IN THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT

STATE OF MISSOURI, ET AL.,

Plaintiffs-Appellees,

v.

JOSEPH R. BIDEN, JR., ETAL.,

 $Defendants\hbox{-}Appellants.$

On Appeal from the U.S. District Court for the Eastern District of Missouri (4:21-cv-01329-MTS)

MOTION FOR LEAVE TO FILE BRIEF OF AMERICAN COLLEGE OF PHYSICIANS, AMERICAN ACADEMY OF FAMILY PHYSICIANS, AMERICAN ACADEMY OF PEDIATRICS, AMERICAN COLLEGE OF CHEST PHYSICIANS, AMERICAN COLLEGE OF MEDICAL GENETICS AND GENOMICS, AMERICAN GERIATRICS SOCIETY, AMERICAN MEDICAL WOMEN'S ASSOCIATION, AMERICAN SOCIETY FOR CLINICAL PATHOLOGY, AMERICAN SOCIETY FOR ECHOCARDIOGRAPHY, AMERICAN SOCIETY OF HEMATOLOGY, AMERICAN THORACIC SOCIETY, AND AMERICAN LUNG ASSOCIATION AS AMICI CURIAE IN SUPPORT OF DEFENDANTS-APPELLANTS' EMERGENCY MOTION FOR STAY PENDING APPEAL

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Appellate Case: 21-3725 Page: 1 Date Filed: 12/07/2021 Entry ID: 5105693

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Appellate Case: 21-3725 Page: 2 Date Filed: 12/07/2021 Entry ID: 5105693

MOTION FOR LEAVE TO FILE BRIEF AS AMICI CURIAE

Pursuant to Federal Rule of Appellate Procedure 29, Proposed Amici move for leave to file the attached brief in support of Defendants-Appellants' emergency motion for stay pending appeal.

Proposed *Amici* include membership organizations of physicians and an organization representing patients:

The American College of Physicians is the largest medical specialty organization in the U.S. Its membership includes 161,000 internal medicine physicians, related subspecialists, and medical students. Internists apply scientific knowledge and clinical expertise to the diagnosis, treatment, and compassionate care of adults across the spectrum from health to complex illness. ACP and its physician members lead the profession in education, standard-setting, and the sharing of knowledge to advance the science and practice of internal medicine.

Founded in 1947, the American Academy of Family Physicians is one of the largest national medical organizations, representing 133,500 family physicians and medical students nationwide. AAFP seeks to improve the health of patients, families, and communities by advocating for the health of the public and by supporting its members in providing continuous comprehensive health care to all.

The American Academy of Pediatrics was founded in 1930 and is a national, non-for-profit professional organization dedicated to furthering the interests of child and adolescent health. The AAP's membership includes over 67,000 primary care pediatricians, pediatric medical subspecialists, and pediatric surgical specialists. Over the past year-and-a-half, the AAP has devoted substantial resources to researching the scientific literature regarding how to treat COVID-19 and reduce its spread so that the AAP can provide up-to-date, evidence-based guidance for pediatricians and public health officials.

The American College of Chest Physicians is comprised of over 19,000 physicians, advance practice providers, respiratory therapists, and other front line health care professionals who provide patient care in pulmonary, critical care, and sleep medicine. CHEST serves as an important connection to clinical knowledge, research and resources, including through its highly respected peer-reviewed journal, clinical practice guidelines, and consensus statements. CHEST is interested in

providing evidence-based guidance on respiratory disease-related public health issues and advocating for best practices in patient care.

The American College of Medical Genetics and Genomics is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the U.S. that represents the full spectrum of medical genetics disciplines in a single organization. The ACMG is dedicated to improving health through the clinical and laboratory practice of medical genetics and to guiding the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

The American Geriatrics Society is a nationwide, not-for-profit society of geriatrics healthcare professionals founded in 1942 and dedicated to improving the health, independence, and quality of life of older people. AGS's 6,000+ members include geriatricians, geriatrics nurse practitioners, social workers, family practitioners, physician assistants, pharmacists, and internists who are pioneers in advanced-illness care for older individuals, with a focus on championing

interprofessional teams, eliciting personal care goals, and treating older people as whole persons. AGS advocates for policies and programs that support the health, independence, and quality of life of all of us as we age. AGS has a strong interest in policies to prevent and mitigate COVID-19 infection as an important public health intervention for the health and safety of our nation—but most critically for our vulnerable populations.

The American Medical Women's Association is the oldest multispecialty organization dedicated to advancing women in medicine and improving women's health. With a mission to advance women in medicine, advocate for equity, and ensure excellence in health care, AMWA envisions a healthier world where women physicians achieve equity in the medical profession and realize their full potential and where patients receive unbiased care.

The American Society for Clinical Pathology is a 501(c)(3) non-profit medical specialty society representing more than 100,000 members. ASCP is one of the nation's largest medical specialty societies and the world's largest organization representing the field of laboratory medicine and pathology. ASCP membership is uniquely diverse,

consisting broadly of board-certified pathologists, other physicians, clinical scientists, certified medical technologists and technicians, and educators. Together, ASCP's mission is to provide excellence in education, certification, and advocacy on behalf of patients, pathologists, and laboratory professionals to advance medicine and improve patient care. ASCP has on several occasions this year outlined its unwavering support for vaccine uptake and related mandates.*

The American Society for Echocardiography is the Society for Cardiovascular Ultrasound Professionals[™]. Founded in 1975, ASE is the largest global organization representing cardiovascular ultrasound imaging. ASE is the leader and advocate for physicians, sonographers, scientists, veterinarians, students, and all those with an interest in echocardiography, setting practice standards and guidelines for the field. The Society is committed to advancing cardiovascular ultrasound to improve lives.

^{*} See, e.g., Statement Supporting OSHA's COVID Vaccine Requirement (Nov. 17, 2021), https://bit.ly/3dun6uS; To End the Pandemic, ASCP Urges that All Americans Be Vaccinated (Aug. 11, 2021), https://bit.ly/3IvV6VS; Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care (July 29, 2021) https://bit.ly/3IvV6VS.

The American Society of Hematology is the world's largest professional society of hematologists, including approximately 18,000 clinicians and researchers, who are dedicated to furthering the understanding, diagnosis, treatment, and prevention of disorders affecting the blood. ASH believes that vaccinations offer the best protection against contracting COVID-19, prevent severe illness and hospitalization, and will help save lives.

The American Thoracic Society is an international, nonprofit, nonpartisan organization with more than 15,000 physicians, scientists, nurses, and respiratory therapists dedicated to improving the health and wellbeing of patients suffering from critical care illness, pulmonary disease and sleep disordered breathing. ATS's members are on the front lines of the COVID response, treating patients with COVID in hospital ICUs, inpatient hospital wards and caring for patients with long-COVID. Given ATS's close and daily interaction with COVID patients, ATS's members are also at significant risk for occupational exposures to COVID. As such the ATS has a compelling interest in seeing the federal government establish and enforce science-based vaccination and testing policy to protect the American public from further spread of COVID.

The American Lung Association is the nation's oldest voluntary health organization committed to a world free of lung disease. SARS-COV-2 (COVID-19) is a respiratory disease that has a dramatic impact on people with lung diseases including lung cancer and chronic obstructive pulmonary disease. The American Lung Association strongly supports vaccinations and has created public education and information to increase access and overcome vaccine hesitancy. The Lung Association has also invested significant resources in research, education and public policy advocacy regarding the adverse health effects caused by COVID-19.

Proposed Amici have a strong interest in promoting public health and reducing the spread of COVID-19, particularly within their own workplaces. The attached brief reflects Proposed Amici's extensive review of medical literature supporting the efficacy and safety of the COVID-19 vaccines authorized or approved by the Food and Drug Administration. Accordingly, the proposed brief will assist the Court because it sets forth medical and scientific information demonstrating that the vaccination rule promulgated by the Centers for Medicare & Medicaid Services is neither arbitrary nor capricious and that

maintaining the stay of that standard would cause severe and irreparable harm to the public interest. Federal courts of appeals have previously accepted *amicus curiae* briefs on behalf of medical professionals in other cases addressing federal vaccination policies. See, e.g., Order, In re MCP No. 165, Occupational Safety and Health Administration Rule on COVID-19 Vaccine and Testing, 86 Fed. Reg. 61402, No. 21-7000 (6th Cir. Dec. 3, 2021), ECF No. 299.

Counsel for Proposed *Amici* have consulted with the parties' counsel. Counsel for all parties have consented to this motion.

Pursuant to Federal Rule of Appellate Procedure 29(a)(4)(E), Proposed *Amici* state that no counsel for any party authored the proposed brief in whole or in part, and no person or entity, other than Proposed *Amici* and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

Respectfully submitted,

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

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/s/ Rachel L. Fried

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Appellate Case: 21-3725 Page: 12 Date Filed: 12/07/2021 Entry ID: 5105693 CERTIFICATE OF SERVICE

I hereby certify that on December 7, 2021, a true and accurate

copy of the foregoing motion was electronically filed with the Court

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accomplished through the Court's electronic filing system.

/s/ Rachel L. Fried

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Appellate Case: 21-3725 Page: 13 Date Filed: 12/07/2021 Entry ID: 5105693

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CORPORATE DISCLOSURE STATEMENTS

The American College of Physicians is a non-profit entity and has no parent corporation. No publicly owned corporation owns 10% or more of the stocks of the American College of Physicians.

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Other Authorities P	
Am. Med. Ass'n, AMA, AHA, ANA urge vaccinations as U.S. reaches 750,000 COVID-19 deaths, https://bit.ly/3C07CIS	8
Mike Baker & Giulia Heyward, <i>Idaho allows overwhelmed</i> hospitals across the state to ration care if necessary, N.Y. Times (Sept. 16, 2021), https://nyti.ms/30Ee0ZP	10
Jack J. Barry et al., Unvaccinated Workers Say They'd Rather Quit Than Get a Shot, but Data Suggest Otherwise, Scientific American (Sept. 24, 2021), https://bit.ly/3kUYKOT	10
Alex Bhattacharya et al., Healthcare-associated COVID-19 in England: a national data linkage study, 85 J. of Infection 565 (2021), https://bit.ly/31xXHO9	4
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 Rep. 1539 (2021), https://bit.ly/3kvoBwR	11
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 Rep. 1081 (2021), https://bit.ly/306e4Bg	11
CDC, Appendices (Nov. 12, 2021), https://bit.ly/3nbxAos	12
CDC, Benefits of Getting a COVID-19 Vaccine (last updated Nov. 29, 2021), https://bit.ly/3H6BsiF	5
CDC, COVID Data Tracker (Dec. 7, 2021), https://bit.ly/3Du7Glz	2

CDC, COVID Data Tracker Weekly Review, Centers for Disease Control and Prevention (Dec. 3, 2021), https://bit.ly/3EYAdAb	2
CDC, Delta Variant: What We Know About the Science (Aug. 26, 2021), https://bit.ly/3plAmcy	3
CDC, Disease Burden of Flu (Oct. 4, 2021), https://bit.ly/3ocAuZA	2
CDC, How Well Flu Vaccines Work: Questions & Answers (last visited Nov. 9, 2021), https://bit.ly/3HifLMP	6
CDC, Rates of laboratory-confirmed COVID-19 hospitalizations by vaccination status, (last updated Dec. 2, 2021), https://bit.ly/3oIwsZ4	7
CDC, Use of Cloth Masks to Control the Spread of SARS- CoV-2 (May 7, 2021), https://bit.ly/30inWYx	3
CDC, Vaccination to Prevent COVID-19 Outbreaks with Current and Emergent Variants — United States, 2021 (July 27, 2021), https://bit.ly/3GhocGC	10
COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402 (Nov. 5, 2021)	8
Carlos del Rio et al., Confronting the Delta Variant of SARS-CoV-2, Summer 2021, 326 JAMA 1001 (2021), https://bit.ly/3bVL5Cj	9
FDA, COVID-19 vaccine safety surveillance (Jul. 12, 2021), https://bit.ly/3y1dDET	5
Ashley Fowlkes et al., Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020—August 2021, 70 Morbidity & Mortality Weekly Rep. 1167 (2021), https://bit.ly/3px2OGB.	6

Jessica Ibiebele et al., Occupational COVID-19 exposures and secondary cases among healthcare personnel, 49 Am. J. of Infection Control 1334 (2021), https://bit.ly/3lI0lIo	2
Kathy Katella, Comparing the COVID-19 Vaccines: How Are They Different?, Yale Med. (Nov. 19, 2021), https://bit.ly/307jEU5	6
Clark Kauffman, <i>Iowa's nursing home infections and outbreaks are up 20% over last week</i> , Iowa Cap. Dispatch (Oct. 29, 2021), https://bit.ly/3oIpMu0	4
Nicola P. Klein et al., Surveillance for Adverse Events After COVID-19 mRNA Vaccination, 326 JAMA 1390 (2021), https://bit.ly/3F1XQYM	5
Katherine Lontok, <i>How Effective Are COVID-19 Vaccines in Immunocompromised People</i> , Am. Society for Microbiology (Aug. 12, 2021), https://bit.ly/3F24HBh	9
Apoorva Mandavilli, <i>C.D.C. Internal Report Calls Delta Variant as Contagious as Chickenpox</i> , N.Y. Times (Jul. 30, 2021), https://nyti.ms/3EtJXTb	3
Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021)	7
Temet M. Michael et al., Epidemiology of Covid-19 in a Long-Term Care Facility in King County, Washington, 382 New Eng. J. of Med. 2005 (2020), https://bit.ly/3pBvoXy	4
Γahmina Nasserie et al., Assessment of the Frequency and Variety of Persistent Symptoms: A Systematic Review, JAMA Netw. Open, May 26, 2021, https://bit.ly/3qocFkk	3
Long H. Nguyen et al., Risk of COVID-19 among front-line health-care workers and the general community: a prospective cohort study, 5 Lancet e475 (2020),	1
https://bit.ly/31ABwY2	+

Pfizer, Pfizer and BioNTech Announce Phase 3 Trial Data Showing High Efficacy of a Booster Dose of Their COVID- 19 Vaccine (Oct. 21, 2021), https://bit.ly/3EXQa9K	6
Aaron Richterman et al., Hospital-Acquired SARS-CoV-2 Infection: Lessons for Public Health, 324 JAMA 2155 (2020), https://bit.ly/3Irc8Va	4, 12
Amber K. Sabbatini, et al., Excess Mortality Among Patients Hospitalized During the COVID-19 Pandemic, 16 J. Hosp. Med. 596 (2021), https://bit.ly/3Hs5EEU	9
Karen Shen et al., Estimates of COVID-19 Cases and Deaths Among Nursing Home Resident Not Reported in Federal Data, JAMA Network Open (Sept. 9, 2021), https://bit.ly/3lG02h2	3
Tim Stelloh, Alabama heart patient dies after hospital contacts 43 ICUs in 3 states, family says, NBC News (Sept. 12, 2021), https://nbcnews.to/3nyOz4t	9
Sara Y. Tartof et al., Effectiveness of mRNA BNT162b2 COVID-19 Vaccine Up to 6 Months, 398 Lancet 1407 (2021), https://bit.ly/3ouPvqS	7
Mark W. Tenforde, Association Between mRNA Vaccination and COVID-19 Hospitalization and Disease Severity, 326 JAMA 2043 (2021), https://bit.ly/3bZBHhb	7
WHO, Preventing and mitigating COVID-19 at work, at 2, World Health Organization (May 19, 2021), https://bit.ly/3wMJ451	13
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 Rep. 1520 (2021), https://bit.ly/3D1ZRn4	5

INTEREST OF AMICI CURIAE

As set forth in the accompanying motion for leave to file, *Amici* are associations representing medical professionals and patients across disciplines. They accordingly have a strong interest in both patient care and the applicability of the CMS rule to their members' workplaces.¹

INTRODUCTION

The United States is in an unprecedented and ongoing public health crisis as it battles COVID-19—a battle that can be won only with widespread vaccination. While vaccination of all workers is critical to protecting public health and safety, it is even more urgent that healthcare workers be vaccinated: the potential for transmission of the SARS-CoV-2 virus in healthcare settings puts not only frontline workers, but also patients, at risk. *Amici*'s extensive review of the medical literature demonstrates that COVID-19 vaccines authorized or approved by the Food and Drug Administration are safe and effective, and the widespread use of those vaccines is the best way to keep COVID-19 from spreading within healthcare facilities. Maintaining the injunction

¹ *Amici* 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 *amici*, their members, and their counsel contributed money intended to fund this brief.

against the Centers for Medicare & Medicaid Services' interim final rule requiring vaccination of covered healthcare facility staff² would therefore severely and irreparably harm patients and undermine the public interest.

ARGUMENT

I. COVID-19 poses a grave danger to the health of healthcare facility staff and patients.

COVID-19 presents a severe risk to public health. Although most people infected with the virus will experience mild to moderate symptoms, individuals with COVID-19 can become seriously ill or die at any age. As of December 7, 2021, there have been over forty-nine million confirmed cases of COVID-19 in the United States,³ leading to more than 3,400,000 hospitalizations⁴ and over 787,000 deaths—more than twenty-one times the number of people in the United States who die from influenza in the average year.⁵ Even those who recover from COVID-19 may experience debilitating symptoms lasting for several months after

² Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021).

³ *COVID Data Tracker*, Centers for Disease Control and Prevention (Dec. 7, 2021), https://bit.ly/3Du7Glz.

⁴ COVID Data Tracker Weekly Review, CDC (Dec. 3, 2021), https://bit.ly/3EYAdAb.

⁵ Disease Burden of Flu, CDC (Oct. 4, 2021), https://bit.ly/3ocAuZA.

the acute phase of infection. A systematic review of forty-five studies found that 73% of infected individuals experienced at least one long-term symptom.⁶

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.⁷ Crucially, over 50% of the spread of the virus may be from individuals who have no symptoms at the time of transmission.⁸

Transmission in healthcare facilities has been a major factor in the spread of COVID-19. Since the beginning of the COVID-19 outbreak in February 2020, COVID-19 has ravaged nursing homes, long-term care facilities, and hospitals. A study found that "[u]p to 1 in 6 SARS-CoV-2

⁶ Tahmina Nasserie et al., Assessment of the Frequency and Variety of Persistent Symptoms: A Systematic Review, JAMA Netw. Open, May 26, 2021, https://bit.ly/3qocFkk.

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/3EtJXTb.

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

⁹ See, e.g., Karen Shen et al., Estimates of COVID-19 Cases and Deaths Among Nursing Home Resident Not Reported in Federal Data, at 2, JAMA Network Open (Sept. 9, 2021), https://bit.ly/3lG02h2 ("[N]ursing")

infections among hospitalised patients with COVID-19 in England during the first 6 months of the pandemic could be attributed to [healthcare-associated] transmission."¹⁰ Another study found that frontline healthcare workers had a three-fold risk of contracting SARS-CoV-2 compared to the general population.¹¹ And healthcare facilities are still loci of outbreaks of the Delta variant. Outbreaks in Iowa nursing homes during October 2021, for example, caused at least 370 residents and staff to become infected.¹² Requiring healthcare facility staff to be vaccinated is therefore a crucial step toward protecting healthcare staff and patients from COVID-19.

homes have been centers for outbreaks and excess mortality from the COVID-19 pandemic"); Aaron Richterman et al., *Hospital-Acquired SARS-CoV-2 Infection: Lessons for Public Health*, 324 JAMA 2155 (2020), https://bit.ly/3Irc8Va; see also, e.g., Temet M. Michael et al., *Epidemiology of Covid-19 in a Long-Term Care Facility in King County, Washington*, 382 New Eng. J. of Med. 2005 (2020), https://bit.ly/3pBvoXy. ¹⁰ Alex Bhattacharya et al., *Healthcare-associated COVID-19 in England: a national data linkage study*, 85 J. of Infection 565 (2021), https://bit.ly/31xXHO9.

¹¹ Long H. Nguyen et al., Risk of COVID-19 among front-line health-care workers and the general community: a prospective cohort study, 5 Lancet e475 (2020), https://bit.ly/31ABwY2.

¹² Clark Kauffman, *Iowa's nursing home infections and outbreaks are up* 20% over last week, Iowa Cap. Dispatch (Oct. 29, 2021), https://bit.ly/3oIpMu0.

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

COVID-19 vaccines are safe. Before FDA authorized/approved and CDC recommended use of the COVID-19 vaccines in the population, scientists conducted extensive clinical trials. FDA, CDC, and their advisory committees conducted rigorous reviews of the data, and continue to monitor the vaccines' safety. A study of over six million people who received the Pfizer or Moderna vaccines found that serious side effects are very rare. Another study concluded that there is no increased risk for mortality among recipients of any of the COVID-19 vaccines, and that vaccine recipients in fact had lower non-COVID-19 mortality risks than did unvaccinated people. 15

COVID-19 vaccines are also effective. First, each of the three vaccines greatly reduces the likelihood of contracting infection. The

¹³ Benefits of Getting a COVID-19 Vaccine, CDC (last updated Nov. 29, 2021), https://bit.ly/3H6BsiF; Nicola P. Klein et al., Surveillance for Adverse Events After COVID-19 mRNA Vaccination, 326 JAMA 1390, (2021), https://bit.ly/3F1XQYM; COVID-19 vaccine safety surveillance, FDA (Jul. 12, 2021), https://bit.ly/3y1dDET.

¹⁴ Klein et al., *supra* n. 13.

¹⁵ 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 Rep. 1520 (2021), https://bit.ly/3D1ZRn4.

Pfizer, Moderna, and J&J/Janssen vaccines are 91.3%, 90%, and 72% effective against infection, respectively. A study of vaccine effectiveness between December 14, 2020 and August 14, 2021 found that vaccines were 80% effective at preventing SARS-CoV-2 infection among frontline workers. Although the vaccines' efficacy wanes over time, initial data on Pfizer booster shots show that they may boost the vaccine efficacy to over 95%. For comparison, the flu vaccination reduces the risk of flu illness by between forty and sixty percent.

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.²⁰ The vaccines are likewise highly effective

¹⁶ Kathy Katella, Comparing the COVID-19 Vaccines: How Are They Different?, Yale Med. (Nov. 19, 2021), https://bit.ly/307jEU5.

¹⁷ Ashley Fowlkes et al., Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021, 70 Morbidity & Mortality Weekly Rep. 1167 (2021), https://bit.ly/3px2OGB.

¹⁸ 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.

¹⁹ How Well Flu Vaccines Work: Questions & Answers, CDC (last visited Nov. 9, 2021), https://bit.ly/3HifLMP.

²⁰ Katella, *supra* n. 16.

against hospital admissions, "even in the face of widespread dissemination of the delta variant." 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. ²² As of October 30, 2021, the age-adjusted rate of COVID-19 associated hospitalizations in unvaccinated adults was more than 12 times that of fully vaccinated adults. ²³

Third, evidence suggests that those who are fully vaccinated are contagious for shorter periods than unvaccinated people.²⁴ Most importantly, "[r]egardless of viral loads in vaccinated and unvaccinated individuals, the fact remains clear that unvaccinated people pose a

 21 Sara Y. Tartof et al., *Effectiveness of mRNA BNT162b2 COVID-19 Vaccine Up to 6 Months*, 398 Lancet 1407, 1407 (2021), https://bit.ly/3ouPvqS.

²² Mark W. Tenforde, Association Between mRNA Vaccination and COVID-19 Hospitalization and Disease Severity, 326 JAMA 2043 (2021), https://bit.ly/3bZBHhb.

²³ See Rates of laboratory-confirmed COVID-19 hospitalizations by vaccination status, CDC (last updated Dec. 2, 2021), https://bit.ly/3oIwsZ4.

²⁴ See 86 Fed. Reg. at 61,558.

higher risk of transmission to others than vaccinated people, simply because they are much more likely to get COVID-19 in the first place."25

III. The more healthcare facility staff who get vaccinated, the safer healthcare facilities become.

The more healthcare facility staff who get vaccinated, the closer we are to slowing the spread of the virus, creating a safer environment, and preventing staff and patient illness due to COVID-19. As the American Medical Association has explained, "[t]he only way to truly end this pandemic is to ensure *widespread* vaccination." 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 from COVID-

²⁵ COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61,402, 61,419 (Nov. 5, 2021).

²⁶ 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.

19."²⁷ 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 vaccination²⁸—and who may be particularly likely to encounter workers in healthcare facilities, where social distancing is not an option.

Widespread vaccination also protects against overwhelming healthcare systems with COVID-19 patients. "COVID-19 surges [a]re associated with higher rates of in-hospital mortality among patients without COVID-19, suggesting disruptions in care patterns for patients with many common acute and chronic illnesses." For example, during the pandemic, an antiques dealer in Alabama died from a cardiac event after dozens of intensive care units in three states turned him down for lack of space. One Idaho hospital canceled elective procedures and

²⁷ Carlos del Rio et al., Confronting the Delta Variant of SARS-CoV-2, Summer 2021, 326 JAMA 1001, 1002 (2021), https://bit.ly/3bVL5Cj.

²⁸ Katherine Lontok, *How Effective Are COVID-19 Vaccines in Immunocompromised People?*, Am. Soc'y for Microbiology (Aug. 12, 2021), https://bit.ly/3F24HBh.

²⁹ See Amber K. Sabbatini, et al., Excess Mortality Among Patients Hospitalized During the COVID-19 Pandemic, 16 J. Hosp. Med. 596, 596 (2021), https://bit.ly/3Hs5EEU.

³⁰ Tim Stelloh, Alabama heart patient dies after hospital contacts 43 ICUs in 3 states, family says, NBC News (Sept. 12, 2021), https://nbcnews.to/3nyOz4t.

postponed necessary procedures, including excising brain tumors.³¹ Although the district court concluded that the CMS rule "will have a crippling effect" on healthcare facilities by creating a shortage of services, Op. at 29-30, the court did not address the strain on the system that results from the uncontrolled spread of COVID-19.³² Widespread vaccination will result in fewer severe cases requiring medical intervention and fewer infections among healthcare workers, freeing up crucial resources to provide quality care to patients facing non-COVID-related illnesses. Low vaccination rates, not vaccination mandates, pose the real threat of overwhelming the healthcare system.³³

³¹ Mike Baker & Giulia Heyward, *Idaho allows overwhelmed hospitals across the state to ration care if necessary*, N.Y. Times (Sept. 16, 2021), https://nyti.ms/30Ee0ZP.

³² Any concern that the CMS rule will lead staffers to quit their jobs en masse rather than become vaccinated, placing strain on the healthcare system, has not been borne out in hospital systems that have already imposed mandates. See Jack J. Barry et al., Unvaccinated Workers Say They'd Rather Quit Than Get a Shot, but Data Suggest Otherwise, Scientific American (Sept. 24, 2021), https://bit.ly/3kUYKOT.

³³ Vaccination to Prevent COVID-19 Outbreaks with Current and Emergent Variants — United States, 2021, CDC (July 27, 2021), https://bit.ly/3GhocGC (indicating that residents of nursing homes in which 75% or less of staff are vaccinated experience higher rates of SARS-CoV-2 infection).

IV. Widespread vaccination is the most effective way to protect healthcare facility staff and patients 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, hospitalization, and death to the degree that vaccination does. The science is clear: no arguments against the need for vaccination are medically valid, other than to accommodate a medical contraindication.

Natural immunity—the immunity against SARS-CoV-2 that develops following recovery from infection—is not an adequate substitute for vaccination.³⁴ Studies have shown that unvaccinated people are at least twice as likely to become reinfected as are vaccinated people.³⁵

Other mitigation measures, such as mask wearing and social distancing, remain important. They do not, however, provide the same

³⁴ 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 Rep. 1539 (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).

³⁵ 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 Rep. 1081 (2021), https://bit.ly/306e4Bg.

level of protection against COVID-19 as does vaccination. Although face masks can be highly effective at limiting the transmission of SARS-CoV-2, many people choose not to wear face masks, even when encouraged or legally required to do so. Noncontinuous mask-wearing and other inadequate personal protective equipment use has been linked to transmission of the virus in healthcare facilities.³⁶ Vaccination is even more essential for healthcare facility staff, who may not be able to completely physically distance from others during the performance of their duties.³⁷

Even for those who primarily work remotely, vaccination provides the best protection against COVID-19. The virus spreads through respiratory droplets or aerosols when an infected individual talks, breathes heavily, sings, coughs, or sneezes. Particles containing the virus can spread more than six feet, and infection can occur in a matter of minutes.³⁸ Infection can thus occur even in environments where staff use

³⁶ Richterman, supra n. 9; Jessica Ibiebele et al., Occupational COVID-19 exposures and secondary cases among healthcare personnel, 49 Am. J. of Infection Control 1334 (2021), https://bit.ly/3lI0lIo.

³⁷ Richterman, *supra* n. 9.

 $^{^{38}\,}Appendices,$ CDC (Nov. 12, 2021), https://bit.ly/3nbxAos ("close contact" definition).

of shared spaces is staggered or reduced, or where staff are in physical proximity to each other only rarely.³⁹ And because staff who do not interact with patients can transmit the virus to those who do, a rule that applied only to staff members with patient contact would be insufficiently protective. Immediate, widespread vaccination against COVID-19 is the surest way to protect healthcare facility staff, patients, and the public, and to end this costly pandemic.

CONCLUSION

For the reasons stated above and in Defendants-Appellants' filings, Amici urge this Court to grant Defendants-Appellants' emergency motion for stay pending appeal.

Respectfully submitted,

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³⁹ Indeed, the World Health Organization considers remote workers at "lower risk[]," not no risk, of infection. *Preventing and mitigating COVID-19 at work*, at 2, World Health Organization (May 19, 2021), https://bit.ly/3wMJ451.

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I hereby certify that on December 7, 2021, a true and accurate

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