No. 21A240

In the Supreme Court of the United States

JOSEPH R. BIDEN, JR., PRESIDENT OF THE UNITED STATES, ET AL.,
Applicants,

v.

MISSOURI, ET AL.,
Respondents.

ON APPLICATION FOR A STAY OF THE INJUNCTION ISSUED
BY THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
PENDING APPEAL TO THE UNITED STATES COURT
OF APPEALS FOR THE EIGHTH CIRCUIT
AND FURTHER PROCEEDINGS IN THIS COURT

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF NOBEL LAUREATE DR. LUC MONTAGNIER, YALE PROFESSOR OF EPIDEMIOLOGY DR. HARVEY RISCH, AND M-RNA VACCINATION CO-INVENTOR DR. ROBERT MALONE AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

MARY HOLLAND
Counsel of Record
ROBERT F. KENNEDY, JR.
JED RUBENFELD
1227 N. Peachtree Parkway, Suite 202
Peachtree City, GA 30269
(202) 854-1310
mary.holland@childrenshealthdefense.org

Counsel for Amici Curiae

MOTION FOR LEAVE TO FILE BRIEF

Drs. Luc Montagnier, Harvey Risch, and Robert Malone hereby respectfully request leave to file the enclosed brief as *amici curiae* in support of the Applicants' application for a stay or preliminary injunction, including—because of the emergency nature and scheduling of this case—leave to file the proposed brief without ten days' notice to the parties, as ordinarily required by this Court's Rule 37.2(a), to file it without advance consent of the parties, and to file it in 8½- by 11-inch format. Should the Court require refiling of this brief in booklet form, Amici hereby commit to doing so.

Amici are eminent scientists with extensive expertise in virology, COVID, and the COVID vaccines. Dr. Montagnier is a co-winner of the 2008 Nobel Prize in Medicine, Dr. Risch is a Yale Professor of Epidemiology, and Dr. Malone is co-inventor of mRNA concepts and processes used in the existing COVID vaccines. Each has a strong interest in fighting the COVID pandemic on the basis of science and fact, and each is profoundly concerned, particularly with the rise of the Omicron variant, that COVID vaccine mandates are scientifically unjustified at this time, that such mandates may actually exacerbate the pandemic, and that the parties defending such mandates are doing so on the basis of inadequate data, false assumptions, or simple misinformation. It is amici's belief and hope that this brief will be of great benefit to the Court by highlighting critical facts concerning Omicron—facts not addressed in the administrative record. Amici also have an interest in correcting an important false statement of fact in an amicus brief submitted by the American Medical Association et al. so that the Court is not led into error thereby.

For the foregoing reasons, Amici respectfully move for leave to file the attached *amicus curiae* brief.

Dated: January 6, 2022

Respectfully submitted,

DocuSigned by:
Mary S. Holland
99C3FFC6EFB6452...

Mary Holland
Counsel of Record
Robert F. Kennedy, Jr.
Jed Rubenfeld
1227 N. Peachtree Parkway, Suite 202
Peachtree City, GA 30269
(202) 854-1310
mary.holland@childrenshealthdefense.org

No. 21A240

In the Supreme Court of the United States

JOSEPH R. BIDEN, JR., PRESIDENT OF THE UNITED STATES, ET AL.,
Applicants,

v.

MISSOURI, ET AL.,
Respondents.

ON APPLICATION FOR A STAY OF THE INJUNCTION ISSUED
BY THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
PENDING APPEAL TO THE UNITED STATES COURT
OF APPEALS FOR THE EIGHTH CIRCUIT
AND FURTHER PROCEEDINGS IN THIS COURT

MOTION FOR LEAVE TO FILE BRIEF AND BRIEF OF NOBEL LAUREATE DR. LUC MONTAGNIER, YALE PROFESSOR OF EPIDEMIOLOGY DR. HARVEY RISCH, AND M-RNA VACCINATION CO-INVENTOR DR. ROBERT MALONE AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS

MARY HOLLAND
Counsel of Record
ROBERT F. KENNEDY, JR.
JED RUBENFELD
1227 N. Peachtree Parkway, Suite 202
Peachtree City, GA 30269
(202) 854-1310
mary.holland@childrenshealthdefense.org

Counsel for Amici Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

Code of Federal Regulations

Federal Register

Internet Sources

Other Authorities

INTEREST OF AMICI CURIAE

Amici are eminent academic and clinical scientists with extensive medical expertise, deep research knowledge of COVID and the COVID vaccines, and a strong interest in fighting the COVID pandemic on the basis of science and fact, rather than politics or profit. Each is profoundly concerned, particularly with the rise of the Omicron variant, that COVID vaccine mandates are scientifically unjustified at this time, that such mandates may actually exacerbate, rather than ameliorate, the pandemic, and that the parties defending such mandates are doing so on the basis of inadequate data, false assumptions, or simple misinformation.

Dr. Luc Montagnier, winner of the 2008 winner of the Nobel Prize in Medicine for discovery of the human immunodeficiency virus (HIV), is one of the most highly honored and accomplished virologists in the world. A member of the French Académie Nationale de Médecine, Dr. Montagnier has won over twenty major awards and honors of high scientific distinction, including the French National Order of Merit, the French Légion d'Honneur, the Lasker Award, the Scheele Award, the Louis-Jeantet Prize for medicine, the Gairdner Award, the Golden Plate Award of the American Academy of Achievement, the King Faisal International Prize, and the Prince of Asturias Award.

Dr. Harvey Risch, Professor of Epidemiology at the Yale School of Public Health, is a practicing epidemiologist with more than 40 years of research experience, a member of the Society for Epidemiologic Research, and an elected Fellow of the American College of Epidemiology. The winner of prestigious awards for his cancer research, Dr. Risch has published approximately 400 peer-reviewed original research papers in very well-regarded scientific journals and has an h-index of 97, with more than 43,000 publication citations to-date. In May 2020, Dr. Risch published the seminal paper on early treatment of high-risk Covid outpatients in the *American Journal of Epidemiology* (https://doi.org/10.1093/aje/kwaa093), which has been downloaded more than

90,000 times, and has co-authored two papers that form the now-standard understanding of early outpatient Covid-19 management (https://doi.org/10.1016/j.amjmed.2020.07.003 and https://rcm.imrpress.com/EN/10.31083/j.rcm.2020.04.264).

Dr. Robert Malone, an internationally eminent scientist with expertise in virology, immunology, and molecular biology, is one of the original inventors of mRNA vaccination and DNA vaccination. His discoveries in mRNA non-viral delivery systems are considered the key to the current COVID-19 vaccine strategies. Dr. Malone has close to 100 peer-reviewed publications and published abstracts with over 12,000 citations. He has been a member and chair of study panels of the United States Department of Defense and the National Institute of Allergic and Infectious Diseases (NAIAD), a division of the National Institutes of Health, and has served on NAIAD panels convened to advise the government on COVID treatments.

Amici also have an interest in correcting an important false statement of fact in an amicus brief submitted by the American Medical Association et al. (the "AMA Brief") so that the Court is not led into error thereby.

INTRODUCTION AND SUMMARY OF ARGUMENT

No rational health policymaker would ever mandate a vaccine for a disease in the absence of evidence that the vaccine is effective against that disease. Such a mandate would be illogical, indefensible, contrary to the public interest, and almost certainly unlawful. Yet that is indisputably the case for the vaccine mandates at issue here.

In December 2021, a radically mutated new COVID variant known as Omicron became the overwhelmingly dominant strain in the United States, surging from 2% of infections on December 4 to over 95% of infections by January 1, 2002. By mid-January, Omicron is expected to account for substantially all US COVID cases. *See* Statement of Facts *infra*.

And no one knows whether the existing COVID vaccines are effective against it.

Preliminary data indicate that the COVID vaccines have severely-reduced efficacy against Omicron, but the truth, conceded by vaccine manufacturers themselves, is that "nobody really has efficacy data." As the CDC says, we simply "don't yet know . . . the severity of illness [Omicron] causes, *or how well available vaccines . . . work against it*." See Statement of Facts infra. Indeed, there is evidence that vaccination may have "negative efficacy" against Omicron, *increasing* infection rates. Confronted with that possibility in a recent interview, the CEO of a leading vaccine manufacturer could not and did not rule it out, saying rather, "we will obviously have to assess it" when data on omicron becomes available. *See infra* Point II(B).

In these circumstances, the vaccine mandates must be stayed. No matter the standard of review, a vaccine mandate cannot be permitted without any evidence of efficacy. Judicial review of agency action is properly "confined to the full administrative record before the agency at the time the decision was made." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 82 (2d Cir. 2006) (quoting *Envtl. Def. Fund, Inc. v. Costle*, 657 F.2d 275, 284 (D.C. Cir. 1981)). "If the agency

action, once explained by the proper agency official, is not sustainable on the record itself, the proper judicial approach" is "to vacate the action and to remand the matter back to the agency for further consideration." *Envtl. Def. Fund*, 657 F.2d at 285 (citing *Camp v. Pitts*, 411 U.S. 138, 143 (1973)). Accordingly, the vaccine mandates before the Court must be stayed, because there is no evidence in the administrative record—nor any evidence outside that record—of vaccine efficacy against the virus we now face.

STATEMENT OF FACTS

The vaccine mandates before the Court were issued on November 5, 2021. *See* COVID-19 Vaccination and Testing; Emergency Temporary Standard, 86 Fed. Reg. 61402 (Nov. 5, 2021) (hereafter "OSHA Mandate"); Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555 (Nov. 5, 2021) (hereafter "CMS Mandate"). At that time, the Delta variant comprised nearly 100% of all US COVID cases. *See* CDC, COVID Data Tracker: Variant Proportions, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (chart showing that approximately 99% of all US COVID cases were B.1.6172 (Delta) infections from Sept. 25, 2021 through Nov. 6, 2021) (hereafter "CDC, Variant Proportions").

The agencies issuing the mandates before this Court were well aware of Delta's then-overwhelming prevalence. *See, e.g.*, OSHA Mandate, 86 Fed. Reg. 61409 ("Delta now accounts for more than 99% of circulating virus nationwide."). As a result, appropriately, both OSHA and CMS considered the Delta variant at length and in detail. *See* OSHA Mandate, 86 Fed. Reg. 61409-11, 61416-19; CMS Mandate, 86 Fed. Reg. 61558-59, 61565, 61585. Crucially, both agencies expressly found, and cited studies purporting to show, that the COVID vaccines remained

highly effective against Delta infection and transmission.[1] Thus both agencies acknowledged and at least purported to satisfy their scientific and legal duty to demonstrate vaccine efficacy specifically against the then-dominant Delta variant.

Today, however, Omicron is dominant. From November 27, 2021 to January 1, 2002, Omicron exploded from 0% to over 95% of all US COVID cases. CDC, Variant Proportions, *supra*. By mid-January, it is expected that Omicron will represent substantially all US COVID cases.

Omicron is a radically mutated form of COVID, "with upwards of 50 mutations in its genome, 30 of which exist in the gene encoding Spike—the SARS-CoV-2 surface protein responsible for binding to human ACE2 receptors to facilitate infection, and the immunogen used in all vaccines currently authorized for general use."[2] Because some of Omicron's "deletions and mutations are known to lead to increased transmissibility, higher viral binding affinity, and higher antibody escape,"[3] because the effects of many of its other mutations remain unknown, and because of its rapid spread in highly vaccinated populations, Omicron has created "a high level of uncertainty" about the ability of the existing COVID vaccines to protect against it.[4] As a result,

---

[1] *See, e.g.*, OSHA Mandate, 86 Fed. Reg. 61418 ("Vaccines continue to provide robust protection for vaccinated individuals against SARS-CoV-2 infections," including Delta infections); *id*. ("research suggests that [for] the Delta variant . . . vaccination . . . still significantly reduces transmission risk in comparison to infected unvaccinated individuals"); CMS Mandate, 86 Fed. Reg. 61565 ("a recent study found that, between December 14, 2020, and August 14, 2021, full vaccination with COVID-19 vaccines was 80 percent effective in preventing RT-PCR-confirmed SARS-CoV-2 infection among frontline workers . . . . While vaccine effectiveness point estimates did decline over the course of the study as the Delta variant became predominant, the protection afforded by vaccination remained significant"); *id*. at 61585 ("evidence also suggests that vaccinated people who become infected with Delta have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk") (citations omitted).

[2] AMERICAN SOCIETY OF MICROBIOLOGY, *How Ominous Is the Omicron Variant* (*B.1.1.529*)?, Dec. 16, 2021, https://asm.org/Articles/2021/December/How-Ominous-is-the-Omicron-Variant-B-1-1-529.

[3] *See, e.g.*, THE LANCET, *Omicron SARS-CoV-2 variant: a new chapter in the COVID-19 pandemic*, Dec. 11, 2021, https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)02758-6/fulltext.

[4] *Id*. ("Importantly, the effects of most of the remaining omicron mutations are not known, resulting in a high level of uncertainty about how the full combination of deletions and mutations will affect viral

"Researchers worldwide are racing to understand the threat that the [Omicron] variant . . . poses to the world" and "to gain an understanding of . . . its potential to evade vaccines."[5]

Preliminary studies indicate that the existing COVID vaccines have severely-reduced or even *negative* efficacy against Omicron infections. *See infra* Point II(B). In one of the few available studies, after just 30 days, the Pfizer and Moderna vaccines had no statistically significant positive effect against Omicron infection (their effect became statistically indistinguishable from zero), and after 90 days, their efficacy was statistically significantly *negative*, meaning that vaccination led to *increased* infection. *See id*. Confirming this result, real-world data show vaccinated individuals having *higher* rates of Omicron infection than the unvaccinated. *See id*. But the truth, conceded even by vaccine manufacturers, is that for now, "nobody really has efficacy data."[6] As the CDC says, "we don't yet know . . . the severity of illness [Omicron] causes, *or how well available vaccines . . . work against it*."[7]

In their lengthy reports supporting the mandates, neither OSHA nor CMS cited a single study showing vaccine effectiveness against Omicron. Neither agency wrote a single word about Omicron or the fact that, with Omicron, vaccination appears to be associated with *increased* infection rates. The simple reason for this omission is that Omicron had not yet been discovered, and the agencies were addressing variants that are no longer of any relevance. In other words, the

---

behaviour and susceptibility to natural and vaccine-mediated immunity."); SCIENCE, *COVID-19 vaccine breakthrough infections*, Dec. 23, 2021, https://www.science.org/doi/full/10.1126/ science.abl8487 (noting "[c]ontinued transmission in highly vaccinated populations").

[5] NATURE, *How bad is Omicron? What scientists know so far*, Dec. 2, 2021, https://www.nature.com/ articles/d41586-021-03614-z.

[6] Talia Kaplan, *Novavax at 'tipping point' with COVID vaccine: CEO*, Dec. 27, 2021, https://www.foxbusiness.com/ healthcare/novavax-at-tipping-point-with-covid-vaccine-ceo (quoting Novovax CEO Stanley Erck).

[7] CDC, Omicron Variant: What You Need to Know, https://www.cdc.gov/coronavirus/2019-ncov/variants/omicron-variant.html.

vaccine mandates before the Court rest on data, findings and conclusions that are now obsolete. Unless the mandates are stayed, OSHA and CMS will be forcing COVID vaccines on people without ever having analyzed, and without producing any evidence of, vaccine efficacy against the virus we now face.

ARGUMENT

THE MANDATES MUST BE STAYED BECAUSE THE AGENCIES NEVER CONSIDERED VACCINE EFFICACY, AND THERE IS NO EVIDENCE SHOWING VACCINE EFFICACY, AGAINST THE VIRUS WE NOW FACE

"It is a staple of administrative law that federal courts may not uphold a rule on a ground never addressed by the agency." *MCP No. 165 v. United States DOL***,** No. 21-7000, 2021 U.S. App. LEXIS 37024 at * 33 (6th Cir. Dec. 15, 2021) (Sutton, J. dissenting from denial of initial hearing en banc) (citing *SEC v. Chenery Corp.*, 318 U.S. 80, 87 (1943)). Judicial review of agency action is properly "confined to the full administrative record before the agency at the time the decision was made . . . not some new record completed initially in the reviewing court." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d at 82 (quoting *Envtl. Def. Fund, Inc. v. Costle*, 657 F.2d at 284). "If the agency action, once explained by the proper agency official, is not sustainable on the record itself, the proper judicial approach" is "to vacate the action and to remand the matter back to the agency for further consideration." *Envtl. Def. Fund*, 657 F.2d at 285 (citing *Camp v. Pitts*, 411 U.S. at 143). Accordingly, the vaccine mandates before the Court must be stayed, because there is no evidence in the administrative record—and indeed no evidence outside that record—of vaccine efficacy against the virus we now face.

I. Where, as Here, a Vaccine Mandate is Said To Be Necessary to Prevent the Spread of a Contagious Disease, the Vaccine Must Be Shown To Be Effective Not Against Severe Disease Outcomes Such As Hospitalization or Death, But Rather Against Infection and Transmission

Vaccine efficacy can refer to entirely different measures, such as a vaccine's prevention of infection or its prevention of severe disease outcomes like hospitalization and death.[8] Where, as here, the putative justification for a vaccine mandate is to prevent the spread of a contagious disease, efficacy must be shown not against disease outcomes, but rather against *infection* and *transmission*.

A. The Principal Justification for Vaccine Mandates in General, and for these Vaccine Mandates in Particular, Is Prevention of Transmission and Spread of Disease

At least for adults, in a free society with constitutional liberties, including the liberty to refuse unwanted medical treatment, the principal justification for any vaccine mandate is preventing "injury that may be done to others"—*i.e.*, preventing "transmission and spread of [the] disease." *See, e.g.*, *Jacobson v. Massachusetts*, 197 U.S. 11, 26, 34 (1905); cf. *Cruzan v. Missouri Dep't of Health*, 497 U.S. 261, 278 (1990) (describing *Jacobson* as holding that individual's "constitutionally protected liberty interest in refusing unwanted medical treatment" was overcome by state's interest in "preventing disease"); *The Case for Mandatory Vaccination*, NATURE **575**, S58-S60 (Nov. 27, 2019) (given the individual's right to refuse consent to unwanted medical treatment, mandatory vaccination of adults is justifiable only where "failure to vaccinate not only puts the unvaccinated individual at risk, but also anyone they come into contact with").

[8] *See, e.g., What defines an efficacious COVID-19 vaccine? A review of the challenges assessing the clinical efficacy of vaccines against SARS-CoV-2*, THE LANCET INFECTIOUS DISEASES **21**, 2, E-26-E35 (Feb. 1, 2021) ("Many different endpoints are used in vaccine research to define efficacy . . . . Outcomes might include reduction in infection . . ., severity of resultant clinical disease . . ., or duration of infectivity.").

There can be no doubt that the vaccine mandates before the Court depend for their validity on this harm-to-others rationale, because both agencies said so. *See* CMS Mandate, 86 Fed. Reg. 61561 (issuing vaccine mandate for health care workers "because vaccination of staff is necessary for the health and safety *of individuals to whom care and services are furnished*") (emphasis added); OSHA Mandate, 86 Fed. Reg. 61432 ("Vaccination against COVID-19 is thus *particularly important in reducing the potential for workers to become infected and spread the virus to others at the workplace,* in addition to protecting the worker from severe health outcomes if they are infected.") (emphasis added). Indeed, the OSHA mandate indicates on its face that preventing transmission to others is the agency's primary goal, because the mandate allows employers *either* to vaccinate their workers *or* to test-and-mask unvaccinated workers while removing those who test positive. 29 C.F.R. 1910.501(d)(2). The latter option makes sense only if OSHA's primary goal was not to protect an unvaccinated worker from himself (*i.e.*, from his own decision not to vaccinate), but rather to prevent him from spreading the disease to others.

B. Mandating Vaccination to Prevent the Spread of COVID Requires Vaccine Efficacy Against Infection and/or Transmission, Not Hospitalization or Death

Where the claimed justification for a vaccine mandate is to prevent the spread of a contagious disease, what matters is its efficacy not against disease outcomes, but against *infection* and *transmission*. A vaccine can prevent the spread of a contagious disease if and only if—and only to the extent that—it can prevent vaccinated individuals from being infected and/or from transmitting that disease to other people. Thus "if mandatory vaccination is considered necessary to interrupt transmission chains and prevent harm to others, there should be sufficient evidence that the vaccine is efficacious in *preventing serious infection and/or transmission*." WORLD HEALTH ORGANIZATION, *COVID-19 and mandatory vaccination: Ethical considerations and caveats*, Apr. 13, 2021, at p. 2 (available at https://www.who.int/publications/i/item/WHO-2019-

nCoV-Policy-brief-Mandatory-vaccination-2021.1) (emphasis added); NATURE, *Can COVID vaccines stop transmission? Scientists race to find answers*, Feb. 19, 2021, https://www.nature.com/articles/d41586-021-00450-z (COVID vaccines can prevent "viral spread" if, but only if, they not only reduce severe disease outcomes such as hospitalization and death, but "also *stop people from getting infected and passing on the SARS-CoV-2 virus*") (emphasis added).

II. There Is No Evidence Establishing that the COVID Vaccines Are Effective Against Omicron Infection or Transmission, and Preliminary Evidence Suggests the Opposite.

A. There Is No Evidence Whatsoever in the Administrative Record that the COVID Vaccines are Effective Against Omicron

While the administrative record in these cases contains considerable discussion of vaccine effectiveness against Delta, it contains no data whatsoever on vaccine effectiveness against Omicron, which had not been discovered at the time the mandates were issued. For this reason alone, the mandates should be stayed.

B. Preliminary Data Indicate that the COVID Vaccines Do Not Effectively Prevent Infection with or Transmission of Omicron.

Preliminary but substantial data indicate that the existing COVID vaccines have "severely reduced" or even *negative* efficacy against Omicron. Laboratory researchers were the first to make this discovery: "*[I]n vitro* findings using authentic SARS-CoV-2 variants indicate that in contrast to the currently circulating Delta variant, the neutralization efficacy of vaccine-elicited sera against Omicron was severely reduced."[9] On Dec. 17, 2021, the CDC reported on the first 43 Omicron

[9] A. Wilhelm et al., *Reduced Neutralization of SARS-CoV-2 Omicron Variant by Vaccine Sera*, Dec. 13, 2021, https://www.medrxiv.org/content/10.1101/2021.12.07.21267432v4.

cases found in the U.S., finding that 79% of those infected were fully vaccinated.[10] One of the few existing studies found that *after just 30 days*, the Moderna and Pfizer vaccines had no statistically significant positive effect against Omicron infection (their effect became statistically indistinguishable from zero), and after 90 days both vaccines showed statistically significant *negative effectiveness*, meaning that vaccinated individuals were *more* likely to be infected.[11] Consistent with negative efficacy against Omicron, the province of Ontario, Canada reports that the rate of COVID infection since December 25, 2021, is now *higher* among vaccinated individuals than among unvaccinated.[12] The same appears to be true in Denmark, where almost 90% of Omicron cases are in vaccinated individuals.[13]

Enhanced susceptibility to a new COVID variant in vaccinated individuals is not illogical. It could be expected, for example, if the new variant originated in vaccinated individuals, as has been hypothesized in the case of Omicron.[14] It is an axiom of viral evolutionary biology that imperfect vaccines can enable development of vaccine-resistant strains and thereby worsen a

---

[10] CDC, SARS-CoV-2 B.1.1.529 (Omicron) Variant — United States, December 1–8, 2021 (Dec. 17, 2021), https://www.cdc.gov/mmwr/volumes/70/wr/mm7050e1.htm?s_cid=mm7050e1_w#contribAff.

[11] C.H. Hanson et al., *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* (Dec. 23, 2021), https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v3.full-text (preprint) (figure and table showing higher rates of infection for vaccinated versus unvaccinated).

[12] ONTARIO, COVID-19 Vaccination Data, https://covid-19.ontario.ca/data (Dec. 31, 2021) (graph entitled "COVID-19 cases by vaccination status").

[13] According to Danish government data, 89.7% of the country's Omicron cases are in vaccinated individuals (many with a booster shot). STATEN SERUM INSTITUT, COVID-19 Rapport om omikronvarienten at 6, table 4 (Dec. 21, 2021), https://www.docdroid.com/C9UY7Ef/dk-serum-institut-rapport-omikronvarianten-21122021-14tk-pdf. Because that figure is higher than the percentage of vaccinated individuals in the population as a whole, *see* Johns Hopkins Univ. Coronavirus Resource Center, Denmark, https://coronavirus.jhu.edu/region/denmark (79% of Denmark population vaccinated), this means the rate of Omicron infection among the vaccinated is higher than among the unvaccinated.

[14] X. Li, *Omicron: Call for updated vaccines*, J. OF MEDICAL VIROLOGY, Dec. 20, 2021, https://onlinelibrary.wiley.com/doi/10.1002/jmv.27530 ("Omicron is likely to have been generated from a chronically infected COVID-19 patient vaccinated with an mRNA- or non-mRNA-based vaccine. As such, it is critical that vaccinologists systematically evaluate the role of these vaccines in generating novel SARS-CoV-2 variants . . . via breakthrough vaccine-elicited immunity.").

pandemic, as many leading scientists fear with respect to the COVID vaccines. In the words of Nobel Prize winner in Medicine Dr. Luc Montagnier, "The [COVID] vaccines don't stop the virus, they do the opposite—they 'feed the virus,' and facilitate its development into stronger and more transmissible variants."[15]

Asked about the possibility of negative efficacy in a recent interview, the CEO of BioNTech, co-manufacturer of the Pfizer vaccine, could not and did not try to rule it out, saying instead "we will obviously have to assess it" when more data on omicron becomes available.[16] A vaccine mandate is without doubt scientifically, ethically, and legally indefensible if, as here, (a) there is evidence indicating negative efficacy, (b) there is no evidence or data yet available to disprove negative efficacy; and (c) the agencies issuing the mandate have not to date made any findings on, or indeed even investigated, the issue.

Moreover, it is well known that vaccinated individuals with breakthrough COVID infections carry viral loads at least as high as unvaccinated infected individuals and are therefore just as contagious.[17] That is why CDC Director Rochelle Walensky said in August 2021, "[The vaccines] continue to work well for Delta, with regard to severe illness and death . . . [b]ut what *they can't do anymore is prevent transmission*." CNN, *Fully vaccinated people who get a Covid-*

[15] RAIR Foundation USA video with Nobel Laureate Luc Montagnier, May 18, 2021, https://rair foundation.com/bombshell-nobel-prize-winner-reveals-covid-vaccine-is-creating-variants/.

[16] Pascale Davies, *Omicron: 3 vaccine doses are not enough to stop the new COVID variant, warns BioNTech CEO*, Dec. 20, 2021, https://www.euronews.com/next/2021/12/20/omicron-3-vaccine-doses-are-not-enough-to-stop-the-new-covid-variant-warns-biontech-ceo.

[17] *See, e.g.*, A. Singanayagam et al., *Community transmission and viral load kinetics of the SARS-CoV-2 delta* (*B.1.617.2*) *variant in vaccinated and unvaccinated individuals in the UK: a prospective, longitudinal, cohort study*, THE LANCET INFECTIOUS DISEASES, Oct. 29, 2021, https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(21)00648-4/fulltext ("fully vaccinated individuals with breakthrough infections have peak viral load similar to unvaccinated cases and can efficiently transmit infection in household settings, including to fully vaccinated contacts"); K.K. Riemersma et al., *Shedding of Infectious SARS-CoV-2 Despite Vaccination*, Nov. 6, 2021, https://www.medrxiv.org/content/10.1101/2021.07.31.21261387v6 (preprint) ("finding no difference in infectious virus titer between" "vaccinated and unvaccinated persons").

19 breakthrough infection can transmit the virus, CDC chief says, Aug. 6, 2021, https://www.cnn.com/2021/08/05/health/us-coronavirus-thursday/index.html (emphasis added); *see also* AP, *CDC changes course on indoor masks in some parts of the US*, July 27, 2021, https://apnews.com/article/health-coronavirus-pandemic-79959d313428d98ab8aa905bbe287ba0 (quoting CDC Director Walensky as saying viral loads in nose and throat of vaccinated and unvaccinated are "indistinguishable"). Again quoting Nobel laureate Dr. Montagnier, "the vaccines Pfizer, Moderna, Astra Zeneca do not prevent the transmission of the virus person-to-person, and the vaccinated are just as transmissive as the unvaccinated."[18]

While a preliminary study suggests that booster shots may temporarily increase effectiveness against Omicron, it also finds that efficacy against Omicron infection remains far below that of Delta, and the increased protection wanes very quickly.[19] As the COVID vaccine manufacturers themselves concede, individuals with boosters remain "likely" to catch and pass on Omicron: "We must be aware that even triple-vaccinated are likely to transmit the disease."[20] More fundamentally, boosters are *not required* by either the OSHA or CMS mandate and are not included in the definition of fully vaccinated.[21] In other words, both mandates will leave on the job, in the workplace, tens of thousands of unboosted but vaccinated employees who have little, or negative protection against infection, and who will be just as contagious when infected.

---

[18] RAIR Foundation USA video with Nobel Laureate Luc Montagnier, May 18, 2021, https://rair foundation.com/bombshell-nobel-prize-winner-reveals-covid-vaccine-is-creating-variants/.

[19] UK Health Security Agency, SARS-CoV-2 variants of concern and variants under investigation in England, at 24-27 (Dec. 23, 2021), https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1043807/technical-briefing-33.pdf.

[20] Davies, *supra* note 16 (quoting BioNTech CEO Ugur Sahin).

[21] See OSHA, Emergency Temporary Standard, https://www.osha.gov/coronavirus/ets2/faqs ("Booster shots and additional doses are not included in the definition of fully vaccinated under the ETS."); CMS Mandate, 86 Fed. Reg. 61563 ("individuals are considered fully vaccinated for COVID-19 14 days after receipt of either a single-dose vaccine (Janssen/Johnson & Johnson) or the second dose of a two-dose primary vaccination series (Pfizer-BioNTech/Comirnaty or Moderna)").

Both mandates were based on a finding that vaccinated workers (including the already-vaccinated) were protected against infection by Delta—a finding that is now completely obsolete, because vaccinated individuals have little or negative protection against Omicron, the virus we now face. A vaccine that cannot stop transmission is a private health decision, not a public health measure.

III. The AMA Amicus Brief Flagrantly Misrepresents Vaccine Efficacy

According to the AMA Amicus Brief, "The Pfizer, Moderna, and J&J/Janssen vaccines are 91.3%, 90%, and 72% effective against infection, respectively." AMA Brief at 10-11. It is therefore supposed to follow that the vaccines will be effective at preventing the spread of COVID because so many fewer people will be infected. *Id.* But the AMA Brief's assertion about the vaccines' effectiveness against infection is so flagrantly misleading it is nearly an ethical violation.

First, the AMA has reported these efficacy percentages as current fact when, as stated in the very source that the AMA cites, they were merely the numbers initially put forward by the vaccine manufacturers, applicable only to the original COVID strain, and were already disproven months ago by independent researchers testing the vaccines against the Delta variant.[22] For example, again as reported in the AMA's own source, the Pfizer vaccine was shown by Israeli data to be *only 39%* effective against Delta infection, and the Moderna vaccine was found to be "two times weaker" against Delta.[23]

Second, even more important, the AMA Brief's claim that the vaccines are "91.3%, 90%, and 72% effective against infection" fails to mention that these numbers have absolutely no

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

[23] *Id.* The Johnson & Johnson vaccine was also found to have reduced efficacy against Delta, but no infection percentages are given. *Id.*

applicability to the virus we now face—the Omicron variant. Omicron had already surged when the AMA Brief was filed, and reference to Omicron appears in that brief, yet the AMA neglects to mention that there is currently no data proving vaccine efficacy against Omicron, or that preliminary data suggests severely reduced and even *negative* vaccine efficacy against Omicron infection. Accordingly, the AMA Brief's efficacy assertions should be ignored.

CONCLUSION

Because neither OSHA nor CMS has done any analysis at all of vaccine effectiveness against the COVID virus as it now exists; because high uncertainty concerning vaccine efficacy against Omicron is universally acknowledged; because the preliminary data suggest severely reduced or even *negative* vaccine efficacy against Omicron infection; and because as a result there is simply no evidence that vaccination will curb the spread of the virus we now face, the OSHA and CMS vaccine mandates should be stayed.

DATED: January 6, 2022

Respectfully Submitted,

DocuSigned by:
Mary S. Holland
99C3FFC6EFB6452...

Mary Holland
Counsel of Record
Robert F. Kennedy, Jr.
Jed Rubenfeld
1227 N. Peachtree Parkway, Suite 202
Peachtree City, GA 30269
(202) 854-1310
mary.holland@childrenshealthdefense.org

CERTIFICATION OF WORD COUNT

We hereby certify that the total word count of the above-enclosed brief, excluding the cover page and tables, is less than 6,000 words.

DATED: January 6, 2022

Respectfully Submitted,

DocuSigned by:
Mary S. Holland
99C3FFC6EFB6452...

Mary Holland
Counsel of Record
Robert F. Kennedy, Jr.
Jed Rubenfeld
1227 N. Peachtree Parkway, Suite 202
Peachtree City, GA 30269
(202) 854-1310
mary.holland@childrenshealthdefense.org