# PROTECTING INDIVIDUAL RIGHTS

# in the Era of COVID-19

Children's Health Defense

December 2020

# EXECUTIVE SUMMARY

- Compulsory vaccination violates fundamental human rights, notably the right to prior, free and informed consent for medical interventions. Common law, state and federal statutes, the Nuremberg Code (1947), and the 2005 UNESCO Declaration on Bioethics and Human Rights establish the necessity of informed consent.
- COVID-19 must not become a pretext for forced vaccination.
- The legal edifice shoring up compulsory vaccination rests on a Supreme Court decision that is more than a century old. Subsequent lower court decisions about vaccine mandates differ radically from what the Supreme Court envisioned and have led to results that fail to safeguard health and individual rights.
- Twentieth-century progress in sanitation, hygiene, refrigeration, and the provision of clean water produced dramatic declines in infectious disease. The decline in infectious disease had little to do with vaccination.
- Vaccines cause injuries and death that are far from "rare" or "one in a million." A 2010 study commissioned by the Department of Health and Human Services (HHS) reports at least one vaccine injury for every 39 vaccines given.
- The Vaccine Adverse Event Reporting System (VAERS) does an extremely poor job of capturing adverse events, with fewer than 1% reported. The CDC refuses to take recommended steps to strengthen VAERS data.
- A flawed and corrupt regulatory process enables vaccine safety shortcuts and fraud. No clinical trial for vaccines given to babies and toddlers has used an inert placebo control group, and most trials have followed young recipients for only a few days or weeks.
- Under the 1986 National Childhood Vaccine Injury Act (NCVIA), vaccine manufacturers and healthcare providers cannot be held liable for vaccine injuries from federally recommended vaccines. The Act allows companies to escape scrutiny and the document discovery associated with litigation.
- Under the 2005 Public Readiness and Emergency Preparedness (PREP) Act, manufacturers, healthcare providers, and government officials will be immune from liability for potential COVID-19 vaccine injuries and deaths. Compensation through its Countermeasures Injury Compensation Program is likely to be minuscule.
- HHS has a statutory obligation to study vaccine injuries, improve vaccine safety, and report biannually to Congress—but it has never once done so in over 30 years.
- The National Vaccine Injury Compensation Program, also created in 1986, pits vaccine-injured claimants against HHS in an adversarial and usually unsuccessful process. In over three decades, the program has compensated only a third of the petitions filed. Even so, compensation awarded to date exceeds $4.4 billion.

- Vaccine-induced immunity—if it occurs at all—wanes over time, sometimes rapidly. Outbreaks of conditions such as measles, mumps, pertussis, and chickenpox in highly vaccinated populations are not uncommon. Herd immunity and disease eradication cannot be reliably achieved through vaccination.
- American children have never been sicker. The passage of the NCVIA enabled an explosion of liability-free vaccines and one of the most aggressive childhood vaccine schedules in the world. Over half (54%) of American children now develop at least one chronic health condition, and many have multiple health challenges.
- COVID-19 vaccines include gene-altering and inflammation-promoting technologies that may create genetic changes that may pass to future generations. Lawyers must not provide cover for liability-free medical interventions that carry profound unknown, de facto experimental risks.


## Introduction

Compulsory vaccination violates fundamental human rights, including the right to prior, free, and informed consent to all medical interventions. Children's Health Defense strongly supports the right of individuals to make voluntary choices regarding vaccines with the healthcare providers of their choice.

International human rights agreements provide a critical point of departure for understanding the centrality of informed consent. The Nuremberg Code—arising in the aftermath of World War II medical atrocities—codified the principle of voluntary consent, describing it as "absolutely essential."[1] In the context of experimentation on human subjects, the Code states that persons should be able to exercise "free power of choice":

> *[W]ithout the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraints or coercion.*

In 2005, the UNESCO Declaration on Bioethics and Human Rights extended the consent principle to "any preventive, diagnostic and therapeutic medical intervention," stating that such interventions are "only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information."[2] These principles represent the cornerstone of modern medical ethics.

In addition, federal and state statutes and common law protect informed consent, the right to refuse unwanted medical interventions, autonomy, bodily integrity, free exercise of religion, parental rights, and many other relevant rights.

## COVID-19: A Pretext for Medical Coercion?

On May 13, 2020, the New York State Bar Association (NYSBA)—the nation's largest—issued a report on COVID-19.[3] In a report written by its Health Law Section Task Force, the NYSBA took the extraordinary step of recommending that mandatory vaccination for

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COVID-19 be required not just in New York State but in the entire United States as soon as the "efficacy of a COVID-19 vaccine has been confirmed" (pp. 60 and 82). The three pages focused on vaccination argued that such a measure would be "supported by the authority of the state police power"—but said nothing about the Nuremberg Code, informed consent, bodily integrity, free exercise of religion, privacy, parental rights, the right to refuse unwanted medical interventions, equal protection, due process, or the doubtful safety of a novel COVID-19 vaccine (admittedly being developed at warp speed) that did not then exist.[4]

A month later (June 12), in response to strong pushback from many corners, the NYSBA softened its pro-mandate wording somewhat and then, on June 13, deferred formal consideration of the amended report until November 7, 2020.[5] The June language added mention of "safety," "scientific evidence," and "testing" but continued to support mandatory vaccination if deemed "necessary" by unelected public health authorities, recommending:

> *That a vaccine ["after testing and as supported by scientific evidence"], subject to scientific evidence of safety and efficacy, be made widely available, and widely encouraged, and if the public health authorities conclude necessary, required, unless a person's physician deems vaccination to be clinically appropriate.*

At the November 7 meeting, the NYSBA went ahead and endorsed a resolution to "consider" a COVID-19 vaccine mandate, "as may be necessary"; under such circumstances, the Bar Association stated that it would expect "due consideration of the expert medical and scientific consensus


regarding the safety and efficacy of a vaccine and the need for required inoculation." The NYSBA's vaguely worded resolution remains unsupportable because mandates violate the fundamental principle of prior, free, and informed consent.

## Compulsory Vaccination Rests on a Shaky Legal Edifice

The legal edifice shoring up compulsory vaccination in the U.S. relies primarily on two century-old Supreme Court decisions: *Jacobson v. Massachusetts,* 197 U.S. 11 (1905)[6] and *Zucht v. King,* 260 U.S. 174 (1922).[7] The narrow *Jacobson* decision justified an adult mandate of one vaccine for one disease (smallpox) "on an emergency basis" and under circumstances of "imminent danger." It did *not* give a green light to forced vaccination but instead concurred with Massachusetts' imposition of a $5 fine (the equivalent of about $145 currently) on adults refusing or neglecting to comply with smallpox vaccination requirements. *Jacobson v. Massachusetts* explicitly left children out of the mandate as being too vulnerable. Moreover, *Jacobson* contained robust cautionary language that called attention to the potential for "arbitrary and oppressive" abuse of police power.

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In 1922, the curt *Zucht v. King* decision—only three paragraphs


long—sanctioned vaccine mandates as a condition for public school attendance, shifting legal attention away from *Jacobson's* focus on adults. That decision represents the last time that the Supreme Court has reviewed the issue of compulsory vaccination directly. Subsequent lower-court decisions about childhood vaccine mandates are radically different from what the 1905 Supreme Court envisioned and have led to perverse results that do not safeguard children's rights and health.[8]

While *Jacobson* articulates several criteria to limit vaccine mandates or other emergency measures to situations of grave danger and demands that courts strike down arbitrary and oppressive actions, courts have in fact upheld almost all vaccine mandates and several odious government acts in the name of *Jacobson's* emergency powers. For instance, the U.S. Supreme Court, in *Buck v. Bell*, 247 U.S. 200 (1927),[9] held that forced sterilization was lawful, even though it is recognized as an international war crime today (Rome Statute of the International Criminal Court, Art. 8(2)(b) xxii)).[10] In 1947, resting on emergency powers, the U.S. Supreme Court upheld a California statute to intern loyal, peaceful citizens of Japanese descent by reason of their ancestry alone, in *Korematsu v. United States*, 323 U.S. 214 (1944).[11] Decades later, the U.S. government officially apologized for the act and awarded compensation to survivors.[12] Lawyers, in particular, must be skeptical of government's emergency claims that deprive citizens of fundamental rights.

## Context Is Relevant

The context for health and disease has changed fundamentally since the Supreme Court's 1905 decision.[13] In 1905, household-level indoor plumbing was extremely rare (reaching 1% of U.S. homes only by 1920),[14] there was no electricity and thus no refrigerators to preserve fresh food, and antibiotics had not yet been invented. Historical evidence shows that as the U.S. made progress in sanitation, hygiene, refrigeration, and the provision of clean water, the nation experienced dramatic declines in infectious disease—and contrary to popular belief,

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these declines had little, if anything, to do with vaccination.[15] Civil engineers, not vaccine scientists, produced the gains in life expectancy witnessed over the 20th century.[16] When low-income countries implement water, sanitation, and hygiene interventions, they achieve similarly remarkable health improvements.[17]

Citizens in the early 20th century had valid reasons for rejecting smallpox vaccination. In a book published in 1899, a doctor reported that smallpox mortality doubled (going from roughly 7% to 15%) *after* adoption of smallpox vaccination.[18] From 1900-1904, the U.S. case fatality rate (the proportion of persons with a disease who die from that disease) for the most serious form of smallpox was about 16.5%.[19] (In comparison, the observed case-fatality ratio for confirmed COVID-19 cases is currently estimated at about 2.4%.)[20]

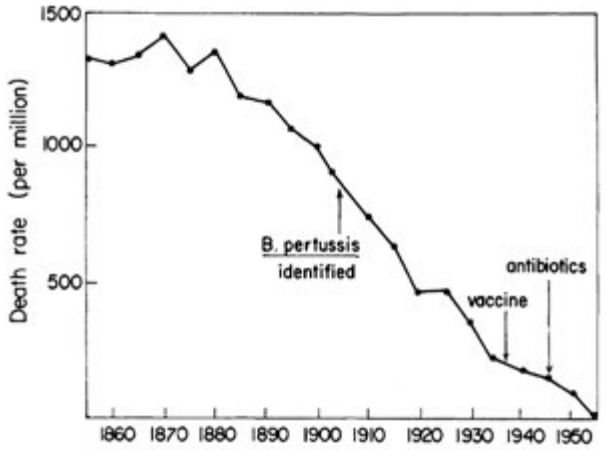
Reflecting on European smallpox outbreaks, the doctor writing in 1899 stated that faith in vaccination received a "rude shock" when "[e]very country in Europe was invaded with a severity greater than had ever been witnessed during the three preceding centuries."[21] He also noted that "many vaccinated persons in almost every place were attacked by small-pox before any unvaccinated persons took the disease." In this physician's estimation, these facts alone were "sufficient to overthrow the entire theory of the protective efficacy of vaccination."

## Vaccine Injuries and Deaths Are Not Uncommon

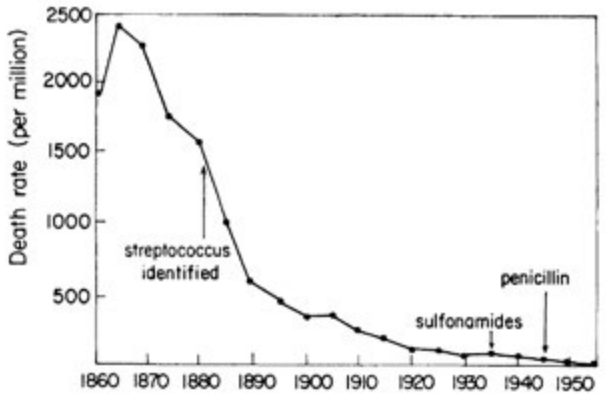
A century after the smallpox era, vaccines continue to cause injuries and death—and despite what vaccine manufacturers and public health officials would like us to believe, the risk of adverse outcomes is far from "rare" or "one in a million." A 2010 Agency for Healthcare Research and Quality (AHRQ) study sponsored by the U.S. Department of Health and Human Services (HHS) reported at least one vaccine injury for every 39 vaccines given.[22]

The Vaccine Adverse Event Reporting System (VAERS) provides a further window into vaccine-related injuries and deaths.[23] VAERS is a "passive" surveillance system—meaning a system that receives voluntary reports submitted by doctors and patients but which does not actively monitor injuries and deaths. The 2010 AHRQ study found that VAERS does an extremely poor job of capturing vaccine adverse events, with fewer than 1% reported.[24] Even so, in 2019 alone, VAERS received 58,049 reports of adverse events following vaccination, including 5,072 hospitalizations, 1,498 permanent disabilities, and 608 deaths.

Mean annual death rate from measles in children under 15 years of age, England and Wales.



Mean annual death rate from whooping cough in children under 15 years of age, England and Wales.



Mean annual death rate from scarlet fever in children under 15 years of age, England and Wales.

Both the Centers for Disease Control and Prevention (CDC) and the U.S. Food and Drug Administration (FDA) like to criticize VAERS (which they jointly run), stating that "VAERS data interpreted alone or out of context can lead

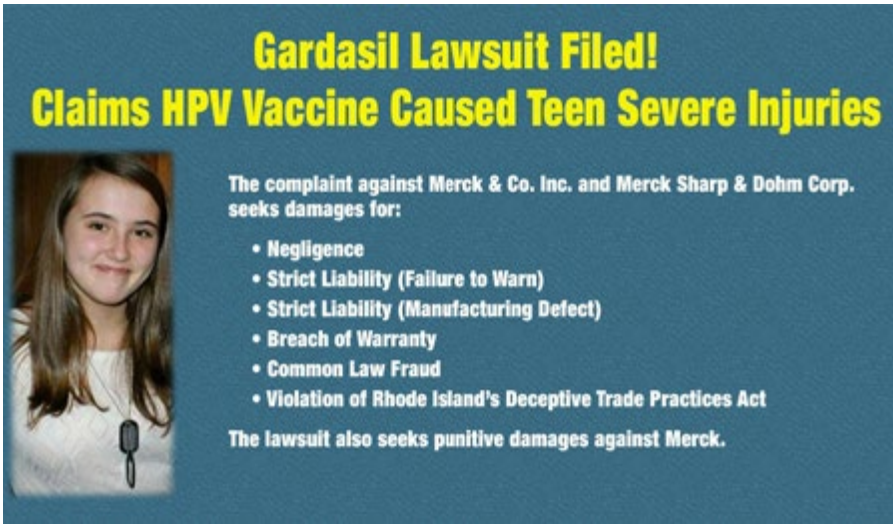
to erroneous conclusions."[25] However, the CDC refuses to take recommended steps to strengthen VAERS data—measures urged by its own consultants.[26] As the Informed Consent Action Network (ICAN) asked in a December 2018 letter to the HHS Secretary and the Acting Director of the National Vaccine Program Office,

> *The fact that HHS has refused to automate this process leads to the question of whether the decision to keep VAERS as a passive reporting system is intentional in order to hamper its ability to provide reliable information regarding the rate at which a given injury occurs after a given vaccine.*[27]

## Questionable Assertions of Vaccine Safety

Even with its inadequacies, it is evident that VAERS represents the tip of a massive vaccine injury iceberg. A flawed and corrupt regulatory process enables this situation. The FDA licenses U.S. vaccines as "biologics" rather than drugs. As a result (as explained in an October 2017 ICAN white paper):

> *[V]accines are not required to undergo long-term double-blind inert-placebo controlled trials to assess safety. In fact,* ***not a single one*** *of the clinical trials for vaccines given to babies and toddlers had a control group receiving an inert placebo. Further, most pediatric vaccines currently on the market have been approved based on studies with inadequate follow-up periods of only* ***a few days or weeks.*** *[…] Follow-up periods of 4 or 5 days are not nearly long enough to detect possible adverse effects such as autoimmune or neurological disorders, seizures, or death.*[28] [Emphasis added]




Problems with vaccine safety regulation go beyond inadequate study designs to include alleged fraud committed with the complicity of captured regulators.[29] A current civil case is proceeding on behalf of a young woman (now in her mid-20s) who has suffered from systemic autoimmune dysregulation since receiving, at age 16, a third dose of the HPV vaccine Gardasil.[30] The case alleges that Merck (Gardasil's manufacturer) "committed fraud during its clinical trials and then failed to warn [vaccine recipients] about the high risks and meager benefits of the vaccine." The FDA not only gave Gardasil the green light, despite extensive problems that should have attracted its attention, but granted approval on a fast-tracked basis, later okaying Gardasil for additional age groups and uses.[31] In fiscal year 2019, 50% of the FDA's budget for medical product safety (including vaccines) came from pharmaceutical industry "user fees."[32] In essence, the industry pays FDA regulators' salaries and has the clout that goes along with the money.

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## Vaccine Companies Are Not Liable for Their Products

Not only do vaccines, as "biologics," bypass the more rigorous and lengthy safety testing required of non-vaccine drugs, but federally recommended

childhood and adult vaccines hold the unparalleled status of being completely exempt from product liability. As a result of the National Childhood Vaccine Injury Act (NCVIA) passed in 1986,[33] vaccine manufacturers and healthcare providers cannot be held liable for vaccine injuries—"no matter how toxic the ingredients, how negligent the manufacturer or how grievous the harm"[34]—if caused by vaccines recommended for routine child or adult use by the CDC's Advisory Committee on Immunization Practices (ACIP). By forestalling lawsuits, the Act and *Bruesewitz v. Wyeth*,[35] a 2011 Supreme Court decision interpreting it, allow vaccine companies to escape the scrutiny and document discovery associated with litigation.

HHS has a statutory obligation to study vaccine injuries and take measures to improve vaccine safety. The NCVIA established this legal obligation because Congress recognized that with the removal of liability, companies would no longer have any incentive to make vaccines safe. Though HHS must report to Congress every two years on its vaccine safety efforts, a U.S. district court found that HHS had never done so even once in over 30 years.[36] [37]

## Obtaining Compensation for Vaccine Injuries Is an Uphill Battle

To placate vaccine-injured consumers, Congress created the National Vaccine Injury Compensation Program (NVICP) as part of the 1986 Act.[38] The NVICP is a highly flawed program funded through an excise tax on childhood vaccines. Despite Congress's professed intent to create a non-adversarial, "accessible and efficient forum for individuals found to be injured by certain vaccines,"[39] nothing could be further from how the NVICP actually

operates. In practice, the NVICP pits HHS—supported by a fleet of Department of Justice (DOJ) lawyers—as adversaries against vastly outflanked petitioners. In over three decades—with 22,507 total petitions filed—only 7,666 (34%) have been determined compensable, while the rest have lost or been dismissed.[40] Even so, the compensation awarded to date exceeds $4.4 billion.[41]

NVICP petitioners face a three-year statute of limitations (from the time of the vaccine injury) and a strenuous burden of proof, particularly if—as is the case 99% of the time—the illness, injury, or condition does not fall within the narrow parameters of the NVICP's Vaccine Injury Table.[42] Moreover, HHS can, almost at will, "delete injuries and conditions for which compensation would be available and... change the applicable time periods by which the onset of symptoms must occur," further eliminating avenues to compensation.[43]

In 2007-2008, during an Omnibus Autism Proceeding (OAP) orchestrated on behalf of 5,400 families who had filed claims for vaccine-induced autism, allegedly fraudulent actions by DOJ lawyers resulted in

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dismissal of the claims.[44] Subsequent whistleblower evidence suggests that the lawyers concealed evidence and intentionally misrepresented the opinion of their own expert witness, who had shown how vaccines may cause autism in a subset of children.[45] The OAP claims' potential value (over $100 billion) "would have bankrupted the [compensation] program many times over."[46]

## Vaccine Immunity Is Short-lived and Often Ineffective

Up to 12% of vaccinated individuals never show any evidence of the antibodies that scientists consider the marker of vaccine-induced protection.[47] Moreover, taking the example of measles, even when a vaccine appears to "take," vaccinated individuals "have lower levels of measles-specific antibody than do those with immunity derived from exposure to wild-type" measles.[48]

Decades of experience prove that the notions of vaccine herd immunity and disease eradication through vaccination are illusory. Outbreaks of measles,[49] mumps,[50] pertussis,[51] and chickenpox[52] in highly vaccinated populations are not uncommon. It is well known that whatever artificial immunity a vaccine may mobilize wanes—sometimes rapidly—and additional boosters do not solve the problem. In a CDC study of 18-28 year-olds given a third dose of the measles-mumps-rubella (MMR) vaccine, protection petered out in less than a year, forcing the study's authors to argue against a routine third dose.[53] Because of vaccination, diseases now endanger age groups that were once well protected in the pre-vaccine era. For example, infants born to mothers who experience natural measles are protected, but babies born to measles-vaccinated mothers are not.[54]

## American Children Are Not Healthy

American children have never been sicker than today. The childhood epidemic of poor health escalated after 1986, coterminous with the passage of the National Childhood Vaccine Injury Act. With the corresponding explosion of liability-free childhood vaccines following passage of the 1986 Act, the U.S. now has one of the world's most aggressive childhood vaccine schedules.

The United States ranks 35th in overall health outcomes,[55] making it, by most measures (including infant mortality)[56] the sickest country in the developed world. About one in eight American children born in 1986 (12.8%) later developed a chronic condition,[57] but in the far more heavily vaccinated generation of children born after 1986, over half (54%) develop at least one chronic illness.[58] Prevalent conditions include neurodevelopmental and autoimmune disorders, asthma, allergies and obesity.

## More Immunity from Liability

Under the 2005 Public Readiness and Emergency Preparedness (PREP) Act, manufacturers, healthcare providers and even government policy makers will be fully immune from liability for COVID-19 vaccines. The PREP Act

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allows the HHS Secretary to issue a Declaration:

> *[T]hat provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats, and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency.*[59]

On February 4, 2020—with only 11 Americans documented with COVID-19 at the time—the HHS Secretary issued just such a Declaration (published on March 17 in the Federal Register),[60] placing eventual coronavirus vaccines under the PREP Act's liability-free umbrella and condemning those who are eventually injured or die from these "countermeasures" to the opaque and stingy Countermeasures Injury Compensation Program.[61]

## Who Decides?

There are many critical concerns that strongly weigh against mandates for COVID-19 vaccines—or any vaccine. In addition to the fundamental ethical principle of prior, free and informed consent, one cannot view mandates as ethical or lawful in a context that permits complete evasion of legal liability; permits serious conflicts of interest; relies on questionable science; censors inconvenient science; camouflages massive and likely unsolvable problems with safety and efficacy; and trounces constitutionally guaranteed individual rights.

COVID-19 vaccines raise even more urgent concerns. With the 21st-century fusion of pharma and biotech,[62] the developers of COVID-19 vaccines are seeking to deploy gene-altering and inflammation-promoting technologies that do not operate like medicines at all.[63] These technologies risk possibly permanent changes that could have dramatic implications for future generations.[64]

People must not let their professional associations be co-opted to provide cover for liability-free medical coercion at the expense of the unalienable individual rights to bodily integrity, free exercise of religion, privacy, parental rights, the right to refuse unwanted medical interventions, equal protection and due process.

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