Case No. 21A15

IN THE

Supreme Court of the United States

In re Ryan Klaassen, et al.,

Petitioners,

ON EMERGENCY APPLICATION FOR WRIT OF INJUNCTION

To the Honorable Amy Coney Barrett
Associate Justice of the Supreme Court of the United States and
Circuit Justice for the Seventh Circuit

MOTION FOR LEAVE TO FILE BRIEF OF *AMICUS CURIAE* PHYSICIANS FOR INFORMED CONSENT

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Physicians for Informed Consent ("Amicus") moves the Court for leave to file an *amicus* brief in support of Petitioners' Emergency Application for Writ of Injunction. This amicus motion is unopposed.

In support of this motion, Amicus assert that the district court ruling failed to apply strict scrutiny to Respondent's infringement upon the Petitioners' fundamental right to informed consent and informed refusal in vaccination, protected by the Fourteenth Amendment. *Amicus* request that this motion to file the attached *amicus* brief be granted.

Amicus further requests to make this motion on 8½-by-11 inch paper, and to do so without ten days' advance notice to the parties. No counsel for a party authored this motion or the proposed amicus brief in whole or in part, and no person other than amicus, its members, or its counsel made a monetary contribution to fund the motion or brief.

Dated: August 10, 2021 Respectfully submitted,

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PHYSICIANS FOR INFORMED CONSENT
IN SUPPORT OF PETITIONERS

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TABLE OF CONTENTS

Page #

TABLE OF CONTENTS I

TABLE OF AUTHORITIES .... I-IV

IDENTITY AND INTEREST OF *AMICUS CURIAE* 1

SUMMARY OF ARGUMENT 2

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 spread of SARS-CoV-2 or COVID-19, and in fact there is evidence to the contrary. 6

C. Those previously infected with COVID-19 should have at least the same rights as those vaccinated for COVID-19. 10

CONCLUSION 13

CERTIFICATE OF COMPLIANCE 14

TABLE OF AUTHORITIES

Federal Cases

Union Pac. Ry. Co. v. Botsford,
141 U.S. 250, 251 (1891) 3, 4

Washington v. Harper,
494 U.S. 210, 229 (1990) 4

Other Authorities

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AMICUS BRIEF RE INFORMED CONSENT

IDENTITY AND INTEREST OF *AMICUS CURIAE*

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. The parties have consented to this request.

SUMMARY OF ARGUMENT

Respondents' vaccine mandate would not pass strict scrutiny for scientific reasons.

There is no evidence that any of the currently available EUA COVID-19 vaccines prevent the spread 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. Therefore, there is no scientific justification to segregate vaccinated and unvaccinated people. This is particularly important in light of super precedent *Brown v. Board* prohibiting separate but equal schooling.

There is compelling 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, those previously infected with COVID-19 should have at least the same rights as 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 (2021). 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." Citation: 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-obstetrics-and-gynecology.

Safeguarding informed consent/refusal is indeed essential to a successful doctor-patient relationship. Vaccination carries risk of harm, and is an invasive medical procedure. For a state or federally funded institution to engage in medical bulling or coerce this medical procedure upon patients is a direct infringement upon the rights of bodily integrity and privacy.

The fundamental right of bodily integrity has been 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.")

Applying *Jacobson v. Massachusetts* to the modern day, leading scholars at Boston University George Annas, Wendy Mariner, and Leonard Glantz wrote 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 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 self-quarantine] 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/.

B. There is no evidence that COVID-19 vaccines prevent the spread of SARS-CoV-2 or COVID-19, and in fact there is evidence to the contrary.

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 segregate between vaccinated and unvaccinated people.[1] 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.physiciansforinformedconsent.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.physiciansforinformedconsent.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.

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[1] This is particularly important in light of super precedent *Brown v. Board* prohibiting separate but equal schooling.

Government statements confirm 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.

In July 2021, in a Barnstable County town in Massachusetts, 469 COVID-19 cases were identified among Massachusetts residents who had traveled to the town and 346 (74%) occurred in fully vaccinated persons. Of the five hospitalized cases, four were vaccinated. The CDC also concluded, "Cycle threshold values were similar among specimens from patients who were fully vaccinated and those who were not," which means vaccinated and unvaccinated persons can equally spread SARS-CoV-2 and there is no scientific basis for discrimination based on vaccination status. 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."[2]

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[2] Brown CM, Vostok J, Johnson H, et al. 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.

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.

Other outbreaks have similarly shown that vaccinated persons can become infected. "More staff are getting COVID than we saw before, and it's mostly vaccinated staff. And that's just because of the easing of restrictions," said Dr. Lukejohn Day, the Chief Medical Officer of San Francisco General Hospital. Larsen, K. 'Physicians, nurses, ancillary staff': How hundreds of SFGH and UCSF staff got infected with COVID. ABC 7 News (July 30, 2021). https://abc7news.com/coronavirus-outbreak-san-francisco-general-hospital-sf-covid-ucsf/10920805/ ("We are seeing it among physicians, nurses, ancillary staff, we sort of are seeing that across the board.")

In Iceland where mostly the same vaccines that are available in the US are being used, most of the current SARS-CoV-2 infections are occurring among fully *vaccinated* persons. See Covid-19 in Iceland – Statistics. Number of vaccinated individuals among domestic infections – Iceland. https://www.covid.is/data (accessed August 9, 2021).

C. Those previously infected with COVID-19 should have at least the same rights as 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, those previously infected with COVID-19 should have at least the same rights as those vaccinated for COVID-19.

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. Citations:

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

2. 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. 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.

Of note, as of July 1, 2021, there have been 177.4 million SARS-CoV-2 infections in the U.S., which is 53.8% of the U.S. population. Citation to *Statistical Analysis of the Frequency of SARS-CoV-2 Infections in the United States:*

> A Stanford University systematic review that included 69 antibody studies estimated that the COVID-19 infection fatality rate (IFR) in the United States ranges from 0.3% to 0.4%.[a] Data analysis herein uses the midpoint of that range, 0.35%. An IFR of 0.35% is also supported by an analysis published in *Clinical Infectious Diseases* that estimated that there were 44.8 million symptomatic COVID-19 illnesses in February–September 2020.[b] Additionally, since 33% of all SARS-CoV-2 infections are asymptomatic,[c] there were an estimated 66.9 million (44.8 million/[100%-33%]) total number of SARS-CoV-2 infections in that time period. There were also 213,000 COVID-19 deaths in February–September 2020,[d] resulting in a COVID-19 IFR of 0.32% (213,000/66.9 million). As of July 1, 2021, there have been about 621,000 COVID-19 deaths in the U.S.[d] As the COVID-19 IFR is about 0.35%, as of July 1, 2021 there have been about 177.4 million SARS-CoV-2 infections (621,000/0.35%), which is 53.8% of the population of the U.S. (330 million).

[a] Ioannidis, JPA. Infection fatality rate of COVID-19 inferred from seroprevalence data. Bulletin of the World Health Organization. 2020 Oct 14 [cited 2021 Apr 16]. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7947934/

[b] Reese H, Iuliano AD, Patel NN, Garg S, Kim L, Silk BJ, Hall AJ, Fry A, Reed C. Estimated incidence of coronavirus disease 2019 (COVID-19) illness and hospitalization—United States, February–September 2020. Clin Infect Dis. 2020; Nov 25;ciaa1780. https://doi.org/10.1093/cid/ciaa1780.

[c] Oran DP, Topol EJ. The proportion of SARS-CoV-2 infections that are asymptomatic: a systematic review. Ann Intern Med. 2021 May;174(5):655-62. https://doi.org/10.7326/M20-6976.

[d] Worldometer. Coronavirus: United States. https://www.worldometers.info/coronavirus/country/us/.

In Israel, where only the Pfizer vaccine was used, new data indicate that nearly 40% of new COVID-19 patients were vaccinated - compared to just 1% who had been infected previously. Rosenberg, D. Natural infection vs vaccination: which gives more protection? Israel National News (July 13, 2021). https://www.israelnationalnews.com/News/News.aspx/309762.

Separating people depending on their COVID-19 vaccination status is unscientific, and not equal. We urge the Court to reject the vaccine mandate and instead uphold the equal protection of law that treats Americans the same, regardless of their vaccination status.

CONCLUSION

Applying strict scrutiny, the Court should find Respondent's vaccine mandate fails to advance a compelling government interest that is narrowly tailored to protect public health.

Dated: August 10, 2021

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This brief is in compliance with the 6,500 word limit, as permitted by FRAP 32(a)(7)(B), exclusive of items exempt under FRAP 32(f). An electronic word count performed on the final version of the text reported 2,264 words.

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