

No. 21-1511

In the
Supreme Court of the United States

JOY GARNER, individually and on behalf of
THE CONTROL GROUP, et al.,
Petitioners,

v.

JOSEPH R. BIDEN, JR., in his official capacity as
PRESIDENT OF THE UNITED STATES OF AMERICA,
Respondent.

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

**BRIEF OF CHILDREN'S HEALTH DEFENSE
AS *AMICUS CURIAE*
IN SUPPORT OF PETITIONERS**

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**IDENTIFICATION AND
INTEREST OF *AMICUS CURIAE*¹**

Children’s Health Defense (“CHD”) is a national non-profit 501(c)(3) organization. CHD has no parent corporation. No publicly held company has a 10 percent or greater ownership interest. CHD’s mission is to end the epidemic of children’s chronic health conditions by working aggressively to eliminate harmful exposures to environmental toxins via education, to obtain justice for those already injured, and to promote protective safeguards.

Amicus offers this brief to explain why the U.S. President’s COVID-19 vaccine mandates, requiring participation in a potentially dangerous medical procedure without free and informed consent, amount to an unethical coercive human medical experiment. In the case of the COVID-19 vaccines, placebo-controlled clinical trials should have occurred to address vaccine safety and efficacy, but did not. Indeed, the United States is at a tipping point — if unvaccinated Americans, such as the Petitioners, no longer exist, scientists then will never be able to properly evaluate COVID-19 and other vaccines’ impact on Americans’ health.

Amicus also respectfully submits this brief to draw attention to the reality that American children today are the sickest generation in our country’s history. Aggressively promoting COVID-19 vaccines

¹ It is hereby certified that *amici curiae* have received written permission from Petitioners’ Counsel, Gregory J. Glaser, and Respondent’s Counsel, Solicitor General Elizabeth B. Prelogar, to file this brief. The parties received notice of the intention to file this brief at least 10 days prior to the filing of it. No person or entity other than the named *amicus*, their members or counsel has (i) paid in whole or in part for the preparation of this brief; or (ii) authored in whole or in part this brief.

to children will eliminate an unvaccinated control group while children are at virtually zero risk of serious complications from COVID-19. Without the Court’s intervention to safeguard and preserve the control group of unvaccinated Americans, and in particular the youngest controls, critical scientific evidence will be lost, causing irreparable harm to Petitioners and to health science more broadly.

This *amicus* brief is submitted in support of the Petitioners, Joy Garner, individually and on behalf of The Control Group, *et al.*

INTRODUCTION AND SUMMARY OF ARGUMENT

This case addresses one of the most fundamental rights of all Americans: “No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law.” *Union Pac. Ry. v. Botsford*, 141 U.S. 250, 251 (1891). Similarly, this Court in *Cruzan v. Director, Missouri Dep’t of Health*, 497 U.S. 261 (1990), held that the right to refuse medical treatment is a constitutionally protected liberty interest guaranteed by the due process clause of the Fourteenth Amendment.

Petitioners are requesting declaratory relief to reaffirm these fundamental rights, in the face of actions by President Biden that run roughshod over the U.S. Constitution while destroying the health of millions of Americans.

On September 9, 2021, President Biden issued an unprecedented executive order mandating COVID-19 vaccination for employees of any company

or organization with 100 or more employees (the “OSHA” mandate).² On the same day, President Biden issued a second, similar order requiring COVID-19 vaccination for all workers employed by the federal government,³ and a third order requiring COVID-19 vaccination for employees at federal government contracting companies.⁴ Although the OSHA mandate was subsequently withdrawn as a result of this Court's decision to stay that mandate⁵ (as were the other two executive orders), President Biden’s actions effectively compelled hundreds of millions of Americans to receive COVID-19 shots. In addition to threatening Americans’ ability to keep their jobs and support their families, the President’s vaccine mandates encouraged private employers, schools and universities, and public businesses and accommodations to impose their own vaccine requirements, conditioning vaccination as a prerequisite for remaining employed, gaining an

² Fact Sheet: *Biden Administration Announces Details of Two Major Vaccination Policies*, WHITEHOUSE.GOV (Nov. 4, 2021). <https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/>.

³ Executive Order on Requiring Coronavirus Disease 2019 Vaccination for Federal Employees (September 9, 2021). <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-requiring-coronavirus-disease-2019-vaccination-for-federal-employees/>.

⁴ Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors, (September 9, 2021). <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/09/09/executive-order-on-ensuring-adequate-covid-safety-protocols-for-federal-contractors/>

⁵ *National Federation of Independent Business, et al. v. Department of Labor, Occupational Safety and Health Administration, et al.*, 595 U.S. ___, 142 S.Ct. 661 (2022).

education, and even buying food and accessing basic services.⁶

But beyond the wholesale violation of nearly every American’s constitutional rights to personal and bodily integrity, the COVID-19 vaccine mandates have resulted in unspeakable harm to millions of Americans, and have resulted in the deaths of thousands of people. Although the President and public health officials argue that COVID-19 vaccine mandates are legally and ethically justified, all vaccines are serious medical interventions that unquestionably can and do injure and cause death for some people. This is particularly true for COVID-19 vaccines that became available through a rushed “Operation Warp Speed.” Recent data from the Center for Disease Control and Prevention (CDC) Vaccine Adverse Event Reporting System (VAERS) show that there have been 1,287,595 adverse events related to COVID-19 vaccinations, including 235,041 adverse events labeled “serious” and 28,532 deaths (including “foreign deaths”) as of May 27, 2022.⁷ Of the 12,779 reported deaths in the U.S., 16 percent occurred within 24 hours of vaccination, 20 percent occurred within 48 hours of vaccination, and 59 percent occurred in people who experienced an onset of

⁶ “We know from experience that most employers will comply with OSHA requirements without an OSHA inspection, just as most people obey the law without a police officer looking over their shoulder.” David Michaels & Jordan Barab, *We Ran OSHA. Here’s the Truth About the So-Called Vaccine Mandate*, TIME (Nov. 30, 2021). <https://time.com/6124687/osha-vaccine-mandate-explained/>.

⁷ Megan Redshaw, *More Than 8,000 New COVID Vaccine Injuries Reported to VAERS, CDC Data Show*, THE DEFENDER (May 6, 2022). <https://childrenshealthdefense.org/defender/covid-vaccine-injuries-vaers-cdc-data>.

symptoms within 48 hours of vaccination.⁸ Moreover, it has been well documented from a U.S.-funded study that fewer than one percent of all adverse events are reported to the CDC’s VAERS.⁹ These extraordinarily high reported numbers are certainly a vast undercount of the actual injuries and deaths following COVID-19 vaccination.

To date, the National Vaccine Injury Compensation Program (NVICP) has paid out nearly \$4 billion to compensate victims of (non-COVID-19) vaccine injuries and deaths since Congress created the federal program in 1986 while offering vaccine manufacturers and healthcare providers virtually unlimited liability protection.¹⁰ COVID-19 vaccine injuries may not be compensated under the NVICP because the Food And Drug Administration (FDA) has not yet licensed COVID-19 vaccines.¹¹ COVID-19 shots are “Emergency Use Authorization” (EUA) only, and therefore experimental with potentially dangerous, life-altering ramifications. Under the Nuremberg Code, an internationally recognized

⁸ See search results from the VAERS Database:

<https://medalerts.org/vaersdb/findfield.php?TABLE=ON&GROUP1=ONS&EVENTS=ON&VAX=COVID19&VAXTYPES=COVID-19&STATE=NOTFR>

⁹ Tracy A. Lieu et al., *Real-time vaccine safety surveillance for the early detection of adverse events*. 45 (10 Supl 2) MED CARE S89. (Oct. 2007). doi: 10.1097/MLR.0b013e3180616c0a; PMID: 17909389.

¹⁰ *Vaccine Injury Compensation Program*, U.S. DEPARTMENT OF JUSTICE (Sept. 24, 2018). <https://www.justice.gov/civil/vicp>.

¹¹ Emergency Use Authorization for Vaccines Explained, U.S. FOOD AND DRUG ADMINISTRATION. <https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained/>.

peremptory norm, “The voluntary consent of the human subject is absolutely essential.”¹²

Federal officials claim the power to override Americans’ fundamental rights to bodily integrity and medical decision-making — even in the face of millions of vaccine-induced injuries and thousands of deaths — based largely on the notion of vaccine-induced “herd immunity.” Public health officials borrowed the herd immunity concept from observation of natural disease outbreaks and applied the concept to vaccine-acquired immunity.¹³ Officials argue that when a sufficient proportion of the population is vaccinated against a particular disease, they are therefore theoretically immune to it and the disease will disappear.¹⁴

But actual “herd immunity” and disease eradication is almost never achievable through vaccination under real-world conditions, for several reasons. These include the fact that a significant portion of the population do not have an immune response to vaccination (“vaccine failure”) and, even for those vaccinated people who respond to the vaccination, immunity wanes and frequent booster shots are required for most vaccine regimens. As a result, in any population of “fully vaccinated” people, many bodies will not respond to the vaccines and for others, vaccine effectiveness inevitably wanes.

¹² See The Nuremberg Code. *Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10*, Vol. 2, pp. 181-182. Washington, D.C.: U.S. G.P.O. (1949). NIH reprint: <https://history.nih.gov/display/history/Nuremberg+Code>.

¹³ Marco Caceres, *The Misunderstood Theory of Herd Immunity*, THE VACCINE REACTION (June 20, 2015). <https://thevaccine-reaction.org/2015/06/the-misunderstood-theory-of-herd-immunity/>

¹⁴ *Id.*

Vaccination will not lead to disease eradication, which is the goal of vaccine-induced “herd immunity.” Vaccine-induced herd immunity is a myth.

Yet based on this mythology, the President imposed various mandates to coerce Americans to accept COVID-19 vaccination, overriding any personal concerns even when it is apparent that any individual’s decision to remain unvaccinated will have no impact on any other individual or on the broader community.

Unvaccinated Americans, such as Petitioners, are a dwindling group, as public health officials employ increasingly coercive tactics to compel vaccination, threatening their very economic survival, as well as cutting off access to essential services, including basic educational services for their children. But beyond the harmful impact of vaccine mandates and federal coercion on unvaccinated Americans, the damage to vaccinated Americans’ health and safety resulting from the unprecedented mass COVID-19 vaccination efforts is incalculable. These devastating casualties, viewed more broadly, represent a devastating and continuing threat to the very survival of the American population. Beyond the threats to the health and safety of millions of individual vaccine recipients, and the harm imposed on people who refuse to accept COVID-19 vaccines, the cumulative effect on American society has been and will continue to be devastating. This impact is arguably worse than any wartime casualties since the Second World War. This is a national security emergency.

Here, unvaccinated Petitioners refuse to serve as human test subjects for COVID-19 vaccinations, particularly where regulators have not yet conducted proper studies of their safety and efficacy comparing

vaccinated and unvaccinated populations. Under these extraordinary circumstances, Petitioners reasonably believe that their bodily integrity is under threat and that they will continue to experience imminent threat of injury from coercive vaccination mandates. They have suffered damage to their economic well-being, and on a daily basis experience severe limitations on their rights to travel, to receive medical services, and to access public services, as well as innumerable other obstacles that prevent them from simply living their lives as free and independent natural human beings.

Petitioners ask this Court to provide declaratory relief affirming their fundamental human rights to personal autonomy and bodily integrity before it is too late. The President's unconstitutional power grab in imposing vaccine mandates and other forms of coercion that clearly violate fundamental constitutional rights cannot be permitted to stand. Without such relief, the Petitioners will continue to face extraordinary pressure to conform rather than be allowed their personal liberty to make medical decisions for themselves and their children, as guaranteed under the U.S. Constitution.

Further, Petitioners seek to remain intact and preserve themselves as a completely unvaccinated control group, necessary to conduct a true randomized, double-blind clinical trial comparing the health outcomes of a fully unvaccinated control group versus a group vaccinated with COVID-19 and other vaccines. Without the Court's intervention, President Biden's vaccine mandates will continue to threaten the Petitioners' constitutional rights, health, and safety as well as risk national security and public safety.

ARGUMENT

I. PETITIONERS HAVE A FUNDAMENTAL RIGHT TO BODILY INTEGRITY WHEN MAKING MEDICAL DECISIONS FOR THEMSELVES AND THEIR CHILDREN.

There is no doubt that forcing an individual to be injected with an experimental or even approved product containing unknown ingredients constitutes a significant physical intrusion into a nonconsenting person's body and explicitly violates the rights to bodily integrity guaranteed under the U.S. Constitution. For over a century, this Court has held that an individual's right to bodily autonomy is sacrosanct. "No right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Union Pac. Ry. v. Botsford*, 141 U.S. at 251.

While a number of state courts have ruled that the right to refuse unwanted medical treatment is embedded in the Bill of Rights as a federal right to privacy, the Supreme Court in *Cruzan v. Dir, Mo. Dep't of Health*, 497 U.S. 261, held that the right to refuse treatment is a constitutionally protected liberty interest guaranteed by the Fourteenth Amendment's due process clause. *Id.* at 278 n.9. The Supreme Court recognized the importance of the constitutionally protected right to bodily autonomy and the need to preserve procedural safeguards, even if the individual is incompetent and needs a proxy to refuse unwanted medical treatment. *Id.*

In its review of the legal framework around the right to bodily integrity, the *Cruzan* Court explained

that “[t]he principle that a competent person has a constitutionally protected liberty interest in refusing unwanted medical treatment may be inferred from our prior decisions.” *Cruzan*, 497 U.S. at 278. To support this legal analysis, the Court first cited *Washington v. Harper*, 494 U.S. 210 (1990), where the Court recognized that prisoners possess “a significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the due process clause of the Fourteenth Amendment.” *Id.* at 221–22. The *Cruzan* Court highlighted that “[t]he forcible injection of medication into a nonconsenting person’s body represents a substantial interference with that person’s liberty.” *Id.* at 229. Second, the *Cruzan* Court cited *Vitek v. Jones*, 445 U.S. 480 (1980), where the Supreme Court had previously acknowledged that the involuntary commitment of an incarcerated patient to a psychiatric hospital, coupled with mandatory behavior modification as a treatment for mental illness, implicated liberty interests protected by the due process clause of the Fourteenth Amendment. *Id.* at 494. Third, the Court cited *Parham v. J. R.*, 442 U.S. 584 (1979), where the Court recognized that “a child, in common with adults, has a substantial liberty interest in not being confined unnecessarily for medical treatment.” *Id.* at 600. In this landmark case, the Court ruled that parents have the right to make decisions for their children in areas of health, education, and family life based on the presumption that parents make decisions for their children that are in their best interests.

Several years later, the Court held in *Washington v. Glucksberg*, 521 U.S. 702 (1997) that the “liberty” protected by the Fourteenth Amendment’s due process clause included the right to “bodily integrity” and “guarantees more than fair

process ... the [Due Process] Clause also provides heightened protection against government interference with certain fundamental rights and liberty interests.” *Id.* at 720–21. Here, the Court ruled that the government was forbidden to infringe upon certain “fundamental” liberty interests at all, no matter the process, unless that infringement is narrowly tailored to serve a compelling government interest. *Id.* at 721. As part of its analysis, the *Glucksberg* Court explained that the patient's constitutional right to refuse unwanted medical treatment stems from the fundamental human right of self-determination.

The concept of self-determination is deeply rooted in U.S. law, with a strong judicial deference for individual autonomy. Indeed, the concepts of bodily integrity and the right to autonomy are the cornerstones upon which Justice Cardozo explained the doctrine of informed consent. “Every human being of adult years and sound mind has a right to determine what shall be done with his own body and a surgeon who performs an operation without consent commits an assault and is liable for damages.” *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914). In other words, consent is meaningless unless the individual understands the medical treatment or procedure that is being offered, including the risks, benefits, and available alternatives, and has every opportunity to accept or refuse the treatment or procedure.

Here, Petitioners argue that the President's COVID-19 vaccine mandates coerced participation in an unethical human experiment. There is no question that the experimental COVID-19 vaccines are unavoidably unsafe for many people and carry great risk of irreparable physical harm, including death, in light of the latest CDC's VAERS data cited

above.

Further, coercion to accept COVID-19 vaccinations to date fails to offer adequate information about potential side effects under the FDA’s EUA process.¹⁵ In fact, the package inserts that normally contain important information on vaccine ingredients, safety and efficacy, as well as potential adverse reactions, are intentionally left blank, requiring the participant to locate “fact sheets” online that are difficult if not impossible to find.

Under the current circumstances, Petitioners argue that the President’s mandates and other coercive policies to compel non-consenting adults to participate in an ongoing medical experiment with unknown health consequences “represents a substantial interference with that person’s liberty.” *Washington v. Harper*, 494 U.S. at 229. The Supreme Court’s jurisprudence on personal autonomy makes clear that the due process clause of the Fourteenth Amendment specifically protects constitutional rights and liberties “so rooted in the traditions and conscience of our people as to be ranked fundamental and implicit in the concept of ordered liberty,” such that “neither liberty nor justice would exist if they were sacrificed.” *Moore v. City of East Cleveland*, 431 U.S. 494, 502 (1977). The Court has historically recognized that every person has a constitutionally-protected liberty interest under the due process clause to refuse unwanted medical treatment.

The right to personal autonomy in the context of experimental vaccines is clear under U.S. law, but the right to personal autonomy and private decision-making even in the context of approved vaccines is no less sacrosanct.

¹⁵ 21 U.S.C. § 360bbb–3 - Authorization for medical products for use in emergencies.

II. COVID-19 VACCINES HAVE NOT BEEN SHOWN TO BE EFFECTIVE, SAFE OR NECESSARY FOR CHILDREN.

Within a few months of the COVID-19 outbreak, scientists knew that risks were stratified according to age and underlying risk factors. Healthy people under age 50 were likely to experience COVID-19 in the same way as other coronaviruses — like a bad head cold or a flu that caused symptoms for less than a week. The elderly, by contrast — especially if they had underlying health problems like obesity, diabetes or chronic problems with their lungs, heart or kidneys — were more likely to get very sick or die. Even so, survival rates in the elderly remain 97 percent or better through age 79, falling to about 92 percent only for those aged 80 and above.¹⁶

While public health officials have insisted that COVID-19 vaccines are safe and effective, no governmental health agency or pharmaceutical company has provided scientific data to prove that COVID-19 vaccines are safe or effective for children. To the contrary, there is no compelling scientific evidence or public health rationale for vaccinating children against COVID-19. The CDC's own data show that 75 percent of all children have already acquired natural immunity to COVID-19 and that natural immunity provides a broader spectrum and more durable immunity than vaccine-induced immunity.¹⁷ As already noted by leading public

¹⁶ Megan O'Driscoll et al., *Age-specific mortality and immunity patterns of SARS-CoV-2*, 590 NATURE 140 (2021). <https://doi.org/10.1038/s41586-020-2918-0>.

¹⁷ Kristie E.N. Clarke et al., *Seroprevalence of Infection-Induced SARS-CoV-2 Antibodies — United States, September 2021–February 2022*, 71 MMWR 606 (2022). <https://www.cdc.gov/mmwr/volumes/71/wr/pdfs/mm7117e3-H.pdf>

health officials in March 2020, “Either children are less likely to become infected, which would have important epidemiologic implications, or their symptoms were so mild that their infection escaped detection, which has implications for the size of the denominator of total community infections.¹⁸ In fact, the risk of death to a healthy child is statistically zero.¹⁹ Further empirical evidence shows that healthy children are able to recover from COVID more easily than adults.²⁰

To make matters worse, a recent study indicated that COVID-19 vaccines only provide 12 percent effectiveness in limiting the already miniscule risk of COVID to children ages 5 to 11 after a 7-week observation period.²¹ Even the CDC admits that COVID-19 vaccines neither stop infection nor

¹⁸ Anthony S. Fauci, H. Clifford Lane & Robert R. Redfield, *Covid-19 Navigating the Uncharted*, 382 NEJM 1268 (March 26, 2020). <https://www.nejm.org/doi/full/10.1056/nejme2002387>.

¹⁹ A. L. Sorg et al., *Risk of Hospitalization, severe disease, and mortality due to COVID-19 and PIMS-TS in children with SARS-CoV-2 infection in Germany*, MEDRXIV (Nov. 30, 2021). <https://doi.org/10.1101/2021.11.30.21267048>.

²⁰ Kevin J. Selva et al., *Systems serology detects functionally distinct coronavirus antibody features in children and elderly*, 12 NATURE COMMUNICATIONS 2037 (2021). <https://doi.org/10.1038/s41467-021-22236-7>;

Alexander C. Dowell et al., *Children develop robust and sustained cross-reactive spike-specific immune responses to SARS-CoV-2 infection*. 23 NATURE IMMUNOLOGY 40 (2022). <https://doi.org/10.1038/s41590-021-01089-8>.

²¹ Vajeera Dorabawila et al., *Effectiveness of the BNT162b2 vaccine among children 5-11 and 12-17 years in New York after the Emergence of the Omicron Variant*, MEDRXIV (Feb. 28, 2022). <https://www.medrxiv.org/content/10.1101/2022.02.25.22271454.v1.full.pdf>

prevent transmission.²² Moreover, administering a COVID-19 vaccine carries real risk of potential adverse events, including death.

The FDA has also acknowledged that COVID-19 vaccines may cause myocarditis, a potentially fatal heart condition.²³ The CDC's own preliminary data show that there has been an increased risk of myocarditis in children following COVID-19 vaccination.²⁴ In fact, as of February 4, 2022, nearly half of children diagnosed with myocarditis still had symptoms three months later, and 39 percent of those children had to restrict their activity. Sadly, even some previously healthy child athletes have died from heart failure after mandated COVID-19 vaccination.²⁵ Despite the evidence that these risks far outweigh any benefits of COVID-19 vaccination in

²² *Science Brief: COVID-19 Vaccines and Vaccination*, CDC.GOV (Sept. 15, 2021). <https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html>.

²³ FDA, *Letter to Pfizer Inc.*, Aug. 23, 2021. <https://www.fda.gov/media/151710/download>

²⁴ *Myocarditis Outcomes Following mRNA COVID-19 Vaccination*, CDC.GOV (Feb. 4, 2022). https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2022-02-04/04_COVID-Kracalic-508.pdf;

Gilbert T. Chua et al., *Epidemiology of Acute Myocarditis/Pericarditis in Hong Kong Adolescents Following Comirnaty Vaccination*, CLINICAL INFECTIOUS DISEASES: ciab989 (Nov. 28, 2021). <https://doi.org/10.1093/cid/ciab989>;

Katie A. Sharff et al., *Risk of Myopericarditis following COVID-19 mRNA vaccination in a Large Integrated Health System: A Comparison of Completeness and Timeliness of Two Methods*, MEDRXIV (Dec. 27, 2021). <https://doi.org/10.1101/2021.12.21.21268209>

²⁵ Mordechai Sones, *5-fold increase in sudden cardiac and unexplained deaths among FIFA athletes in 2021*, AMERICA'S FRONTLINE DOCTORS (Nov. 18, 2021). <https://americasfrontlinedoctors.org/2/frontlinenews/500-increase-in-sudden-cardiac-and-unexplained-deaths-among-fifa-athletes-in-2021/>.

children, public health officials continue to push the shots.

It is bitterly ironic that when physicians can customize chemotherapy to the genome of particular tumors, and integrative medicine is gaining traction to evaluate each patient individually, the world is being pushed to take COVID-19 injections studied only in extremely healthy, young adults. People with comorbid conditions or autoimmune disease, and pregnant and breastfeeding women, were specifically excluded from the initial clinical trials. In addition, most older people experience immunosenescence²⁶ and were excluded from initial trials.²⁷ Although most children have robust innate immune systems, they too were excluded because, when it comes to the health and safety of our children, even a small risk is not worth taking if the potential consequences include serious or fatal short-term outcomes or life-long health and financial consequences. It is impossible to overstate the imminent danger that America's children now face from the government's unprecedented coercive vaccine policies and mandates. If history is any indicator, COVID-19 vaccines likely will be placed on the CDC's recommended childhood vaccine schedule, opening the door for state mandates. Once that happens, America's children may be irreparably harmed, changing the trajectory of children's lives forever. Studies already show that, after receiving COVID-19 vaccines, once-healthy adolescents have experienced

²⁶ Immunosenescence means that older individuals are more vulnerable to a variety of viral, bacterial, and fungal infections as they age.

²⁷ Anna Aiello et al. *Immunosenescence and its hallmarks: How to oppose aging strategically? A review of potential options for therapeutic intervention*. FRONT IMMUNOL. (Sept. 25, 2019). <https://doi.org/10.3389/fimmu.2019.02247>.

blood clots, uncontrolled bleeding, paralysis, abnormal menses, extreme fatigue, and death. The actual science shows that not only are COVID-19 vaccines unnecessary and ineffective in children and teens, but they can be harmful and even deadly.²⁸

The risk of suffering an adverse event after vaccination, particularly in children, clearly outweighs any potential benefits.

III. THE GOAL OF “HERD IMMUNITY” IS UNATTAINABLE THROUGH VACCINATION AND DOES NOT JUSTIFY VACCINE COERCION.

“Herd immunity” is a largely theoretical concept, yet for decades it has furnished one of the key underpinnings for vaccine mandates. Public health officials borrowed the herd immunity concept from observation of natural disease outbreaks and applied the concept to vaccine-acquired immunity.²⁹ Officials argue that when a sufficient proportion of the population is vaccinated against a particular disease, and are therefore theoretically immune to it, the disease will disappear.³⁰

However, actual “herd immunity” and disease eradication is almost never achievable through vaccination under real-world conditions for several reasons. First, vaccines often fail to perform in the manner predicted for everyone who receives a vaccination. For example, the phenomenon of “primary vaccine failure” occurs in at least 2 to 10

²⁸ Vinay Prasad et al, *CDC's All-or-Nothing Approach to Teen COVID Vaccination Is All Wrong*, MEDPAGE TODAY (June 29, 2021). <https://www.medpagetoday.com/opinion/second-opinions/93340>.

²⁹ Caceres, *The Misunderstood Theory of Herd Immunity*, *supra*.

³⁰ *Id.*

percent of healthy individuals; these individuals are “non-responsive” to a given vaccine, meaning that they fail to mount “sufficient protective antibody responses” after either the initial vaccine or a booster shot.³¹

Further, the concept of “waning immunity” in the context of vaccination is real. It means that the duration of vaccine-acquired immunity is often short. A short duration, as is the case with COVID-19 vaccines, can have a considerable impact on the epidemiological patterns of infectious disease. A short duration of vaccine-acquired immunity means that any “herd immunity” acquired through vaccination wanes over time.³²

In addition to the short-term viability of vaccine-induced “herd immunity” and the impact of vaccine failure on a significant minority, there are numerous examples of vaccine failure that not only make herd immunity nearly impossible to achieve but also permit the occurrence of illness in highly or even fully vaccinated populations. There are numerous examples of this phenomenon spanning decades. For example, there was a measles outbreak in a Texas high school in 1985 where 99 percent of the students had been vaccinated and 96 percent had detectable measles antibodies. The authors of the outbreak report acknowledged that “such an outbreak should

³¹ Ursula Wiedermann, Erika Garner-Spitzer, & Angelika Wagner, *Primary vaccine failure to routine vaccines: Why and what to do?*, 12 HUMAN VACCINES AND IMMUNO-THERAPEUTICS 239 (Feb. 7, 2015). <https://www.Tandfonline.com/doi/full/10.1080/21645515.2015.1093263/>.

³² Tiffany Leung et al, *Infection-acquired versus vaccine-acquired immunity in an SIRWS model*, 3 INFECTIOUS DISEASE MODELING 118 (2018). <https://www.sciencedirect.com/science/article/pii/S2468042718300150?via%3Dihub>.

have been virtually impossible.”³³ Similarly, in December 2019, a pertussis outbreak closed a Texas school despite a 100 percent vaccination rate.³⁴

The denial of any individual’s right to bodily autonomy because of herd immunity is unjustifiable. The goal of vaccine-induced herd immunity cannot serve as the basis for overriding any individual’s right to personal autonomy when mass vaccination does not provide society-wide immunity. COVID-19 mandates are particularly irrational as science now establishes that they do not stop infection or transmission but merely prevent severe disease, although even this claim is questionable.

IV. PUBLIC INTEREST REQUIRES THAT PUBLIC HEALTH OFFICIALS CONDUCT A SCIENTIFIC STUDY BASED ON TRUE CONTROLS COMPARING HEALTH OUTCOMES OF THE UNVACCINATED VS. THE VACCINATED.

Can a control group of fully unvaccinated adults and children, such as the Petitioners, establish a cause-and-effect relationship between vaccination and the debilitating health conditions of vaccinated Americans? Vaccine mandates have always been contentious, but COVID-19 vaccine mandates have highlighted the issue as never before. The legitimacy of compulsory vaccination raises fundamental legal, medical, and ethical issues for all Americans.

³³ Tracy L. Gustafson et al., *Measles outbreak in a fully immunized secondary-school population*. 316 NEJM 771 (Mar. 1, 1987) <https://www.nejm.org/doi/full/10.1056/NEJM198703263161303>.

³⁴ Madeline Farber, *Whooping cough outbreak closes Texas school despite 100 percent vaccination rate: officials*. FOX NEWS (Dec. 19, 2019). <https://www.foxnews.com/health/whooping-cough-outbreak-texas-catholic-school/>.

Fully unvaccinated individuals such as Petitioners, who have avoided all vaccinations, including those for COVID-19, demand that public health agencies conduct unbiased clinical studies for vaccine safety and efficacy that include comparison of the health outcomes between highly vaccinated and completely unvaccinated individuals. Despite a compelling need for an objective peer-reviewed study or randomized clinical trial between the wholly unvaccinated and highly vaccinated, such a study has never been performed. Petitioners demand a higher standard for clinical trials to advance public health.

The bedrock of ethical medicine requires a well-established balancing test that shows whether the medical intervention's benefits outweigh its risks. The very foundation for the FDA's drug regulatory review of the human drug and biologics process is based upon a risk/benefit assessment throughout the drug development life-cycle, including premarket and post-market phases.³⁵ Simply stated, if a new drug or biologic is discovered not to be safe or effective for its intended purpose, then it is the FDA's duty to withdraw its authorization or approval. The Food, Drug and Cosmetic Act (Act) authorizes the Secretary of the Department of Health and Human Services, an executive agency, to immediately suspend a new drug or biologic upon finding an imminent hazard to public health after due notice and opportunity for hearing.³⁶

The FDA is a watchdog agency designed to

³⁵ See *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022*, FDA.GOV, <https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUser/UCM511438.pdf>.

³⁶ 21 U.S.C. §355(d)(1)-(2),(4)-(5).

protect the public from any drugs or biologics found to be unsafe or ineffective, yet the FDA relies upon data and studies conducted by the very manufacturers who create the drugs and biologics and who earn significant profits from their marketing. Unfortunately, not only does the FDA rely upon biased, market-driven safety and efficacy studies when approving new drugs and biologics, but it takes much too long to identify and recall dangerous drugs. History is littered with examples where FDA-approved drugs have caused serious adverse events and even death in an unsuspecting public. For example, pharmaceutical manufacturers' blockbuster drugs from Vioxx to Fen-phen to Lymerix, have settled some of the biggest healthcare product liability settlements ever due to the industry's trend for the ascension of marketing over science. In these particular cases, the pharmaceutical company ignored early warning signs that their drug was causing serious adverse events and even death in some of the patients. Although the FDA has the authority to take these dangerous drugs or biologics off the market, drug recall can be a slow process when company executives and government regulators share conflicts of interest and place profits over people.³⁷

V. THE MISUNDERSTOOD LEGACY OF *JACOBSON V. MASSACHUSETTS.*

The legal edifice shoring up America's compulsory vaccine program relies on a century-old Supreme Court decision. In the 1905 case of

³⁷Harlan M. Krumholz et al., *What Have We Learnt from Vioxx?* 2007 BMJ 334 (January 18, 2007). <https://doi.org/10.1136/bmj.39024.487720.68>.

Jacobson v. Massachusetts, 197 U.S. 11 (1905), the Court balanced an individual’s liberty interest in declining an unwanted smallpox vaccine against the State’s interest in public health. The Court upheld the Massachusetts Supreme Court decision that the individual who refused the vaccine had to pay a fine for noncompliance. *Id.* at 19. Although the *Jacobson* Court endorsed a monetary fine for failure to comply, the Court also admonished: “[W]e deem it appropriate ... to observe ... that the police power of a State, whether exercised by the legislature, or by a local body acting under its authority, may be exerted in such circumstances or by regulations so arbitrary and oppressive in particular cases as to justify the interference of the courts to prevent wrong and oppression ... All laws should receive a sensible construction. **General terms should be so limited in their application as not to lead to injustice, oppression, or absurd consequence.**” [emphasis added]. *Id.* at 38–39.

Here, *Jacobson* provides robust cautionary language calling attention to the potential for arbitrary and oppressive abuse of the police power and warning against going “far beyond what [is] reasonably required for the safety of the public, as to authorize or compel the courts to interfere for the protection of such persons.” *Id.* at 28. “If they [public health officials] act in an arbitrary manner, depriving any individual of a right protected by the Fourteenth Amendment, their action in such individual case is void.” *Id.* at 20.

The *Jacobson* Court urged future courts to be vigilant to examine and thwart unreasonable assertions of state power.³⁸ Notably, even before the

³⁸ *Vaccine Mandates: An Erosion of Civil Rights?* CHILDREN’S HEALTH DEFENSE (Nov. 2020). <https://childrenshealthdefense>.

Nuremberg Code, the Court did not condone forced vaccination but rather imposed a relatively modest monetary fine for non-compliance.

Rather than follow the *Jacobson* Court’s cautionary words to support only limited, monetary penalties for non-compliance, state courts and later the Supreme Court expanded *Jacobson* beyond the notion of imminent danger or necessity. For example, in 1916, Alabama³⁹ and Kentucky⁴⁰ courts allowed states to mandate vaccination for prevention of smallpox epidemics, stating that state Boards of Health were not required to wait until an epidemic actually existed before taking action. The Alabama court also broadened the rationale for mandates to children. Decisions in Mississippi⁴¹ and Texas⁴² in the early 1930s granted public health authorities the leeway to define public health emergencies in whatever manner they saw fit. A New Jersey court in the late 1940s interpreted *Jacobson* as justifying all vaccine mandates, disregarding its language to reject “unreasonable, arbitrary and oppressive” state actions. *Jacobson v. Massachusetts*, 197 U.S. at 17. An Arkansas court in the early 1950s suggested that anyone questioning vaccine safety or efficacy should lodge objections with the Board of Health rather than the court. *Seibold v. Ft. Smith Special School Dist.*, 218 Ark. 560 (1951).

In 1922, in the three-paragraph *Zucht v. King* decision, the U.S. Supreme Court upheld vaccine mandates as a condition for public school attendance, further expanding *Jacobson* by allowing a mandate

org/wp-content/uploads/ebook-vaccine-mandates-an-erosion-of-civil-rights-english.pdf

³⁹ *Herbert v. Bd. of Educ.*, 197 Ala. 617 (1916).

⁴⁰ *Board of Trustees v. McMurtry*, 169 Ky. 457 (1916).

⁴¹ *Hartman v. May*, 168 Miss. 477 (1934).

⁴² *Texas Employers' Ins. Ass'n v. Mitchell*, 27 S.W.2d 600 (1930).

exclusively for children rather than the entire population. *Zucht v. King*, 260 U.S. 174 (1922).

Although vaccination mandates had become legally well-entrenched by the mid-1950s — regardless of emergency and all but erasing *Jacobson*'s cautionary language — this legal framework emerged in the context of a single vaccine for smallpox, a contagious, life-threatening disease. Notably, this Court has not revisited *Jacobson* in light of its subsequent jurisprudence on the right to bodily integrity or the right to privacy, articulated in the 1965 *Griswold v. Connecticut* decision and beyond. *Griswold* held specifically that “the Fifth Amendment ... enables the citizen to create a zone of privacy which government may not force him to surrender to his detriment.” *Griswold v. Connecticut*, 381 U.S. 479, 484 (1965).

Sadly, today's public health agencies have breached America's trust from conflicts of interest and corporate greed that fuel collusion between the pharmaceutical industry and government regulators. Further, *Jacobson*'s legal framework moves towards obsolescence in light of vast changes in medicine and constitutional law since 1905. The threat of loss of bodily autonomy causes irreparable harm to Petitioners. “[E]ven in a pandemic, the Constitution cannot be put away and forgotten.” *Roman Catholic Diocese v. Cuomo*, 141 S.Ct. 63; 208 L.Ed.2d 206 (2020).

Acting as a control group of fully *unvaccinated* individuals, Petitioners seek the Court's intervention to uphold their right to refuse participation in the COVID-19 vaccine campaign currently underway and in the vast array of government-mandated vaccination requirements.

CONCLUSION

For the foregoing reasons, *Amicus* respectfully requests that the Court issue a writ of certiorari and affirm Petitioners’ fundamental right to bodily integrity.

Respectfully submitted,

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