No. 25-204

IN THE

Supreme Court of the United States

JERI PEARSON, *et al.*,
Petitioners,

v.

SHRINERS HOSPITALS FOR CHILDREN, INCORPORATED, *et al.*,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Fifth Circuit

Amici Curiae Brief of America's Frontline Doctors and Dr. Simone Gold, M.D., J.D., in Support of Petitioners for Reversal

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C. "Mandating" dangerous experimental drugs — drugs never approved by the FDA, despite erroneous media reports to the contrary — absent voluntary, coercion-free informed consent violates well-established constitutional principles, including the right to refuse medical treatment and of personal bodily integrity; violates civil and criminal federal and state laws prohibiting medical battery, negligent injuring, assault, and negligent homicide; and violates numerous federal regulations requiring informed consent and full disclosure, including 21 U.S.C. § 360bbb-3, 21 C.F.R. § 50.20, 21 C.F.R. § 50.25, 45 C.F.R. § 46.116, and the Nuremberg Code. 16

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A MATTER OF GREAT PUBLIC IMPORTANCE

Coercively mandating dangerous and possibly fatal experimental drugs, by overriding informed consent, cannot be countenanced. This is about saving lives.

The Free Speech Foundation, d/b/a America's Frontline Doctors and Dr. Simone Gold, M.D., J.D., the founder and physician member ("*Amici Curiae*" or "AFLDS") respectfully file this *amici curiae* brief in support of the Petitioners for reversal in *Jeri Pearson, et al. v. Shriners Hospitals for Children, Incorporated, et al.,* No. 25-204.[1]

This *amici curiae* brief offers an important *medical and legal* perspective to this Court on a matter of great public importance, by demonstrating that the Respondents engaged in unconstitutional, illegal, and possibly criminal activity by "mandating" dangerous experimental medical treatments in violation of informed consent, their own agreements, and the numerous clearly established laws and regulations enumerated herein.

These unconstitutional, illegal, irrational and medically dangerous coercive mandates should be rejected.

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[1] Pursuant to Rule 37.6, it is hereby certified that no counsel or any party authored or prepared this brief in whole or in part, and no such counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. The parties received timely notice of the filing of this *amici curiae* brief.

INTEREST OF *AMICI CURIAE*

AFLDS *Amici Curiae* is a non-partisan, not-for-profit organization of thousands of member physicians from across the country, representing a range of medical disciplines and practical experience on the front lines of medicine, and Dr. Simone Gold, M.D., J.D., its founder and expert physician and attorney member, with over twenty years experience as an emergency room physician in minority communities around the nation.[2]

AFLDS' programs focus on 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.

[2] https://americasfrontlinedoctors.org/about-us

Dr. Gold and AFLDS publicly supported the position, as early as October, 2020, that experimental mRNA injections are not "vaccines," because they do not prevent infection or transmission, and they are neither "safe" nor "effective."[3] They are personal medical treatments only. This view is now known to be scientifically and legally correct.

"Informed consent" cannot truly be informed unless there is a *full* disclosure of all known benefits and risks. Voluntary informed consent can never be coerced, subjected to undue influence, nor distorted by censored and incomplete information, especially regarding experimental or investigational drugs. Detailed informed consent regulations governing experimental, investigational drugs at 45 C.F.R. §46.116 are binding upon both private and public actors, and were violated in this case.

SUMMARY OF ARGUMENT

Coercively "mandating" dangerous and possibly fatal experimental drugs cannot be countenanced. This is about saving lives. Illegally mandating a dangerous experimental medical treatment which does not prevent infection or transmission, and which also has *severe undisclosed side effects including death*, under the coercive threat of loss of employment, violates informed consent, well-established constitutional provisions, numerous civil and criminal laws and regulations, is completely irrational, and against public policy.

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[3] https://aflds.org/about-us/press-releases/americas-frontline-doctors-supports-the-filing-of-a-petition-for-preliminary-injunction-to-prevent-kaiser-permanente-from-enforcing-their-vaccine-mandate

The mRNA injections introduced to treat COVID-19 are now scientifically demonstrated to be neither safe nor effective, but rather disabling and causative of death at high rates. This is now widely understood, and the federal and state governments are responding to these facts by changing policy.

At the time of Respondents' "mandate," the mRNA injections were indisputably investigational. Thus, the detailed informed consent regulations governing experimental, investigational drugs at 45 C.F.R. §46.116 were binding upon both public and private actors, and were violated in this case.

Respondents contractually agreed to act as public actors and agents, with all of the attendant (and crucially important) informed consent and constitutional responsibilities and obligations. See *Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261 (1990) and its progeny.

Whether Respondents are responsible state actors under 42 U.S.C. § 1983 due to the contractual web of federal, state and healthcare provider agreements and responsibilities, as asserted by Petitioners, is a broad area of inquiry subject to discovery. This issue should not be dismissed via a premature Rule 12(b)(6) motion. At this juncture, any doubt should be resolved in favor of voluntary patient freedom of choice, and against coercing unwanted and dangerous experimental medical treatments upon anyone. This is good public policy.

The Petition for a Writ of Certiorari should be granted.

ARGUMENT

A. Illegally "mandating" a dangerous experimental treatment which does not prevent infection or transmission, and which has *severe undisclosed side effects, including death*, under the coercive threat of loss of employment, violates informed consent, well-established constitutional provisions, and numerous civil and criminal laws and regulations. Governments everywhere are increasingly recognizing that such mandates were and are completely irrational, bad public policy, and cannot be sustained.

It is now becoming widely known that the experimental mRNA injections introduced to treat COVID-19 are neither "safe," on account of their terrible safety profiles, nor "effective," because they do not stop transmission of the virus or protect other people. Further, these "mandated" drugs are *dangerous*. They can and do kill people.[4] These experimental, investigational[5] drugs *offer no protection for other people*. They are personal medical treatments only. Mandating dangerous investigational drugs is completely irrational and against public policy. *See, e.g., Cooper v. Roswell Park Comprehensive Cancer Center*, 196 N.Y.S.3d 325,

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[4] *See* https://openvaers.com/covid-data, and Section B, *infra.*

[5] *See* the December 11, 2020 EUA letter to Pfizer stating that the Pfizer-BioNTech COVID-19 Vaccine is an "investigational vaccine not licensed for any indication." 86 Fed. Reg. 5202 (January 19, 2021).

(Sup Ct, Aug. 17, 2023), finding that the decision to terminate a nurse because of her refusal to take a COVID-19 injection was "irrational."[6]

In response to the true facts of lack of safety and efficacy, government policies and recommendations have changed.

HHS Secretary Kennedy announced on May 27, 2025 that the COVID vaccine for healthy children and healthy pregnant women was removed from the CDC's recommended immunization schedule, changing previous CDC recommendations.[7]

In dynamic testimony before Congress on May 21, 2025, followed by rousing applause, renowned expert cardiologist Dr. Peter A. McCullough, M.D. explained exactly why the experimental mRNA injections were neither safe nor effective, and were dangerous.[8]

At least five recent and reliable medical studies further explode the "safe and effective" narrative.[9]

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[6] As in Petitioners' case here, medical personnel were especially targeted with "mandated" COVID-19 injections, and sudden adult deaths have risen in this group. *See, e.g.,* "33 nurses 'died suddenly' in the US this past week [No causes of death were listed]," https://markcrispinmiller.substack.com/p/33-nurses-died-suddenly-in-the-us

[7] https://x.com/SecKennedy/status/1927368440811008138

[8] "TRUTH BOMB: Peter McCullough Doesn't Hold Back — 'IT WAS NOT SAFE BY DESIGN,'" https://x.com/ChildrensHD/status/1925355939369988144

[9] Five recent papers show vaccine COVID vaccine harms outweigh any benefits:

The Pfizer injection increases your all cause mortality by greater than 36%. Retsef Levi, *et al*. "Twelve-month all-cause mortality after initial COVID-19 vaccination with Pfizer-BioNTech or mRNA-1273 among adults living in Florida,"

Florida state Surgeon General Dr. Joseph A. Ladapo called for a complete halt in the use of COVID-19 mRNA "vaccines," citing contamination concerns.[10]

Louisiana health officials shifted away from the policy of promoting COVID-19 and flu vaccinations,

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https://doi.org/10.1101/2025.04.25. 25326460

Women who got the shot were 30 to 50 percent less likely to give birth, *see* Vibeke Manniche, *et al.* "Rates of successful conceptions according to COVID-19 vaccination status: Data from the Czech Republic." https://www.preprints.org/manuscript/202504.2487/v1?utm_source=substack&utm_medium=email

One paper shows a high correlation (.5, highly statistically significant) between vaccination and death. E.O. Okoro, *et al.* "Paradoxical increase in global COVID-19 deaths with vaccination coverage: World Health Organization estimates (2020–2023)." *International Journal of Risk & Safety in Medicine*. 2025;0(0). https://journals.sagepub.com/doi/10.1177/09246479251336610

There is a strong correlation between the uptake of the vaccine and excess all-cause mortality. *See* Raphael Lataster, Ph.D. "European excess mortality correlates with COVID-19 vaccination into 2024." *Bulgarian Medicine* 13:2 (2023). https://www.skirsch.com/covid/lataster.pdf

A vaccine dose fatality rate of 0.35% in Europe is greater than the infection fatality rate of 0.1% for COVID. *See* André Redert, Ph.D. "Causal effect of covid vaccination on mortality in Europe." February 2023. https://www.researchgate.net/publication/368777703_Causal_effect_of_covid_vaccination_on_mortality_in_Europe

[10] **"**The Surgeon General outlined concerns regarding nucleic acid contaminants in the approved Pfizer and Moderna COVID-19 mRNA vaccines, particularly in the presence of lipid nanoparticle complexes, and Simian Virus 40 (SV40) promoter/enhancer DNA.**"** "Florida State Surgeon General Calls for Halt in the Use of COVID-19 mRNA Vaccines." https://www.floridahealthgov/newsroom/2024/01/20240103-halt-use-covid19-mrna-vaccines.pr.html

citing concerns about the efficacy and safety of these vaccines.[11] The Louisiana Health Department stated that medicine is not "one size fits all." All patients are different, with different medical needs. Therefore, it is inappropriate and possibly medical malpractice to issue blanket medical treatment recommendations or requirements to broad categories of patients, without first assessing and examining each patient individually, and without diagnosing their unique medical conditions by a qualified medical professional.

There has been a wave of bills introduced in state legislatures recently, including Iowa, Kentucky, Montana, Minnesota, Idaho and others, which seek to limit or ban entirely the administration of these experimental mRNA injections, or gene therapy, due to the terrible safety profiles of these experimental drugs.[12]

If these investigational drugs were truly safe, why are states seeking to ban them?

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[11] "Citing concerns about the efficacy and safety of vaccines, state officials will instead encourage residents to consult their doctor about vaccination, Louisiana Department of Health spokesperson Emma Herrock said in a statement. 'In general, the department is shifting away from one-size-fits-all paternalistic guidance to a more informative approach aimed at enabling individuals, in consultation with their doctor, to make better decisions for themselves,' the statement said." "Louisiana health officials 'shifting away' from policy of promoting COVID, flu vaccinations." https://www.nola.com/news/politics/vaccine-louisiana-policy-covid-flu/article_3e0521bc-c096-11ef-bfd3-fb389

[12] *See, e.g.,* Iowa House File 712, Bill SF360; Kentucky House Bill 469; Montana House Bill 371; Idaho Senate Bill 1036; Minnesota HF 3152, HF 3219.

Many European countries, including Finland, Sweden, Denmark, the United Kingdom and Slovakia have taken similar actions in limiting or eliminating their previous blanket mRNA injection recommendations.[13,14]

The rulings below failed to follow the lead of *Nat'l Fed'n of Indep. Bus. v. DOL, OSHA*, 595 U.S. 109 (2022), in which this Court stayed the OSHA nationwide employee vaccine mandate, and *Georgia v. President of the United States*, 46 F.4th 1283 (11th Cir. 2022), which upheld the nationwide injunction pausing the federal contractor vaccine mandate. *See also Texas v. Becerra*, 577 F.Supp.3d 527 (N.D.Tex. 2021) and 667 F.Supp.3d 252 (N.D.Tex. 2023) (HHS lacked authority to mandate any specific type of medical treatments, specifically a vaccine for Head Start staff, contractors and volunteers; court vacated the federal rule entirely.)

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[13] "Finland joins Sweden and Denmark in limiting Moderna COVID-19 vaccine," https://www.reuters.com/world/europe/finland-pauses-use-moderna-covid-19-vaccine-young-men-2021-10-07/

"England Refuses to Offer COVID Shots to Kids Under 12, While US Cities Mandate Them. Who's Right?": "... the UKHSA's decision puts England in line with several other European countries—including Sweden, Finland, Norway, and Denmark—that do not offer or recommend mRNA vaccines to healthy young children." https://fee.org/articles/england-refuses-to-offer-covid-shots-to-kids-under-12-while-us-cities-mandate-them-who-s-right/

[14] Michael Nevradakis, Ph.D. "Slovak Government Report Calls for Ban of 'Dangerous' mRNA Vaccines," *Science, Public Health Policy and the Law*. https://publichealthpolicyjournal.com/slovak-government-report-calls-for-ban-of-dangerous-mrna-vaccines/

In *Medical Professionals for Informed Consent v. Bassett*, 78 Misc. 3d 482 (Sup Ct. Jan. 13, 2023), the court granted a declaratory judgment to a group of doctors and nurses, holding that the hospital and "covered entities" vaccine mandate ordered by the New York State Department of Health (DOH) was null, void, and of no effect. The vaccine mandate was then dropped by DOH, so any appeal was deemed moot.[15]

These vaccine mandate cases are flooding the lower courts. These medical freedom public policy issues should be urgently addressed by this Court, especially since lives are at stake.

In all good conscience, how can anyone coercively "mandate" any drug that might kill a patient, without voluntary, coercion-free consent, and without being fully informed of the risks?

B. It is undisputed that the mandated experimental, investigational mRNA injectable drugs have shockingly high fatality rates. The CDC's own reporting system has documented millions of adverse reactions, disabilities and hospitalizations and a tragic <u>38,773</u>

[15] These issues are extremely likely to recur, yet are evading review. Threats of new pandemics are coming in from many quarters. Further, numerous anti-mandate cases like this one have flooded American courts. Many of these cases follow a predictable pattern: at the point plaintiffs start to win at trial or on appeal, the mandate is tactically dropped by the government agency. This is likely to continuously recur if not corrected now. *See* "New risks raise pandemic threat on a global scale," https://www.gpmb.org/ news/news/item/14-10-2024-new-risks-raise-pandemic-threat-on-a-global-scale

> **<u>fatalities</u> attributable to these mRNA injections through August 29, 2025. Previously, a vaccine would be pulled from the market after only a few deaths. A medical mandate to take an experimental injection is against public policy.**

The CDC's Vaccine Adverse Event Reporting System (VAERS) data show that as of April 25, 2025, there have been **38,773 deaths in America alone,** which thousands of medical professionals have independently attributed to fatal adverse reactions to the mandated experimental mRNA injections, a.k.a. "vaccines."[16] This cannot reasonably be considered "safe" or "effective." Additionally, VAERS recorded 73,866 permanently disabled persons, 221,257 hospitalizations, 156,907 urgent care visits, 248,414 doctor visits, 17,941 cases of Bell's Palsy, 5,194 miscarriages, 22,362 heart attacks, 29,012 Myocarditis/Pericarditis cases, and 10,976 cases of Anaphylaxis.[17]

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[16] https://openvaers.com/covid-data

[17] These figures are even more astonishing when it is considered that they likely represent less than 1% of the true adverse events and fatalities due to the COVID-19 injections. In 2011, an investigation of VAERS by Harvard Pilgrim Health Care Inc. reported: "Adverse events from drugs and vaccines are common, but underreported. … *fewer than 1% of vaccine adverse events are reported* [to the FDA]. Low reporting rates preclude or slow the identification of 'problem' drugs and vaccines that endanger public health. New surveillance methods for … vaccine adverse effects are needed." *See* Ross Lazarus, *et al*., "Electronic Support for Public Health—Vaccine Adverse Event Reporting System," AHRQ Grant Final Report, 2011. https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf

Thus the American *reported* death toll has now risen to an astonishing *38,773 deaths*. This shocks the conscience. Even if only a certain percentage of these COVID-19 mRNA injection adverse reaction reports are accurate, the death toll and the accompanying risks remain unacceptable. *How can anyone mandate anything that might kill you?*

High adverse reaction statistics obviously form a reasonable basis for some patients to avoid risky experimental mRNA injections in favor of safer alternatives, in the exercise of voluntary consent, free of coercion, and after the required full disclosure of these medical risks.

In stark contrast to recent experience, in 1976, after only 32 deaths were attributable to the swine flu vaccine, the United States government halted the mass vaccination campaign.[18] The New York Times reported on October 13, 1976 that the swine flu program was halted in nine states after only three deaths were attributed to the vaccine shots.[19]

Japanese researchers linked these experimental mRNA injection side effects to 201 types of diseases.[20] In another recent Japanese study,

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[18] Art Moore. "CDC data signaling vaccine catastrope: It took only 32 deaths to halt 1976 shot campaign." *World Net Daily*, February 14, 2022. https://www.wnd.com/2022/02/cdc-data-signaling- vaccine-catastrophe/

[19] Harold M. Schmeck, Jr. "Swine flu program is halted in 9 states as 3 die after shots," *The New York Times*, October 13, 1976.

[20] Lee Harding. "Japanese researchers say side effects of COVID vaccines linked to 201 types of diseases," *Western Standard*, January 15, 2024. https://www.westernstandard.news/news/japanese-researchers-say-side-effects-of-covid-vaccines-linked-to-201-types-of-diseases/51661

researchers found on autopsy multiple micro-scars in the hearts of mRNA-vaccinated patients who died suddenly of unexplained cardiac arrest, thus raising the question of a link between the experimental mRNA injections and sudden cardiac arrest.[21]

Further, an alarming new Yale study shows that COVID vaccines may cause T-cell exhaustion, leading to an acquired immune deficiency. Could this be "...a vaccine that weakens immunity instead of strengthening it?"[22]

An authoritative new study examining the link between the COVID-19 vaccine and Myocarditis was just published this year. The study's conclusion: "*We urge governments to remove the COVID-19 mRNA products from the market due to the well-documented risk of myocardial damage."*[23]

Another recent study highlighted that Pfizer's post-marketing surveillance analysis showed a miscarriage rate of 81%, a 5-fold increase in

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[21] Tomomi Koizumi and Masao Ono. "Cardiac Multiple Micro-Scars: An Autopsy Study," *J Am Coll Cardiol Case Rep.* 30(5) 10383, March 2025. https://www.jacc.org/doi/10.1016/j.jaccas.2024.103083

[22] https://x.com/drsimonegold/status/1892626222250639592; *see also* Bornali Bhattacharjee, *et al.* "Immunological and Antigenic Signatures Associated with Chronic Illnesses after COVID-19 Vaccination," *medRxiv*, February 25, 2025. https://www.medrxiv.org/content/10.1101/2025.02.18.25322379v2

[23] M. Nathaniel Mead, *et al.* "Myocarditis after SARS-CoV-2 infection and COVID-19 vaccination: Epidemiology, outcomes, and new perspectives," *Intl J Cardiovascular Rsch & Innovation*, 3(1) 1–43, Jan–Mar 2025. https://cardiovascular-research-and-innovation.reseaprojournals.com/Articles/myocarditis-after-sars-cov-2-infection-and-covid-19-vaccination-epidemiology-outcomes-and-new-perspectives)

stillbirths, an 8-fold increase in neonatal deaths, and a 13% incidence of breastfeeding complications in newborns whose mothers received the COVID shots:[24]

> Results: The CDC/FDA's safety signals were breached for all 37 AEs following COVID-19 vaccination in pregnancy including miscarriage, chromosomal abnormalities, fetal malformations, cervical insufficiency, fetal arrhythmia, hemorrhage in pregnancy, premature labor/delivery, preeclampsia, preterm rupture of membranes, placental abnormalities, fetal growth restriction, stillbirth, newborn asphyxia and newborn death. Conclusions: We found unacceptably high breaches in safety signals for 37 AEs after COVID-19 vaccination in pregnant women. *An immediate global moratorium on COVID-19 vaccination during pregnancy is warranted.* (emphasis added)

Further, a massive new study released in March, 2025 found that among 1.7 million people, COVID-19 "vaccination" increased the risk of "Inner Ear Disorders by 237%, Menstrual Disorders by 216%, Glaucoma by 186%, and Endometriosis by 150%, along with many other negative side effects."[25]

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[24] James A. Thorp, *et al*. "Are COVID-19 Vaccines in Pregnancy as Safe and Effective as the Medical Industrial Complex Claim? Part I," *Science, Public Health Policy and the Law*, 2/08/2025. https://publichealthpolicyjournal.com/are-covid-19-vaccines-in-pregnancy-as-safe-and-effective-as-the-medical-industrial-complex-claim-part-i/

[25] Hong Jin Kim, *et al*. "Broad-Spectrum Adverse Events of Special Interests Based on Immune Response Following

It is very dangerous to fail to disclose to patients, as required, this truthful and accurate medical information in any ill-conceived and coercively mandatory vaccination campaign. It is unconscionable to attempt to coercively mandate such a dangerous experimental drug which does not protect other people.

Amici Curiae maintain, supported by voluminous scientific research, that early COVID-19 treatments with hydroxychloroquine ("HCQ") and Nobel prize-winning Ivermectin are quite safe and effective, contrary to the incessant government narratives against such treatment options.[26,27,28] These are

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COVID-19 Vaccination: A Large-Scale Population-Based Cohort Study,"*J. Clin. Med.* 14(5) 1767, March 6, 2025. https://www.mdpi.com/2077-0383/14/5/1767

[26] A white paper draws the reader's attention to the indisputable safety of hydroxychloroquine ("HCQ"), an analog of the same quinine found in tree barks that George Washington used to protect his troops. "A White Paper on Hydroxychloroquine," by Dr. Simone Gold, M.D., J.D., is the culmination of months-long research from all sources. It explains how Americans have come to be in the grip of fear. All the myths and all the misconceptions about a safe, generic drug that has been FDA approved for 65 years, given to pregnant women, breast-feeding women, children, the elderly, and the immune-compromised for years and decades without complication, are finally put to rest. https://americasfrontlinedoctors.org/index/covid/hydroxychloroquine/white-paper/

[27] As of July 4, 2025, a global, real-time meta-analysis includes 424 Hydroxychloroquine ("HCQ") COVID-19 studies, from more than 8,646 scientists and 591,536 patients in 59 countries. At least 406 studies are peer reviewed, with 402 comparing treatment and control groups. The studies indicate a statistically significant improvement for mortality, hospitalization, recovery, cases, and viral clearance, and there is 66 percent less death in 38 early treatment trials. *See* https://c19hcq.org/

reasonable alternatives to more dangerous experimental mRNA injections, as determined within each protected doctor/patient relationship.

Amici Curiae maintain, supported by voluminous scientific research, that experimental mRNA injections are neither "safe" nor "effective."

C. "Mandating" dangerous experimental drugs — drugs never approved by the FDA, despite erroneous media reports to the contrary — absent voluntary, coercion-free informed consent violates well-established constitutional principles, including the right to refuse medical treatment and of personal bodily integrity; violates civil and criminal federal and state laws prohibiting medical battery, negligent injuring, assault, and negligent homicide; and violates numerous federal regulations requiring informed consent and full disclosure, including 21 U.S.C. § 360bbb-3, 21 C.F.R. § 50.20, 21 C.F.R. § 50.25, 45

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[28] As of September 16, 2025, a global, real-time meta-analysis includes 106 Ivermectin COVID-19 studies. The studies indicate Ivermectin reduces risk for COVID-19 with very high confidence for mortality, ventilation, ICU admission, hospitalization, recovery, cases and viral clearance. (No treatment, vaccine, or intervention is 100 percent effective and available.) Thus all practical, effective, and safe means should be used based on risk/benefit analysis. Over 20 countries adopted Ivermectin for COVID-19. Ivermectin may now be purchased over the counter in the state of Tennessee and many other states. https://c19ivm.org/

C.F.R. § 46.116, and the Nuremberg Code.

Respondents did not comply with well-established regulations governing informed and voluntary patient consent for experimental, investigational drugs, free from coercion and undue influence, and with full disclosure of the risks. *See* 21 C.F.R. § 50.20, 21 C.F.R. § 50.25, and 45 C.F.R. § 46.116, entitled "Protection of Human Subjects," also known as the longstanding and well-established "Common Rule."[29]

These federal regulations are mandatory for both public and private actors, embody most of the Nuremberg principles, and apply to all experimental drugs issued under an emergency use authorization (EUA), pursuant to 21 U.S.C. § 360bbb-3. These experimental gene therapy injections promoted by Respondents were always only offered under an EUA, and were never approved by the FDA.[30] The controversial approval of "Comirnaty," a legally

[29] https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

[30] On August 23, 2021, the FDA approved a COVID-19 drug called "Comirnaty," with a long list of *required future safety studies*; however, Comirnaty was not in use in the United States. *On the same day,* the FDA extended the EUA for the experimental mRNA COVID-19 drugs which were actually in use in America. This created a great deal of confusion. It was erroneously reported that the mRNA injections actually in use had now been approved by the FDA. However, this was not true. The EUA for these experimental mRNA injections was only extended. Therefore, all of the laws and regulations applicable to experimental drugs discussed herein were still in full force and effect at the time of the mandate. *See* https://www.fda.gov/media/151710/download

distinct drug from Pfizer BioNTech COVID-19 vaccine, with somewhat differing formulations, different manufacturing oversight and differing adverse reactions, did not change the experimental EUA nature of the various COVID-19 gene therapy injections actually in use in the United States and still under EUA.

Lower courts have at times erroneously concluded that Pfizer's COVID-19 injection was approved by the FDA,[31] but in fact, it was the Pfizer drug Comirnaty that was approved. The EUA for the COVID-19 vaccine was merely extended. Both actions were taken on the same day, August 23, 2021, causing much confusion.

Studies have demonstrated differences between Comirnaty and the mandated EUA COVID-19 injections. The mandated EUA COVID-19 injections have been found to have higher rates of Myocarditis, which can be fatal.[32,33] The approval of Comirnaty

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[31] *See John Does 1–2, et al., v. Kathy Hochul, Governor of New York, et al.*, No. 24-1015, Appendix B (E.D.NY opinion) at 14a; Appendix A (2nd Cir. 2024 opinion) at 20a, 21a, and 39a.

[32] A paper authored by Luigi Cari and others shows that Spikevax-Moderna mRNA induces higher spike protein expression per dose than Comirnaty, and this higher dose correlates with increased myocarditis risk compared to Comirnaty. *See* Luigi Cari, et al. "Differences in the expression levels of SARS-CoV-2 Spike Protein in cells treated with mRNA-based COVID-19 vaccines: A study on vaccines from the real world." *Vaccines* (Basel) 11(4):879. Apr 21, 2023 https://pubmed.ncbi.nlm.nih.gov/37112792/

Jesús Hermosilla, *et al.* "Analysing the in-use stability of mRNA-LNP COVID-19 vaccines Comirnaty™ (Pfizer) and Spikevax™ (Moderna): A comparative study of the particulate." *Vaccines* (Basel) 11(11):1635. Oct 25, 2023. https://pubmed.ncbi.nlm.nih.gov/38005967/

did not nullify the applicability of 21 U.S.C. § 360bbb-3, the informed consent regulations, or the constitutional and statutory provisions.

Because Respondents coercively promoted an experimental drug, these informed consent and full disclosure regulations were also mandatory.

The detailed federal regulations mirror the Nuremberg Code.[34] For example, 21 C.F.R. § 50.25, Elements of informed consent, provides:

> (a) Basic elements of informed consent ... the following information shall be provided ...
> (1) ... identification of any procedures which are experimental.
> (2) A description of any reasonably foreseeable risks or discomforts ...
> (3) A description of any benefits to the subject ...
> (4) A disclosure of appropriate alternative procedures or courses of treatment ...
> (5)–(7)
> (8) A statement that participation is voluntary, that refusal to participate will

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Lizhou Zhang, *et al*. "Effect of mRNA-LNP components of two globally-marketed COVID-19 vaccines on efficacy and stability." *NPJ Vaccines* 8(1):156 (2023). https://pubmed.ncbi.nlm.nih.gov/ 37821446/

[33] Josh Guetzkow and Retsef Levi. "Effect of mRNA vaccine manufacturing processes on efficacy and safety still an open question" (letter to the Editor), BMJ 2022;378:o1731. July 12, 2022. https://www.bmj.com/content/378/bmj.o1731/rr-2

[34] *Trials of War Criminals Before the Nuernberg Military Tribunals Under Control Council Law No. 10*, Volume II (U.S. Government Printing Office 1949), p. 181. https://www.gutenberg.org/ebooks/54905

involve no penalty or loss of benefits ...
(b) Additional elements of informed consent:
(1)–(6)

The threat of job loss totally nullified voluntary employee/patient consent, free from threat and undue influence as required by 21 C.F.R. § 50.25(a)(8). No attempt was made to advise the employee/patients of the substantial known risks of these experimental drugs as required by 21 C.F.R. § 50.25(a)(2), (4), and (6).

The death toll as recorded by VAERS is at an unacceptably high level. Patients are entitled to be informed of these "substantial" risks. *See also Grimes v. Kennedy Krieger Institute, Inc.,* 366 Md. 29 (Md. 2001) enforcing principles of informed consent and Nuremberg in a Maryland poisoning case.

The Nuremberg Code, an international code of ethical principles adopted in the aftermath of war crimes committed by the German Nazis during WWII, was expressly intended to prohibit involuntary medical experimentation upon humans. The "informed consent" Nuremberg principles have been largely codified domestically through the adoption of 21 C.F.R. § 50.20, 21 C.F.R. §50.25, and 45 C.F.R. 46 (the "Common Rule").

Federal law, incorporating most of the Nuremberg Code, guarantees that investigational drugs must only be offered on a voluntary basis after full disclosure of risks, and with voluntary informed consent free from coercion. *See* 21 U.S.C. § 360bbb-3, 21 C.F.R. §50.20, 21 C.F.R. §50.25, and 45 C.F.R. §46.116. Consent can never be coerced.

21 U.S.C. § 360bbb-3 mandates that the administration of experimental biological agents are strictly voluntary, requiring informed consent after a full disclosure of risks. This principle is binding upon Respondents both in their capacity as state actors carrying out the will of the government via their contractual agreements to do so, as well as by informed consent regulations binding upon private actors.

Respondents violated these mandatory federal laws and regulations. The issue regarding whether or not Respondents are responsible state actors subject to the federal consent rules under 42 U.S.C. § 1983, as asserted by Petitioners, is to be deemed as true, and should be subject to discovery rather than decided on a mere Rule 12(b)(6) motion, particularly since lives are at stake.

The constitutional principles guaranteeing every individual the right to refuse medical treatment and the right of personal bodily integrity are similarly well-established, and were also willfully ignored by the Respondents. *See, e.g., Cruzan v. Dir., Mo. Dep't. of Health*, 497 U.S. 261, 270 (1990) ("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"); *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"); *Schloendorff v Society of New York Hospital*, 211 N.Y. 125, 129 (1914) ("[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body"); and *Canterbury v. Spence*, 464 F.2d 772, 780 (1972)

("the root premise is the concept, fundamental in American jurisprudence, that '[e]very human being of adult years and sound mind has a right to determine what shall be done with his body…' True consent to what happens to one's self is the informed exercise of a choice"). *See also Doe #1 v. Rumsfeld*, 297 F. Supp. 2d 119, 134–35 (D.D.C. 2003) ("United States cannot demand that members of the armed forces also serve as *guinea pigs for experimental drugs"* (emphasis added)*); Downer v. Veilleux*, 322 A.2d 82 (Me. 1974); and *Cobbs v. Grant,* 8 Cal.3d 229 (1972).

In *Vacco v. Quill*, 521 U.S. 793, 800 (1997), this Court stated, "*Everyone*, regardless of physical condition, is entitled, if competent, to refuse unwanted lifesaving medical treatment." (emphasis added).

Courts have consistently upheld a patient's well-established right to refuse unwanted medical treatments on constitutional grounds for decades. See *Mills v. Rogers*, 457 U.S. 291 (1982) *Guardianship of Roe*, 383 Mass. 415 (1981), *Riggins v. Nevada*, 504 U.S. 127 (1992), and *Sell v. United States*, 539 U.S. 166 (2003).

State criminal laws prohibiting assault, battery, and negligent homicide are implicated. Federal criminal laws prohibiting the violation of constitutional rights are implicated. *See* 18 U.S.C. §241.

Preservation of the absolute right of voluntary, informed patient consent and medical freedom, and the constitutional right to refuse medical treatment are paramount considerations here. Informed and

voluntary consent to medical treatments can never be coerced under the threat of losing one's livelihood.

These constitutional principles, and the other federal and state laws cited herein were fully binding upon Respondents and are excellent public policy.

Voluntary, coercion-free and fully informed consent to medical treatments is inviolate. Unwitting and unwilling medical experimentation upon humans is abhorrent and cannot be upheld.

D. The CDC's operational guidance for COVID-19 vaccine distribution relied upon a web of binding agreements among federal, state, and local governments and frontline providers to ensure that the COVID-19 vaccination program *was implemented in adherence with federal guidance and requirements.* All actors, including providers involved in the federal distribution program via the states, were contractually and legally bound to comply with federal rules concerning investigational drugs.

The CDC's *COVID-19 Interim Operational Guidance: Jurisdiction Operations* established a web of contracts and cooperative endeavor agreements among federal, state, local officials and providers, with the stated goal of closely monitoring vaccination activities at the local level *to ensure that the COVID-19 Vaccination Program was implemented throughout the local jurisdiction in adherence with*

federal guidance and requirements.[35] This contractually imposed affirmative obligations upon state and local officials and providers to comply with all federal guidance and requirements binding upon state actors, including all of the federal constitutional and statutory informed consent provisions discussed above as a condition for participation in the COVID-19 Vaccination Program, in effect making them responsible as state actors as well. This is a broad area of inquiry which must be subject to discovery, and which is inappropriate for a premature pretrial Rule 12(b)(6) dismissal, especially considering the public importance of these issues. Voluntary, coercion-free and fully informed consent to medical treatments is inviolate. Unwitting and unwilling medical experimentation upon humans is abhorrent and cannot be upheld under any rationale.

The *COVID-19 Interim Operational Guidance: Jurisdiction Operations - Version 2.0* states:

> Regardless of the jurisdiction's governance structure, it is imperative that state and local authorities combine and coordinate efforts. *State-level personnel must closely monitor activities at the local level to ensure the COVID-19 Vaccination Program is implemented throughout the jurisdiction in adherence with federal guidance and requirements*, and that there is equitable access to COVID-19 vaccination across all

[35] *See COVID-19 Interim Operational Guidance: Jurisdiction Operations,* October 29, 2020, Version 2.0, Section 2: COVID-19 Organizational Structure and Partner Involvement, p. 8. https://www.cdc.gov/vaccines/imz-managers/downloads/Covid-19-Vaccination-Program-Interim_Playbook.pdf

> areas. Local personnel likely have a better understanding of perceptions, unique challenges, and successful mitigation strategies within their communities. (emphasis added)[36]

Thus, state and local providers and partners *were required as a condition of their participation in the COVID-19 Vaccination Program to adhere to all applicable federal guidance and requirements* binding upon state actors.

Respondents could not evade their contractual responsibilities and obligations to follow all constitutional provisions guaranteeing the right to refuse medical treatments, and the federal informed consent regulations based upon the Nuremberg Code and the Belmont Report,[37] that is, 21 U.S.C. §360bbb-3, 21 C.F.R. § 50.20, 21 C.F.R. § 50.25, 45 C.F.R. § 46.116 *et. seq.*, under the COVID-19 Vaccination Program, by merely claiming to be "private actors."

The federal government entered agreements with each state's public health officials to distribute the COVID-19 vaccines through the enrollment of state healthcare providers. Thus, the state providers were obligated as both state and federal actors to follow all federal rules as outlined above. In addition,

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[36] *Id.*

[37] The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. *Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research* U.S. Department of Health and Human Services, April 18, 1979. Available at https://www.hhs.gov/ohrp/sites/default/files/the-belmont-report-508c_FINAL.pdf

Respondent hospital providers were obligated directly via their Federalwide Assurance agreement to comply with those rules.[38]

Respondents contractually agreed to act as public actors and agents, with all of the attendant (and crucially important) informed consent and constitutional responsibilities and obligations. *See Cruzan v. Director, Missouri Dept. of Health*, 497 U.S. 261 (1990) and its progeny.

Discovery has barely begun in this case. This contractual web of federal, state and local agreements and responsibilities must be the subject of thorough and adequate discovery before any premature pretrial Rule 12(b)(6) or Rule 56 dismissal should be entertained, especially considering the public importance of these issues.

CONCLUSION

It is undisputed that forced or coerced experimentation on human beings against their will is reprehensible and should never be allowed by any court, as the lessons of Nuremberg and the Tuskegee experiment teach.[39] Fortunately, the many legal protections discussed above have been implemented against such injustices. These protections preclude the enforcement of involuntary experimental, investigational — and literally life-threatening — medical mandates such as those promoted by Respondents herein.

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[38] As described by Petitioners in their petition for *certiorari*.

[39] *See* Elizabeth Nix. "Tuskegee Experiment: The Infamous Syphilis Study," *History*, May 16, 2017. https://www.history.com/news/the-infamous-40-year-tuskegee-study

Any illegal mandate of a dangerous experimental personal medical treatment, under the coercive threat of loss of employment, especially when such treatment does not prevent infection or transmission and has *severe undisclosed side effects including death* — clearly violating informed consent, the Constitution, and the numerous well-established laws enumerated herein — is irrational and against public policy.

This mandated monstrous experiment is sadly analogous to the infamous Tuskegee experiment, and must never be allowed to be repeated.

The petition for *certiorari* should be granted and the rulings below should be reversed.

Respectfully submitted,

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