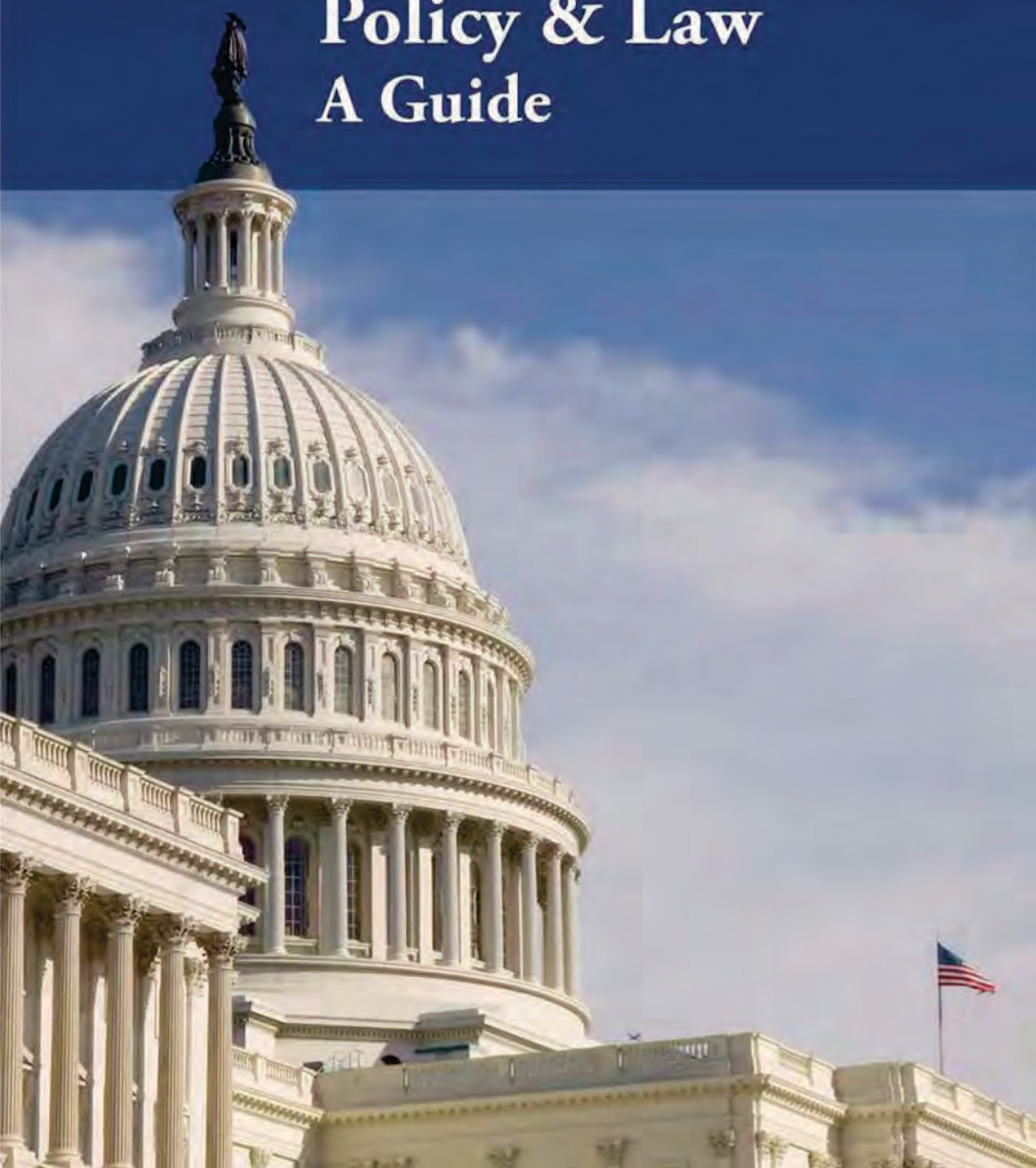
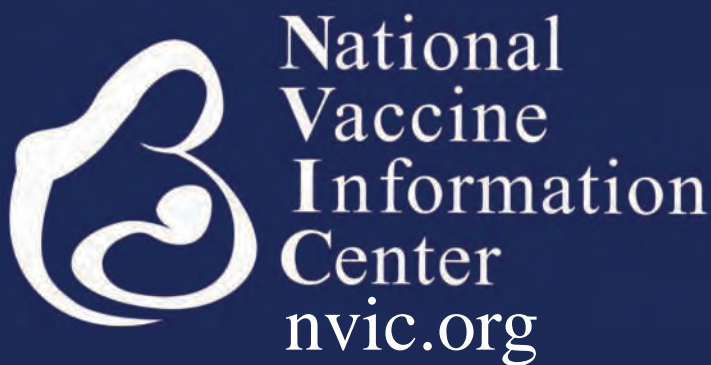


# Reforming Vaccine Policy & Law A Guide



**by Barbara Loe Fisher**  
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National Vaccine Information Center



An educational non-profit charity founded in 1982

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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. Since our founding in 1982, the National Vaccine Information Center (NVIC) has worked 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.

While the precautionary principle – “first, do no harm” – is central to prevention of vaccine injuries and deaths, the informed consent principle is central to the ethical practice of medicine. The individual’s right to exercise informed consent to medical risk-taking can be defined as a human right. Without it, the will of a powerful majority 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 for 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 law must protect, and to violate would be oppression.”** – *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 U.S. laws and regulations for human research subject protections, pharmaceutical and medical product labeling and medical care 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 (1946)*

# The Precautionary Principle

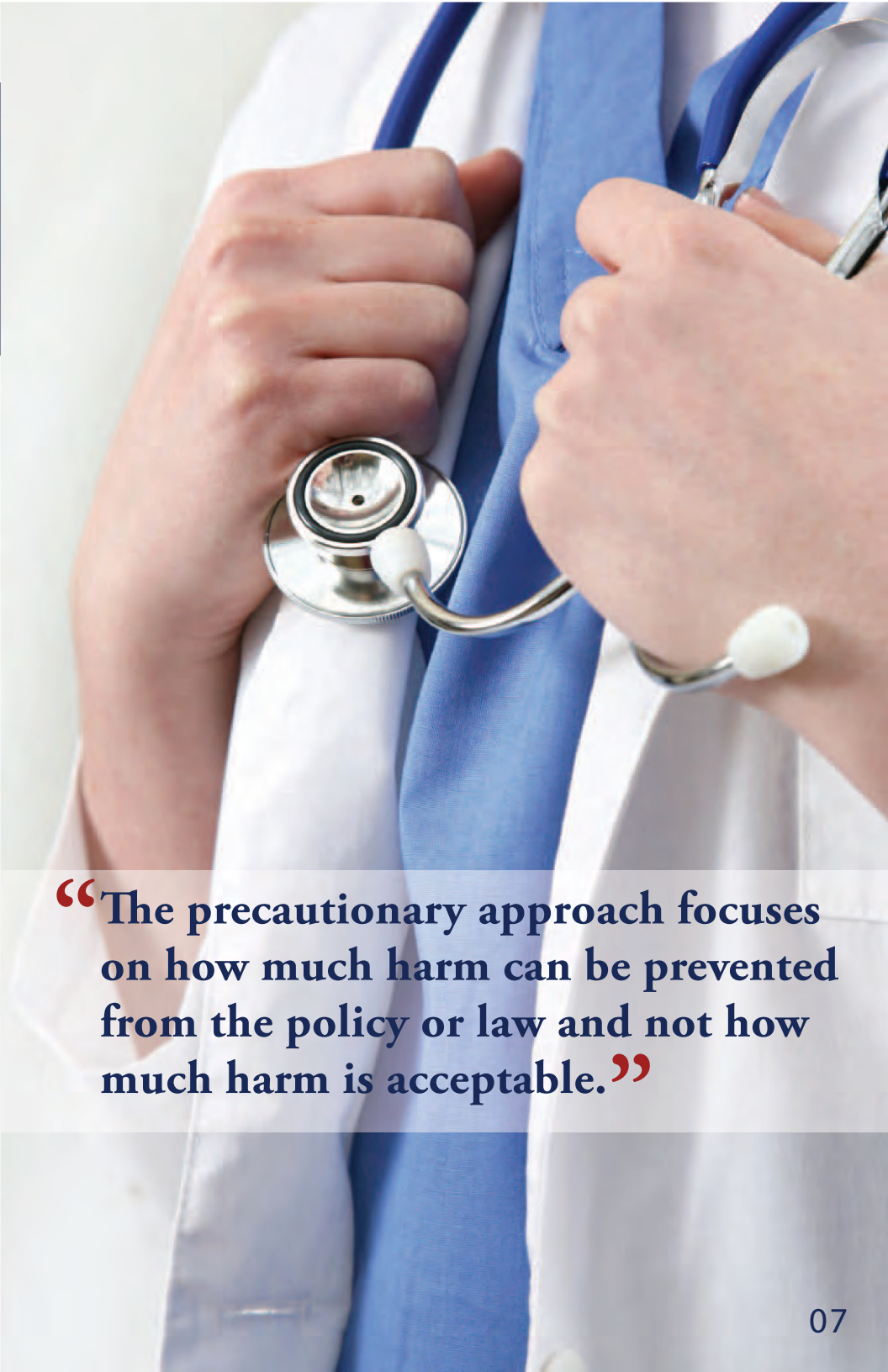
**First, Do No Harm.** The precautionary principle is based on the “first, do no harm” approach to sound public policy decision-making. It acknowledges that humans are fallible and act in ways that can cause unintended serious, widespread and measureable harm to people, wildlife and the environment. 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.





**“The precautionary approach focuses on how much harm can be prevented from the policy or law and not how much harm is acceptable.”**

# 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** by state legislatures or state health officials through rule making;
- **Required** as a condition of employment for adults by some private corporations or state agencies operating hospitals, schools and other public facilities; and
- **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.



# 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 shield drug companies and doctors from civil product liability and malpractice lawsuits for injuries and deaths caused by federally recommended and state mandated vaccines. The law, which acknowledged that vaccines can cause harm, created a federal vaccine injury compensation program.

**\$3 Billion in Vaccine Injury Compensation.** By 2013, nearly \$3 billion dollars in federal compensation had been paid to children and adults who have been injured or died from federally recommended and state mandated vaccines, even though two out of three applicants are denied federal compensation.

**Vaccine Safety Provisions Ignored.** The co-founders of NVIC worked with Congress to secure vaccine informing, recording and adverse reaction reporting provisions in the 1986 law. Although doctors and all vaccine providers are protected from vaccine injury lawsuits, many do not comply with the 1986 law's vaccine safety provisions. There are no 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;
- **do not** record vaccine-related adverse events in the permanent medical record.

### **Most Vaccine Reactions Are Not Reported To**

**Government.** It is estimated that only one to 10 percent of all serious health problems, hospitalizations, injuries and deaths that occur after vaccinations given to children or adults are ever reported to the federal Vaccine Adverse Events Reporting System (VAERS). Instead of reporting to federal health agencies responsible for monitoring vaccine safety, most pediatricians and vaccine providers are either not reporting at all or sending vaccine reaction reports directly to vaccine manufacturers.

### **U.S. Supreme Court Barred Vaccine Injury Lawsuits.**

In 2011, the U.S. Supreme Court ruled that vaccines are “unavoidably unsafe” and effectively gave drug companies selling vaccines in the U.S. complete product liability protection from lawsuits when vaccines licensed and recommended by the federal government cause an injury or death.

# Smallpox Vaccine: The First Mandate

In the 19th century, smallpox was the first vaccine to be recommended by medical doctors for widespread use in the United States. In 1855, Massachusetts was the first state legislature to pass a law requiring proof of smallpox vaccination in order for a child to attend public school.

**One Vaccine Required in 1940.** In 1905, the U.S. Supreme Court in *Jacobsen v. Massachusetts* affirmed the legal right of state legislatures to pass laws mandating use of smallpox vaccine by residents. Between 1905 and 1940, smallpox vaccine was the only vaccine required by states 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.”

- *Jacobsen v. Massachusetts* (1905)





# Dozens of Vaccinations Recommended and Mandated Today

Since 1940, federal health agencies and medical trade associations have recommended 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 take federal vaccine recommendations and promote the addition of newly licensed vaccines to state mandates for children.

**23 Doses of 7 Vaccines.** In 1983, 23 doses of 7 vaccines (DPT, MMR and polio) were federally recommended and state required for school attendance.

**69 Doses of 16 Vaccines.** By 2013, the CDC and medical trade groups were recommending that children receive 69 doses of 16 vaccines starting on the day of birth to age 18 with 49 doses of 14 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.

## **2013 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**
- (3) 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**
- (3) human papillomavirus (HPV) shots**
- (2) meningococcal (MCV) shots**

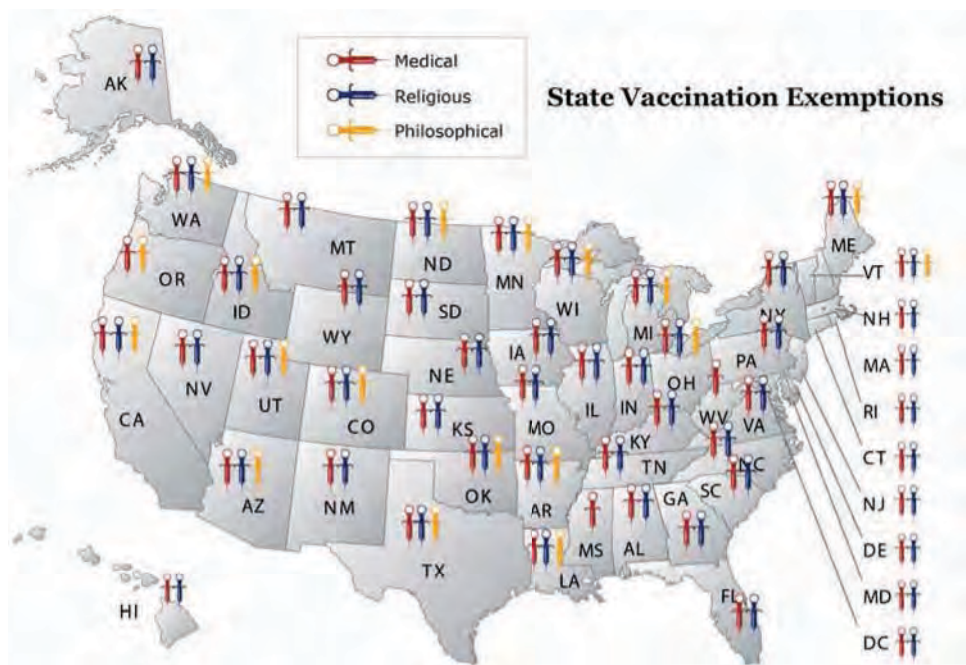
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**69 Total Doses of Vaccines**

# Dozens of Vaccinations Recommended and Mandated Today

## State Vaccine Laws and Exemptions

Vaccine laws from all 50 states and a map of state vaccine exemptions for daycare and school entry can be accessed on [NVIC.org](http://NVIC.org).





### **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 as adults working in health, child care and other professions are being subjected to vaccine requirements as a condition of employment.

**Annual Flu Shots Throughout Life.** The CDC now recommends that all Americans get a flu shot every year starting at six months old. The recommendation that all healthy adults, including pregnant women in any trimester, get an annual flu shot has become part of government and private company employment policies without adequate informed consent protections. 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.

# Child Vaccination Rates At All-Time High

Many European and other developed nations encourage but do not mandate vaccinations for children or adults. The U.S. recommends and mandates more vaccines 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 2012, the CDC reported that vaccination rates among pre-school children 19 to 35 months old “remained stable or increased compared with 2010 for all recommended vaccines.” and that “the percentage of children who had not received any vaccines remained less than 1%.”

## National Pre-School Vaccine Coverage Rates

- (3) **DTaP shots (95.5%)**
- (1) **MMR shot (91.6%)**
- (3) **hepatitis B shots (91.1%)**
- (3) **Hib shots (94%)**
- (3) **pneumococcal shots (93.6%)**
- (3) **polio shots (93.9%)**
- (1) **varicella zoster shot (90.8%)**
- (1) **hepatitis A shot (81.2%)**
- (2) **rotavirus shots (67.3%)**

**Kindergarten.** According to the CDC, vaccination rates among kindergarten children for DTaP, MMR and varicella shots “remained high and exemption levels remained stable for the 2012–13 school year compared with the 2011–12 school year.”

### **National Kindergarten Vaccine Coverage Rates**

- (4) or more DTaP shots (95.1%)**
- (2) MMR shots (94.5%)**
- (2) varicella zoster shots (93.8%)**

**Vaccine Exemption Rate.** Only 1.8% of all children entering kindergarten in the 2012-2013 school year had a medical, religious or conscientious belief exemption to vaccination on file with schools. CDC clarified that “an exemption does not necessarily imply a child was not vaccinated” and more than 99% of kindergarteners had received at least one vaccine.

**High School.** The CDC reported high vaccination rates among children between 13 and 17 years old during 2012.

### **National High School Vaccine Coverage Rates**

- (1) Tdap booster shot (84.6%)**
- (2) MMR shots (91.4%)**
- (3) hepatitis B shots (92.8%)**
- (1) or more meningococcal shots (74%)**

# Vaccination Costs Increasing

As the numbers of federally recommended and state mandated vaccinations have increased during the past three decades, there has been a corresponding increase in direct costs to parents, health insurance companies and the American taxpayer.

**“The cost of vaccinating a child with all federally recommended vaccines in a private pediatrician’s office increased from \$80 per child in 1982 to more than \$2,300 per child in 2013.”**

Over 4,000 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.





# New Vaccines for Infectious & Non-Infectious Diseases



New vaccines are being developed for infectious and non-infectious diseases, including: gonorrhea; syphilis; chlamydia; HIV/AIDS; genital herpes; RSV, cytomegalovirus; hepatitis C; tuberculosis; e-coli; norovirus; salmonella; malaria; botulism; West Nile virus; asthma; diabetes; obesity; high blood pressure; anti-cocaine and heroin use; anti-smoking and tooth decay.

**Genetically Engineered Vaccines.** Most of these new vaccines are being genetically engineered using lab-altered animal and insect cells and will contain various ingredients, including non-human protein and genetic materials, chemicals, and novel adjuvants using nanoparticle and other experimental technologies designed to hyper-stimulate the immune system. Individual adverse responses to these new vaccines may not be fully known until after licensure and widespread use.

# 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.



## 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**)

# 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;”

– *Institute of Medicine (2013)*

## **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**

# Chronic Disease & Disability Increases

During the past five decades, there has been a significant decline in reported cases of many infectious diseases experienced in childhood for which vaccines have been recommended and mandated in the U.S. At the same time, there has been an unprecedented and unexplained increase in the numbers of children suffering with chronic disease and disability, while the U.S. infant mortality rate has become one of the worst among developed nations.

**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. 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. Almost one out of every two adults is living with at least one chronic illness and the percentage of chronically ill children and adolescents increased from 1.8% in the 1960's to more than 7% in 2004.

**Immune and Brain Dysfunction.** Since the early 1980's, there has been a dramatic, unexplained rise in inflammatory and neurodevelopmental disorders among infants and children, including autoimmunity and allergy.

**Learning Disabilities:** In 1976, 1 child in 30 was learning disabled.

**Today 1 child in 6 is learning disabled.**

**Asthma:** In 1980, 1 child in 27 had asthma.

**Today 1 child in 9 has asthma.**

**Autism:** In the 1990's, 1 child in 555 developed autism.

**Today 1 child in 50 develops autism.**

**Diabetes:** In 2001, 1 child in 500 had diabetes.

**Today 1 child in 400 has diabetes.**





# Chronic Disease & Disability Increases



**U.S. Infant Mortality High.** In 2011 in America, 6 out of every 1,000 babies born alive died 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.

**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 need to create special education classrooms in nearly every public school. Parents raising sick and developmentally delayed children filling special education classrooms do not know how their children will be cared for when they are disabled adults.

**Legitimate Questions.** Many 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 and why children in other nations do not. 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.

**Few Scientifically Sound Studies.** For eight routinely used 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 an IOM Committee to determine whether more than 100 serious brain and immune system problems, such as multiple sclerosis, arthritis, lupus, stroke, SIDS, autism and asthma, were or were *not* caused by the vaccines.

**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.”

*- Institute of Medicine (2012)*

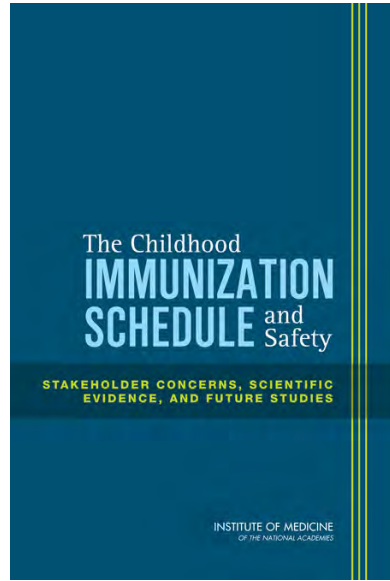
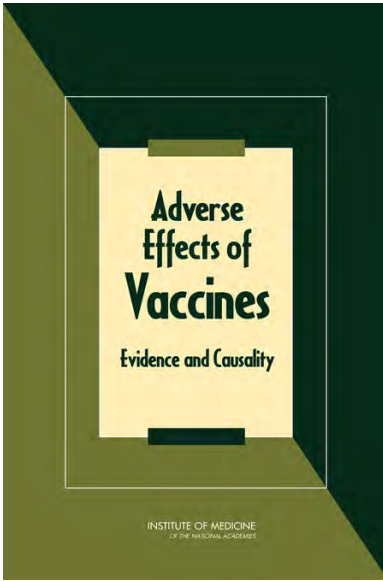
# Knowledge Gaps & Individual Susceptibility

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 only could find fewer than 40 scientific studies published in the previous decade, which addressed the safety of the federally recommended infant and early childhood vaccine schedule.

**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.”**

*- Institute of Medicine (2013)*



# Vaccines Can Fail To Protect

Vaccines may provide temporary immunity but sometimes do not provide individuals with even short-term protection from infection. Pertussis and influenza vaccines are two examples. Fully vaccinated children and adults can get infected with and transmit pertussis and influenza to others. In 2013, the CDC stated that “Vaccine-preventable diseases continue to be transmitted despite high levels of vaccination at the national and state levels.”

## **Herd Immunity: Natural and Vaccine Acquired.**

Experience with the natural infection provides a different, usually longer lasting immunity than artificially acquired immunity from vaccination. Depending upon the infectious disease, a combination of naturally acquired and vaccine acquired immunity contributes to “herd” (community) immunity in populations.

**“Herd immunity, or community immunity, is a situation in which, through vaccination or prior illness, a sufficient proportion of a population is immune to an infectious disease, making its spread from person to person unlikely.”**

*- Centers for Disease Control (2013)*



**Pertussis (Whooping Cough) Vaccines.** CDC officials acknowledge that unvaccinated individuals are not the primary cause of recently reported pertussis outbreaks: *“If pertussis is circulating in the community, there is still a chance that a fully vaccinated person can catch this very contagious disease. When you or your child develops a cold that includes a prolonged or severe cough, it may be pertussis.”*

According to the CDC, the current B. pertussis vaccine in DTaP and Tdap shots is 80 to 90 percent effective but vaccine acquired immunity wanes after two to five 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 flu shots have limited effectiveness: *“Unfortunately, some people can get infected with the flu virus the flu vaccine is designed to protect against despite getting vaccinated. Protection provided by the flu vaccination can vary widely, based in part on health and age factors of the person getting vaccinated.”*

According to the CDC, the 2012/2013 influenza vaccine was found to be 9 to 56 percent effective, with the elderly receiving little or no protection.

# Vaccine Exemptions in State Public Health Laws

In the early 1970's, 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-1980's, 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 providing liability protection to drug companies and doctors, 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.** All states but West Virginia and Mississippi continue to allow 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 are lobbying in state legislatures to pass laws severely restricting or eliminating the religious exemption, 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 2013, there were 17 states providing for a personal, philosophical or conscientious belief exemption to vaccination. However, like with the religious exemption, special interest groups are lobbying in state legislatures to pass laws that either eliminate or create high barriers to obtain this exemption.

# Sanctions for Non-Compliance Expanding

Since 1986, public health, medical trade and drug company lobbyists have urged state legislatures to pass laws or approve regulations legally requiring Americans to purchase and use a rapidly expanding list of government recommended vaccines or suffer societal sanctions, including being barred 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.**
- Getting health insurance, including through Medicare and Medicaid: **No shots, no health insurance.**
- 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.**
- Engaging in other activities in a public setting.

**Read reports of vaccine choice harassment  
on NVIC.org's 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 many 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 will not provide 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. There is an unequal sharing of vaccine risks in America due to:

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

**It is not humane 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 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.”**



# Reform of State Vaccine Laws Needed

“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.”

*- First Amendment, US Constitution*

**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. 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.

**No Sanctions.** Citizens filing medical, religious or conscientious belief exemptions should not be questioned or sanctioned by government officials. 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, 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.

**Non-Discrimination Clauses.** The U.S. Constitution guarantees individual civil liberties and the protection of vulnerable minorities from exploitation by a powerful majority. 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.

# Reform of State Vaccine Laws Needed



The National Vaccine Information Center 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. Drug companies, doctors and all vaccine providers are shielded 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 non-compliance with these vaccine safety provisions.

# Reform of State Vaccine Laws Needed

**Flexible Medical Exemptions.** Medical exemptions to vaccination help protect children and adults with individual susceptibility from suffering harm from vaccination for biological, genetic 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 judgement 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 conforms 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.



# 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.

**Support for Informed Health Care Choices.** NVIC is a consumer-operated organization and does not give medical advice or make recommendations to individuals about 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.

**Programs and Services.** NVIC provides the following programs and services to the public:

- **Information** about vaccines and diseases;
- **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](https://www.nvic.org) to learn how to make educated vaccine decisions for yourself or your children.



# NVIC Advocacy Portal

**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.

The public is becoming more aware of expanding vaccine requirements and new vaccines being developed that will be promoted for mandatory use once they are licensed. Many educated consumers and health care professionals are seeking greater flexibility in making personal health care choices and support stronger vaccine safety and informed consent protections in state vaccine policies and laws.

**State-Based Communications Network.** Among NVIC's more than 60,000 followers and supporters from every state are families with healthy children and those with vaccine injured children, doctors, nurses and holistic health care professionals. They are using the NVIC Advocacy Portal, which is a free online communications network. Portal users receive email alerts about proposed state legislation that will restrict or expand vaccine-related informed consent rights in public health, education and employment policies and laws.



**NVIC Advocacy Portal.** Registered users of the free online NVIC Advocacy Portal are electronically connected with their legislators through their smart phones or computers. NVIC's advocacy team works with state-based vaccine safety and informed consent advocates to provide informational support and guidance.



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Below is a selected list of references for this guide. The fully referenced guide with live links to references is posted on NVIC.org.

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# 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.

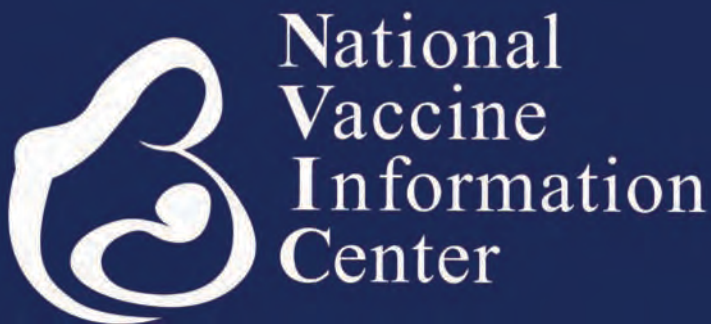
During the 1980's and 1990's, NVIC advocated for the use of a less reactive pertussis vaccine, which was licensed in 1996, and for replacement of the live oral polio vaccine (OPV) with inactivated polio vaccine (IPV) in 1999 to prevent cases of vaccine strain polio paralysis in the U.S. NVIC sponsored an International Scientific Workshop on Pertussis and Pertussis Vaccine in 1989 and four International Public Conferences on Vaccination between 1997 and 2009.

For more than three decades, NVIC has represented public vaccine safety and informed consent concerns on government advisory committees and public engagement projects and in scientific meetings, legislative hearings and in major print and broadcast news reports. NVIC maintains the oldest and largest consumer-operated website on vaccination on the Internet at [www.NVIC.org](http://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 National Vaccine Information Center (NVIC), is a leading informed consent advocate and non-medical expert on vaccine science, policy, law, and ethics. She is co-author of the seminal book *DPT: A Shot in the Dark* (Harcourt Brace Jovanovich, 1985) and 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). She coordinated five scientific conferences, including the 1989



International Scientific Conference on Pertussis and Pertussis Vaccines, and four International Public Conferences on Vaccination in 1997, 2000, 2002 and 2009. A commentator and video blogger for NVIC and Mercola.com, her consumer advocacy work was featured in the 2011 film documentary, *The Greater Good*.



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