

No. 26-220

In the
Supreme Court of the United States

BETH BOYD., *et al.*,
Petitioners,

v.

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

On Petition for a Writ of Certiorari to the United
States Court of Appeals for the Third 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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-------------------------	----

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------------------------------	---

OTHER REFERENCES

“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	12
Suzanne Burdick. “Elon Musk reveals COVID vaccine injury after former Pfizer official admits shots likely killed tens of thousands in Germany,” April 13, 2026. https://childrenshealthdefense.org/defender/elon-musk-covid-vaccine-injury-former-pfizer-official-shots-likely-killed-thousands-germany/	10
Bornali Bhattacharjee, <i>et al.</i> “Immunological and Antigenic Signatures Associated with Chronic Illnesses after COVID-19 Vaccination,” <i>medRxiv</i> , February 25, 2025. https://www.medrxiv.org/content/10.1101/2025.02.18.25322379v2	19
CDC, <i>COVID-19 Interim Operational Guidance: Jurisdiction Operations</i> , October 29, 2020, Version 2.0. https://www.cdc.gov/vaccines/imz-managers/downloads/Covid-19-Vaccination-Program-Interim_Playbook.pdf	5–6

Luigi Cari, <i>et al.</i> “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.” <i>Vaccines</i> (Basel) 11(4):879. Apr 21, 2023 https://pubmed.ncbi.nlm.nih.gov/37112792	25
FDA Biologics License Application Approval for Comirnaty, August 23, 2021. https://www.fda.gov/media/151710/download	24
FDA Safety Communication. “FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines Regarding Myocarditis and Pericarditis Following Vaccination. June 25, 2025. https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-required-updated-warning-labeling-mrna-covid-19-vaccines-regarding-myocarditis-and	20
“England Refuses to Offer COVID Shots to Kids Under 12, While US Cities Mandate Them. Who’s Right?” https://fee.org/articles/england-refuses-to-offer-covid-shots-to-kids-under-12-while-us-cities-mandate-them-who-s-right	15
“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/	15

- “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>..... 14
- Simone Gold, M.D., J.D. “A White Paper on Hydroxychloroquine,” <https://americasfrontlinedoctors.org/index/covid/hydroxychloroquine/white-paper/> 22
- 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> 25
- 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>..... 18
- 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> 25

https://aflids.org/about-us/press-releases/america-frontline-doctors-supports-the-filing-of-a-petition-for-preliminary-injunction-to-prevent-kaiser-permanente-from-enforcing-their-vaccine-mandate	3
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https://x.com/SecKennedy/status/1927368440811008138	13
Hong Jin Kim, <i>et al.</i> “Broad-Spectrum Adverse Events of Special Interests Based on Immune Response Following COVID-19 Vaccination: A Large-Scale Population-Based Cohort Study,” <i>J. Clin. Med.</i> 14(5) 1767, March 6, 2025. https://www.mdpi.com/2077-0383/14/5/1767	21
Tomomi Koizumi and Masao Ono, “Cardiac Multiple Micro-Scars: An Autopsy Study,” <i>J Am Coll Cardiol Case Rep.</i> 30(5) 10383, March 2025. https://www.jacc.org/doi/10.1016/j.jaccas.2024.103083	19

- 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> 14
- 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>..... 17–18
- 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,” <https://doi.org/10.1101/2025.04.25.25326460> 13
- “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-fb389831770e.html..... 14
- Vibeke Manniche, *et al.* “Batch-Dependent Safety Signal: Nationwide Analysis of Suspected Adverse Events Following COVID-19 Vaccination in Germany,” March 10, 2026. <https://www.preprints.org/manuscript/202603.0688> 20

- 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=submit&utm_medium=email..... 13
- 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>)..... 19
- Art Moore. “CDC data signaling vaccine catastrophe: 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/>..... 18
- 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/> 15–16

- “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> 16
- Elizabeth Nix. “Tuskegee Experiment: The Infamous Syphilis Study,” *History*, May 16, 2017. <https://www.history.com/news/the-infamous-40-year-tuskegee-study> 28–29
- 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>..... 13–14
- 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..... 14
- Harold M. Schmeck, Jr. “Swine flu program is halted in 9 states as 3 die after shots,” *The New York Times*, October 13, 1976. <https://www.nytimes.com/1976/10/13/archives/swine-flu-program-is-halted-in-9-states-as-3-die-after-shots.html>..... 18

- Keisuke Takada, *et al.* “SARS-CoV-2 mRNA vaccine-related myocarditis and pericarditis: An analysis of the Japanese Adverse Drug Event Report database,” *J Infect Chemother.*, January 2025, 31(1):102485. <https://pubmed.ncbi.nlm.nih.gov/39103148/> 19
- 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/> 20
- Trials of War Criminals Before the Nuernberg Military Tribunals Under Control Council Law No. 10*, Volume II (U.S. Government Printing Office 1949). <https://www.gutenberg.org/ebooks/54905> 27
- “TRUTH BOMB: Peter McCullough Doesn’t Hold Back — ‘IT WAS NOT SAFE BY DESIGN,’” <https://x.com/ChildrensHD/status/1925355939369988144>..... 13
- 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/> 25

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 (“AFLDS”), respectfully file this *amici curiae* brief in support of the Petitioners for reversal in *Boyd, et al. v Shriners Hospital for Children, et al.*, 26-220.¹

Amici Curiae have filed *amici* briefs in recent cases affecting public health and medical freedom such as *Chiles v. Salazar*, No. 24-539, *Does 1-2 v. Hochul*, No. 24-1015; *Stockton v. Brown*, No. 25-606; *Mirabelli v. Bonta*, No. 25A810; and *Heath v. EcoHealth Alliance, Inc.*, No. 25-740.

AFLDS also filed briefs in cases recently decided by this Honorable Court, such as *Miller v. McDonald*, No. 25-133; *United States v. Skrmetti*, No. 23-477; and *Mahmoud v. Taylor*, No. 24-297 (2024).

This *amici curiae* brief offers an important *medical and legal* perspective to this Court on a matter of great public importance, by demonstrating that Respondents engaged in unconstitutional activity by “mandating” dangerous experimental medical treatments in violation of informed consent,

¹ No counsel or any party authored or prepared this brief in whole or in part, or made a monetary contribution intended to fund its preparation or submission. The *Boyd* parties received timely notice of this brief’s filing.

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.

INTEREST OF *AMICI CURIAE*

Amici Curiae are the Free Speech Foundation, d/b/a America’s Frontline Doctors (“*Amici Curiae*” or “AFLDS”), 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 its founder and expert physician with over twenty years’ experience as an emergency room physician in minority communities, Dr. Simone Gold, M.D., J.D.²

AFLDS’ programs focus on critical issues, including:

- Providing Americans with science-based facts about COVID-19;
- Combating COVID-19 with evidence-based approaches without compromising constitutional freedoms;
- Advancing healthcare policies that protect the physician-patient relationship;
- Expanding COVID-19 treatment options for all Americans who need them; and

² <https://americasfrontlinedoctors.org/about-us>.

- Strengthening the voices of frontline doctors in the national healthcare conversation.

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 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.

SUMMARY OF ARGUMENT

The CDC’s operational guidance for the nationwide COVID-19 vaccine distribution program 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 all federal guidance, requirements and constraints. All actors involved in the federal distribution program were contractually and legally bound to comply with federal constitutional and statutory rights, obligations, and rules concerning investigational

³ <https://aflids.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>

drugs. *See, e.g., West v. Atkins*, 487 U.S. 42, 48-57 (1988).

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. This was not at issue when *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) was decided, and vaccine efficacy and safety was assumed.

At the time of Respondents’ “mandates,” the mRNA injections were indisputably investigational. Thus, the informed consent regulations governing experimental, investigational drugs, including 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, were binding upon both public and private actors.

To “mandate” an experimental and personal 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 well-established constitutional provisions, numerous civil and criminal laws and regulations, and is irrational and against public policy.

Further, Respondents contractually agreed to act with all federal (and crucially important) informed consent and constitutional responsibilities and obligations as a condition of participation in the CDC’s COVID-19 Vaccination Program.

Discovery has not yet begun in this case. Petitioners’ fundamental rights violation claims

should not be prematurely dismissed. 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 petitions for writs of *certiorari* should be granted.

ARGUMENT

- I. The CDC's operational guidance for nationwide 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 all federal guidance, requirements and constraints*. All actors involved in the federal distribution program were contractually and legally bound to comply with federal constitutional and statutory rights, obligations, and rules concerning experimental, investigational drugs. Respondents violated binding informed consent and experimental drug regulations.

The CDC's *COVID-19 Interim Operational Guidance: Jurisdiction Operations* established a web of contracts and cooperative 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 (“Program”) was implemented throughout local jurisdictions “*in adherence with federal guidance and requirements*.”⁴ This contractually imposed affirmative obligations upon states and *state providers* to comply with all federal guidance, constitutional and statutory provisions, rules and requirements, including all informed consent provisions, as a condition for participation in the Program. This broad area of inquiry must be subject to discovery, and is inappropriate for a premature Rule 12(b)(6) dismissal, especially considering the public importance of these issues. Unwitting and unwilling medical experimentation upon humans is abhorrent and cannot be upheld under any rationale.

The federal government entered agreements with each state’s public health officials to distribute the COVID-19 vaccines through state healthcare providers. Enrolled state providers such as Shriners Hospitals for Children were obligated as state *and* federal actors to follow all federal rules as outlined above, and Respondent providers were obligated directly via the Federalwide Assurance agreement to comply.⁵

All participants in the Program, including Respondent Shriners, contractually agreed to all

⁴ 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

⁵ As described by Petitioners in their petition.

federal rights, obligations, and rules including the necessity of informed consent, free from coercion, and were required to follow all informed consent rules and constitutional provisions such as the personal right to refuse medical treatments under *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261 (1990). This included all statutes and rules governing experimental drugs binding upon both public and private actors. And the Pfizer/BioNTech experimental drug was *never* approved by the F.D.A., contrary to the erroneous findings of the Third Circuit.

As an example, 21 C.F.R. § 50.25(a)(8) provides that persons administered experimental, investigational drugs be furnished with:

(8) A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

A Program participant employer “mandate” that coerces employees to take experimental drugs clearly violates these provisions. The Third Circuit ignored Respondent Shriners’ contractual agreements to follow all constitutional and statutory provisions binding on the state government and themselves as investigational drug providers, by erroneously finding that Comirnaty, an approved vaccine, was “the functional equivalent” of the Pfizer/BioNTech

COVID-19 experimental mRNA injection.⁶ Comirnaty was not being distributed through the CDC program, however; Shriners’ mandated the experimental injection only, the only drug it agreed to distribute under the CDC program.

All actors involved in the federal distribution program were contractually and legally bound to comply with federal constitutional and statutory rights, obligations, and rules concerning investigational drugs. *See, e.g., West v. Atkins*, 487 U.S. 42, 48-57 (1988) (doctor under contract to provide medical services to inmates at a state prison hospital acts “under color of state law,” within the meaning of § 1983).

The Third Circuit erroneously created a distinction between “Shriners internal vaccine mandate” and Shriners’ participation in the “state’s public vaccination program,” ignoring the operation of the contractual and legal obligations which Shriners entered into upon participation as a state provider of the emergency vaccines under the CDC program.⁷ Thus, the Third Circuit concluded that Shriners had authority to coerce its employees into receiving an investigational drug without regard to its state and federal agreements regarding the voluntary, informed consent nature of such drugs. There is *no* authority, under state or federal law, to “mandate” any person to inject a drug under investigational status; no American can be coerced to participate in a medical experiment. *See, e.g., 21 C.F.R. § 50.25, supra.*

⁶ *See Boyd* Appendix, App. 3a, n.1.

⁷ *See Boyd* Appendix, App. 7a.

II. *Cruzan v. Dir., Mo. Dep’t of Health*
requires personal medical treatment decisions to be strictly voluntary and free from coercion or pressure. The courts below erred in allowing Respondents to evade their state and federal contractual responsibilities to follow applicable federal constitutional and statutory provisions as Program participants or as private parties by coercively “mandating” a dangerous experimental treatment which does not prevent infection or transmission, and which has *severe undisclosed side effects, including death*.

To “mandate” an experimental and personal medical treatment which does not prevent infection to oneself, or transmission to other people, and which also has *severe undisclosed side effects including death*, under the coercive threat of loss of employment, violates well-established constitutional provisions and numerous civil and criminal laws and regulations

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.⁸ These experimental, investigational drugs *offer no*

⁸ See <https://openvaers.com/covid-data>.

*protection for other people.*⁹ They are personal medical treatments only.

Dr. Helmut Sterz, Pfizer’s former chief toxicologist, admitted early in 2026, during a German COVID-19 inquiry, that an estimated 60,000 people died in Germany from Pfizer’s COVID-19 vaccine Comirnaty. An estimated 25 severe side effects from the vaccine occurred for every *one* severe course of infection the shots allegedly prevented.¹⁰

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. By contrast, when *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) was decided — well before *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261 (1990) — the safety and efficacy of the smallpox vaccine then in use was assumed. The circuit courts have failed to recognize that *Jacobson* was decided well before Congress passed the FDCA in exercise of its commerce power and required approval of drugs introduced or delivered into interstate commerce, as well as the consent of subjects given experimental drugs. A fundamental question, never addressed in *Jacobson*, and still not addressed, is whether state *or* private actors can

⁹ 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).

¹⁰ Burdick, Suzanne. “Elon Musk reveals COVID vaccine injury after former Pfizer official admits shots likely killed tens of thousands in Germany,” April 13, 2026. <https://childrenshealthdefense.org/defender/elon-musk-covid-vaccine-injury-former-pfizer-official-shots-likely-killed-thousands-germany/>

mandate drugs which are not legally approved for commerce under federal law.

The original three-judge panel opinion of the Ninth Circuit in *Health Freedom Defense Fund, Inc. v. Carvalho*, 104 F.4th 715 (9th Cir. 2024) correctly distinguished *Jacobson*:

Jacobson, however, did not involve a claim in which the compelled vaccine was “designed to reduce symptoms in the infected vaccine recipient rather than to prevent transmission and infection.” The district court thus erred in holding that *Jacobson* extends beyond its public health rationale—government’s power to mandate prophylactic measures aimed at preventing the recipient from spreading disease to others—to also govern “forced medical treatment” for the recipient’s benefit.

Id., at 725 (some internal citations omitted).

The three-judge panel recognized that forcibly mandated personal medical treatments upon employee/patients could not be justified by the “protection of the public” rationale of *Jacobson*, when the mRNA injections did not stop infection or transmission or afford protection for others.

Unfortunately, this correct and significant panel decision was overturned by the *en banc* Ninth Circuit in *Health Freedom Defense Fund, Inc. v. Carvalho*, 148 F.4th 1020 (9th Cir. 2025), an error now final after a denial of *certiorari*, and an error other circuit courts have been emboldened to repeat.

Many states recognize that this is an important issue. The Attorneys General of twelve states filed an excellent *amici curiae* brief in *Carvalho*, No. 25-765, precisely analyzing why *Jacobson* is distinguishable from the COVID-19 “mandates” of experimental vaccines, and calling for the reaffirmation of the fundamental right to be free from compelled medical treatments.¹¹

Mandating unwanted and dangerous investigational drugs is irrational, pointless, and against good public policy. *See, e.g., Cooper v. Roswell Park Comprehensive Cancer Center*, 196 N.Y.S.3d 325, (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.”¹²

III. Respondents’ illegal mandates under coercive threat of loss of employment violates informed consent, well-established constitutional provisions, and numerous civil and criminal laws and regulations. Governments are increasingly recognizing such mandates as irrational and against public policy.

¹¹ *See* Brief for the States of Texas, *et al.*, in Support of Petitioners, https://www.supremecourt.gov/DocketPDF/25/25-765/395027/20260129162315271_25-765_Amici%20Brief.pdf

¹² 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>

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.¹³

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.¹⁴

Many more recent and reliable medical studies further explode the “safe and effective” narrative.¹⁵

¹³ <https://x.com/SecKennedy/status/1927368440811008138>

¹⁴ “TRUTH BOMB: Peter McCullough Doesn’t Hold Back — ‘IT WAS NOT SAFE BY DESIGN,’” <https://x.com/ChildrensHD/status/1925355939369988144>

¹⁵ Five recent papers show vaccine COVID vaccine harms outweigh any benefits:

The Pfizer injection increases 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,” <https://doi.org/10.1101/2025.04.25.25326460>

Women who got the shot were 30–50 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 between vaccination and death. E.O. Okoro, *et al.* “Paradoxical increase in global COVID-

Florida state Surgeon General Dr. Joseph A. Ladapo called for a complete halt in the use of COVID-19 mRNA “vaccines,” citing contamination concerns.¹⁶

Louisiana health officials shifted away from promoting COVID-19 and flu vaccinations.¹⁷ 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

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 vaccine uptake 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

¹⁶ “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>

¹⁷ Louisiana Department of Health 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.” “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

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.

A wave of bills introduced in state legislatures recently, including Iowa, Kentucky, Montana, Minnesota, Idaho and others, 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.¹⁸

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

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.^{19,20}

¹⁸ 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.

¹⁹ “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 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/>

²⁰ Michael Nevradakis, Ph.D. “Slovak Government Report Calls for Ban of ‘Dangerous’ mRNA Vaccines,” *Science, Public Health Policy and the Law*. <https://publichealthpolicyjournal.com/>

The ruling 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.); *Miller v. McDonald*, 223 L. Ed. 2d 270 (2025) (school vaccine mandate rejected).

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 mandate was then dropped by DOH, so any appeal was deemed moot.²¹

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.

slovak-government-report-calls-for-ban-of-dangerous-mrna-vaccines/

²¹ These issues are extremely likely to recur, yet are evading review. While new pandemics threaten, numerous anti-mandate cases have also flooded American courts. Illegal mandates may 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>

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?

IV. 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 39,205 fatalities attributable to these mRNA injections through July 31, 2026. 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 July 31, 2026, there have been **39,205 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.”²² This cannot remotely be considered “safe” or “effective.” Additionally, VAERS recorded 74,902 permanently disabled persons, 5,223 miscarriages, 22,560 heart attacks, and 29,264 Myocarditis/Pericarditis cases.²³

²² <https://openvaers.com/covid-data>

²³ These figures are even more astonishing when it is considered that they likely represent less than 1% of the true adverse events and fatalities attributable to COVID-19 injections. In

Thus the American *reported* death toll has now risen to an astonishing *39,205 deaths*.

High adverse reaction statistics obviously form a reasonable basis for some patients to avoid risky investigational 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 its mass vaccination campaign.²⁴ The campaign was halted in nine states after only *three* deaths were attributed to the vaccine shots.²⁵

Japanese researchers linked these experimental mRNA injection side effects to 201 types of diseases.²⁶ In another Japanese study, researchers found on autopsy multiple micro-scars in the hearts of mRNA-vaccinated patients who died suddenly of

2011, an investigation of VAERS by Harvard Pilgrim Health Care Inc. reported: “Adverse events ... are common, but ... *fewer than 1% of vaccine adverse events are reported* [to the FDA].” <https://digital.ahrq.gov/sites/default/files/docs/publication/r18hs017045-lazarus-final-report-2011.pdf>

²⁴ Art Moore. “CDC data signaling vaccine catastrophe: 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/>

²⁵ Harold M. Schmeck, Jr. “Swine flu program is halted in 9 states as 3 die after shots,” *The New York Times*, October 13, 1976.

²⁶ 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>

unexplained cardiac arrest, thus raising the question of a link between the experimental mRNA injections and sudden cardiac arrest.²⁷ And in yet another recent Japanese study, SARS-CoV-2 mRNA vaccination was significantly associated with the onset of myocarditis/pericarditis in the Japanese. The influencing factors included being less than 30 years old, and male.²⁸

Further, an alarming Yale study showed 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?”²⁹

An authoritative 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.*”³⁰

²⁷ 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>

²⁸ Keisuke Takada, *et al.* “SARS-CoV-2 mRNA vaccine-related myocarditis and pericarditis: An analysis of the Japanese Adverse Drug Event Report database,” *J Infect Chemother.*, January 2025, 31(1):102485. <https://pubmed.ncbi.nlm.nih.gov/39103148>

²⁹ <https://x.com/drsimonegold/status/189262622250639592>; 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>

³⁰ M. Nathaniel Mead, *et al.* “Myocarditis after SARS-CoV-2 infection and COVID-19 vaccination: Epidemiology, outcomes, and new perspectives,” *Intl J Cardiovascular Rsch &*

Accordingly, in June 2025 the FDA found it necessary to approve an updated, stricter warning label for mRNA COVID-19 vaccines, regarding the risks of myocarditis and pericarditis following COVID-19 vaccination.³¹

A brand-new German study shows mRNA “vaccines” were not safe when first rolled out, and that adverse events were batch-dependent; with some batches worse than others.³²

Another recent study highlighted that Pfizer’s post-marketing surveillance analysis showed a miscarriage rate of 81%, a 5-fold increase in stillbirths, an 8-fold increase in neonatal deaths, and a 13% incidence of breastfeeding complications in newborns whose mothers received the COVID shots:³³

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>(emphasis added)

³¹ “FDA Approves Required Updated Warning in Labeling of mRNA COVID-19 Vaccines Regarding Myocarditis and Pericarditis Following Vaccination. June 25, 2025. <https://www.fda.gov/vaccines-blood-biologics/safety-availability-biologics/fda-approves-required-updated-warning-labeling-mrna-covid-19-vaccines-regarding-myocarditis-and>

³² Vibeke Manniche, *et al.* “Batch-Dependent Safety Signal: Nationwide Analysis of Suspected Adverse Events Following COVID-19 Vaccination in Germany,” March 10, 2026. <https://www.preprints.org/manuscript/202603.0688>

³³ 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/>

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 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.”³⁴

It is 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 mandate a dangerous experimental drug which does not protect other people.

³⁴ Hong Jin Kim, *et al.* “Broad-Spectrum Adverse Events of Special Interests Based on Immune Response Following 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>

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.^{35,36,37} These are 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.”

³⁵ A white paper draws attention to the indisputable safety of hydroxychloroquine (“HCQ”), an analog of the quinine from 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. All the myths and misconceptions about a safe, generic drug, FDA-approved for 65 years and given to pregnant and breast-feeding women, children, the elderly, and the immune-compromised for decades without complication, are finally put to rest. <https://americasfrontlinedoctors.org/index/covid/hydroxychloroquine/white-paper/>

³⁶ As of August 31, 2026, 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. 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/>

³⁷ As of September 18, 2026, 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, and recovery. Over 20 countries adopted Ivermectin for COVID-19 and it may now be purchased over the counter in many states. <https://c19ivm.org/>

- V. **“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 rights 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.**

Although the mandated mRNA injections are investigational, 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, “Protection of Human Subjects,” long known as the “Common Rule.”³⁸

These federal regulations are mandatory for public actors, embody most of the Nuremberg principles, and apply to all experimental drugs issued under an emergency use authorization (EUA),

³⁸ <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html>

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.³⁹ The controversial approval of “Comirnaty,” a legally 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.

As pointed out by the Third Circuit, numerous circuits have erroneously concluded that Pfizer’s COVID-19 injection was approved by the FDA,⁴⁰ but only Pfizer drug “Comirnaty” was approved while the EUA COVID-19 injection was *extended*. Both actions were taken on August 23, 2021, causing much confusion. The Third Circuit erred in finding that these two different drugs were equivalent. Only Comirnaty was approved by the F.D.A., and it was

³⁹ 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 actually in use. This created much confusion; it was erroneously reported that the mRNA injections actually in use had been approved by the FDA. *This was never true*. The EUA for the experimental mRNA injections was only extended. Therefore, all laws and regulations applicable to experimental drugs were still in full force and effect at the time of the mandates. See <https://www.fda.gov/media/151710/download>

⁴⁰ See *John Does 1–2 v. Hochul*, No. 24-1015, Appendix at 20a, 21a, and 39a.

never available in the United States to be utilized in any hospital “mandate” such as Shriners’.

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.^{41,42} The approval of Comirnaty 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 Nuremberg Code, an international code of ethical principles adopted in the aftermath of WWII

⁴¹ A paper authored by Luigi Cari and others shows that Spikevax-Moderna mRNA induces higher spike protein expression per dose than Comirnaty, and this correlates with increased myocarditis risk. See “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/>

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/>

⁴² Josh Guetzkow and Retsef Levi. “Effect of mRNA vaccine manufacturing processes on efficacy and safety still an open question,” *BMJ* 2022;378:o1731. July 12, 2022. <https://www.bmj.com/content/378/bmj.o1731/rr-2>

Nazi war crimes, was expressly intended to prohibit involuntary medical experimentation upon humans. The detailed federal regulations mirror the Nuremberg Code.⁴³ For example, 21 C.F.R. §50.25, Elements of informed consent, requires the identification of any experimental procedures, a description of any reasonably foreseeable risks or discomforts, a description of any benefits, a disclosure of alternative procedures, and a statement that refusal to participate will involve no penalty.

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. Part 50.

Federal law thus 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 in their capacity as state actors and via their contractual agreements to do so. Respondents

⁴³ *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>

violated these mandatory federal laws and regulations.

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*, 497 U.S. at 270 (“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 personal 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. Unwitting and unwilling medical experimentation upon humans is abhorrent and cannot be upheld.

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.⁴⁴

⁴⁴ *See* Elizabeth Nix. “Tuskegee Experiment: The Infamous

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

Respectfully submitted,

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Syphilis Study,” *History*, May 16, 2017. <https://www.history.com/news/the-infamous-40-year-tuskegee-study>