoV-2 were significantly more likely to report going to an office or school setting than adults who tested negative. ¹² Protecting workers from COVID-19 is especially important given that "a large proportion of the United States workforce, across a variety of occupational sectors, are exposed to disease or infection at work more than once a month." ¹³

II. Vaccines provide a safe and effective way to help reduce transmission of COVID-19 in the workplace.

COVID-19 vaccines are safe. Before FDA authorized/approved and CDC recommended use of the COVID-19 vaccines in the population, scientists conducted clinical trials. FDA, CDC, and their advisory

¹¹ Charisse Jones & Matt Wynn, Coronavirus and the Workplace: The Virus Causes Record Numbers of Job Absences in 2020, USA Today (Jan. 21, 2021), https://bit.ly/3C39lgx.

¹² Kiva A. Fisher et al., Telework Before Illness Onset Among Symptomatic Adults Aged ≥18 Years With and Without COVID-19 in 11 Outpatient Health Care Facilities — United States, July 2020, 69 Morbidity & Mortality Weekly Rpt. 1648 (Apr. 28, 2020), https://bit.ly/3F5Ybt8.

¹³ Marissa G. Baker et al., Estimating the burden of United States workers exposed to infection or disease: A key factor in containing risk of COVID-19 infection, PLoS ONE (2020), https://bit.ly/3BWDoq8.

committees conducted rigorous reviews of the data,¹⁴ and continue to monitor their safety.¹⁵ A study of over six million people who received the Pfizer or Moderna vaccines found that serious side effects are very rare.¹⁶ Another study found no increased risk for mortality among recipients of any of the COVID-19 vaccines, and that vaccine recipients had lower non-COVID-19 mortality risks than did unvaccinated people.¹⁷

COVID-19 vaccines are also effective. First, each of the three vaccines greatly reduces the likelihood of contracting infection. The Pfizer, Moderna, and J&J/Janssen vaccines are 91.3%, 90%, and 72% effective against infection, respectively. Although the vaccines' efficacy wanes over time, initial data on Pfizer booster shots show that they may

 $^{^{14}}$ Benefits of Getting a COVID-19 Vaccine, CDC (Nov. 5, 2021), https://bit.ly/3H6BsiF.

¹⁵ Nicola P. Klein et al., Surveillance for Adverse Events After COVID-19 mRNA Vaccination, 326 J. Am. Med. Ass'n 1390, (Sep. 3, 2021), https://bit.ly/3F1XQYM; COVID-19 vaccine safety surveillance, FDA (Jul. 12, 2021), https://bit.ly/3wxPlB.

¹⁶ Klein et al., *supra* n. 15.

¹⁷ Stanley Xu et al., COVID-19 Vaccination and Non-COVID-19 Mortality Risk — Seven Integrated Health Care Organizations, United States, December 14, 2020–July 31, 2021, 70 Morbidity & Mortality Weekly Rpt. 1520 (Oct, 29, 2021), https://bit.ly/3D1ZRn4.

¹⁸ Kathy Katella, Comparing the COVID-19 Vaccines: How Are They Different?, Yale Med. (Nov. 3, 2021), https://bit.ly/307jEU5.

boost efficacy to over 95%. ¹⁹ For comparison, the flu vaccination reduces the risk of flu illness by between forty and sixty percent. ²⁰

Second, each of the three vaccines is even more effective against serious illness and death. Studies have estimated the Pfizer, Moderna, and J&J/Janssen vaccines as 95.3–97%, 95%, and 86% effective against severe disease, respectively.²¹ The vaccines are likewise highly effective against hospital admissions, "even in the face of widespread circulation of the delta variant."²² According to one analysis, between March 11 and August 15, 2021, unvaccinated people accounted for 84.2% of patients hospitalized for COVID-19, including those infected with the Delta variant.²³

The initial rollout of COVID-19 vaccines in the United States "was associated with reductions in COVID-19 cases, emergency department

¹⁹ Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID-19 Vaccine, Pfizer (Oct. 21, 2021), https://bit.ly/3EXQa9K.

²⁰ How Well Flu Vaccines Work: Questions & Answers, CDC (last visited Nov. 9, 2021), https://bit.ly/3HifLMP.

²¹ Katella, *supra* n. 18.

²² Sara Y Tartof et al., Effectiveness of mRNA BNT162b2 COVID-19 Vaccine Up to 6 Months, 398 Lancet 1407, 1407 (Oct. 16, 2021).

²³ Mark W. Tenforde, Association Between mRNA Vaccination and COVID-19 Hospitalization and Disease Severity, J. Am. Med. Ass'n (Nov. 4, 2021), https://bit.ly/3bZBHhb.

visits, and hospital admissions among older adults."²⁴ In August 2021, unvaccinated people had a 6.1 times greater risk of testing positive for COVID-19, and an 11.3 times greater risk of dying from COVID-19, than fully vaccinated people.²⁵

Third, as OSHA acknowledged, evidence suggests that those who are fully vaccinated are contagious for shorter periods than unvaccinated people.²⁶ Most importantly, "[r]egardless of viral loads in vaccinated and unvaccinated individuals, the fact remains clear that unvaccinated people pose a higher risk of transmission to others than vaccinated people, simply because they are much more likely to get COVID-19 in the first place."²⁷

²⁴ Lucy A. McNamara et al., Estimating the Early Impact of the US COVID-19 Vaccination Programme on COVID-19 Cases, Emergency Department Visits, Hospital Admissions, and Deaths Among Adults Aged 65 Years and Older: An Ecological Analysis of National Surveillance Data, Lancet (Nov. 3, 2021), https://bit.ly/31NqTRq.

²⁵ Rates of COVID-19 Cases and Deaths by Vaccination Status, CDC (last visited Nov. 9, 2021), https://bit.ly/3F3YMLV.

²⁶ See COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402, 61,419 (Nov. 5, 2021). ²⁷ Id.

III. The more workers who get vaccinated, the safer the workplace becomes.

The more workers who get vaccinated, the closer we are to slowing the spread of the virus and creating a safer environment. As the AMA has explained, "[t]he only way to truly end this pandemic is to ensure widespread vaccination." Infectious diseases such as COVID-19 continue to circulate as long as the average infected individual is able to transmit the disease to one or more uninfected individuals within the community. Widespread vaccination is the only practical way to push the effective reproduction rate of the SARS-CoV-2 virus below one, the rate at which endemic transmission begins to die out.

Widespread vaccination reduces the likelihood of infections among both vaccinated and unvaccinated people. "[S]tates with high vaccination rates (>70% of the population) are reporting lower numbers of vaccine breakthrough cases as well as hospitalizations and deaths

 $^{^{28}}$ Press Release, Am. Med. Ass'n, AMA, AHA, ANA urge vaccinations as U.S. reaches 750,000 COVID-19 deaths (Nov. 4, 2021) (emphasis added), https://bit.ly/3C07CIS.

²⁹ See generally Paul Fine et al., "Herd Immunity": A Rough Guide, 52 Clinical Infectious Diseases 911 (2011).

from COVID-19."³⁰ This is particularly important for people who cannot get vaccinated due to age or medical condition, as well as immunocompromised people, who remain particularly susceptible to infection even after vaccination.³¹ The Fifth Circuit's suggestion that COVID-19 no longer poses a significant danger due to the nation's overall vaccination rate does not address this issue.³²

History has shown that vaccine requirements are critical to achieving the degree of vaccination necessary to curb or eradicate infectious disease. Countries or states that mandated smallpox vaccination saw 10 to 30 times fewer smallpox cases than those that declined to do so.³³ Before compulsory school vaccination laws were in place throughout the United States, states with strict vaccination requirements had incidence rates of measles less than half those of

³⁰ Carlos del Rio et al., Confronting the Delta Variant of SARS-CoV-2, Summer 2021, 326 J. Am. Med. Ass'n 1001, 1002 (2021), https://bit.ly/3bVL5Cj.

³¹ How Effective Are COVID-19 Vaccines in Immunocompromised People?, Am. Soc'y for Microbiology (Aug. 12, 2021), https://bit.ly/3F24HBh.

 $^{^{32}}$ See BST Holdings, 2021 WL 5279381, at *5.

³³ Rajaie Batniji, *Historical Evidence to Inform COVID-19 Vaccine Mandates*, 397 Lancet 791 (2021) (citing Frank Fenner, et al., World Health Org., *Smallpox and Its Eradication* (1988)).

states that did not.³⁴ More recently, Ohioans exposed to measles abroad resulted in "the largest outbreak documented in the United States in more than two decades.³⁵ Approximately 89% of those who contracted measles were unvaccinated, but "high baseline vaccination coverage in the general community was probably effective against further spread of measles."³⁶

COVID-19 spreads in communities with fewer vaccinated individuals, even if they are within or adjacent to communities with a higher proportion of vaccinated individuals. The more people who share a workspace who are vaccinated, the better protected all workers—vaccinated and unvaccinated alike—will be.

IV. Widespread vaccination is the most effective way to protect workers from COVID-19.

The statistics on COVID-19 vaccine efficacy speak for themselves.

No other measure has been shown to reduce the risk of infection,

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³⁴ Kevin M. Malone & Alan R. Hinman, Vaccination Mandates: The Public Health Imperative and Individual Rights, in Law in Public Health Practice 262 (1st ed., 2003), https://bit.ly/3BUviyg.

³⁵ Paul A. Gastañaduy et al., *A Measles Outbreak in an Underimmunized Amish Community in Ohio*, *in* New Eng. J. Med. 1343, 1349 (2016), https://bit.ly/3Cm0RkY.

³⁶ *Id.* at 1350.

hospitalization, and death to the degree that vaccination does. Although misinformation about their efficacy abounds, the science is clear: no arguments against the need for vaccination are medically valid, other than instances where an individual has a medical contraindication.

Natural immunity—the immunity against SARS-CoV-2 that develops following recovery from infection—is not an adequate substitute for vaccination.³⁷ Infection, unlike vaccination, carries a significant risk of death or serious illness. Moreover, vaccination better protects previously infected people against reinfection. Studies have shown that unvaccinated people are at least twice as likely to become reinfected as are vaccinated people.³⁸ There is no evidence that vaccination is harmful to people who were previously infected.

³⁷ See Catherine H. Bozio et al., Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19-Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity – Nine States, January-September 2021, 70 Morbidity & Mortality Weekly Rpt. 1539 (Nov. 5, 2021), https://bit.ly/3kvoBwR (finding 5.5 times higher odds of laboratory-confirmed COVID-19 among previously infected patients than among fully vaccinated patients).

³⁸ Alyson M. Cavanaugh et al., Reduced Rick of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May—June 2021, 70 Morbidity & Mortality Weekly Rpt. 1081 (2021); Meredith Wadman, Having SARS-CoV-2 Once Confers Much Greater Immunity Than a Vaccine — but Vaccination Remains Vital, 373 Science 1067 (Aug. 26, 2021), https://bit.ly/2YB8I08.

Other mitigation measures, such as mask wearing and social distancing, remain important. They do not, however, provide the same level of protection against COVID-19 as does vaccination. Although wearing a face mask can be highly effective at limiting the transmission of SARS-CoV-2, many people choose not to wear them, even when encouraged or legally required to do so. Noncontinuous face mask wearing has been shown to result in the spread of COVID-19 in the workplace.³⁹

The ETS's alternative to vaccination—testing at regular intervals—protects workers better than no requirement at all. It does not, however, rise to the level of protection that widespread uptake of vaccinations would provide. The ETS is appropriately structured to "strongly encourag[e] vaccination." Immediate, widespread vaccination against COVID-19 is the surest way to protect the U.S. workforce and the public and to end this costly pandemic.

³⁹ Donatella Sarti et al., *COVID-19 in Workplaces: Secondary Transmission*, 65 Annals of Work Exposures & Health 1145 (2021), https://bit.ly/3Cj6oJ3.

⁴⁰ 86 Fed. Reg. at 61,402.

CONCLUSION

For the reasons stated above and in Respondents' filings, the American Medical Association urges this Court to grant Respondents' emergency motion to dissolve the stay of enforcement of the ETS.

Respectfully submitted,

/s/ Rachel L. Fried

Rachel L. Fried

Counsel of Record

Jessica Anne Morton

Jeffrey B. Dubner

JoAnn Kintz*

DEMOCRACY FORWARD

FOUNDATION

P.O. Box 34553

Washington, DC 20043

(202) 448-9090

rfried@democracyforward.org
jmorton@democracyforward.org
jdubner@democracyforward.org
jkintz@democracyforward.org

Counsel for Proposed Amicus Curiae American Medical Association

*Not admitted in the District of Columbia; practicing under the supervision of Democracy Forward lawyers

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CERTIFICATE OF SERVICE

I hereby certify that on November 23, 2021, a true and accurate

copyof the foregoing motion was electronically filed with the Court

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/s/ Rachel L. Fried

Date: November 23, 2021

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