# In the Supreme Court of the United States

## 

ANTHONY MARCIANO, individually and on behalf of all other individuals similarly situated,

Applicant/Petitioner,

v.

ERIC ADAMS, Mayor of the City of New York, in his official capacity; ASHWIN VASAN, Commissioner of Health and Mental Hygiene, in his official capacity; KEECHANT SEWELL, Police Commissioner, in her official capacity; THE NEW YORK CITY BOARD OF HEALTH; and THE CITY OF NEW YORK,

Respondents.

On Emergency Application for Writ of Injunction to the Honorable Clarence Thomas

## BRIEF OF AMICUS CURIAE PHYSICIANS FOR INFORMED CONSENT IN SUPPORT OF APPLICANT/PETITIONER

		GREGORY J. GLASER <i>COUNSEL OF RECORD</i> 4399 BUCKBOARD DRIVE #423 COPPEROPOLIS, CA 95228 (925) 642-6651 GREG@PICPHYSICIANS.ORG		
SEPTEMBER 24, 2022			Co	UNSEL FOR AMICUS CURIAE
SUPREME COURT PRESS	•	(888) 958-5705	*	Boston, Massachusetts

### TABLE OF CONTENTS

TABLE OF AUTHORITIES	. ii
IDENTITY AND INTEREST OF AMICUS CURIAE	. 1
SUMMARY OF ARGUMENT	. 1
ARGUMENT	. 2
A. INFORMED CONSENT/REFUSAL IN VACCINATION IS A FUNDAMENTAL RIGHT TRIGGERING STRICT SCRUTINY.	. 2
B. THERE IS NO EVIDENCE THAT COVID-19 VACCINES PREVENT THE INFECTION OR TRANSMISSION OF SARS-COV-2 OR COVID-19, AND IN FACT THERE IS EVIDENCE TO THE CONTRARY (THAT IT HAS A NEGATIVE EFFECT ON IMMUNITY)	. 9
C. THOSE PREVIOUSLY INFECTED WITH COVID-19 SHOULD NOT HAVE LESS RIGHTS THAN THOSE VACCINATED FOR COVID-19	12
D. COVID-19 VACCINES HAVE HAD NO MEASURABLE IMPACT ON THE COVID- 19 MORTALITY RATE	13
CONCLUSION	15

#### TABLE OF AUTHORITIES

CASES
<i>Addington v. Texas,</i> 441 U.S. 418 (1979)
Carey v. Population Services Intl, 431 U.S. 678 (1977)
<i>City of Newark v. JS</i> , 279 N.J. Super. 178 (1993)
<i>Foucha v. Louisiana</i> , 504 U.S. 71 (1992)
<i>Green v. Edwards</i> , 164 W.Va. 326 (1980)
<i>Jacobson v. Massachusetts</i> , 197 U.S. 11 (1905)
John Doe #1 #14 & Jane Doe #1 #2 v. Austin, No. 3:21-cv-1211-AW-HTC, 2021 U.S. Dist. LEXIS 236327 (N.D. Fla. Nov. 12, 2021)
<i>O'Connor v. Donaldson</i> , 422 U.S. 563 (1975)
Panhandle Eastern Pipeline Co. v. State Highway Commission, 294 U.S. 613 (1935)
Union Pac. Ry. Co. v. Botsford, 141 U.S. 250 (1891)
<i>Vitek v. Jones</i> , 445 U.S. 480 (1980)
<i>Washington v. Harper</i> , 494 U.S. 210 (1990)
STATUTES

## 

Page

#### **OTHER AUTHORITIES**

American College of Obstetricians and Gynecologists, <i>Ethical issues with vaccination in obstetrics and gynecology</i> . Committee Opinion No. 829. OBSTET GYNECOL 2021;138:e16-23. https://www.acog.org/ clinical/clinical-guidance/committee-opinion/articles/2021/07/ethical-issues- with-vaccination-in-obstetrics-and-gynecology
American Medical Association, <i>AMA Principles of Medical Ethics: I, II, V, VIII. Informed Consent.</i> (2022) https://www.ama-assn.org/delivering-care/ethics/informed-consent
Brown CM, et al, <i>Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine</i> <i>Breakthrough Infections, Associated with Large Public Gatherings</i> — <i>Barnstable County, Massachusetts, July 2021.</i> MMWR MORB MORTAL WKLY REP 2021;70:1059-1062. https://www.cdc.gov/mmwr/volumes/70/wr/ mm7031e2.htm
Bryant A, et al, <i>Ivermectin for prevention and treatment of COVID-19 infection: a systematic</i> <i>review, meta-analysis, and trial sequential analysis to inform clinical</i> <i>guidelines.</i> AM J THER. 2021 Jun 21;28(4):e434-60. https://www.ncbi.nlm.nih. gov/pmc/articles/PMC8248252/
C19early.com, <i>COVID-19 early treatment: real-time analysis of 2,118 studies</i> [cited 2022 Sept 18]. https://c19early.com/
C19early.com, <i>COVID-19 studies: ivermectin</i> ; [cited 2022 Sept 18]. https://c19ivermectin. com
C19early.com, <i>COVID-19 studies: vitamin D</i> ; [cited 2022 Sept 18]. https://c19vitamind.com 8
C19early.com, <i>HCQ for COVID-19: real-time meta analysis of 362 studies</i> ; [cited 2022 Sept 18]. https://hcqmeta.com
CDC (September 8, 2022), Immunization Information Systems, COVID-19 Vaccine Related Codes. https: //www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html
CDC, Interim Public Health Recommendations for Fully Vaccinated People. Covid-

Page
<i>19, Vaccines.</i> Updated July 28, 2021. https://www.cdc.gov/coronavirus/2019- ncov/vaccines/fully-vaccinated-guidance.html
Centers for Disease Control and Prevention, Washington, D.C.: U.S. Department of Health and Human Services. <i>COVID</i> <i>data tracker: trends in number of COVID-19 cases and deaths in the US</i> <i>reported to CDC, by state/territory</i> ; [cited 2022 Apr 2]. https://covid.cdc.gov/ covid-data-tracker/#trends_totaldeaths
CNN Situation Room, <i>The Situation Room, interview with CDC Director Walensky</i> . (August 5, 2021) https://twitter.com/CNNSitRoom/status/142342230188274892911
Colson, T., <i>Top WHO scientist says vaccinated travelers should still quarantine, citing</i> <i>lack of evidence that COVID-19 vaccines prevent transmission</i> . BUSINESS INSIDER. https://www.businessinsider.com/who-says-no-evidence-coronavirus- vaccine-prevent-transmissions-2020-12?op=1
Dennis JM, et al, <i>Improving survival of critical care patients with coronavirus disease 2019 in</i> <i>England: a national cohort study</i> , March to June 2020. CRIT CARE MED. 2021 Feb 1;49(2):209-14. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7803441/7
FDA Vaccines and Related Biological Products Advisory Committee, FDA briefing document: Application for licensure of a booster dose for Comirnaty (COVID-19 Vaccine, mRNA). FDA Vaccines and Related Biological Products Advisory Committee Meeting: September 17, 2021. https:/ /www.fda.gov/media/152176/download
FDA Vaccines and Related Biological Products Advisory Committee, FDA briefing document: <i>EUA amendment request for a booster dose for the</i> <i>Janssen COVID-19 vaccine.</i> Vaccines and Related Biological Products Advisory Committee Meeting: October 15, 2021. https://www.fda.gov/media/ 153037/download
Fraiman J, et al, Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. VACCINE. 2022 Sep 22;40(40):5798-5805. https://pubmed.ncbi.nlm.nih.gov/36055877/6
Horwitz LI, et al, <i>Trends in COVID-19 risk-adjusted mortality rates.</i> J HOSP MED. 2021 Feb;16(2):90-2. https://www.journalofhospitalmedicine.com/jhospmed/article/ 230561/hospital-medicine/trends-covid-19-risk-adjusted-mortality-rates7

Page
------

Ilie PC, et al, <i>The role of vitamin D in the prevention of coronavirus disease 2019 in</i> <i>and mortality.</i> AGING CLIN EXP RES. 2020 Jul;32(7):1195-8. https://www. nlm.nih.gov/pmc/articles/PMC7202265/	w.ncbi.
Ioannidis, JPA, <i>Reconciling estimates of global spread and infection fatality rates of C</i> <i>19: an overview of systematic evaluations.</i> EUR J CLIN INVEST. 2021;51:e13554. https://onlinelibrary.wiley.com/doi/epdf/10.1111/eci.13	
Lin, DY, et al, <i>Letter to the Editor: Effects of Vaccination and Previous Infection on</i> <i>Omicron Infections in Children</i> . NEW ENGLAND JOURNAL OF MEDICINE. (September 2022) https://www.nejm.org/doi/full/10.1056/NEJMc22093	
Manskar, N, <i>Moderna boss says COVID-19 vaccine not proven to stop spread of viru</i> YORK POST. (November 24, 2020) https://nypost.com/2020/11/24/mode boss-says-covid-shot-not-proven-to-stop-virus-spread/	erna-
Mariner, W et al., Jacobson v. Massachusetts: It's Not Your Great-Great-Grandfather's H Health Law, 95 AM. J. PUB. HEALTH 581 (2005). https://www.ncbi.nlm. gov/pmc/articles/PMC1449224/	nih.
Massetti, PhD, et al., Summary of Guidance for Minimizing the Impact of COVID-19 on Ind. Persons, Communities, and Health Care Systems — United States, Au 2022. Weekly/August 19, 2022/71(33);1057-1064. https://www.cdc.gov/n volumes/71/wr/mm7133e1.htm	<i>ıgust</i> mmwr/
Physicians for Informed Consent, <i>COVID-19 — Disease Information Statement (DIS).</i> Aug 2021. https:// physiciansforinformedconsent.org/covid-19/	
Physicians for Informed Consent, Janssen (Johnson & Johnson) COVID-19 Vaccine: Short-Term Efficacy Safety Data. May 2021. https://www.physiciansforinformedconsent.org COVID-19-vaccines	ç/
Physicians for Informed Consent, <i>Moderna COVID-19 vaccine: short-term efficacy and safety data.</i> Apr 2 https://www.physiciansforinformedconsent.org/COVID-19-vaccines	

Physicians for Informed Consent, <i>Pfizer-BioNTech COVID-19 vaccine: short-term efficacy and safety data.</i> Jun 2021. https://www.physiciansforinformedconsent.org/COVID-19-vaccines 10
Shitrit P, et al, <i>Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly</i> <i>vaccinated population, Israel, July 2021.</i> Euro Surveill. 2021 Sep;26(39). https://pubmed.ncbi.nlm.nih.gov/34596015/
Stieg, C, Dr. Fauci on CDC mask guidelines: 'We are dealing with a different virus now. CNBC (July 28, 2021) https://www.cnbc.com/2021/07/28/dr-fauci-on-why-cdc- changed-guidelines-delta-is-a-different-virus.html
Subramanian SV, et al, Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States. EUR J EPIDEMIOL. 2021 Sep 30:1-4. https://pubmed.ncbi.nlm.nih.gov/34591202/
Thomas SJ, et al, <i>C4591001 Clinical Trial Group. Safety and efficacy of the BNT162b2 mRNA</i> <i>covid-19 vaccine through 6 months.</i> N ENGL J MED. 2021 Nov 4;385(19):1761- 73. https://pubmed.ncbi.nlm.nih.gov/34525277
U.S. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: Janssen Ad26.COV2.S vaccine for the prevention of COVID-19. Vaccines and Related Biological Products Advisory Committee Meeting: February 26, 2021. https://www.fda.gov/media/146217/download10, 13
U.S. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee. <i>FDA briefing</i> <i>document: Moderna COVID-19 vaccine.</i> Vaccines and Related Biological Products Advisory Committee Meeting: December 17, 2020. https://www.fda. gov/media/144434/download
U.S. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: <i>Pfizer-BioNTech COVID-19 vaccine</i> . Vaccines and Related Biological Products Advisory Committee Meeting: December 10, 2020. https:/ /www.fda.gov/media/144245/download



#### **IDENTITY AND INTEREST OF AMICUS CURIAE1**

Amicus Curiae is PHYSICIANS FOR INFORMED CONSENT ("PIC"), a 501(c)(3) educational nonprofit organization focused on science and statistics. PIC delivers data on infectious diseases and vaccines, and unites doctors, scientists, healthcare professionals, attorneys, and families who support voluntary vaccination. In addition, its COALITION FOR INFORMED CONSENT consists of about 300 U.S. and international organizations.

This brief is submitted pursuant to leave requested by the unopposed accompanying motion.



#### SUMMARY OF ARGUMENT

Respondents' vaccine mandate would not pass strict scrutiny for scientific reasons, because there is no legal or scientific justification for Respondents to discriminate against unvaccinated people.

There is no evidence that any of the currently available COVID-19 vaccines prevent the infection or transmission of SARS-CoV-2 or COVID-19, and in fact there is evidence that the spread of SARS-CoV-2 occurs in spite of vaccination. CDC data show mass vaccination with the COVID-19 vaccine has had no measurable impact on the COVID-19 mortality rate in the U.S.

<sup>&</sup>lt;sup>1</sup> Amicis curiae states that no counsel for a party authored any part of this brief, and no person or entity other than amicus and their counsel made a monetary contribution to the preparation or submission of this brief.

Yet there is evidence that the vaccines have a rapidly declining effect on immunity within just a few months, to the point of zero immunity within six months. Previous SARS-CoV-2 or COVID-19 infection is more effective at preventing SARS-CoV-2 or COVID-19 infection than COVID-19 vaccines, thereby removing any purported justification for depriving unvaccinated people of their Constitutionally protected rights. Those previously infected with COVID-19 should not have less rights than those vaccinated for COVID-19.



#### ARGUMENT

# A. INFORMED CONSENT/REFUSAL IN VACCINATION IS A FUNDAMENTAL RIGHT TRIGGERING STRICT SCRUTINY.

Universally recognized by physicians, informed consent/refusal in vaccination is

a fundamental right, as it is essential to the patient's bodily integrity. See e.g.,

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making." Citation: American Medical Association (2022), AMA Principles of Medical Ethics: I, II, V, VIII. Informed Consent. https://www.ama-assn.org/delivering-care/ ethics/informed-consent.

Informed consent is a core component of the ethical clinical relationship. As with all forms of medical therapy, informed consent should precede vaccination administration... If the patient declines, this informed refusal of recommended vaccination should be respected .... Patients who decline vaccination should continue to be supported with appropriate care options that honor their autonomous choices."

*Ethical issues with vaccination in obstetrics and gynecology.* (2021) Committee Opinion No. 829. American College of Obstetricians and Gynecologists.

OBSTET GYNECOL 2021;138:e16-23. https://www.acog.org/clinical/clinical-guidance/ committee-opinion/articles/2021/07/ethical-issues-with-vaccination-in-obstetricsand-gynecology.

Safeguarding informed consent/refusal is indeed essential to a successful doctorpatient relationship. Vaccination carries risk of harm and is an invasive medical procedure. For a state or federally funded institution to engage in coercing this medical procedure upon patients (by threating to strip their livelihood) is a direct infringement upon the right of bodily integrity.

The fundamental right of bodily integrity has been well recognized in the United States. As this Supreme Court found in *Union Pac. Ry. Co. v. Botsford*, 141 U.S. 250, 251 (1891), "No right is held more sacred, or is more carefully guarded by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *See also Washington v. Harper*, 494 U.S. 210, 229 (1990) ("The forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty.")

Petitioner's brief discusses a method advocated by legal scholars to bring *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) in line with intermediate scrutiny if not strict scrutiny.

For example, applying *Jacobson* to the modern day, leading scholars at Boston University published wisely:

Public health programs that are based on force are a relic of the 19th century; 21st century public health depends on good science, good communication, and trust in public health officials to tell the truth. In each of these spheres, constitutional rights are the ally rather than the enemy

3

of public health. Preserving the public's health in the 21st century requires preserving respect for personal liberty.

Even in an emergency, when there is a rapidly spreading contagious disease and an effective vaccine, the state is not permitted to forcibly vaccinate or medicate anyone. The constitutional alternative is to segregate infected and exposed people separately [allowing selfquarantine] to prevent them from transmitting the disease to others.

While [the Supreme Court] has not decided a case that involved isolation or quarantine for disease, it has held that civil commitment for mental illness is unconstitutional unless a judge determines the person is dangerous by reason of a mental illness [citations omitted]. Assuming, as most scholars do, that the law governing commitment to a mental institution also applies to involuntary confinement for contagious diseases, the government would have the burden of proving, by "clear and convincing evidence," that the individual actually has, or has been exposed to, a contagious disease and is likely to transmit the disease to others if not confined [citations omitted].

In cases that involve civil commitment or involuntary hospitalization for mental illness, the Court has required the state to prove—by clear and convincing evidence—that a person is mentally ill and that the illness renders the person dangerous to others. *Foucha v. Louisiana*, 504 U.S. 71 (1992), *Carey v. Population Services Intl*, 431 U.S. 678 (1977), *O'Connor v. Donaldson*, 422 U.S. 563, 580 (1975), *Addington v. Texas*, 441 U.S. 418, 425 (1979), *Vitek v. Jones*, 445 U.S. 480, 494 (1980).

When the HIV epidemic began in 1981, these principles from the 1970s reminded legislators at both the state and federal levels that people could not be involuntarily detained simply because they had HIV infection. Only a few individuals who imminently threatened to infect other people by deliberate or uncontrollable behavior would meet the constitutional test. More recently, the same approach has been used by lower courts in some cases that involved people who had active, contagious tuberculosis. *City of Newark v. JS*, 279 N.J. Super. 178 (1993). *Green v. Edwards*, 164 W.Va. 326 (1980).

Jacobson v. Massachusetts: It's Not Your Great-Great-Grandfather's Public Health

Law, 95 AM. J. PUB. HEALTH 581, 588 (2005). https://www.ncbi.nlm.nih.gov/pmc/

articles/PMC1449224/.

Petitioner Marciano's brief (at page 32) references the quarantine rights and procedures meant to govern New York City. If such procedures had been actually implemented faithfully as individualized due process, there would have been little room for executive rule by fiat. The vaccine mandates that have transpired in New York City since 2021, and indeed throughout the Nation, have circumvented individualized due process, to the extent due process should require the government to meet a meaningful burden of proof before tribunals making evidentiary findings at individualized hearings. Such due process would have provided, as the New York legislature appears to have intended, checks and balances against executive rule by fiat.

In Panhandle Eastern Pipeline Co. v. State Highway Commission, 294 U.S. 613,

622 (1935), this Court stated famously,

The police power of a state, while not susceptible of definition with circumstantial precision, must be exercised within a limited ambit and is subordinate to constitutional limitations. It springs from the obligation of the state to protect its citizens and provide for the safety and good order of society. Under it there is no unrestricted authority to accomplish whatever the public may presently desire. It is the governmental power of selfprotection and permits reasonable regulation of rights and property in particulars essential to the preservation of the community from injury.

Public health authority is not unlimited, but rather is limited by courts assessing whether injury is being done to individuals and the community. The scientific authorities presented in this amicus brief are intended to so aid the Court, especially to the extent the burden should be upon the government to meet strict scrutiny. Here are some of the key data points highlighting the importance of informed consent, which further emphasize that Respondents' vaccine mandate should not survive any level of scrutiny:

Because all subjects in the COVID-19 clinical trials were observed for only two to six months, the long-term safety of COVID-19 vaccines for any age group is not known. Meanwhile, substantial risks of the vaccine are increasingly calculable, such as myocarditis and pericarditis.<sup>2</sup>

The clinical trials detected that vaccine immunity wanes significantly over a short period of time. For example, the Pfizer vaccine efficacy decreased by 8% to 18% within only six months, and the Johnson & Johnson vaccine efficacy decreased by 25% to 29% within only six months.<sup>3</sup> Additionally, the efficacy measured in the clinical trials was against the original Wuhan strain, not the new variants.

In clinical trials, a third dose of Pfizer or Moderna vaccine or a second dose of Johnson & Johnson vaccine has not been evaluated for efficacy against disease, but

<sup>&</sup>lt;sup>2</sup> Fraiman J, et al (September 2022). Serious adverse events of special interest following mRNA COVID-19 vaccination in randomized trials in adults. VACCINE. 2022 Sep 22;40(40):5798-5805. https://pubmed.ncbi.nlm.nih.gov/36055877/

<sup>&</sup>lt;sup>3</sup> Thomas SJ, et al (November 2021), C4591001 Clinical Trial Group. Safety and efficacy of the BNT162b2 mRNA covid-19 vaccine through 6 months. N ENGL J MED. 2021 Nov 4;385(19):1761-73. https://pubmed.ncbi.nlm.nih.gov/34525277.

FDA (October 2021). Vaccines and Related Biological Products Advisory Committee. FDA briefing document: *EUA amendment request for a booster dose for the Janssen COVID-19 vaccine.* Vaccines and Related Biological Products Advisory Committee Meeting: October 15, 2021. https://www.fda.gov/media/153037/download.

See also, Lin, DY, et al (September 2022), Letter to the Editor: Effects of Vaccination and Previous Infection on Omicron Infections in Children. NEW ENGLAND JOURNAL OF MEDICINE. https://www.nejm.org/doi/full/10.1056/NEJMc2209371 ("rapid decline in protection")

rather antibody counts were observed in a small number of vaccinated subjects for only one month.  $^4$ 

Treatments for COVID-19 have improved significantly since the pandemic began in early 2020, resulting in improved survival rates in hospitalized cases.<sup>5</sup> Indeed, for people not living in a nursing home, the overall survival rate of COVID-19 is 99.8% in the U.S., and 99.999% for children specifically.<sup>6</sup>

Hundreds of studies have observed the effectiveness of various treatments, the most studied being ivermectin, vitamin D, hydroxychloroquine (HCQ), and monoclonal antibodies.<sup>7</sup> These treatments may also be beneficial for prophylaxis (i.e., pre-exposure or post-exposure prevention of symptomatic COVID-19 infections).<sup>8</sup>

<sup>&</sup>lt;sup>4</sup> See footnote 2, and FDA (September 2021). Vaccines and Related Biological Products Advisory Committee. FDA briefing document: *Application for licensure of a booster dose for Comirnaty (COVID-19 Vaccine, mRNA)*. Vaccines and Related Biological Products Advisory Committee Meeting: September 17, 2021. https://www.fda.gov/media/152176/download.

<sup>&</sup>lt;sup>5</sup> Horwitz LI, et al (2021) *Trends in COVID-19 risk-adjusted mortality rates.* J HOSP MED. 2021 Feb;16(2):90-2. https://www.journalofhospitalmedicine.com/jhospmed/article/230561/hospital-medicine/ trends-covid-19-risk-adjusted-mortality-rates.

Dennis JM, et al (2021). *Improving survival of critical care patients with coronavirus disease 2019 in England: a national cohort study*, March to June 2020. CRIT CARE MED. 2021 Feb 1;49(2):209-14. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7803441/.

<sup>&</sup>lt;sup>6</sup> Ioannidis, JPA. *Reconciling estimates of global spread and infection fatality rates of COVID- 19: an overview of systematic evaluations.* EUR J CLIN INVEST. 2021;51:e13554. https://onlinelibrary.wiley. com/doi/epdf/10.1111/eci.13554.

Physicians for Informed Consent (2021). COVID-19 — Disease Information Statement (DIS). Aug 2021. https://physiciansforinformedconsent.org/covid-19/.

<sup>7</sup> C19early.com. *COVID-19 early treatment: real-time analysis of 2,118 studies* [cited 2022 Sept 18]. https://c19early.com/.

<sup>&</sup>lt;sup>8</sup> C19early.com. COVID-19 studies: ivermectin; [cited 2022 Sept 18]. https://c19ivermectin.com.

Bryant A, et al (2021). *Ivermectin for prevention and treatment of COVID-19 infection: a systematic review, meta-analysis, and trial sequential analysis to inform clinical guidelines*. AM J THER. 2021 Jun 21;28(4):e434-60. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8248252/.

Ultimately, history favors those who uphold civil rights, such as Petitioner.

As a housecleaning matter, Petitioner Marciano's brief states at pages 25 and

31,

A majority of this Court would likely agree, as it did in NFIB, the City Respondents' have no inherent legislative authority to engage in fundamental, medical policy decisions reserved for the legislature ... A majority of this Court would likely agree this case is not about police power to mandate a legislatively authorized vaccination as erroneously determined below.

Amicus Curiae concurs this case does not concern a legislative vaccine mandate.

However, had the New York legislature explicitly granted authority to the mayor to mandate a COVID-19 vaccine on city employees, amicus submits a mandate would still violate strict scrutiny for the scientific and ethical reasons stated herein, which are in addition to the reasons stated in Petitioner's brief.

Amicus was unable to locate any evidence in this case that an FDA-approved COVID-19 vaccine (Comirnaty or Spikevax) was available to Petitioner Anthony Marciano. This absence of evidence appears consistent with healthcare observations in real-time that EUA label vaccines are widely available, but not FDA-approved vaccines. *See* CDC (September 8, 2022). *Immunization Information Systems, COVID-19 Vaccine Related Codes.* https://www.cdc.gov/vaccines/programs/iis/COVID-19-related-codes.html ("These vaccines are listed separately because they represent

C19early.com. COVID-19 studies: vitamin D; [cited 2022 Sept 18]. https://c19vitamind.com.

Ilie PC, et al (2020). The role of vitamin D in the prevention of coronavirus disease 2019 infection and mortality. AGING CLIN EXP RES. 2020 Jul;32(7):1195-8. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7202265/.

C19early.com. *HCQ for COVID-19: real-time meta analysis of 362 studies*; [cited 2022 Sept 18]. https://hcqmeta.com.

NDCs that will not be manufactured or made available in the near term even if authorized.")

This supports Petitioner's statutory argument for informed consent pursuant to 21 U.S.C. § 360bbb-3; *John Doe #1 #14 & Jane Doe #1 #2 v. Austin*, No. 3:21-cv-1211-AW-HTC, 2021 U.S. Dist. LEXIS 236327, at \*17 (N.D. Fla. Nov. 12, 2021) (finding that EUA vaccines cannot be mandated, "Because the plaintiffs have not shown they are (or will be) required to receive an EUA-labeled, non-BLA-compliant vaccine, the plaintiffs have not shown a likelihood of success").

#### B. THERE IS NO EVIDENCE THAT COVID-19 VACCINES PREVENT THE INFECTION OR TRANSMISSION OF SARS-COV-2 OR COVID-19, AND IN FACT THERE IS EVIDENCE TO THE CONTRARY (THAT IT HAS A NEGATIVE EFFECT ON IMMUNITY)

Government statements confirm there is no evidence that COVID-19 vaccines prevent the spread of SARS-CoV-2 or COVID-19.

Therefore, there is no scientific justification to discriminate against unvaccinated people. Clinical trials for the Pfizer-BioNTech, Moderna, and Janssen (Johnson & Johnson) COVID-19 vaccines were not designed to observe asymptomatic infection with SARS-CoV-2 or the effect of the vaccine on the spread (transmission) of COVID-19. Consequently, in its briefing document for each vaccine, the U.S. Food and Drug Administration (FDA) states that "it is possible that asymptomatic infections may not be prevented as effectively as symptomatic infections" and "data are limited to assess the effect of the vaccine against transmission of SARS-CoV-2 from individuals who are infected despite vaccination." Furthermore, "additional evaluations including data from clinical trials and from vaccine use post-authorization will be needed to assess the effect of the vaccine in preventing virus shedding and transmission, in particular in individuals with asymptomatic infection." Citations:

- 1. U.S. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: *Pfizer-BioNTech COVID-19 vaccine*. Vaccines and Related Biological Products Advisory Committee Meeting: December 10, 2020. https://www.fda.gov/media/ 144245/download.
- 2. Physicians for Informed Consent. *Pfizer-BioNTech COVID-19 vaccine: short-term efficacy and safety data.* Jun 2021. https://www.physicians forinformedconsent.org/COVID-19-vaccines.
- 3. U.S. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: Moderna COVID-19 vaccine. Vaccines and Related Biological Products Advisory Committee Meeting: December 17, 2020. https://www.fda.gov/media/144434/download.
- 4. Physicians for Informed Consent. *Moderna COVID-19 vaccine: short-term efficacy and safety data.* Apr 2021. https://www.physiciansforinformed consent.org/COVID-19-vaccines.
- 5. U.S. Food and Drug Administration, Vaccines and Related Biological Products Advisory Committee. FDA briefing document: Janssen Ad26.COV2.S vaccine for the prevention of COVID-19. Vaccines and Related Biological Products Advisory Committee Meeting: February 26, 2021. https://www.fda.gov/media/146217/download.
- 6. Physicians for Informed Consent. Janssen (Johnson & Johnson) COVID-19 Vaccine: Short-Term Efficacy & Safety Data. May 2021. https://www. physiciansforinformedconsent.org/COVID-19-vaccines.

For over one year now, government statements have repeatedly confirmed that

COVID-19 vaccines do not prevent the spread of SARS-CoV-2 or COVID-19, and

that both vaccinated and unvaccinated persons equally transmit the virus. For example:

- NIAID Director Dr. Anthony Fauci: "We know now as a fact that [vaccinated people with Covid-19] are capable of transmitting the infection to someone else."9
- CDC Director Dr. Rochelle Walensky: "[W]hat the [vaccines] can't do anymore is prevent transmission."<sup>10</sup>
- WHO Chief Scientist Dr. Soumya Swaminathan: "At the moment I don't believe we have the evidence of any of the vaccines to be confident that it's going to prevent people from actually getting the infection and therefore being able to pass it on."<sup>11</sup>
- Chief Medical Officer of Moderna Dr. Tal Zaks: "There's no hard evidence that [the vaccine] stops them from carrying the virus transiently and potentially infecting others who haven't been vaccinated."<sup>12</sup>

And these admissions from government officials have been supported by real-

time data, such as the CDC study of one COVID-19 outbreak in July 2021 where

74% of cases were fully vaccinated. 13

<sup>12</sup> Manskar, N (November 24, 2020). *Moderna boss says COVID-19 vaccine not proven to stop spread of virus*. NEW YORK POST. https://nypost.com/2020/11/24/moderna-boss-says-covid-shot-not-proven-to-stop-virus-spread/.

<sup>&</sup>lt;sup>9</sup> Stieg, C (July 28, 2021), *Dr. Fauci on CDC mask guidelines: We are dealing with a different virus now.* https://www.cnbc.com/2021/07/28/dr-fauci-on-why-cdc-changed-guidelines-delta-is-a-different-virus. html.

<sup>&</sup>lt;sup>10</sup> CNN (August 5, 2021), *The Situation Room, interview with CDC Director Walensky*. https://twitter.com/CNNSitRoom/status/1423422301882748929.

<sup>&</sup>lt;sup>11</sup> Colson, T. (December 29, 2020), *Top WHO scientist says vaccinated travelers should still quarantine, citing lack of evidence that COVID-19 vaccines prevent transmission.* BUSINESS INSIDER. https://www.businessinsider.com/who-says-no-evidence-coronavirus-vaccine-prevent-transmissions-2020-12?op=1.

<sup>&</sup>lt;sup>13</sup> Brown CM, et al (2021). Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021. MMWR MORB MORTAL WKLY REP 2021;70:1059-1062. https://www.cdc. gov/mmwr/volumes/70/wr/mm7031e2.htm.

Another CDC statement highlighting this, "...preliminary evidence suggests that fully vaccinated people who do become infected with the Delta variant can spread the virus to others." CDC. *Interim Public Health Recommendations for Fully Vaccinated People. Covid-19, Vaccines.* Updated July 28, 2021. https://www.cdc.gov/coronavirus/2019-ncov/vaccines/fully-vaccinated-guidance.html.

Another study of a COVID-19 outbreak in July 2021 published in *Eurosurveillance* found that "all transmissions between patients and staff occurred between masked and vaccinated individuals, as experienced in an outbreak from Finland." The authors state that the study "challenges the assumption that high universal vaccination rates will lead to herd immunity and prevent COVID-19 outbreaks."<sup>14</sup>

A Harvard study investigating COVID-19 cases across 68 countries and across 2,947 counties in the U.S. found "no significant signaling of COVID-19 cases decreasing with higher percentages of population fully vaccinated."<sup>15</sup>

# C. THOSE PREVIOUSLY INFECTED WITH COVID-19 SHOULD NOT HAVE LESS RIGHTS THAN THOSE VACCINATED FOR COVID-19

There is evidence that previous SARS-CoV-2 or COVID-19 infection is more effective at preventing SARS-CoV-2 or COVID-19 infection than COVID-19 vaccines. Therefore, it follows that those previously infected with COVID-19 should not have less rights than those vaccinated for COVID-19.

Recent CDC guidance recognizes vaccinated and unvaccinated people should be treated alike for COVID-19 testing purposes.<sup>16</sup>

<sup>&</sup>lt;sup>14</sup> Shitrit P, et al (2021). Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021. Euro Surveill. 2021 Sep;26(39). https://pubmed.ncbi.nlm. nih.gov/34596015/.

<sup>&</sup>lt;sup>15</sup> Subramanian SV, et al (2021). Increases in COVID-19 are unrelated to levels of vaccination across 68 countries and 2947 counties in the United States. EUR J EPIDEMIOL. 2021 Sep 30:1-4. https://pubmed.ncbi.nlm.nih.gov/34591202/.

<sup>16</sup> Massetti, PhD, et al. (August 2022), Summary of Guidance for Minimizing the Impact of COVID-19 on Individual Persons, Communities, and Health Care Systems — United States, August 2022. Weekly/August 19, 2022/71(33);1057-1064. https://www.cdc.gov/mmwr/volumes/71/wr/mm7133e1. htm ("When implemented, screening testing strategies should include all persons, irrespective of vaccination status.")

The Janssen (Johnson & Johnson) COVID-19 vaccine clinical trial included over 2,000 subjects that had contracted SARS-CoV-2 before the study. The trial recorded the incidence of COVID-19 in that unvaccinated group at least 28 days after the vaccination of the other subjects in the study. The COVID-19 incidence of the unvaccinated group with prior SARS-CoV-2 infection was 0.1% (2/2,021), whereas the COVID-19 incidence of vaccinated subjects was 0.59% (113/19,306). These data suggest that there are six times more cases of COVID-19 in vaccinated subjects than in unvaccinated subjects previously infected with SARS-CoV-2. This also means that an unvaccinated person previously infected with SARS-CoV-2 has 99.9% chance of being protected from a repeat infection. <sup>17</sup>

#### D. COVID-19 VACCINES HAVE HAD NO MEASURABLE IMPACT ON THE COVID-19 MORTALITY RATE

CDC data show mass vaccination with COVID-19 vaccines has had no measurable impact on the COVID-19 mortality rate in the U.S. In the nine months before the introduction of mass vaccination (April 2020 through December 2020), there were about 356,000 COVID-19 deaths or 39,500 deaths per month — a mortality rate of 0.120 per 1,000 people. In the nine months after the introduction of mass vaccination (January 2021 through September 2021), there were 342,000

<sup>17</sup> Physicians for Informed Consent. Janssen (Johnson & Johnson) COVID-19 Vaccine: Short-Term Efficacy & Safety Data. May 2021. https://www.physiciansforinformedconsent.org/COVID-19-vaccines.

FDA (2021). Vaccines and Related Biological Products Advisory Committee. FDA briefing document: Janssen Ad26.COV2.S vaccine for the prevention of COVID-19. Vaccines and Related Biological Products Advisory Committee Meeting: February 26, 2021. Table 14: vaccine efficacy of first occurrence of moderate to severe/critical COVID-19, including non-centrally confirmed cases, with onset at least 14 or at least 28 days after vaccination, by baseline SARS-CoV-2 status, per protocol set; 30. https://www.fda.gov/media/146217/download.

COVID-19 deaths or 38,000 deaths per month — a mortality rate of 0.115 per 1,000 people. And in the five months that followed (October 2021 through February 2022), there were an additional 249,000 COVID-19 deaths or 49,800 deaths per month — a mortality rate of 0.151 per 1,000 people.<sup>18</sup>

<sup>&</sup>lt;sup>18</sup> Centers for Disease Control and Prevention. Washington, D.C.: U.S. Department of Health and Human Services. *COVID data tracker: trends in number of COVID-19 cases and deaths in the US reported to CDC, by state/territory*; [cited 2022 Apr 2]. https://covid.cdc.gov/covid-data-tracker/ #trends\_totaldeaths.



#### CONCLUSION

Petitioner should retain the right and dignity of informed consent/refusal without penalty. The scientific data demonstrate that vaccine mandates have not been proven to create a safer environment. Applying strict scrutiny, Respondents' vaccine mandate fails to advance a compelling government interest that is narrowly tailored to protect public health. If there is any doubt here, it helps to remember that history favors upholding civil rights.

Respectfully submitted,

/s/ Gregory J. Glaser

GREGORY J. GLASER *COUNSEL OF RECORD* 4399 BUCKBOARD DRIVE #423 COPPEROPOLIS, CA 95228 (925) 642-6651 GREG@PICPHYSICIANS.ORG

Counsel for Amicus Curiae Physicians for Informed Consent

SEPTEMBER 24, 2022