REFORMING VACCINE POLICY & LAW
A GUIDE

National Vaccine Information Center
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INTRODUCTION

The informed consent and precautionary principles together serve as an ethical foundation for protecting consumer rights and ensuring product and patient safety. Founded in 1982 to prevent vaccine injuries and deaths through public education, the National Vaccine Information Center (NVIC) has worked since then to improve the safety of vaccines and vaccine policies, as well as to secure vaccine informed consent protections in U.S. public health policies and laws.¹

While the precautionary principle – “first, do no harm”- is central to the prevention of vaccine injuries and deaths, the informed consent principle is central to the ethical practice of medicine. The individual’s right to autonomy and exercise of voluntary, informed consent to medical risk-taking has been defined internationally as a human right since 1947, when the Nuremberg Tribunal at The Doctor’s Trial issued The Nuremberg Code to protect human subjects in scientific experiments.²

In the second half of the 20th century, affirmation of the human right to autonomy and the ethical principle of informed consent was increasingly applied to the treatment of patients by physicians. Without legal informed consent protections in the practice of medicine, the will of a powerful majority creating and implementing medical policy can lead to oppression of a vulnerable minority, especially if there are gaps in medical knowledge about genetic, biological, environmental or other high-risk factors that place some individuals at greater risk than others for suffering harm.

The National Vaccine Information Center (NVIC) defends the legal right of individuals and parents to have access to full and accurate information about the risks and complications of infectious diseases and vaccines and make voluntary health care decisions for themselves and their children.

“ All too will bear in mind this sacred principle, that though the will of the majority is in all cases to prevail, that will, to be rightful, must be reasonable: that the minority possess their equal rights, which equal laws must protect, and to violate would be oppression.”³

Thomas Jefferson
THE INFORMED CONSENT PRINCIPLE

AN ETHICAL GUIDE
The informed consent principle has guided the ethical practice of modern medicine since the mid-20th century. It has been incorporated into international and U.S. laws and regulations for human research subject protections, pharmaceutical and medical product labeling and medical care legal guidelines. Informed consent means that an adult or parent of a minor child must:

- **be given complete and accurate information** about the benefits and risks of a medical procedure or pharmaceutical product;
- **be free to make a voluntary decision** about whether or not to take the risk;
- **not be subjected to harassment, coercion or sanctions** for making an informed, voluntary decision about taking a risk.

Respect for the informed consent principle is essential when medical interventions associated with public health policy, such as government recommendations and requirements for vaccine use, may:

- **raise risks** for injury or death among susceptible individuals due to genetic, biological and environmental differences that may or may not be known;
- **fail** to work and provide intended benefits.

“The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.”

Nuremberg Code (1947)
THE PRECAUTIONARY PRINCIPLE

FIRST, DO NO HARM.
The precautionary principle is based on the “first, do no harm” approach to sound public policy decision-making. It acknowledges that humans are fallible and act in ways that can cause unintended serious, widespread and measurable harm to people, wildlife and the environment. The precautionary principle recognizes that harms have taken place or may take place because the full impact of a public policy may not be known before implementation due to:

- **SCIENTIFIC UNCERTAINTY;**
- **INCOMPLETE EVALUATION; AND**
- **LIMITED UNDERSTANDING**

of the range of potential negative effects on human health or the environment.

The precautionary approach focuses on how much harm can be prevented from the policy or law and not how much harm is acceptable. Respect for the precautionary principle is especially important when doctors cannot reliably predict ahead of time which individuals will be harmed when a medical intervention, such as vaccination, becomes public health policy or law.
VACCINES FEDERALLY RECOMMENDED & STATE MANDATED

Unlike prescription drugs administered to the sick, vaccines are pharmaceutical products primarily administered to healthy people. Like prescription drugs, vaccines carry two risks and those risks can be greater for some than others: first, vaccines may cause injury or death from complications; and second, vaccines may fail to prevent infection and transmission of infection.

IN THE U.S., VACCINES ARE:

- **Developed** by federal health agencies and private drug companies;
- **Manufactured** and sold by private drug companies;
- **Licensed** by the federal Food and Drug Administration (FDA);
- **Recommended** for universal use by the federal Centers for Disease Control (CDC) and private medical trade associations, such as the American Academy of Pediatrics (AAP) and American Medical Association (AMA);
- **Mandated** in most cases by state legislatures or state health officials through agency rulemaking;
- **Required** as a condition of employment for adults by some private corporations or state agencies operating hospitals, schools and other public facilities;
- **Shielded** by Congress and the U.S. Supreme Court from pharmaceutical corporation product liability and physician malpractice civil lawsuits when vaccinations cause the injury or death of an individual.

Like prescription drugs, vaccines carry two risks and those risks can be greater for some than others.
THE NATIONAL
CHILDHOOD VACCINE
INJURY ACT OF 1986

In 1986, Congress passed the National Childhood Vaccine Injury Act in response to calls by the pharmaceutical industry, American Academy of Pediatrics and other medical trade groups to completely shield drug companies and doctors from civil product liability and malpractice lawsuits for injuries and deaths caused by DPT, polio, MMR or other vaccines federally recommended and state mandated for children. The 1986 Act was a historic acknowledgment by the U.S. government that vaccines can cause injury and death. The law did not shield doctors and other vaccine providers from medical malpractice lawsuits and did not protect drug companies from design defect product liability lawsuits when it was enacted in 1986. However, over several decades, the law was substantially eroded by congressional amendments, federal agency rulemaking and a 2011 U.S. Supreme Court ruling that eliminated all product liability for vaccine manufacturers.

NEARLY $5 BILLION IN VACCINE INJURY COMPENSATION.
The 1986 law created a federal vaccine injury compensation program (VICP) for persons who have been injured or died after receiving federally recommended and state mandated childhood vaccines. By January 2022, nearly five billion dollars in federal compensation had been paid for vaccine injuries and deaths, even though two out of three applicants are denied compensation and very few children receive awards today.

VACCINE SAFETY PROVISIONS IGNORED.
The co-founders of NVIC worked with Congress to secure ground-breaking vaccine informing, recording, adverse reaction reporting and research provisions in the 1986 Act. Unfortunately, although doctors and all vaccine providers are protected from vaccine injury lawsuits, many do not comply with the 1986 law’s vaccine safety provisions. The Act does not provide for legal sanctions for pediatricians or other vaccine providers who fail to obey the federal law and:

**DO NOT** report serious health problems following vaccination to federal health officials;
**DO NOT** provide written vaccine risk/benefit information to parents or patients before vaccines are given; and
**DO NOT** record vaccine-related adverse events in the permanent medical record.

The National Childhood Vaccine Injury Act of 1986 was historic acknowledgment by the U.S. government that vaccines can cause injury and death.
MOST VACCINE REACTIONS ARE NOT REPORTED TO GOVERNMENT.

It is estimated that less than one percent of all serious health problems, hospitalizations, injuries and deaths that occur after vaccinations given to children or adults in the U.S. are ever reported to the federal Vaccine Adverse Events Reporting System (VAERS) created under the 1986 National Childhood Vaccine Injury Act. Instead of reporting to federal health agencies responsible for monitoring vaccine safety, most pediatricians and most vaccine providers either are not reporting at all or are sending vaccine reaction reports directly to vaccine manufacturers. As of January 14, 2022, there had been 1,915,359 vaccine-related adverse events reported to VAERS since the vaccine reaction reporting system became operational in 1990.

U.S. SUPREME COURT BARRED VACCINE INJURY LAWSUITS.

In 2011, a U.S. Supreme Court ruling effectively gave drug companies complete product liability protection when federally licensed vaccines recommended for children and mandated by states cause harm, even when there is evidence the vaccine was defectively designed. The ruling ignored the law’s legislative history, which demonstrated that Congress created the VICP as an administrative alternative to a lawsuit rather than an exclusive legal remedy. Provisions in the original law that was enacted in November 1986 allowed vaccine injured petitioners to file a lawsuit in civil court against negligent physicians or vaccine manufacturers if (1) federal compensation was denied; (2) the compensation award was inadequate; or (3) it could be proven the vaccine manufacturer could have made a vaccine safer.
SMALLPOX VACCINE: THE FIRST MANDATE

In the 18th and 19th centuries, smallpox (vaccinia) vaccine was the first to be recommended by medical doctors for widespread use in the United States. In 1809, Massachusetts was the first state to pass a law requiring smallpox vaccination and, in 1855, Massachusetts became the first state legislature to pass a law requiring proof of smallpox vaccination for children to attend school. Smallpox is the only human infectious disease that public health officials have declared eradicated through use of quarantines and mass vaccination campaigns.

ONE VACCINE REQUIRED IN 1940.

In 1905, the U.S. Supreme Court in *Jacobson v. Massachusetts* affirmed the constitutional authority of state legislatures to pass laws mandating use of smallpox vaccine by residents. However, language included in the ruling also cautioned against inflexible implementation of public health laws requiring vaccine use that would lead to injustice and oppression, such as in the case of an individual with a health condition that makes vaccination “cruel and inhuman in the last degree,” presumably because it could injure or kill the person.

Between 1905 and 1940, smallpox vaccine was the only vaccine required in state public health laws for children to attend school.

*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. It will always, therefore, be presumed that the legislature intended exceptions to its language, which would avoid results of that character. The reason of the law in such cases should prevail over its letter.*

*Jacobson v. Massachusetts (1905)*
Today, federal health agencies and medical trade associations recommend children and adults get multiple doses of many more vaccines for infectious diseases, such as chickenpox and hepatitis B, which do not cause as many deaths or are not as communicable in a public setting as smallpox. State health officials in many states automatically take federal vaccine recommendations and promote the addition of newly licensed vaccines to state mandates for children to attend daycare and school.

**23 DOSES OF 7 VACCINES.**
In 1983, 23 doses of seven vaccines (DPT, MMR, polio) were federally recommended for children to receive before age six and required by states for children to attend kindergarten.

**52 DOSES OF 15 VACCINES.**
By 2022 with the addition of the new COVID-19 vaccine recommendation, the CDC and medical trade groups were recommending that children receive 72 doses of 17 vaccines starting on the day of birth to age 18, with 52 doses of 15 vaccines given before age six. Most states now require more than three dozen doses of a dozen vaccines for children to attend daycare or schools and most colleges also have added vaccine requirements for enrollment.

**FIRST DOSE ON DAY OF BIRTH.**
Between 25 and 35 doses of vaccines are administered to babies by their first birthday, with the first dose of hepatitis B vaccine given at 12 hours old in the newborn nursery. Seven to 10 vaccines may be given on the same day according to the government recommended schedule.

**COMBINATION SHOTS.**
Some vaccines are bundled together like DTaP, MMR, DTaP-HepB-IPV and other “combo” shots.

**2022 CHILD VACCINE SCHEDULE (BIRTH TO 18 YEARS)**

- **(3)** hepatitis B shots
- **(6)** diphtheria (DTaP/Tdap/DT/Td) shots
- **(6)** tetanus (DTaP/Tdap/DT/Td) shots
- **(6)** pertussis (DTaP/Tdap) shots
- **(4)** haemophilus influenza B (Hib) shots
- **(3)** rotavirus shots
- **(4)** polio (IPV) shots
- **(4)** pneumococcal (PCV) shots
- **(19)** influenza shots
- **(2)** varicella zoster (chickenpox) shots
- **(2)** measles (MMR) shots
- **(2)** mumps (MMR) shots
- **(2)** rubella (MMR) shots
- **(2)** hepatitis A shots
- **(2)** human papillomavirus (HPV) shots
- **(2)** meningococcal (MCV) shots
- **(3)** coronavirus (COVID-19) shots

**72 TOTAL DOSES OF VACCINES**
the public are being subjected to vaccine requirements as a condition of employment by government agencies and also by corporations owning hospitals and other public and private facilities.68 69

**STATE VACCINE LAWS AND EXEMPTIONS**

Vaccine laws frequently change. The most current information on vaccine laws for children and adults in all 50 states and a map of state childhood vaccine exemptions for daycare and school entry can be accessed on NVIC’s website under “Law and Policy” at NVIC.org.67

**ADULT VACCINE RECOMMENDATIONS AND MANDATES.**

Today federal health officials recommend that doctors give adults many vaccines that were not routinely given to adults in the past. These new adult vaccine recommendations are being turned into legal mandates because adults working in health care, education, child care, travel, entertainment, food service, sales and other professions interfacing with

**ANNUAL FLU SHOTS THROUGHOUT LIFE.**

The CDC now recommends that all Americans get an influenza vaccination every year starting at six months old, with infants getting two flu shots in the first year of life.70 The recommendation that all healthy adults and pregnant women in any trimester, get an annual flu shot, and that pregnant women receive a Tdap shot with every pregnancy, has become part of government and private company employment policies that may or may not contain adequate informed consent protections.71 Health care workers with excellent work attendance and performance histories have been fired for declining to take an annual flu shot or other vaccines for health, religious or conscientious belief reasons.72 73 74
CHILD VACCINATION RATES AT ALL-TIME HIGH

Up until the past decade, many European and other developed nations strongly encouraged but did not mandate multiple vaccines. The U.S. recommends and mandates more vaccinations than many other countries and, nationally, there is a very high vaccination rate among pre-school, kindergarten and high school children for federally recommended vaccines.

About 95% of all children entering kindergarten have received four or more doses of pertussis containing vaccines (DTaP) and two doses of measles containing vaccines (MMR).

PRE-SCHOOL
In 2020, the CDC reported that vaccination rates among pre-school children 19 to 24 months old “remains high and stable, with recent increases in some vaccines” and that “the percentage of children who received no vaccines was only 1.2%.”

NATIONAL PRE-SCHOOL VACCINE COVERAGE RATES
(3) DTaP shots (93.3%) (3) polio shots (92.1%)
(1) MMR shot (90.7%) (1) varicella zoster shot (90.0%)
(3) hepatitis B shots (91.4%) (1) hepatitis A shot (85.8%)
(3) Hib shots (92.2%) (2) rotavirus shots (75.2%)
(3) pneumococcal shots (91.6%)

KINDERNERKEN.
According to the CDC, for “the 2019-2020 school year, national coverage was approximately 95%” for MMR, DTaP, and varicella vaccine.

NATIONAL KINDERGARTEN VACCINE COVERAGE RATES
(4) or more DTaP shots (94.9%)
(2) MMR shot (95.2%)
(2) varicella zoster shots (94.8%)

VACCINE EXEMPTION RATE.
Only 2.5% of all children entering kindergarten in the 2019-20 school year had a medical, religious or conscientious belief exemption from one or more doses of federally recommended vaccines on file with school and remained unchanged from the previous school year. In 2013, the CDC clarified that “an exemption does not necessarily imply a child was not vaccinated” and more than 99% of kindergarteners received at least one vaccine.

HIGH SCHOOL.
In 2020, the CDC reported that vaccination rates among children between 13 and 17 years old during 2019 remained high with adolescents and teens having received at least:

ADOLESCENT AND TEEN VACCINE COVERAGE RATES
(1) Tdap booster shot (90.2%)
(2) MMR shot (90.7%)
(3) hepatitis B shots (91.6%)
(1) meningococcal shots (88.9%)
(1) HPV shots (71.5%)
Thousands of vaccine clinical trials are being funded or conducted by federal health agencies and pharmaceutical companies, including those testing new, potentially more expensive vaccines that will become candidates for federal recommendations and state vaccine mandates in the future. Most new vaccines will be mandated by state health department officials through rule making procedures rather than a vote taken by state legislators.
VACCINE COMPLICATIONS AND ADVERSE EFFECTS

Like the first vaccine for smallpox, every vaccine recommended today by public health agencies and medical trade associations carries a risk for complications that can be greater for some than others and may lead to chronic brain and immune system damage or death. Between 1991 and 2013, the Institute of Medicine (IOM), National Academy of Sciences, assembled committees of experts to evaluate vaccine safety science and published a series of reports about vaccine adverse effects associated with diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, haemophilus influenza B, hepatitis B, varicella zoster, hepatitis A, rotavirus, pneumococcal, influenza, HPV, and meningococcal vaccines administered to children.

CAUSALLY RELATED TO VACCINATION:

- Acute Encephalopathy (brain inflammation)
- Chronic Nervous System Dysfunction (brain damage)
- Anaphylaxis (whole-body allergic reaction)
- Febrile Seizures (convulsions with fever)
- Guillain Barre Syndrome (peripheral nerve inflammation)
- Brachial Neuritis (arm nerve inflammation)
- Deltoid Bursitis (shoulder inflammation)
- Acute and Chronic Arthritis (joint inflammation)
- Thrombocytopenia (blood coagulation disorder)
- Syncope (sudden loss of consciousness/fainting)
- Hypotonic/Hyporesponsive Episodes (shock and “unusual shock-like state”)
- Protracted, Inconsolable Crying and Screaming
- Vaccine Strain Infection (smallpox, polio, measles, varicella zoster vaccines)
- Death (smallpox, polio, measles vaccines)

U.S. public health officials have acknowledged there are four types of serious adverse events that are reported to be causally related to certain COVID-19 vaccines, including anaphylaxis; TTS - thrombosis with thrombocytopenic syndrome (blood disorder); myocarditis and pericarditis (heart inflammation) and Guillain-Barre Syndrome (nerve inflammation).
CHILD VACCINE SCHEDULE: MORE SAFETY SCIENCE NEEDED

A 2013 report published by the Institute of Medicine, *The Childhood Immunization Schedule and Safety: Stakeholder Concerns, Scientific Evidence and Future Studies*, examined scientific evidence related to the current childhood vaccine schedule. The report concluded that the federally recommended birth to six-year-old child vaccine schedule had not been fully scientifically evaluated.

Most vaccine-related research focuses on the outcomes of single immunizations or combinations of vaccines administered at a single visit. Although each new vaccine is evaluated in the context of the overall immunization schedule that existed at the time of review of that vaccine, elements of the schedule are not evaluated once it is adjusted to accommodate a new vaccine. Thus, key elements of the entire schedule - the number, frequency, timing, order and age at administration of vaccines - have not been systematically examined in research studies.

OUTSTANDING QUESTIONS ABOUT VACCINES & CHRONIC ILLNESS.

The 2013 IOM report also concluded that there is not enough scientific evidence to determine if the recommended child vaccine schedule is or is not associated with the development of the following brain and immune system disorders prevalent among children today:

- Asthma
- Atopy
- Allergy
- Autoimmunity
- Autism
- Learning Disorders
- Communication Disorders
- Developmental Disorders
- Intellectual Disability
- Attention Deficit Disorder
- Disruptive Behavior Disorder
- Tics and Tourette’s Syndrome
- Seizures
- Febrile Seizures
- Epilepsy

Institute of Medicine (2013)
**CHRONIC DISEASE & DISABILITY INCREASES**

Mortality from infectious diseases declined markedly in the U.S. in the 20th and early 21st century and public health officials often attribute a significant portion of the decline among children to the use of multiple vaccines in childhood that are recommended by the government and mandated by states.\(^1\)\(^2\)\(^3\) During the same period of time, there has been a decrease in mortality from infectious diseases, there has been an unprecedented and unexplained increase in the numbers of children suffering with chronic disease and disability,\(^4\) while the U.S. infant mortality rate has become one of the worst among developed nations.\(^5\)\(^6\)\(^7\)

**MULTIPLE CO-FACTORS.**
The causes for this poor child health report card may involve compromised maternal and child nutrition, increased exposure to environmental toxins, sedentary lifestyles and other co-factors that have not yet been identified. Troubling questions remain about why so many infants and children in America are either dying before their first birthday or developing chronic brain and immune system problems that compromise their physical, mental and emotional health into adulthood.

**CHRONIC DISEASE MOST COMMON CAUSE OF DEATH AND DISABILITY.**
The CDC states that chronic diseases are the most common and costly causes of death and disability in the U.S. today. More than half of all adults are living with at least one chronic illness and four in 10 adults suffer with two or more chronic illnesses.\(^8\) This troubling chronic illness statistic played a role in the recent SARS-CoV-2 pandemic causing COVID disease, where the most mortality occurred among adults suffering with chronic diseases, such as diabetes and obesity; heart, kidney and lung disease; neurological disorders and other co-morbidities.\(^9\)

In 1960, 1.8 percent of children in the U.S. were reported to have a health condition severe enough to interfere with normal daily activities. In 2010, it was reported that eight percent of children were suffering with a health condition that limited daily activity – an unexplained 400 percent increase in the span of 50 years.\(^10\)

**IMMUNE AND BRAIN DYSFUNCTION.**
Since the mid-20th century, there has been a dramatic, unexplained rise in inflammatory and neurodevelopmental disorders among infants and children, as well as autoimmunity and allergy.\(^11\)\(^12\)\(^13\)\(^14\)\(^15\)\(^16\)

- **Learning Disabilities:** In 1976, 1 child in 30 was learning disabled.\(^17\) Today 1 child in 6 is learning disabled.\(^18\)
- **Asthma:** In 1980, 1 child in 27 had asthma.\(^19\) Today 1 child in 14 has asthma.\(^20\)\(^21\)
- **Autism:** In the 1970’s, 1 child in 2,500 developed autism.\(^22\) Today 1 child in 44 develops autism.\(^23\)
- **Diabetes:** In 2001, 1 child in 550 had diabetes.\(^24\) Today 1 child in 400 has diabetes.\(^25\)\(^26\)\(^27\)
U.S. INFANT MORTALITY HIGH.
In 2022, the U.S. ranked third in the world for population and 176th for infant mortality out of 227 nations, with five out of every 1,000 babies born alive dying before their first birthday. A 2013 report on global infant mortality revealed that the U.S. has the highest first-day infant death rate out of all industrialized countries in the world. In 2017, with other comparable countries averaging three deaths for every 1,000 babies born alive, the U.S. continued to have the highest infant mortality rate.

SPECIAL EDUCATION CLASSROOMS FOR SPECIAL NEEDS STUDENTS.
The most dramatic manifestation of the new child chronic disease and disability epidemic in America has been the creation of special education classrooms in public schools. During the 2019-20 school year the number of students receiving special education increased to 7.3 million, or 14 percent, of all students aged 3-21 years and among students receiving special education services, the most common category of disability (33 percent) was specific learning disabilities. Parents raising sick and developmentally delayed children requiring special education do not know how their children will be cared for when they are disabled adults.

LEGITIMATE QUESTIONS.
Many young parents, teachers and health care professionals are asking legitimate questions about why American children today receive four times as many vaccinations in infancy and childhood as their grandparents did. They wonder whether increased vaccination is a co-factor in our nation’s poor infant mortality rate and the unexplained rise in chronic inflammatory disorders and learning disabilities.
KNOWLEDGE GAPS & INDIVIDUAL SUSCEPTIBILITY

In 2012, the Institute of Medicine (IOM) published *Adverse Effects of Vaccines: Evidence and Causality* and confirmed there are significant gaps in scientific knowledge about the biological mechanisms of vaccine injury and death.\(^{213}\)

FEW SCIENTIFICALLY SOUND STUDIES.

For 158 reported vaccine adverse events related to eight routinely recommended childhood vaccines (MMR, DTaP, hepatitis B, hepatitis A, varicella zoster, pneumococcal, influenza and meningococcal), there were too few scientifically sound studies published in the medical literature for 134 of the adverse events, which prevented the IOM Committee from determining whether more than 100 serious brain and immune system problems, such as multiple sclerosis, arthritis, lupus, stroke SIDS, autism and asthma, are or are not caused by the vaccines.\(^{214}\)

INDIVIDUAL SUSCEPTIBILITY.

The IOM Committee also confirmed that there are known and unknown biological, genetic and environmental high-risk factors, which can increase “individual susceptibility” to vaccine reactions:

"Both epidemiologic and mechanistic research suggest that most individuals who experience an adverse reaction to vaccines have a pre-existing susceptibility. These predispositions can exist for a number of reasons—genetic variants (in human or microbiome DNA), environmental exposures, behaviors, illness or developmental stage, to name just a few, all of which can interact. Some of these adverse reactions are specific to the particular vaccines, while others may not be. Some of these predispositions may be detectable prior to the administration of vaccine; others, at least with current technology and practice, are not."\(^{215}\)

Institute of Medicine (2012)
A 2013 Institute of Medicine (IOM) report examining the safety of the child vaccine schedule reaffirmed that there are significant gaps in scientific knowledge about vaccine safety. An IOM Committee located fewer than 40 scientific studies published in the previous decade, which addressed the safety of the federally recommended infant and early childhood vaccine schedule, and found that it had never been systematically scientifically reviewed.216

**SUBPOPULATIONS OF SUSCEPTIBLE CHILDREN.**
The IOM Committee found limited scientific knowledge about subpopulations of children, who may be biologically at higher risk for suffering vaccine injury and death.

> The committee found that evidence assessing outcomes in subpopulations of children, who may be potentially susceptible to adverse reactions to vaccines (such as children with a family history of autoimmune disease or allergies or children born prematurely), is limited and is characterized by uncertainty about the definition of populations of interest and definition of exposures or outcomes.217

Institute of Medicine (2013)
VACCINES CAN FAIL TO PREVENT INFECTION AND TRANSMISSION OF DISEASE

Vaccines may provide temporary immunity, but sometimes fail to provide individuals with even short-term protection from infection. Pertussis and influenza vaccines are just two examples. Fully vaccinated children and adults can get symptomatically or asymptomatically infected with and transmit pertussis and influenza to others. The CDC has stated that, “Vaccine-preventable diseases continue to be transmitted despite high levels of vaccination at the national and state levels.”

By January 2021, there was evidence that new coronavirus vaccines could protect against severe COVID-19 disease, hospitalization and death, but prevention of mild or asymptomatic infection and transmission of SARS-CoV-2 in vaccinated persons had not been proven. A year later, after Delta and Omicron variants caused SARS-CoV-2 outbreaks in the U.S. and globally despite widespread vaccination, it was generally acknowledged that COVID-19 vaccines may protect against severe COVID disease but can fail to prevent infection and transmission.

In September 2021, the CDC changed the definition of vaccine from “a product that stimulates a person's immune system to produce immunity to a specific disease” to “a preparation that is used to stimulate the body’s immune response against diseases.” This new definition more accurately describes the potential for vaccines to protect against severe disease, while failing to prevent infection and transmission of disease to others - calling into question the scientific and ethical foundation for mandatory vaccination laws.

HERD IMMUNITY: NATURAL AND VACCINE ACQUIRED.

Originally, the theory of herd immunity involved acquiring natural immunity from infection, which provides a different, often longer lasting immunity than artificially acquired immunity from vaccination. Depending upon the infectious disease, today a combination of naturally acquired and vaccine acquired immunity contributes to “herd” (community) immunity in populations.

When enough of a population is immune to an infectious disease, through vaccination or prior illness, its spread from person to person is unlikely. Public health experts call this ‘herd immunity’ (or community immunity).

Centers for Disease Control (2019)

PERTUSSIS (WHOOPING COUGH) VACCINES.

CDC officials acknowledge that unvaccinated individuals are not the primary cause of reported pertussis outbreaks and state, “Vaccinated children and adults can become infected with and spread pertussis; however, disease is typically much less serious in vaccinated people.”

According to the CDC, the current B. pertussis vaccine in DTaP and Tdap shots is 80 to 90 percent effective and vaccine acquired immunity wanes after two years. In addition, after decades of widespread DPT and DTaP vaccine use, scientists have discovered that B. pertussis bacteria have evolved to potentially make pertussis vaccines less effective.
INFLUENZA VACCINES.
CDC officials acknowledge that influenza vaccine effectiveness varies from year and estimate it has been less than 50 percent effective for most years since 2004.\textsuperscript{241} Effectiveness of the seasonal flu shot is, in part, dependent upon the age, health, and other biological characteristics of the individual receiving the vaccine and how well the selected vaccine strains match influenza virus strains circulating within a population. A 2018 review of influenza vaccine research found many study designs to be biased and vaccine effectiveness in the elderly to be low.\textsuperscript{242}

CORONAVIRUS VACCINES.
The experimental coronavirus vaccines first distributed in the U.S. in 2021 under an Emergency Use Authorization (EUA) granted by the FDA\textsuperscript{243} were designed to prevent severe COVID-19 disease, hospitalization and death.\textsuperscript{244} According to the CDC, asymptomatic and symptomatic vaccinated persons can still become infected with and transmit variants of the SARS-CoV-2 virus that causes COVID-19 disease.\textsuperscript{245 246}
VACCINE EXEMPTIONS IN STATE PUBLIC HEALTH LAWS

In the early 1970s, public health officials and medical trade groups lobbied state legislatures to pass laws in all states requiring children to show proof they had received four or five doses of DPT and polio vaccines and one dose of MMR vaccine in order to attend kindergarten. By the mid-1980s, all 50 states had included provisions in vaccine laws for a medical exemption; 48 states included an exemption for religious or spiritual beliefs; and 22 states included an exemption for personal, philosophical or conscientiously held beliefs.

MEDICAL EXEMPTIONS.

Today, the medical exemption still exists in all 50 states. However, since the 1986 National Childhood Vaccine Injury Act was enacted, vaccine policymakers advocating for stricter implementation of vaccine mandates have significantly narrowed medical contraindications to vaccination. Now, very few medical conditions qualify as an “official” reason for a doctor to grant a medical exemption to vaccination for a child or adult.

RELIGIOUS EXEMPTIONS.

In 2022, all states but West Virginia, Mississippi, Maine, New York, Connecticut, and California allowed an exemption for religious or spiritual beliefs, either in a separate religious belief exemption or included in a personal belief exemption. However, special interest groups continue to lobby state legislatures for religious exemptions to be severely restricted or eliminated, such as unconstitutionally requiring parents to belong to a state-recognized church that officially opposes vaccination or to get a signature from a state-approved doctor, health care worker or health official before filing a religious exemption.

CONSCIENTIOUS BELIEF EXEMPTIONS.

By 2022, there were 16 states providing for a personal, philosophical or conscientious belief exemption to vaccination. However, similar to attacks on religious exemptions, special interest groups are lobbying in state legislatures to pass laws that either eliminate or create high barriers to obtaining this exemption.
SANCTIONS FOR NON-COMPLIANCE EXPANDING

Since 1986, public health, medical trade and drug company lobbyists have urged state legislatures and Congress to pass laws or approve regulations entering all Americans into electronic vaccine tracking systems and legally requiring them to use an expanding list of federally recommended and state mandated vaccines or suffer societal sanctions. Medical facilities, companies, government officials and judges have also participated in applying sanctions to those declining one or more recommended vaccines for themselves or their children, including barring unvaccinated Americans from:

- Attending daycare: NO SHOTS, NO DAYCARE

- Obtaining a public education in elementary, middle school, high school or colleges and universities: NO SHOTS, NO SCHOOL

- Receiving medical care: NO SHOTS, NO MEDICAL CARE

- Entering a hospital for life-saving surgery: NO SHOTS, NO SURGERY

- Getting full health or life insurance coverage: NO SHOTS, NO ADEQUATE HEALTH OR LIFE INSURANCE

- Visiting a child during custody disputes: NO SHOTS, NO CHILD VISITATION RIGHTS

- Obtaining a visa to enter and live in the U.S.: NO SHOTS, NO VISA

- Being employed in the health care, child care, teaching or other professions interfacing with the public: NO SHOTS, NO JOB

- Serving in the U.S. Army, Navy, Air Force and other military branches: NO SHOTS, NO MILITARY SERVICE

- Entering public spaces like a restaurant, gym or theater: NO SHOTS, NO ENTRY

Read reports of vaccine choice harassment on NVIC.org’s Cry for Vaccine Freedom Wall.

FEW MEDICAL CONTRAINDICATIONS.

The incremental narrowing of medical contraindications to vaccination since 1986 has made it almost impossible for a doctor to recommend deferral of vaccination under federal vaccine use guidelines. Restrictive medical contraindication guidelines disqualify 99.99 percent of individuals with autoimmune, neurological and immunosuppressive disorders or those, whose health deteriorated after previous vaccinations - even those exhibiting classic vaccine reaction symptoms followed by permanent injury - from obtaining a medical exemption to vaccination from a doctor.

NO EXCEPTIONS.

Some mandatory vaccination proponents want to further restrict medical exemptions to vaccination so that even fewer children and adults “officially” qualify for a medical exemption to vaccination.

Many pediatricians today refuse to provide medical care for children whose parents do not agree to give them every scheduled federally recommended vaccine, even if there have been symptoms of serious reactions and deterioration in health after previous vaccinations.
VACCINE RISKS UNEQUALLY SHARED IN THE U.S.

The life of a child or adult harmed by a vaccine is as important as the life of a child or adult harmed by an infectious disease.

Inflexible implementation of one-size-fits-all vaccine mandates places a disproportionate and unequal risk burden on those individuals, who are biologically, genetically or environmentally at higher risk for suffering harm from vaccination.301 There is an unequal sharing of vaccine risks in America due to:

- significant gaps in knowledge and incomplete vaccine safety science research;301
- the inability of doctors to predict ahead of time with any certainty which children and adults will be injured or die from vaccination.302

It is not humane, ethical or just to compel everyone to use a pharmaceutical product that carries a greater risk of injury or death for those more vulnerable to suffering harm from the use of that product.

The ethical principle of informed consent to medical risk-taking is protected in vaccine laws when there are flexible medical, religious and conscientious belief exemptions to ensure that human, civil and parental rights are not violated.303 304 305 306 307 Vaccine laws that do not allow flexible exemptions are “cruel and inhuman in the last degree” and should be repealed.
and long-term care providers should be legally required to accept a medical, religious or conscientious belief exemption filed by parents on behalf of minor children or an adult seeking education, employment, medical or long term care and other activities that secure quality of life.\(^{312}\)

**NON-DISCRIMINATION CLAUSES.**

The U.S. Constitution guarantees individual civil liberties and the protection of vulnerable minorities from exploitation by a powerful majority.\(^{313}\) Non-discrimination language, which protects citizens exercising medical, religious and conscientious belief exemptions to vaccination, should be codified into all public health emergency statutes and health, education, labor, employment and medical or long-term care policies recommending or requiring children or adults to use vaccines.

**LEGAL PROTECTIONS FOR VACCINE PROVIDERS.**

Doctors or state designated health care workers administering vaccines should have the legal right to refuse to administer a vaccine to a minor child or adult if, in their professional judgment, the benefits do not outweigh the risks for an individual and there is an increased risk for vaccine injury or death.\(^{314}\)

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**First Amendment, US Constitution**

\[^{308}\] Congress shall make no law respecting an establishment of religion, or prohibiting the free exercise thereof; or abridging the freedom of speech, or of the press; or the right of the people peaceably to assemble, and to petition the government for a redress of grievances.

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**RELIGIOUS AND CONSCIENCE EXEMPTIONS.**

All state public health, education, labor and medical care laws requiring children or adults to use federally recommended vaccines should include religious and conscientious belief exemptions.

U.S. citizens are guaranteed the freedom to follow their conscience and exercise religious beliefs in America.\(^{309}\) State vaccine laws that require adults or parents to belong to a state-recognized church or organized religion in order to file and receive a religious exemption to vaccination are unconstitutional and deny persons adhering to personal spiritual beliefs equal protection under the law.\(^{310}\)

**NO SANCTIONS.**

Citizens filing medical, religious or conscientious belief exemptions should not be questioned or sanctioned by government officials.\(^{311}\) State public health, daycare and school officials, public and private employers, and medical service
The National Vaccine Information Center (NVIC) supports reform of state vaccine laws to include the following safety and informed consent protections:

**FEDERAL VACCINE SAFETY PROVISIONS CODIFIED INTO STATE LAW.**

The federal informing, recording and reporting vaccine safety provisions of the National Childhood Vaccine Injury Act of 1986 are not being universally implemented by pediatricians and other vaccine providers. Congress and the U.S. Supreme Court have shielded drug companies, doctors, and all vaccine providers from civil liability for vaccine injuries and deaths. This increases the need for special efforts to be made by states to provide important information about risks associated with infectious diseases and vaccines and minimize the potential for vaccine injury and death to occur.

The National Vaccine Information Center supports the codification of the following federal informing, recording and reporting vaccine safety provisions into state public health laws that require children or adults to receive federally recommended and state mandated vaccines:

- **Provide** parents and adults receiving vaccines with written vaccine benefit and risk information before administration of vaccines;
- **Keep** permanent written records of vaccine manufacturer names and lot numbers for each vaccination given;
- **Record** serious health problems following vaccination in the permanent medical record;
- **Report** serious health problems, including hospitalizations, injuries and deaths, that occur after vaccination to the federal Vaccine Adverse Event Reporting System (VAERS). Reporting of vaccine adverse events to the vaccine manufacturer is no substitute for reporting to VAERS.

At the state’s discretion, NVIC also supports the inclusion of economic or non-economic penalties for vaccine provider non-compliance with these vaccine safety provisions.

*If the state can tag, track down and force individuals against their will to be injected with biologicals of known and unknown toxicity today, then there will be no limit on which individual freedoms the state can take away in the name of the greater good tomorrow.*

Barbara Loe Fisher (1997)
FLEXIBLE MEDICAL EXEMPTIONS.
Medical vaccine exemptions help protect children and adults with individual susceptibility to suffering harm from vaccination for biological, genetic, epigenetic and environmental reasons, some of which are known and some of which remain unknown. A licensed medical doctor or state designated health care worker administering vaccines should be free to exercise professional judgment and conscience and have the legal right to grant a medical exemption to vaccination, whether or not the reasons for granting the medical exemption strictly conform with federal vaccine contraindication guidelines.

PROTECTION OF MEDICAL EXEMPTIONS.
Doctors and other state designated health care workers administering vaccines, who write medical exemptions to vaccination, should not be questioned or sanctioned by government officials or professional licensing boards for granting medical exemptions. State public health, daycare and school officials, public and private employers and medical service and long term care providers should be legally required to accept a medical exemption written by a licensed medical doctor or state designated health care worker and filed by parents on behalf of a minor child or filed by an adult seeking education, employment, medical or long term care and other activities that secure quality of life.

Medical vaccine exemptions help protect children and adults with individual susceptibility to suffering harm from vaccination for biological, genetic, epigenetic and environmental reasons, some of which are known and some of which remain unknown.
NVIC PROGRAMS AND SERVICES

The National Vaccine Information Center (NVIC) is a charitable non-profit organization founded in 1982. NVIC is dedicated to the prevention of vaccine injuries and deaths through public education and protection of the informed consent and precautionary principles in public health policies and law. NVIC defends civil liberties, including freedom of thought, speech and conscience.

SUPPORT FOR INFORMED HEALTH CARE CHOICES.

NVIC is a consumer-operated organization and does not give medical advice or make recommendations to individuals about the use of vaccines. NVIC encourages informed health care decision-making and supports the availability of all preventive health care options, including vaccines, and the right of consumers to make voluntary health choices. NVIC opposes mandatory vaccination laws that lack informed consent protections and use coercion and punitive sanctions to force vaccine use.

PROGRAMS AND SERVICES.

NVIC provides the following programs and services to the public:

Information about vaccines, diseases and the ethical principle of informed consent to medical risk-taking:

Independent analysis and monitoring of vaccine development, regulation, policy-making, and legislation:

Consumer advocacy to defend the informed consent and precautionary principles and secure and protect vaccine exemptions in public health laws:

Promotion of research to evaluate vaccine safety and identify high-risk factors for vaccine injury:

Counseling and information for the vaccine injured:

NVIC.ORG.

Visit NVIC.org to learn how to make educated vaccine decisions for yourself or your children.
GROWING PUBLIC AWARENESS AND ADVOCACY.
In greater numbers, Americans are empowering themselves with information and proactively taking steps to make nutrition, lifestyle and health care changes to improve wellness. Surveys and studies show that 40% to 60% of the general population and 75% of health care workers in the U.S. use complementary and alternative medicine therapies to stay well.339 340 341 342

The public is becoming more aware of expanding vaccine requirements for children and adults and many people are seeking greater flexibility in making personal health care choices, including nurses and other health care workers,343 and want stronger vaccine safety and informed consent protections in vaccine policies and laws.344 345

STATE-BASED COMMUNICATIONS NETWORK.
Among NVIC’s more than 200,000 followers and supporters from every state are families with healthy children and those with vaccine injured children, as well as doctors, nurses and holistic health care professionals. They are Telegram, Gab, Rumble, MINDS, MeWe, Parler and other social media followers, subscribers of the NVIC Newsletter and The Vaccine Reaction weekly journal newspaper, and are users of the NVIC Advocacy Portal, which is a free online communications network. Portal users receive email alerts about proposed bills that will eliminate, restrict or expand vaccine exemptions or add new vaccine mandates or otherwise affect informed consent rights.

NVICAdvocacy.org
Registered users of the free online NVIC Advocacy Portal are electronically connected with their legislators through their smartphones or computers. NVIC’s advocacy team works with state-based vaccine safety and informed consent advocates to provide informational support and guidance.
ABOUT NVIC AND AUTHOR

NATIONAL VACCINE INFORMATION CENTER (NVIC)

Founded in 1982 by parents of DPT vaccine injured children, the non-profit educational charity the National Vaccine Information Center is dedicated to preventing vaccine injuries and deaths through public education and securing informed consent protections in public health policies and laws. NVIC co-founders worked with Congress to secure informing, recording and reporting vaccine safety provisions in the National Childhood Vaccine Injury Act of 1986. During the 1980s and 1990s, NVIC advocated for the use of a less reactive pertussis vaccine, which was licensed in 1996, and for the replacement of the live oral polio vaccine (OPV) with inactivated polio vaccine (IPV) in 1999 to prevent cases of vaccine strain polio paralysis in the U.S. NVIC sponsored an International Scientific Workshop on Pertussis and Pertussis Vaccine in 1989 and five International Public Conferences on Vaccination between 1997 and 2020. Over a span of four decades, NVIC has represented consumer concerns about vaccine safety and informed consent protections in the public domain, including on government advisory committees and public engagement projects, and in scientific meetings, legislative hearings and in print and broadcast news reports.

NVIC maintains the oldest and largest consumer-operated website on vaccine science, policy, law and ethics on the Internet at www.NVIC.org. The referenced information that NVIC researches, publishes and disseminates to the public about diseases and vaccines reaches millions of people in the U.S. and around the world.

ABOUT THE AUTHOR

Barbara Loe Fisher, co-founder and president of the charitable National Vaccine Information Center (NVIC) is a leading non-medical expert on vaccine science, policy, law and ethics. She has defended informed consent and the right to autonomy and freedom of thought, speech and conscience for four decades. She is co-author of the seminal book DPT: A Shot in the Dark (Harcourt Brace Jovanovich, 1985) and is the author of The Consumer’s Guide to Childhood Vaccines (1997) and Vaccines, Autism and Chronic Inflammation: The New Epidemic (2008). She served as a consumer member of the National Vaccine Advisory Committee (1988-1991); the Institute of Medicine Vaccine Safety Forum (1995-1998); FDA Vaccines and Related Biological Products Advisory Committee (1999-2002); the Vaccine Policy Analysis Collaborative (2002-2005) and the Vaccine Safety Writing Group (2009-2010).

Barbara is also the founder and executive editor of The Vaccine Reaction journal newspaper and a commentator and video blogger for NVIC.org and Mercola.com. She has coordinated six conferences on vaccination sponsored by NVIC, including the 2020 Fifth International Public Conference on Vaccination: Protecting Health and Autonomy in the 21st Century. She has been widely quoted in national and international publications, and has publicly debated more doctors about vaccination and informed consent rights than any other American. Her human rights and consumer advocacy work was featured in the 2011 award-winning film documentary, The Greater Good, and in the 2020 movie 1986: The Act.
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