No. 22-11287

IN THE UNITED STATES COURT OF APPEALS FOR THE ELEVENTH CIRCUIT

HEALTH FREEDOM DEFENSE FUND, ET AL.,

Plaintiffs-Appellees,

V.

Joseph R. Biden, Jr., President of the United States, $\it Et\,AL.$, $\it Defendants-Appellants.$

On Appeal from the U.S. District Court for the Middle District of Florida (8:21-cv-01693-KKM-AEP)

BRIEF OF AMERICAN MEDICAL ASSOCIATION AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS-APPELLANTS

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CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for Proposed Amicus certifies that, to the best of their knowledge, the Certificate of Interested Persons filed by Defendants-Appellants in their May 31, 2022 opening brief contains a correct complete list of the people and entities that have an interest in the outcome of this appeal, other than the following additions:

American Medical Association

Democracy Forward Foundation.

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

Democracy Forward Foundation is a non-profit entity and has no parent corporation. No publicly owned corporation owns 10% or more of the stocks of Democracy Forward Foundation.

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INTEREST OF AMICUS CURIAE1

The American Medical Association 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. They accordingly have a strong interest in providing evidence-based guidance on public health issues and working to reduce the spread of contagious illnesses. Specifically, the AMA has adopted a policy to "work with the Federation [of Medicine] and other stakeholders to strongly support the legal authority of health officials to enact reasonable, evidence-based public health measures, including mandates,

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 its counsel

contributed money intended to fund this brief.

when necessary to protect the public from serious illness, injury, and death and actively oppose efforts to strip such authority from health officials."²

STATEMENT OF THE ISSUES

Whether this Court should reverse the district court's order vacating the Centers for Disease Control and Prevention's mask mandate, given the CDC's statutory responsibility to prevent the transmission of communicable diseases and the efficacy of face masks in preventing the transmission of SARS-CoV-2, the virus that causes COVID-19.

SUMMARY OF THE ARGUMENT

The United States remains in an ongoing public health emergency.

SARS-CoV-2 has wreaked havoc in communities across the country,
taxed hospitals to the point of rationing care, upended the lives of

² AMA, Full Commitment by our AMA to the Betterment and Strengthening of Public Health Systems D-440.922 (2021), https://bit.ly/38teYMe.

countless families, and killed over one million people in the United States.

Controlling the COVID-19 pandemic and protecting the lives of Americans requires a layered prevention strategy. This is particularly important at a time when many are seeking to return to "normal" life as seamlessly as possible. The CDC's decision to require that masks be worn in public transportation settings, when case counts merit additional precaution, is a reasonable judgment to curb the spread of COVID-19, protect those at highest risk, and permit them to participate in public life. And the CDC may reasonably change that judgment as circumstances alter in the future.

For more than two years, the American Medical Association has monitored the COVID-19 pandemic and advocated for evidence-based public health measures to reduce the risk of SARS-CoV-2. AMA's extensive review of the medical literature demonstrates that masks provide a safe and effective means of preventing the spread of SARS-CoV-2 on public transportation and in transportation hubs. Issuing such requirements thus falls within the CDC's core mission of preventing the transmission of communicable disease and protecting public health.

ARGUMENT

I. COVID-19 poses a severe risk to public health.

COVID-19 presents a severe risk to public health. Although most people with COVID-19 will experience mild to moderate symptoms, infected individuals can become seriously ill or die at any age. As of June 7, 2022, there have been over eighty-four million confirmed cases of COVID-19 in the United States,³ leading to more than 4,745,000 hospitalizations⁴ and over one million deaths—more than thirteen times the number of people in the United States who die from influenza in the average two-year span.⁵

As these numbers indicate, SARS-CoV-2 is highly transmissible. The original strain was more contagious than the flu, and the Delta variant of SARS-CoV-2, the leading strain for much of 2021, was more than twice as contagious as previous variants.⁶ The Omicron variant—

³ CDC, COVID Data Tracker (June 7, 2022), https://bit.ly/3Du7Glz.

⁴ CDC, COVID Data Tracker Weekly Review (June 3, 2022), https://bit.ly/3EYAdAb.

⁵ CDC, Disease Burden of Flu (Jan. 7, 2022), https://bit.ly/3ocAuZA.

⁶ CDC, Delta Variant: What We Know About the Science (Aug. 6, 2021), https://bit.ly/3NuNsxh; Apoorva Mandavilli, C.D.C. Internal Report Calls

which now, through its several subvariants, accounts for essentially 100% of new cases in the United States⁷—appears to be more contagious still.⁸ Crucially, over 50% of the spread of the virus may be from individuals who have no symptoms at the time of transmission.⁹

Even those who recover from COVID-19 may experience debilitating symptoms lasting for several months after the acute phase of infection. Estimates of the proportion of people who had COVID-19 who then experience post-COVID conditions or "long COVID" vary. One study has shown that one in five COVID-19 survivors aged 18–64 years, and one in four COVID-19 survivors aged 65 years or older, have experienced at least one incident condition that might be attributable to

Delta Variant as Contagious as Chickenpox, N.Y. Times (Jul. 30, 2021), https://nyti.ms/3EtJXTb.

⁷ CDC, Variant Proportions (June 7, 2022), https://bit.ly/3gNtqiB.

⁸ See Smriti Mallapaty, COVID-19: How Omicron Overtook Delta in Three Charts, Nature (Mar. 10, 2022), https://go.nature.com/3NEgo5u (noting that those infected with Omicron were more than twice as likely as those infected with Delta to spread the infection to those they came in contact with outside the home).

 $^{^9}$ CDC, Use of Cloth Masks to Control the Spread of SARS-CoV-2 (Dec. 6, 2021), https://bit.ly/30inWYx.

previous COVID-19 infection.¹⁰ A systematic review of fifty-seven studies found that more than half of COVID-19 survivors experienced post-acute sequelae (that is, chronic complications of an acute condition) six months after recovery, including difficulty concentrating, generalized anxiety disorder, general functional impairments, and fatigue or muscle weakness.¹¹ Studies also indicate that COVID-19 is associated with increased risk of neurological and psychiatric outcomes.¹²

The widespread availability of vaccination and, more recently, antiviral treatments, has been instrumental in blunting the worst of this impact and saving lives. Although a comprehensive vaccination program remains the most critical tool to combat the ongoing pandemic, it cannot

Lara Bull-Otterson et al., Post-COVID Conditions Among Adult COVID-19 Survivors Aged 18–64 and \geq 65 Years — United States, March 2020–November 2021, 71 Morbidity & Mortality Wkly. Rep. 713, 714 (2022), https://bit.ly/3xuysJ5.

¹¹ Destin Groff et al., Short-term and Long-term Rates of Postacute Sequelae of SARS-CoV-2 Infection: A Systematic Review, 4 JAMA Network Open e2128568, e2128568 (2021), https://bit.ly/3qskBjR.

¹² Maxime Taquet, et al., 6-Month Neurological and Psychiatric Outcomes in 236379 Survivors of COVID-19: A Retrospective Cohort Study Using Electronic Health Records, 8 Lancet Psychiatry 416, 417 (2021), https://bit.ly/3DXTbGo.

protect everyone. Children under five remain ineligible for vaccination, ¹³ and some people who are immunocompromised are unable to receive the full benefit of vaccines. ¹⁴ Moreover, although vaccination has been shown to significantly reduce the likelihood of hospitalization and death from COVID-19, it "confers only partial protection in the post-acute phase of the disease," and so "reliance on it as a sole mitigation strategy may not optimally reduce long-term health consequences of SARS-CoV-2 infection." ¹⁵

A 1

¹³ Although Pfizer and Moderna are developing vaccinations for children under five, which may be approved as soon as this month, the pediatric dose would still exclude children under six months of age. See AMA, Preliminary findings on COVID vaccine for kids under 5 with Andrea Garcia, JD, MPH (May 25, 2022) (transcript available at https://bit.ly/3LWAMxC).

¹⁴ See, e.g., Tanaya Shree et al., CD20-Targeted Therapy Ablates De Novo Antibody Response to Vaccination but Spares Preestablished Immunity, 3 Blood Cancer Discovery 95 (2022), https://bit.ly/3GyTNoQ (finding that, of the patients in a study who had received lymphoma treatment in the six months prior to vaccination, zero developed antibodies from the vaccine).

¹⁵ Ziyad Al-Aly et al., *Long COVID After Breakthrough SARS-CoV-2 Infection*, Nature Med. (2022), https://go.nature.com/3MV0ALI.

II. Masks provide a safe and effective means of reducing SARS-CoV-2 transmission.

The CDC's reliance on masks to reduce the spread of COVID-19 is a reasonable exercise of scientific judgment. As the CDC has explained, masks "reduce the emission of virus-laden droplets . . . , which is especially relevant for asymptomatic or presymptomatic infected wearers who feel well and may be unaware of their infectiousness to others," and who are "estimated to account for more than 50% of SARS-CoV-2" transmissions." Research has demonstrated that consistent use of a face mask or respirator (such as an N95 or KN95 mask) in indoor public settings is associated with lower odds of a positive SARS-CoV-2 test result.¹⁷ The consistent use of any face mask or respirator indoors has been shown to be protective, although the adjusted odds of infection were lowest among people who reported typically wearing an N95 or KN95 respirator, followed by those typically wearing a surgical mask. Moreover, wearing face masks or respirators for source control—that is,

¹⁶ CDC, Science Brief: Use of Masks to Control the Spread of SARS-CoV-2 (Dec. 6, 2021), https://bit.ly/3utvxOA (citations omitted).

¹⁷ See Kristin L. Andrejko et al., Effectiveness of Face Mask or Respirator Use in Indoor Public Settings for Prevention of SARS-CoV-2 Infection—California, February–December 2021, 71 Morbidity & Mortality Wkly. Rep. 212, 213 (2022), https://bit.ly/3afYV56.

in the context of exposure to a person with a confirmed SARS-CoV-2 infection—was associated with similar reductions in risk for infection. ¹⁸ Put simply, if an infected person wears a mask, it reduces their ability to infect others. Data from modeling studies have further demonstrated that "universal masking is the most effective method for limiting airborne transmission of SARS-CoV-2." ¹⁹

Masks are also widely acknowledged to be a safe method of reducing SARS-CoV-2 transmission. A systematic review of twenty-six studies concluded that "[f]ace masks are safe to use and do not cause significant alterations in human physiology."²⁰

Studies have shown that the efficacy of masks applies specifically to the public transportation setting. One model of an urban bus, for instance, found that if no passengers were a mask, twenty-six would

¹⁸ Kristin L. Andrejko et al., *Predictors of Severe Acute Respiratory Syndrome Coronavirus 2 Infection Following High-Risk Exposure*, Clinical Infectious Diseases (2021), https://bit.ly/3xkVfI7.

¹⁹ Gholamhossein Bagheri et al., An Upper Bound on One-to-One Exposure to Infectious Human Respiratory Particles, 118 PNAS e2110117118, at 7 (2021), https://bit.ly/3thAISD.

²⁰ Kamil Litwinowicz et al., *Bayesian Network Meta-Analysis of Face Masks' Impact on Human Physiology*, 12 Sci. Reps. 5823, 5823 (2022), https://go.nature.com/3x4Xsri.

become infected during a fifteen-minute ride; if everyone wore a handmade cloth mask, that number would fall to ten; and if everyone wore a surgical mask, it would fall to zero.²¹ A simulation of public transport in South Korea concluded that mandatory mask-wearing during peak transit hours reduced infection rates by 93.5%.²²

Preventing transmission of SARS-CoV-2 in public transportation is a public health issue. In addition to simply reducing the circulation of the virus in the public generally, protecting passengers and transit workers from infection provides people who do not have access to cars, or who cannot drive or walk because of disabilities or age, a lifeline connecting them to necessary medical appointments, groceries, and public services. As a pre-pandemic literature review concluded, "[t]ransportation barriers to health care access are common, and greater

²¹ Zhihang Zhang et al., *Disease Transmission Through Expiratory Aerosols on an Urban Bus*, 33 Physics of Fluids 015116-1, 015116-12 (2021), https://bit.ly/38TfNyl. The authors assume a 90% blockage rate for the "surgical masks," which suggests they may have N95-type masks in mind.

²² Donggyun Ku et al., Safe Traveling in Public Transport Amid COVID-19, 7 Sci. Advances eabg3691, at 5 (2021), https://bit.ly/3zajOck.

for vulnerable populations."²³ That review found that "[i]n 25 separate studies, 10–51% of patients reported that transportation was a barrier to health care access," resulting in difficulties treating chronic diseases, changing the course of treatment, undertaking preventive interventions, and accessing pharmacies to fill prescriptions.²⁴ And the "patients who carry the highest burden of disease face greater transportation barriers."²⁵

The use of masks on public transit reduces some of these barriers by providing people who are at risk of severe illness a safe means to

²³ Samina T. Syed et al., *Traveling Towards Disease: Transportation Barriers to Health Care Access*, 38 J. Cmty. Health 976 (2013), https://bit.ly/3GBHc3X.

See also Laura Barrie Smith et al., The Effects of a Public Transportation Expansion on No-Show Appointments, 57 Health Servs. Research 472, 480 (2022), https://bit.ly/3PO4V5r (finding that the noshow appointment rate for Medicaid patients dropped by 9.5% (relative to a baseline) after the opening of a nearby light-rail line). Missed appointments in turn affect the entire U.S. health care system—costing an estimated \$150 billion each year. See Am. Hosp. Ass'n, *Transportation* and theRoleof *Hospitals* 12 (2017),https://bit.ly/3azMQYz.

²⁵ Syed, *supra* n. 23.

access medical care.²⁶ But voluntary masking, among those who are at increased risk, provides incomplete protection. As discussed above, the best protection masks provide is in universal masking. Many people who may be at higher risk—including people with certain developmental disabilities, or children under the age of two—cannot wear masks safely,²⁷ and must rely on the masking of those around them to stay safe. The widespread use of face masks on public transit thus serves to prevent people who are infected from spreading illness, keeping transit accessible to those who rely on it for other aspects of their health.

III. Public health authorities such as the CDC are particularly well placed to make public health decisions under evolving circumstances.

The CDC should have the latitude to make a reasonable judgment regarding the use of face masks in light of the evidence supporting their efficacy. Given SARS-CoV-2's high transmissibility, public health

²⁶ One survey has shown that during the first months of the COVID-19 pandemic, as many as one quarter of adults who needed medical care during that period forwent care due to fear of COVID-19 transmission. See Kelly E. Anderson et al., Reports of Forgone Medical Care Among US Adults During the Initial Phase of the COVID-19 Pandemic, 4 JAMA Network Open e2034882 (2021), https://bit.ly/38YKQsw.

²⁷ See CDC, Use and Care of Masks (Feb. 25, 2022), https://bit.ly/3a7NE6y.

conditions can shift rapidly, creating surge conditions before they are readily apparent to the public. For example, when the recent Omicron surge was beginning, around December 18, 2021, the seven-day moving average of cases was 132,692.²⁸ Two weeks later, on January 1, 2022, it had more than tripled, to 420,782.²⁹ And cases peaked two weeks after that, on January 15, 2022, with a seven-day moving average of 810,420—nearly double the number from two weeks before, and more than six times the number from less than a month before.³⁰

Public health authorities must be permitted to take steps commensurate with rising cases. As a former senior advisor for public health in a major metropolitan area put it, public health leaders "must be able to rapidly assess new scientific information and synthesize the key points for different audiences." During the COVID-19 pandemic,

²⁸ CDC, Trends in Number of COVID-19 Cases and Deaths in the US Reported to CDC, by State/Territory (last visited June 7, 2022), https://bit.ly/3an242U.

 $^{^{29}}$ *Id*.

 $^{^{30}}$ *Id*.

³¹ Jay K. Varma et al., 5 Skills Public Health Officials Need to Combat the Next Pandemic, Harv. Bus. Rev. (Dec. 2, 2021), https://bit.ly/34C73dM.

"the volume and velocity of scientific information increased dramatically," so that "there was often not time for outside experts to come to consensus." This requires public health leaders to "go to the primary source and, in real time, make the best interpretation of the data." That process requires meaningful expertise, particularly as public health professionals consult cutting-edge studies that have not yet gone through the peer review process, and therefore require additional scrutiny.

The CDC is thus particularly well placed to make determinations about the measures necessary to promote public health in fast-moving circumstances. And in the case of public transit, where people are often moving between communities and even between countries, a broader view that can factor in the spread of COVID-19 beyond one locality is

 $^{^{32}}$ *Id*.

 $^{^{33}}$ *Id*.

³⁴ Indeed, this Court's own COVID-19 safety standards look to the CDC's guidance on masks. *See* Gen. Order No. 53 (11th Cir. Dec. 27, 2021), https://bit.ly/38vLhtU.

uniquely necessary.³⁵ The CDC thus requires the ability to exercise its judgment in the face of evolving COVID-19 conditions to fulfill its statutory duties to prevent the transmission of communicable disease.

CONCLUSION

For the reasons stated above and in Defendants-Appellants' filings, the American Medical Association respectfully urges this Court to reverse the judgment of the district court.

Respectfully submitted,

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³⁵ See 42 U.S.C. § 264(a) (delegating judgment to "prevent the ... transmission[] or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other").

CERTIFICATE OF COMPLIANCE

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/s/ Jessica Anne Morton

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CERTIFICATE OF SERVICE

I hereby certify that on June 7, 2022, a true and accurate copy of

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through the Court's electronic filing system.

/s/ Jessica Anne Morton

Date: June 7, 2022