IN THE

Supreme Court of the United States

IN RE: MCP NO. 165, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, INTERIM FINAL RULE: COVID-19 VACCINATION AND TESTING; EMERGENCY TEMPORARY STANDARD 86 FED. REG. 61402, ISSUED ON NOVEMBER 4, 2021

[case captions on following pages]

On Applications for Stay or Injunction Pending Review of Petition for Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit

MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF AND BRIEF OF AMERICA'S FRONTLINE DOCTORS AS AMICUS CURIAE IN SUPPORT OF APPLICANTS

GEORGE R. WENTZ, JR. The Davillier Law Group 935 Gravier Street, Ste. 1702 New Orleans, Louisiana 70112 Telephone: (504) 582-6998 gwentz@davillierlawgroup.com GREGORY J. GLASER*
4399 Buckboard Drive #423
Copperopolis, California 95228
Telephone: (925) 642-6651
greg@gregglaser.com

Counsel for Amicus Curiae America's Frontline Doctors

*Counsel of Record

JOB CREATORS NETWORK, ET AL.,

Applicants,

v.

DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., Respondents. NATIONAL FEDERATION OF INDEPENDENT BUSINESS, ET AL., Applicants, v. DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., Respondents. PHILLIPS MANUFACTURING & TOWER COMPANY, ET AL., Applicants, v. DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., Respondents. THE SOUTHERN BAPTIST THEOLOGICAL SEMINARY, ET AL., Applicants, v. DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., Respondents. STATE OF OHIO, ET AL., Applicants, v. DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., Respondents. BST HOLDINGS, LLC, ET AL., Applicants,

v.

DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., Respondents.

HERITAGE FOUNDATION, ET AL.,

Applicants,

v.

ADMINISTRATION, ET AL., $Respondents$.
ION NETWORK, ET AL., Applicants,
ADMINISTRATION, ET AL. $Respondents.$
C., ET AL., $Applicants$,
ADMINISTRATION, ET AL., $Respondents$.
тне Idaho House of $Applicants$,
ADMINISTRATION, ET AL. $Respondents$.
Applicant,

Department of Labor, Occupational Safety and Health Administration, et al., Respondents.

BETTEN CHEVROLET, INC.,

Applicant,

v.	11pp wount,
DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH	Administration, et al., $Respondents.$
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DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH	Administration, et al., $Respondents$.
FABARC STEEL SUPPLY, INC., ET AL., v.	Applicants,
DEPARTMENT OF LABOR, OCCUPATIONAL SAFETY AND HEALTH	Administration, et al., $Respondents$.

MOTION FOR LEAVE TO FILE AMICUS CURIAE BRIEF

America's Frontline Doctors ("Amicus" or "AFLDS") respectfully moves under Supreme Court Rule 37.2 for leave (1) to file the attached brief as amicus curiae in support of the Emergency Applications filed on December 17-22, 2021, seeking a stay or injunction pending review of the Sixth Circuit's decision to dissolve a stay of the Occupational Safety and Health Administration ("OSHA") Emergency Temporary Standard ("ETS") on Coronavirus Disease of 2019 ("Covid-19") vaccination and testing, (2) given the expedited consideration of this matter, to file in unbound format on 8.5-by-11-inch paper, and (3) to the extent leave is required, to file without 10 days' advance notice to the parties of Amicus' intent to file.*

By email on December 28, 2021, *Amicus* sought consent from the parties to file a brief in support of the emergency applications. Counsel for the Applicants in Nos. 21A243, 21A245, 21A247, 21A248, 21A249, 21A250, 21A251, 21A252, 21A258, 21A259, 21A260, and 21A267 consented to the filing. Counsel for the Department of Justice stated the government takes no position. Counsel for the remaining Applicants had not responded as of 12 p.m. on December 30, 2021.

Amicus is a non-partisan, not-for-profit organization of hundreds of member physicians from across the country, representing a range of medical disciplines and practical experience with Covid-19 on the front lines of medicine.

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^{*} No counsel for a party authored this motion 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.

Permitting the filing of the proposed brief would offer an important

perspective to this Court:

It is the consensus of the medical community that the currently available

Covid-19 vaccine injections do not prevent the spread of SARS-CoV-2. Relevant

federal agencies have repeatedly acknowledged this consensus. Therefore, there is

no scientific or legal justification for OSHA to segregate injected and un-injected

people. Indeed, since the Covid-19 injections do not confer immunity upon the

recipients, but are claimed to merely reduce the symptoms of the disease, they do

not fall within the long-established definition of a vaccine at all. They are instead

treatments and must be analyzed as such under the law.

Even if OSHA possessed the statutory and constitutional authority to issue

the ETS now challenged before the Court, which it does not, the substantive due

process clause of the Fifth Amendment would require the federal government to

establish that the OSHA ETS is narrowly tailored to meet a compelling state

interest. This is a standard it cannot meet.

Respectfully submitted this 30th day of December, 2021,

GREGORY J. GLASER*

4399 Buckboard Drive #423

Copperopolis, California 95228

Congory J. Closer

Telephone: (925) 642-6651

greg@gregglaser.com

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GEORGE R. WENTZ, JR. The Davillier Law Group 935 Gravier Street, Ste. 1702 New Orleans, Louisiana 70112 Telephone: (504) 582-6998 gwentz@davillierlawgroup.com

Counsel for Amicus Curiae America's Frontline Doctors

 $[*]Counsel\ of\ Record$

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INTEREST OF AMICUS CURIAE¹

Amicus Curiae is America's Frontline Doctors ("AFLDS"), a non-partisan, not-for-profit organization of hundreds of member physicians who come from across the country, representing a range of medical disciplines and practical experience on the front lines of medicine. AFLDS' programs focus on a number of critical issues including:

- Providing Americans with science-based facts about Covid-19;
- Protecting physician independence from government overreach;
- Combating Covid-19 with evidence-based approaches without compromising constitutional freedoms;
- Fighting medical cancel culture and media censorship;
- Advancing healthcare policies that protect the physician-patient relationship;
- Expanding Covid-19 treatment options for all Americans who need them; and
- Strengthening the voices of frontline doctors in the national healthcare conversation.

Each of AFLDS' member physicians is deeply committed to the guiding principle of medicine: "FIRST, DO NO HARM." They gravely take their ethical

¹ Due the expedited nature of this matter, parties were *not* noticed 10 days prior to the filing of this brief; nevertheless, it is hereby certified that a majority of Applicants have extended written permission to file this brief, and that Respondents take no position with respect to the filing of this brief. Finally, no counsel for a party or a party to this case authored this brief in whole or in part; and no person other than the *Amicus*, its members, or its counsel made a monetary contribution to its preparation or submission.

obligations to their patients. It is axiomatic that a physician's duty is to his or her patient. AFLDS holds sacrosanct the relationship between doctor and patient where informed decisions are to be made, taking into consideration all of the factors relating to the patients' health, risks, co-morbidities and circumstances.

For AFLDS member physicians, the practice of medicine is not simply a job.

Neither is it merely a career. Rather, it is a sacred trust. It is a high calling that

often requires a decade or more of highly focused sacrificial dedication to achieve.

SUMMARY OF ARGUMENT

It is the consensus of the medical community that the currently available Covid-19 vaccine injections ("Covid-19 injections") do not prevent the spread of Covid-19. Relevant federal agencies have repeatedly acknowledged this consensus. Therefore, there is no scientific or legal justification for the Occupational Safety and Health Administration ("OSHA") to segregate injected and un-injected people. Indeed, since the Covid-19 injections do not confer immunity upon the recipients, but are claimed to merely reduce the symptoms of the disease, they do not fall within the long-established definition of a vaccine at all. They are instead treatments and must be analyzed as such under the law.

Even if OSHA possessed the statutory and constitutional authority to issue the Emergency Temporary Standard ("ETS")² now challenged before the Court, which it does not, the substantive due process clause of the Fifth Amendment would require the federal government to establish that the OSHA ETS is narrowly tailored

² 86 FED. REG. 61402 (November 4, 2021).

to meet a compelling state interest. This is a standard it cannot meet.

ARGUMENT

A. Covid-19 injections do not create immunity. They are treatments, not vaccines.

The uncontroverted medical consensus is that existing Covid-19 injections do not prevent infection or transmission of the coronavirus; i.e., they do not create immunity in the recipients. This is admitted openly today, including by U.S. Health Agencies, which is why the CDC Director stated on CNN, "What the vaccines can't do anymore is prevent transmission." Examples abound:

- a. NIAID Director Dr. Anthony Fauci to NPR: "We know now as a fact that [vaccinated people with Covid-19] are capable of transmitting the infection to someone else."4
- b. Dr. Anthony Fauci on November 12, 2021, referring to the experience of health officials regarding the injections:

They are seeing a waning of immunity not only against infection but against hospitalization and to some extent death, which is starting to now involve all age groups. It isn't just the elderly. It's waning to the point that you're seeing more and more people getting breakthrough infections, and more and more of those people who are getting breakthrough infections are winding up in the hospital.⁵

³ CNN. The Situation Room, interview with CDC Director Walensky. (August 5, 2021). https://twitter.com/CNNSitRoom/status/1423422301882748929

Stieg, C. "Dr. Fauci on CDC mask guidelines: 'We are dealing with a different virus now." (July 28, 2021). https://www.cnbc.com/2021/07/28/dr-fauci-on-why-cdc-changed-guidelines-delta-is-a-different-virus.html

Coleman, K (November 12, 2021). Dr. Fauci Just Issued This Urgent Warning to Vaccinated People. Yahoo News. https://www.yahoo.com/lifestyle/dr-fauci-just-issued-urgent-201846228.html

- c. 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."6
- d. Chief Medical Officer of Moderna Dr. Tal Zaks: "There's no hard evidence that it stops [the Covid-19 vaccinated] from carrying the virus transiently and potentially infecting others who haven't been vaccinated."
- e. The Surgeon General of the State of Florida, Dr. Joseph Ladapo, MD, PhD: "... the infections can still happen whether people are vaccinated or not. That's very obvious."8
- f. Professor Sir Andrew Pollard who led the Oxford vaccine team: "We don't have anything that will stop transmission, so I think we are in a situation where herd immunity is not a possibility and I suspect the virus will throw up a new variant that is *even better* at infecting vaccinated individuals."
- g. Dr. Jay Bhattacharya, MD, PhD, Professor of Health Policy, Stanford

⁶ Colson, T. "Top WHO scientist says vaccinated travelers should still quarantine, citing lack of evidence that COVID-19 vaccines prevent transmission." *Business Insider*. (December 29, 2020). https://www.businessinsider.com/who-says-no-evidence-coronavirus-vaccine-prevent-transmissions-2020-12?op=1

Manskar, N. "Moderna boss says COVID-19 vaccine not proven to stop spread of virus." *New York Post*. (November 24, 2020). https://nypost.com/2020/11/24/moderna-boss-says-covid-shot-not-proven-to-stop-virus-spread/.

⁸ WFLA News. "Desantis, Moody Speak Out Against Vaccine Mandates in Clearwater." Twitter Repost. (October 24, 2021). https://twitter.com/4patrick7/status/1452309002021388296?s=21

⁹ Knapton, S. "Delta variant has wrecked hopes of herd immunity, warn scientists." *The Telegraph*. (October 8, 2021). https://www.msn.com/en-gb/health/medical/delta-variant-has-wrecked-hopes-of-herd-immunity-warn-scientists/ar-AAN9O4p

University: "Based on my analysis of the existing medical and scientific literature, any exemption policy that does not recognize natural immunity is irrational, arbitrary, and counterproductive to community health." ¹⁰

h. 2008 Nobel Prize winner in Medicine Dr. Luc Montagnier (also winner of the French National Order of Merit and 20 other major international awards):

The vaccines don't stop the virus, they do the opposite – they 'feed the virus,' and facilitate its development into stronger and more transmissible variants...You see it in each country, it's the same: the curve of vaccination is followed by the curve of deaths ... 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.¹¹

- i. A study of a Covid-19 outbreak in July 2021 published in *Eurosurveillance* observed that 100 percent of severe, critical, and fatal cases of Covid-19 occurred in injected individuals. The authors stated that the study "challenges the assumption that high universal vaccination rates will lead to herd immunity and prevent COVID-19 outbreaks." 12
- j. Dr. Martin Kulldorff, Professor of Medicine at Harvard Medical School:

Bhattacharya, J., et al. "The beauty of vaccines and natural immunity." Smerconish Newsletter. (June 4, 2021). https://www.smerconish.com/exclusive-content/the-beauty-of-vaccines-and-natural-immunity

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

Pnina, S. et al. "Nosocomial outbreak caused by the SARS-CoV-2 Delta variant in a highly vaccinated population, Israel, July 2021." *EuroSurveill*. 26:39. (September 23, 2021). https://doi.org/10.2807/1560-7917.ES.2021.26.39.2100822

"The bottom line is that these vaccines do not prevent transmission." ¹³

k. Dr. Sunetra Gupta, Infectious Disease Epidemiologist and Professor of Theoretical Epidemiology at the University of Oxford:

[I]t is really not logical to use [these] vaccines to protect other people ... I don't think they should be forced [] on the understanding simply because this vaccine does not prevent transmission. So if you just think of the logic of it, what is the point of requiring a vaccine to protect others if that vaccine does not durably prevent onward transmission of a virus?¹⁴

The Court may already be aware of the countless news reports of outbreaks on fully "vaccinated" sports teams¹⁵ and cruise ships,¹⁶ not to mention in the fully "vaccinated" White House.¹⁷ There is simply no question that the Covid-19 injections do not create immunity. This was summed up quite nicely by Moderna Chief Medical Officer Tal Zaks, who "warned that the trial results show that the vaccine can prevent someone from getting sick or 'severely sick,' from COVID-19, however, the results don't show that the vaccine prevents transmission of the virus." Recognition of this fact may explain why, in August of 2021, the CDC

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Adams, P, et al. "Who Are These COVID-19 Vaccine Skeptics and What Do They Believe?" Epoch Times. (October 20, 2021). https://www.theepochtimes.com/who-are-these-covid-19-vaccine-skeptics-and-what-do-they-believe_4043094.html

Allen, R. "Oxford Scientist 'It's Illogical & Unethical To Force Jab On NHS Staff." The Richie Allen Radio Show. (September 9, 2021). https://richieallen.co.uk/oxford-scientist-its-illogical-unethical-to-force-jab-on-nhs-staff/

Associated Press. "US sports leagues cope with COVID-19 outbreaks amid variants." (December 15, 2021). https://www.foxnews.com/sports/us-sports-leagues-cope-with-covid-19-outbreaks-amid-variants

Lemos, G. et al. "17 Covid-19 cases identified on New Orleans-bound cruise ship." CNN. (December 5, 2021). https://www.cnn.com/2021/12/05/us/cruise-ship-norwegian-breakaway-covid-cases/index.html

Chasmar, J. "Psaki doesn't deny White House COVID-19 outbreak." *Yahoo News*. (December 20, 2021). https://news.yahoo.com/psaki-doesn-apos-t-deny-210029232.html

Al-Arshani, S. "Moderna's chief medical officer says that vaccine trial results only show that they prevent people from getting sick – not necessarily that recipients won't still

changed the definition of "vaccination" from "the act of introducing a vaccine into the body to produce immunity to a specific disease" to "the act of introducing a vaccine into the body to produce protection to a specific disease." ¹⁹

However, this newly created CDC definition conflicts with the statutory criteria for a vaccine, which focuses solely upon immunity. In 1986, Congress passed 42 U.S.C. § 300aa-1, which established "a National Vaccine Program to achieve optimal prevention of human infectious diseases through immunization . . ." (emphasis added). Clearly, from both a public health standpoint as well as from a legal standpoint, immunization is the intended sine qua non of vaccination.

Since they do not create immunity, but are claimed to merely reduce the symptoms of the disease, the so called Covid-19 vaccines are treatments, not vaccines.²⁰ Even the FDA has classified them as "CBER-Regulated Biologics" otherwise known as "therapeutics" which fall under the "Coronavirus Treatment Acceleration Program."²¹

be able to transmit the virus." *Business Insider*. (November 2020). https://www.businessinsider.com/moderna-chief-medical-officer-vaccines-interview-2020-11

Attkisson, S. "CDC changes definition of "vaccines" to fit Covid-19 vaccine limitations." (September 8, 2021). https://sharylattkisson.com/2021/09/read-cdc-changes-definition-of-vaccines-to-fit-covid-19-vaccine-limitations/

See, e.g., Moderna Program Patents. (December 2021). https://www.modernatx.com/patents

Nakagami, H. "Development of COVID-19 vaccines utilizing gene therapy technology." *Int Immunol.* 33(10):521-527. (September 25, 2021). https://pubmed.ncbi.nlm.nih.gov/33772572/.

FDA. "Comirnaty. Vaccines, Blood, and Biologics." (December 2021). https://www.fda.gov/vaccines-blood-biologics/comirnaty

FDA. "Coronavirus (COVID-19) | CBER-Regulated Biologics." (2021). https://www.fda.gov/vaccines-blood-biologics/industry-biologics/coronavirus-covid-19-cber-

The FDA's "therapeutics" classification of the injections is consistent with representations made by Pfizer partner BioNTech to the Securities and Exchange Commission ("SEC") in its 2020 Annual Report, where it stated with regard to the mRNA technology forming the basis of its Covid-19 injection:

Although we expect to submit BLAs [biologics license applications] for our mRNA-based product candidates in the United States, and in the European Union, mRNA therapies have been classified as gene therapy medicinal products, and other jurisdictions may consider our mRNA-based product candidates to be new drugs, not biologics or gene therapy medicinal products, and require different marketing applications.²²

Similarly, in its June 30, 2020 Quarterly Report to the SEC, Moderna stated with regard to the mRNA technology underpinning its injection: "Currently, mRNA is considered a gene therapy product by the FDA."²³

Thus, the medical community, the relevant agencies, and both Pfizer and Moderna — the manufacturers of the dominant injections — recognize that the so-called vaccines are therapeutics, or medical treatments. Since they do not achieve immunization, this conclusion is also consistent with Congress' definition of vaccines in establishing the National Vaccine Program in 1986: the "prevention of

regulated-biologic

FDA. "Coronavirus Treatment Acceleration Program(CTAP)." (2021). https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap.

United States Securities and Exchange Commission. *BioNTech SE Form 20-F*. (2020). https://www.sec.gov/Archives/edgar/data/1776985/000156459021016723/bntx-20f 20201231.htm at page 26.

United States Securities and Exchange Commission. *Moderna SE Form 10-Q.* (June 30, 2020). https://www.sec.gov/Archives/edgar/data/1682852/000168285220000017 /mrna-20200630.htm

human infectious diseases through immunization."²⁴ Accordingly, we herein refer to the Covid-19 "vaccines" as Covid-19 injections.

B. The Government's attempt to mandate treatments is subject to strict scrutiny.

The judiciary has too often assumed without analysis that requiring individuals to submit to Covid-19 injections is permissible under the determination made in *Jacobson*.²⁵ However, because these injections do not confer immunity, but are instead merely treatments that may reduce the severity of symptoms, the proper analysis stems from *Cruzan v. Dir.*, *Mo. Dep't of Health*, 497 U.S. 261 (1990).²⁶

In *Cruzan*, the Court addressed whether the parents of a young woman severely brain damaged in a car wreck could compel the hospital to remove her from life support in the absence of any clear directive memorializing her intent. Missouri

²⁴ 42 U.S.C. § 300aa-1 et seq.

²⁵ Jacobson v. Massachusetts, 197 U.S. 11 (1905).

Although Cruzan was decided under the due process clause of the Fourteenth Amendment, this Court has long held that the same substantive due process analysis applied to the states under the due process clause of the Fourteenth Amendment also applies to the federal government under the due process clause of the Fifth Amendment. See, e.g., Bolling v. Sharpe, 347 U.S. 497, 500 (1954) ("In view of our decision that the Constitution prohibits the states from maintaining racially segregated public schools, it would be unthinkable that the same Constitution would impose a lesser duty on the Federal Government.") See also, Adarand Constructors v. Pena, 515 U.S. 200 (1995) (same); Frontiero v. Richardson, 411 U.S. 677 (1973) (holding federal law discriminating on basis of sex unconstitutional under the Fifth Amendment due process clause based on Fourteenth Amendment analysis); Califano v. Goldfarb, 430 U.S. 199 (1977) (striking down federal racial classification on basis of Fifth Amendment due process clause stating that strict scruting is the proper standard for analysis of all racial classifications, whether imposed by a federal, state, or local actor. Id. at 231, superseded by statute); Jimenez v. Weinberger, 417 U.S. 628 (1974) (striking down provision of the Social Security Act based upon illegitimacy applying substantive due process analysis through the due process of clause of the Fifth Amendment).

required clear and convincing evidence of intent to remove a patient from life support, and the parents argued this violated both their and their daughter's Fourteenth Amendment substantive due process rights. Significantly for the issue at hand, the Court began by recognizing a fundamental human right of informed consent to medical treatment stemming from the right of self-determination, stating:

At common law, even the touching of one person by another without consent and without legal justification was a battery. Before the turn of the century, this Court observed that "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." This notion of bodily integrity has been embodied in the requirement that informed consent is generally required for medical treatment. Justice Cardozo, while on the Court of Appeals of New York, aptly described this doctrine: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages." The informed consent doctrine has become firmly entrenched in American tort law. The logical corollary of the doctrine of informed consent is that the patient generally possesses the right not to consent, that is, to refuse treatment. 497 U.S. at 269–270 (citations omitted).

The Court went on to state that "[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions" citing three cases pertinent to our analysis here. First, the *Cruzan* Court cited *Washington v. Harper*, 494 U.S. 210, 221-222 (1990), where the Court recognized that prisoners possess "a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment." Significantly, the

Court in *Harper* stated that "[t]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." 494 U.S. at 229. Second, the *Cruzan* Court cited *Vitek v. Jones*, 445 U.S. 480, 494 (1980), where the Court recognized that the transfer to a mental hospital coupled with mandatory behavior modification treatment implicated liberty interests. Third, the Court cited *Parham v. J. R.*, 442 U.S. 584 (1979) where the Court recognized that "a child, in common with adults, has a substantial liberty interest in not being confined unnecessarily for medical treatment."

Cruzan was followed in 1997 by Washington v. Glucksberg, 521 U.S. 702 (1997), where the issue before the Court was whether the substantive due process right to refuse medical treatment included the right to assisted suicide. The following language of the Court is particularly significant to the issue presently before the Court:

The Due Process Clause guarantees more than fair process, and the "liberty" it protects includes more than the absence of physical restraint. *Collins* v. *Harker Heights*, 503 U.S. 115, 125 (1992) (Due Process Clause "protects individual liberty against 'certain government actions regardless of the fairness of the procedures used to implement them") (quoting *Daniels* v. *Williams*, 474 U.S. 327, 331 (1986)). The Clause also provides heightened protection against government interference with certain fundamental rights and liberty interests. ... We have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment. *Cruzan*, 497 U.S. at 278-279. 521 U.S. at 719-720. (internal citations omitted)

The fact that the *Glucksberg* Court identified the right to refuse unwanted lifesaving medical treatment as one in a long list of traditional fundamental human rights and liberty interests is extremely important because once a right is so

identified, any governmental action infringing upon it is subjected to the "strict scrutiny" test. As stated by the Court in *Glucksberg*, "the Fourteenth Amendment forbids the government to infringe fundamental liberty interests *at all*, no matter what process is provided, unless the infringement is narrowly tailored to serve a compelling state interest." *Glucksberg*, 521 U.S. at 721 (internal quotations omitted, emphasis in original).

The Court's analysis in both *Cruzan* and *Glucksberg* was based upon a sick person asserting a right to deny treatment. The ETS mandate, on the other hand, forces treatment on perfectly healthy people. All of the arguments in favor of self-determination reviewed by the Court in *Cruzan* and *Glucksberg* are even stronger when applied to a perfectly healthy person's right to refuse a treatment on the basis that it *may* make symptoms of a disease that healthy person *may never contract* less severe. And we remember here the uncontroverted medical consensus that Covid-19 injections do *not* prevent infection or transmission of the coronavirus; i.e., *they do not create immunity in the recipients*. The bar should be even higher to force a healthy person to accept "treatment" than to force a sick person to accept critical care. As stated by the Court in *Harper*, where a physically healthy prisoner objected to the administration of antipsychotic drugs, "[t]he forcible injection of medication into a nonconsenting person's body represents a substantial interference with that person's liberty." 494 U.S. at 229.

C. The OSHA ETS is not narrowly tailored to meet a compelling state interest.

1. There is no compelling state interest in mandating Covid-19 injections that do not confer immunity.

The traditional public health justification for mandating a vaccine was set forth in *Jacobson*, *supra*. There the Court stated:

[I]n every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in respect of his liberty may at times, *under the pressure of great dangers*, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand.

197 U.S. at 30 (emphasis added).

Thus, it is the safety of the general public that *Jacobson* cited to justify a vaccine mandate. The *Jacobson* court also stated it in another manner, but again emphasized the public safety underpinning of the policy: "There are manifold restraints to which every person is necessarily subject for the *common good*. On any other basis, organized society could not exist with *safety to its members*." 197 U.S. at 29 (emphasis added).

Jacobson, to the extent that it is still good law (a point neither contested nor conceded by amicus at this time), established that only in the protection of the public from harm does any possible legitimate state interest in compelling vaccines arise. However, since the injections at issue here do not confer immunity on recipients, they in no way protect the public from acquiring the infection. Unlike in Jacobson, where the prevailing and long-held common belief was that the smallpox vaccine would confer immunity with an approximately 98 percent success rate, and prevent the public from being infected with a deadly disease from which

approximately 30 percent of the infected would die, the Covid-19 injections do nothing of the sort. As noted above, it is universally accepted that the Covid-19 injections do not stop the transmission or acquisition of the virus between persons,²⁷ and for those under 80 years of age — those generally in the work force — the percent of infected persons who may die is readily acknowledged as far less than one percent. Accordingly, requiring Covid-19 "vaccination" serves no compelling state interest at all, and fails the fundamental prong of the strict scrutiny test.

2. Even if the ETS served a compelling state interest, it is not narrowly tailored.

As the Fifth Circuit accurately observed, "rather than a delicately handled scalpel, the [OSHA] Mandate is a one-size fits-all sledgehammer that makes hardly any attempt to account for differences in workplaces (and workers) that have more than a little bearing on workers' varying degrees of susceptibility to the supposedly 'grave danger' the Mandate purports to address." *B.S.T. Holdings, LLC et al v. Occupational Safety and Health Administration et al,* Case No. 21-60845 (Fifth Cir., Nov. 12, 2021) ("*B.S.T. Holdings*")(slip opinion at 8).

The Mandate is staggeringly overbroad. Applying to 2 out of 3 private-sector employees in America, in workplaces as diverse as the country itself, the Mandate fails to consider what is perhaps the most salient fact of all: the ongoing threat of COVID-19 is more dangerous to some employees than to other employees. All else equal, a 28 year-old trucker spending the bulk of his workday in the solitude of his cab is simply less vulnerable to COVID-19 than a 62 year-old prison janitor. Likewise, a naturally immune unvaccinated worker is presumably at less risk than an unvaccinated worker who has never had the virus. The list goes on, but one constant remains—the Mandate fails almost

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;1-4. (September 30, 2021). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8481107/

completely to address, or even respond to, much of this reality and common sense.

B.S.T. Holdings (slip opinion at *13).

a. The ETS fails to address risk factors.

It is well established that certain sectors of society are at far greater risk from Covid-19 than other sectors. Having co-morbid conditions is the most important risk and older age is the most widely used proxy for comorbidities. Persons with obesity, diabetes, and cardiac disease are at a much higher risk; residents of long-term care facilities who are 1 percent of the population represent 35 percent of all Covid-19 deaths; and, per the CDC, the mortality rate of persons over 65 is more than 80 times greater than for persons under 30.28 The healthy young and middle age are at a statistical zero risk of death. In addition, the more recent Omicron strain is even milder, and typically clinically indistinguishable from the common cold.29 Vast sectors of society are at extraordinarily low risk from the virus.

The OSHA ETS fails to take any of these differences into account, and simply applies uniformly to everyone working for a company employing 100 people or more. It is indeed a sledgehammer approach.

b. The ETS fails to consider natural immunity.

Perhaps most concerning is that the ETS completely ignores natural

²⁸ CDC. "Underlying Medical Conditions Associated with Higher Risk for Severe COVID-19: Information for Healthcare Providers." (October 14, 2021). https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-care/underlyingconditions.html

Gamble, M. "Dr. Ashish Jha: Time to focus on COVID hospitalizations and deaths, not cases." *Beckers Hospital Review*. (December 28, 2021). https://www.beckers hospitalreview.com/public-health/dr-ashish-jha-time-to-focus-on-covid-hospitalizations-and-deaths-not-cases.html

immunity. Universal principles of virology and immunology teach us that immunity from natural infection is the most complete, most robust, and most durable.³⁰ Consistent with this principle, the evidence establishes that natural immunity acquired by those who have been infected with and recovered from Covid-19 (the "Covid-19 Recovered") acquire complete and lifelong immunity.³¹ Indeed, The Cleveland Clinic found the following: "Individuals who have had SARS-CoV-2 infection are unlikely to benefit from COVID-19 vaccination."³²

There is *no* evidence to support the argument that the Covid-19 Recovered lose their immunity. In fact, there is substantial evidence suggesting it will be lifelong.³³,³⁴ Such evidence includes: University of Washington scientists discovered that prior infection³⁵ with the original SARS-CoV-1³⁶ (which is approximately 78 percent identical to SARS-Cov-2) conferred natural immunity that is robust against

See, e.g., Delves, P, et al. Roitt's Essential Immunology, 13th Edition (2017) https://www.wiley.com/en-us/Roitt%27s+Essential+Immunology%2C+13th+Edition-p-9781118415771

Alexander, PE. "141 Research Studies Affirm Naturally Acquired Immunity to Covid-19: Documented, Linked, and Quoted." *Brownstone Institute*. (October 17, 2021). https://brownstone.org/articles/79-research-studies-affirm-naturally-acquired-immunity-to-covid-19-documented-linked-and-quoted/ (last visited December 28, 2021)

Shrestha, N. "Necessity of COVID-19 vaccination in previously infected individuals." *MedRxiv*. (June 19, 2021). https://www.medrxiv.org/content/10.1101/2021.06.01.21258176v3
Haveri, A. "Persistence of neutralizing antibodies a year after SARS-CoV-2 infection in humans." *Eur. J. Immunol.* 51(12):3202-3213. (Dec. 2021). https://pubmed.ncbi.nlm.nih.gov/34580856/

Block, J. "Vaccinating people who have had covid-19: why doesn't natural immunity count in the US?" *BMJ* 2021;374:n2101. (September 13, 2021). https://www.bmj.com/content/374/bmj.n2101

Callaway, E. "Had COVID? You'll probably make antibodies for a lifetime." *Nature*. (May 26, 2021) https://www.nature.com/articles/d41586-021-01442-9

Doshi, P. "Covid-19: Do many people have pre-existing immunity?" *BMJ* 2020;370:m3563. (September 17, 2020). https://www.bmj.com/content/370/bmj.m3563

Le Bert, N. "SARS-CoV-2-specific T cell immunity in cases of COVID-19 and SARS, and uninfected controls." *Nature*. 584(7821):457-462. (August 2020). https://pubmed.ncbi.nlm.nih.gov/32668444/

the current SARS-CoV-2 eighteen years later;³⁷ The Lancet reports that "infection does protect against reinfection;"³⁸ SCIENCE reports: "Substantial immune memory is generated after natural infection with COVID-19, involving all four major types of immune memory";³⁹ and Nature reports: "SARS-CoV-2 infection induces long-lived bone marrow plasma cells in humans."⁴⁰

The Covid-19 Recovered are now more than half of the U.S. population. "As of July 1, 2021, about 53.8% of the 330 million people living in the U.S. have been infected with SARS-CoV-2...." In December 2021, this number exceeds 200 million people. The OSHA ETS, however, fails to account for the more than 50 percent of the population that is now naturally immune. Far from being narrowly tailored, it is ludicrously overbroad. In addition, OSHA fails to consider the damage done to those naturally immune people forced to take the injections, who are placed at greater risk of harm from the injections in both the short term and the long term. 42

UW Medicine. "Antibody neutralizes SARS and COVID-19 coronaviruses." News Release. (May 18, 2020). https://newsroom.uw.edu/news/antibody-neutralizes-sars-and-covid-19-coronaviruses

Krammer, F. "Comment: Correlates of protection from SARS-CoV-2 infection." *The Lancet.* Vol 397, Issue 10283, P1421-1423. (April 17, 2021). https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00782-0/fulltext

Dan, J. M., et al. "Immunological memory to SARS-CoV-2 assessed for up to 8 months after infection." Science, 371:6529. (January 6, 2021). https://doi.org/10.1126/science.abf4063

Turner, J.S., *et al.* "SARS-Co V-2 infection induces long-lived bone marrow plasma cells in humans." *Nature* 595: 421-425. (2021). <u>https://pubmed.ncbi.nlm.nih.gov/34030176/</u>

Physicians for Informed Consent. "SARS-CoV-2 COVID-19: What You Need To Know." (August 2021). https://physiciansforinformedconsent.org/wpcontent/uploads/2021/08/PIC-COVID-19-Disease-Information-Statement-DIS-August-2021.pdf

Raw, R., et al. "Previous COVID-19 infection, but not Long-COVID, is associated with increased adverse events following BNT162b2/Pfizer vaccination." J Infect 83(3):381-412. (September 2021). https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8164507/

c. The ETS fails to consider available treatment options

The ETS is also not narrowly tailored in that it fails entirely to consider highly effective low risk treatments that make Covid-19 injections unnecessary.

Ivermectin — a cheap, safe, widely available generic medication, whose precursor won the Nobel Prize in Medicine in 2015 — treats and cures Covid-19 in both the early infectious stage and later stages. ⁴³ The evidence is both directly observed in multiple randomized controlled trials and epidemiological evidence worldwide. There are now more than seventy (70) studies demonstrating its efficacy as well as noting that nations that use ivermectin see their death rates plummet to one percent of the death rates of nations that do not.

Hydroxychloroquine (HCQ) is a cheap, safe, widely available generic medication used billions of times annually in all countries around the world, including the United States, where for decades it has been prescribed daily for rheumatoid arthritis and lupus. HCQ treats and cures Covid-19 effectively in the early infectious stage. HCQ also provides substantial reduction in mortality in later stages. 44 There are now more than 300 studies demonstrating its efficacy and nations that use HCQ have 1–10 percent of the death rate of nations that do not. HCQ is on the WHO's List of Essential Medications that all nations should always have available. Chloroquine (an earlier version of HCQ) has been in continuous use

Ivm-meta. "Ivermectin for COVID-19: real-time meta analysis of 71 studies." (December 26, 2021). https://ivmmeta.com/ivm-meta.pdf

HCQ Meta. "HCQ for COVID: real-time meta analysis of 303 Studies." (December 23, 2021). https://hcqmeta.com/; See especially F. Taieb, et al. "Hydroxychloroquine and Azithromycin Treatment of Hospitalized Patients Infected with SARS-CoC-2 in Senegal from March to October 2020." (October 2020).

for Covid-19 in China since February 2020.45

Budesonide, a cheap, safe, widely available generic inhaler medication used commonly in the United States, typically for emphysema, effectively treats Covid-19 while in the early infectious stage.⁴⁶ This was published in *The Lancet* in April 2021.⁴⁷

Monoclonal antibodies are approved for Covid-19 early treatment and are highly effective and universally recognized as safe.⁴⁸

The evidence is overwhelming that low Vitamin D levels are linked to poor outcomes in Covid-19.⁴⁹ Vitamin D therapies are routinely used and being evaluated in trials by ClinicalTrials.Gov.⁵⁰

The FDA very recently gave Emergency Use Authorization to two more

Gao, J., et al. "Breakthrough: Chloroquine phosphate has shown apparent efficacy in treatment of COVID-19 associated pneumonia in clinical studies." *Bioscience Trends*, 14:1, 72-73. (2020). https://www.jstage.jst.go.jp/article/bst/14/1/14 2020.01047/ article

Ramakrishnan, S. *et al.* "Budesonide Dosing for Outpatient COVID per the Oxford RCT." University of Oxford, England. (February 8, 2021). https://www.medrxiv.org/content/10.1101/2021.02.04.21251134v1

Ramakrishnan, S. et al. "Inhaled Budesonide in the treatment of early COVID-19 (STOIC): a phase 2, open-label randomized controlled trial." Respiratory Medicine, The Lancet, Vol 9, Issue 7, 763-772. (July 1, 2021). https://www.thelancet.com/article/S2213-2600(21)00160-0/fulltext

FDA. "Coronavirus (COVID-19) Update: FDA Authorizes New Long-Acting Monoclonal Antibodies for Pre-exposure Prevention of COVID-19 in Certain Individuals." FDA News Release. (December 8, 2021). https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-new-long-acting-monoclonal-antibodies-pre-exposure

Vassiliou, A. et al. "Low 25-Hydroxyvitamin D Levels on Admission to the Intensive Care Unit May Predispose COVID-19 Pneumonia Patients to a higher 28-Day Mortality Risk: A Pilot Study on a Greek ICU Cohort." National Library of Medicine, National Institute of Health. (December 2020). https://pubmed.ncbi.nlm.nih.gov/33316914/

Bychinin, M. "Low Circulating Vitamin D in Intensive Care Unit-Admitted COVID-19 Patients as a Predictor of Negative Outcomes." *J Nutr.* 151(8):2199-2205. (August 7, 2021). https://pubmed.ncbi.nlm.nih.gov/33982128/

⁵⁰ NIH. "Vitamin D and COVID-19 (VIVID)." NCT04536298. (June 14, 2021). https://clinicaltrials.gov/ct2/show/NCT04536298

antiviral pills: Merck's molnupiravir⁵¹ and Pfizer's Paxlovid.⁵²

A narrowly tailored approach would be evidence-based and at most impinge the rights of *only* those at proven risk of adverse consequences from infection. But the ETS instead treats U.S. citizens as livestock, each to be injected simply because they work for a company with 100 or more employees. This is a result the Constitution does not allow, even if it is interpreted to provide OSHA with the authority to promulgate the ETS at issue.

CONCLUSION

The Covid-19 injections do not confer immunity, and therefore do not meet the definition of a vaccine. They are instead treatments and must be analyzed as such. It is a fundamental human right to refuse a medical treatment, as this Court has held. Under the Fifth Amendment's Due Process Clause, strict scrutiny must be applied in the Court's analysis of the OSHA ETS. Because no compelling state interest is served by the ETS, and even if it were, the ETS is a sledgehammer approach rather than a narrowly tailored approach, the ETS cannot survive strict scrutiny analysis.

For the foregoing reasons, this Court should grant the emergency

FDA. Coronavirus (COVID-19) "Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults." FDA News Release. (December 23, 2021). https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain

FDA. "Coronavirus (COVID-19) Update: FDA Authorizes First Oral Antiviral for Treatment of COVID-19. FDA News Release." (December 22, 2021). https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-oral-antiviral-treatment-covid-19

applications.

Respectfully submitted,

GREGORY J. GLASER*
4399 Buckboard Drive #423
Copperopolis, CA 95228
Telephone: (925) 642-6651
greg@gregglaser.com

GEORGE R. WENTZ, JR. The Davillier Law Group 935 Gravier Street, Ste. 1702 New Orleans, Louisiana 70112 Telephone: (504) 582-6998 gwentz@davillierlawgroup.com

Counsel for Amicus Curiae America's Frontline Doctors

^{*} Counsel of Record