



Voices for Vaccines

Vaccines and the Law

An Advocate's Toolkit

Revised September 2014

voicesforvaccines.org

Contents

Welcome.....	2
About Voices for Vaccines.....	2
Introduction: The Power of Vaccination.....	3
Community Immunity.....	3
The Benefits Far Outweigh the Risks.....	4
Vaccines: Support from Global to Local.....	6
Vaccines: Regulating the Product.....	7
Protecting the Public Health: State and Federal Law.....	9
Disease Prevention: The CDC’s Role.....	9
Immunization Schedules.....	9
School Immunization Requirements.....	10
Religious Exemptions.....	10
Vaccines: Individual Choice and Community Welfare.....	11
Community vs. Individual: Achieving a Balance of Rights.....	12
Religion, Employment, and Rights.....	12
Parental Rights and the Child’s Right to Health.....	13
Informed Consent.....	13
The Risks of Vaccinating.....	14
Informed Refusal: The Risks of <i>Not</i> Vaccinating.....	14
Increasing Immunization Rates: The Role of the Law.....	16
Education.....	16
Government-Funded Incentives and Subsidies.....	16
Imposing Costs: Civil Lawsuits.....	17
Imposing Costs: No-Fault Options.....	18
Public Nuisance Laws.....	18
No-Fault Legislation.....	19
Increasing Insurance Premiums.....	19
Limiting Unvaccinated Individuals’ Access.....	19
Vaccine Refusal and Criminal Law.....	19
Forced Vaccination.....	20
Other Issues.....	21
Vaccine Injuries: Compensating the Rare Adverse Event.....	21
NVICP vs. the Courts.....	22
Are Vaccines “Unavoidably Unsafe?”.....	23

Welcome

Voices for Vaccines is pleased to offer this toolkit to parents, providers, and others interested in the relationship between vaccination and United States law. The information in this document will help you build a foundation of knowledge regarding the role of the law in regulating, enforcing, and improving vaccine coverage. We've designed it to provide an overview of vaccines and the law, while including lots of additional information you may refer to if you have more in-depth questions.

Specifically, this document will:

- Explain basic facts about the law as it relates to vaccines.
- Highlight how the law can improve immunization rates.
- Raise some policy options to consider.
- Provide answers to some inaccurate claims you may hear about the law and vaccines.

About Voices for Vaccines

Voices for Vaccines is a parent-led organization that advocates for on-time vaccination and the reduction of vaccine-preventable disease.

At Voices for Vaccines, our mission is to provide families three crucial tools:

- Evidence-based information about the safety and importance of immunization
- A vibrant community of parents who are passionate about preventing disease, disability, and death by supporting and encouraging sound vaccine policies and practices at both the state and national levels
- An opportunity to join the discussion and to actively advocate for on-time immunization

Voices for Vaccines would like to thank Dorit Rubinstein Reiss and Amanda Z. Naprawa for preparing this manual.

Introduction: The Power of Vaccination

Vaccination is one of the most successful and cost-effective public health interventions in history.

Vaccination is cited as one of the “Top 10” public health achievements of the 20th century, with impressive gains in worldwide vaccine coverage and disease protection continuing into the 21st century.

It has been estimated that immunizing the 2009 birth cohort led to:

- Prevention of 42,000 early deaths;
- Prevention of 20 million cases of disease;
- Savings of \$13.5 billion in direct costs; and
- Savings of \$68.8 billion in costs to society.¹



Visit Voices for Vaccines’ [Vaccines page](#) to learn more about each recommended vaccine, and how it helps protect you and your child.

Community Immunity

Vaccination doesn’t just protect one child. When parents vaccinate, their children become a key part of their community’s defense against vaccine-preventable disease (known as *herd* or *community immunity*). Put simply, the more children that undergo on-time vaccination in a community, the less chance an infectious disease has to “jump” from person to person.

Vaccinating your child protects those at significant risk of infection, including:

- Babies too young to be vaccinated;
- Children left intentionally unvaccinated by their parents;
- Individuals with medical conditions that preclude vaccination; and
- Individuals for whom the vaccine did not “take,” or whose immunity has worn off.

It’s often difficult to determine who, or how many, fall into the last two categories. But for these people, community immunity is the best – and perhaps, the *only* – protection they have against vaccine-preventable disease.



¹ Zhou et. Al, Economic Evaluation of the Routine Childhood Immunization Program in the United States, 2009 (2014)

The Benefits Far Outweigh the Risks



Smallpox vaccine and bifurcated needle

All diseases have risks and some diseases can be fatal; some have higher fatality rates than others, but even those with low fatality rates leave families devastated by the loss of a loved one's life. This is why we vaccinate against these diseases.

Serious reactions to modern vaccines can happen, but they are extremely rare.² For example, in a study of patients in 4 health maintenance organizations between 1991 and 1997, there were 5 anaphylactic reactions (severe allergy reactions) out of 7,644,049 vaccine doses (.65cases/1,000,000 million doses).

A 2013 Institute of Medicine report examined the evidence and concluded: "Upon reviewing stakeholder concerns and scientific literature regarding the entire childhood immunization schedule, the IOM committee finds no evidence that the schedule is unsafe."³

Diseases and their Risks

(Based on United States statistics)

Disease we vaccinate against	Risks include
Chicken Pox (Varicella)	Death (1 in 60,000) Bacterial infection of lesions Pneumonia
Diphtheria	Death (1 in 10) Heart disease Nerve damage
Flu (Influenza)	Death (thousands-tens of thousands a year) Pneumonia Encephalitis GBS
Hepatitis A	Death (rare) Liver damage Long period of illness

² <http://pediatrics.aappublications.org/content/early/2014/06/26/peds.2014-1079.abstract>

³ [http://www.iom.edu/~media/Files/Report Files/2013/Childhood-Immunization-Schedule/ChildhoodImmunizationScheduleandSafety_RB.pdf](http://www.iom.edu/~media/Files/Report%20Files/2013/Childhood-Immunization-Schedule/ChildhoodImmunizationScheduleandSafety_RB.pdf)

Disease we vaccinate against	Potential Complications
Meningococcal Disease	Death (3-4 out of 10) Loss of limbs Brain damage Pneumonia
Mumps	Meningitis Encephalitis Deafness Swollen testicles and infertility in men.
Polio	Death Paralysis (about one in 200 polio infections)
Pneumococcal	Death Meningitis Pneumonia
Rotavirus	Deaths (20-60 a year pre vaccine) Dehydration
Rubella	Encephalitis Congenital Rubella Syndrome (CRS): in pregnancy, miscarriages and serious birth defects
Tetanus	Death (1 out of 10) Broken bones Pneumonia Difficulty breathing
Whooping Cough (Pertussis)	Death (mostly infants, 1 out of 500 people) Pneumonia Seizures Broken ribs
Hepatitis B	Death (about 5000 a year) Liver damage Liver cancer
HiB	Death (4 out of 100) Meningitis Blood stream infection Epiglottitis
HPV	Death (about 3000 a year) Cervical cancer Head and neck cancer Penile cancer Vulvar cancer
Measles	Death (1-2 out of 1000) Pneumonia Encephalitis SSPE

More information

<http://www.chop.edu/service/vaccineeducationcenter/lookateachvaccine/>

<http://www.cdc.gov/vaccines/vpdvac/factsheetparents.html>

<http://www.cdc.gov/vaccines/pubs/pinkbook/index.html>

Vaccines: Support from Global to Local

Local, state, national, and international health authorities support vaccination.

City of San Francisco: “Vaccines can prevent many infectious diseases. You should get some vaccinations in childhood, some as an adult, and some for special situations like pregnancy and travel. Make sure you and your family are up-to-date on your vaccinations.”⁴

New York State: “Today's vaccines are among the 21st century's most successful and cost-effective public health tools for preventing disease and death. Thanks to immunizations, debilitating and often fatal diseases like polio, that were once common, are now only distant memories for most Americans.”⁵

The Centers for Disease Control and Prevention: “There's no greater joy than helping your baby grow up healthy and happy. That's why most parents choose immunization. Giving your baby the recommended immunizations by age two is the best way to protect him from 14 serious diseases, like measles and whooping cough.”⁶

The World Health Organization: “Immunization is a proven tool for controlling and eliminating life-threatening infectious diseases and is estimated to avert between 2 and 3 million deaths each year. It is one of the most cost-effective health investments.”⁷

⁴ <http://www.sfcddcp.org/yourvaccines.html>

⁵ <https://www.health.ny.gov/prevention/immunization/>

⁶ <http://www.cdc.gov/vaccines/parents/index.html>

⁷ <http://www.who.int/topics/immunization/en/>

Vaccines: Regulating the Product



Vaccines undergo extensive pre- and post-market testing and regulation.

The Food and Drug Administration (FDA) is the regulatory agency responsible for overseeing the “safety, effectiveness, quality, and security of human and veterinary drugs, vaccines and other biological products.”

As a regulatory agency, the FDA **writes rules** governing the pharmaceutical industry, **monitors for compliance**, and **imposes penalties** where there is non-compliance.

The FDA oversees vaccines both before and after they arrive on the market. Vaccine manufacturers are subject to the detailed requirements that can be found in parts of the Code of Federal Regulations (C.F.R).

The FDA mandates that all new vaccines undergo a lengthy and elaborate **testing process** that includes several phases of clinical trials. The FDA heavily regulates the clinical trial process. Before this complex process can even start, however, anyone attempting to license a vaccine needs to submit an **Investigational New Drug (IND)** application to the FDA. To do so, there must have already been animal and toxicology studies showing that the “product is reasonably safe for initial testing in humans.”

If a vaccine is shown safe and effective in clinical trials, the company needs to file a **Biologics License Application**, which is reviewed by the FDA. If agency staff deems it complete it goes for approval to the **Vaccine and Related Biological Products Advisory Committee**, which includes experts and a consumer representative. The committee makes recommendations about vaccine licensing based on “safety, effectiveness and appropriate use,” according to its charter.

The FDA carefully regulates the labeling – **vial labels and inserts** – of vaccines. The requirements can be found in 21 C.F.R. 201.57 and 21 C.F.R. 610.60. This regulation requires, for example, that all ingredients be listed (with very limited exceptions).

The regulations also require both a list of “warnings and precautions” which include the problems the vaccine may cause and a list of “adverse reactions” – problems reported after the vaccine was administered but not necessarily caused by it.

To prevent liability, company lawyers preparing the insert often include anything reported to them in the list of adverse events, **whether or not there is evidence that it’s caused by the vaccine**. Thus, there may be an extensive list of events, usually accompanied by language explaining that the events are listed regardless of causality.

The FDA’s role in ensuring vaccine safety does not end when the vaccine is approved for human use. The agency continues to monitor the vaccine even after it reaches the market. The FDA has extensive powers to inspect manufacturing facilities and the production process, test samples, and more.

THE FDA MANDATES THAT ALL NEW VACCINES UNDERGO A LENGTHY AND ELABORATE TESTING PROCESS THAT INCLUDES SEVERAL PHASES OF CLINICAL TRIALS.



One way the FDA regulates vaccines is by participating in the **Vaccine Adverse Event Reporting System (VAERS)**. VAERS is a national surveillance system that tracks all reports of suspected reactions to any vaccine. Actual causation is not required in order for a report to be made.

FDA also participates in what is called “Phase IV studies,” studies of vaccine safety after the vaccine is on the market.

If violations or problems are found, the FDA has the authority to issue warning letters; fine a company for some types of violations; order retention, recall or destruction of a product; or order a company to stop manufacturing the vaccine. In extreme cases, the FDA could criminally prosecute responsible individuals.

A more detailed description of the FDA’s role in vaccine licensing and safety monitoring can be found [here](#).

Protecting the Public Health: State and Federal Law

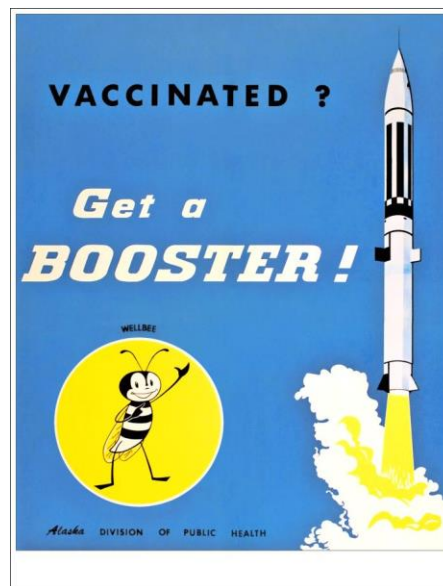
Disease Prevention: The CDC's Role

Whereas the FDA is a regulatory agency, the Centers for Disease Control and Prevention (CDC) is not. The CDC does not oversee and regulate pharmaceutical companies directly. Its mission is to prevent disease of any kind.

To fulfill that mission, the CDC, after a deliberative process with extensive expert input, **recommends vaccine schedules** that balance disease prevention, vaccine safety, and cost-effectiveness.

The CDC promotes those schedules and supports states in implementing vaccination programs to reduce preventable diseases as much as possible.

The CDC also co-manages the VAERS and does its own monitoring for vaccine safety.



Immunization Schedules

The CDC's recommended vaccine schedule is based on what experts determine will offer your child the earliest and safest effective protection against all the diseases against which it is cost-effective to vaccinate. The American Academy of Pediatrics (AAP), along with many other medical organizations, recommends that health care providers adhere to the CDC's recommended schedule.

The recommended schedule comes from the CDC's **Advisory Committee on Immunization Practices (ACIP)** which meets three times per year. The Committee's fifteen voting members include experts with extensive knowledge in infectious diseases, epidemiology, public health, health economics, and other relevant fields, as well as one consumer representative.

The schedule is also approved by the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).

Once approved by the CDC Director, ACIP recommendations become part of the official CDC recommendation and are published in the CDC's Morbidity and Mortality Weekly Report (MMWR). While the director usually accepts the recommendation, doing so is not required, and not all are accepted. This adds yet another layer of **accountability**.

ACIP: Learn More

The Advisory Committee on Immunization Practices meets three times a year to review and issue vaccine schedule recommendations.

For more information on ACIP and its work, visit:

[The Advisory Committee on Immunization Practices \(PDF\)](#)

[The ACIP Charter](#)

[The Childhood Immunization Schedule \(PDF\)](#)

School Immunization Requirements

Today, each state requires children to be immunized against certain diseases before they can attend public school. Some states apply the requirements to day cares and private schools as well, and a very small number of states also apply them to homeschooled children.

Each state determines which vaccines are required before a child can attend school. Because states are not bound by the CDC's recommended childhood immunization schedule, the requirements of each state can differ somewhat. School immunization requirements are influenced by political factors and by what vaccines the state determines are necessary in order to protect public health.

Some states provide information about immunization and exemption rates in specific schools and/or daycares.

Religious Exemptions

A state is not constitutionally required to offer non-medical exemptions for vaccines.⁸

However, if a state does offer a religious exemption, it needs to meet certain requirements:

- The exemption **can't be limited to organized religion**, because that discriminates against those with sincere beliefs that do not belong to an organized religion.⁹
- The fact that a person's official religion does not oppose immunization – or even supports them – does *not* negate a person's sincere belief in opposition to vaccines. **A person is allowed to maintain their own version of her religion**, and as long as she is sincere, that belief qualifies her for a religious exemption, if there is one in her state.¹⁰
- Some states' statutes require a **show of sincerity**, and an exemption can be denied if an applicant cannot prove her sincerity.
- If a state's statute does not require a show of sincerity, at least a few courts have ruled that **state officials cannot question an applicant's claims that their reasons are religious**.¹¹

⁸ Zucht v. King, 260 U.S. 174, 177 (1922).

⁹ Dalli v. Board of Ed. 358 Mass. 753, 754 (1971).

¹⁰ Berg v. Glen Cove City School Dist., 853 F. Supp. 651, 655 (E.D.N.Y. 1994).

¹¹ LePage v. State of Wyoming Department of Health, 18 P.3d 1177, 1180 (2001).

Vaccine Exemptions

At a glance:

- All 50 states currently offer a medical exemption.
- 48 states offer non-medical exemptions – either a religious exemption or a philosophical (also known as “personal belief”) exemption, or both.
- States vary dramatically when it comes to the process of obtaining an exemption.

More Information

More information on school immunization requirements can be found here:

[CDC School Immunization Requirements](#)

[Immunization Action Coalition: State Laws Regarding Vaccination](#)

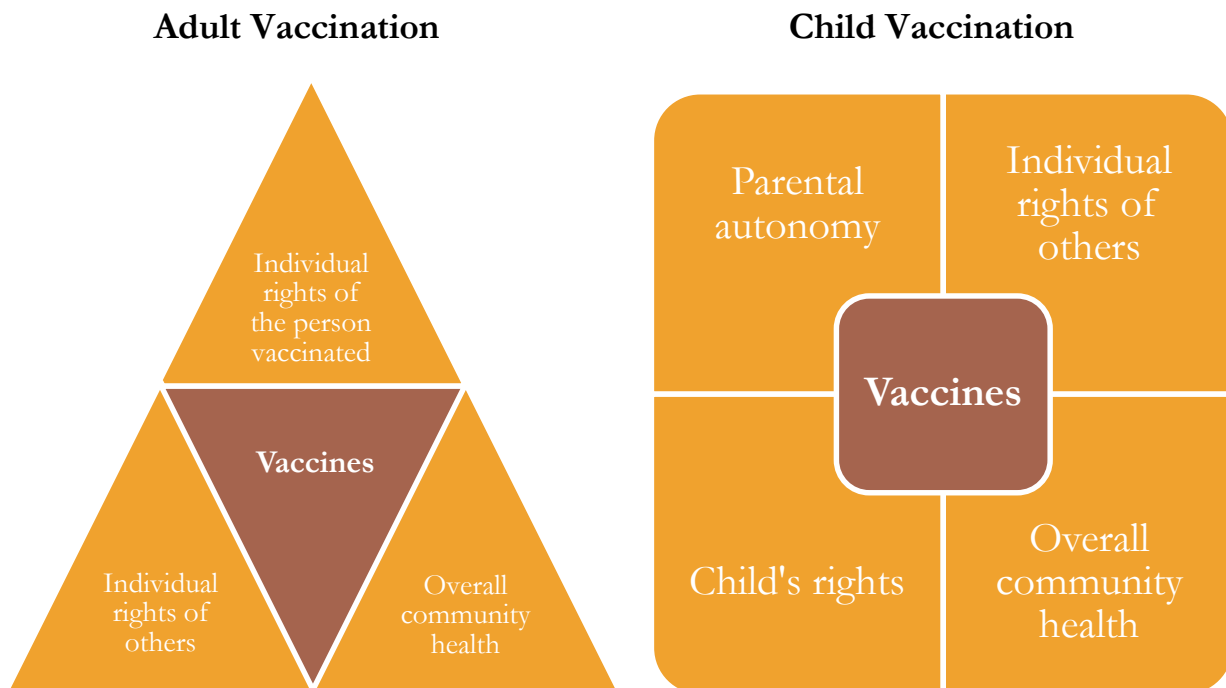
[WebMD: Child Vaccine Exemptions – States Getting Stricter?](#)

Vaccines: Individual Choice and Community Welfare

Several rights and interests affect what the law can do about vaccines:

- Individuals' autonomy to decide what medical treatment to accept or reject for their bodies;
- Parents' right to make decisions for their children;
- Freedom of religion and thought;
- A child's right to health;
- The right of the community to act to protect the public health and prevent outbreaks;
- The rights of others to be free from preventable diseases; and
- Costs to the public purse because of the harms of non-vaccinating.

Below are two frameworks (one for adult vaccination and one for child vaccination) that demonstrate the interplay between these rights and interests.



Community vs. Individual: Achieving a Balance of Rights

Our Supreme Court has long held that **vaccine mandates are constitutional**. When you live in society, your rights may be limited to prevent harm to others or to the general community.¹²

While we respect individual rights, they are not absolute. Individual liberty does not “import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint.”

Every individual’s rights need to be balanced against the rights of others, and the rights of the community as a whole. When public health and safety are involved, the government has authority to impose on individual liberty to protect the greater community.

Religion, Employment, and Rights

This authority extends to religious beliefs. We care about religious freedom; however, we also care about obedience to the law. The Supreme Court ruled that individuals must obey general laws even if they oppose them on religious grounds.¹³

For vaccines, this means that there is **no religious exemption required** under the 1st amendment.¹⁴

So, a state may provide religious waivers from general laws – but it does not have to do so.

EVERY INDIVIDUAL’S RIGHTS NEED TO BE BALANCED AGAINST THE RIGHTS OF OTHERS, AND THE RIGHTS OF THE COMMUNITY AS A WHOLE.

However, this does not mean that individual rights are never protected. In *Jacobson v. Massachusetts*, the Supreme Court suggested that individuals with valid medical reasons that preclude vaccination cannot be required to

vaccinate.

In the context of employment, the **Americans with Disabilities Act** stipulates that employers must accommodate those with a disability that prevents vaccination, unless this accommodation is considered a substantial hardship.

Bringing together employment and religious considerations, the **Civil Rights Act of 1964** states that an employer cannot discriminate on religious ground, and must provide reasonable accommodation to those with sincere religious objections to a work practice. That is, again, unless providing the accommodation imposes a burden (even a minor one) on the employer.

¹² The leading case was *Jacobson v. Massachusetts*, 197 U.S. 11, 25-27 (1905).

¹³ *Employment Division, Dep’t of Human Resources of Oregon v. Smith*, 494 U.S. 872 (1990).

¹⁴ *Workman v. Mingo Board of Education* (2011).

Parental Rights and the Child's Right to Health

Parental rights matter in our legal system. Parents have substantial freedom to determine the education and care of their children.¹⁵

Parental rights are there partly to respect family autonomy and privacy, and partly to allow parents to fulfill their responsibilities to a child.

Children have rights, too. **Parental rights can be limited when they put a child at risk** – for example, when by refusing to vaccinate, a parent leaves a child at risk of a dangerous disease.¹⁶

A state has a responsibility to its most vulnerable citizens, including children. When parental actions place children at risk, the state may regulate.



States have considerable freedom to balance parental rights and children's interests. The decision rests first with our democratically elected legislature, and secondly, with the courts interpreting statutes the legislature passed.

With respect to vaccines, this means that a state can choose what to require and when. For example, California requires vaccines against diphtheria, Hepatitis B, Hib, measles, mumps, pertussis, polio, rubella, tetanus, and varicella (chickenpox). Ohio does not require the Hib vaccine. Only a few states require vaccination against influenza.

Informed Consent

Informed consent means that before a patient undergoes a medical treatment, he should have been informed of the risks and benefits of the treatment, as well as any alternatives to the treatment. Failing to properly inform patients of risks, benefits, and alternatives is considered legally negligent.

In the context of vaccines, **patients deserve to be informed both of the risks of vaccinating, as well as the risks of *not* vaccinating.**

¹⁵ Troxel v. Granville, 530 U.S. 57 (2000).

¹⁶ Prince v. Massachusetts, 321 U.S. 158 (1944).

The Risks of Vaccinating

Under federal law, a provider is required to give a patient a **Vaccine Information Sheet (VIS)** that summarizes the known risks and benefits of the specific vaccine before vaccinating. The VIS provides information on the diseases we vaccinate against, who should get the vaccine, the risks of the vaccine, and how common those risks are. The VIS also includes information on what to do in case of a vaccine injury and how to be compensated in the very rare and unlikely case that someone suffers a serious vaccine injury.

While some states may require more information to be given before a vaccine is administered, the VIS probably covers the information that needs to be given to fulfill the requirements of informed consent when someone vaccinates.

VACCINE INFORMATION STATEMENT	
Tdap Vaccine (Tetanus, Diphtheria, and Pertussis)	
<small>Many Vaccine Information Statements are available in Spanish and other languages. See www.imzmnist.org/via Hojas de información sobre vacunas están disponibles en español y en muchos otros idiomas. Visite www.imzmnist.org/via</small>	
What You Need to Know	
1 Why get vaccinated? <p>Tetanus, diphtheria and pertussis can be very serious diseases, even for adolescents and adults. Tdap vaccine can protect us from these diseases.</p> <p>TETANUS (Lockjaw) causes painful muscle tightening and stiffness, usually all over the body.</p> <ul style="list-style-type: none"> It can lead to tightening of muscles in the head and neck so you can't open your mouth, swallow, or sometimes even breathe. Tetanus kills about 1 out of 5 people who are infected. <p>DIPHTHERIA can cause a thick coating to form in the back of the throat.</p> <ul style="list-style-type: none"> It can lead to breathing problems, paralysis, heart failure, and death. <p>PERTUSSIS (Whooping Cough) causes severe coughing spells, which can cause difficulty breathing, vomiting and disturbed sleep.</p> <ul style="list-style-type: none"> It can also lead to weight loss, incontinence, and rib fractures. Up to 2 in 100 adolescents and 5 in 100 adults with pertussis are hospitalized or have complications, which could include pneumonia or death. <p>These diseases are caused by bacteria. Diphtheria and pertussis are spread from person to person through coughing or sneezing. Tetanus enters the body through cuts, scratches, or wounds.</p> <p>Before vaccines, the United States saw as many as 200,000 cases a year of diphtheria and pertussis, and hundreds of cases of tetanus. Since vaccination began, tetanus and diphtheria have dropped by about 99% and</p>	2 Tdap vaccine <p>Tdap vaccine can protect adolescents and adults from tetanus, diphtheria, and pertussis. One dose of Tdap is routinely given at age 11 or 12. People who did not get Tdap at that age should get it as soon as possible.</p> <p>Tdap is especially important for health care professionals and anyone having close contact with a baby younger than 12 months.</p> <p>Pregnant women should get a dose of Tdap during every pregnancy, to protect the newborn from pertussis. Infants are most at risk for severe, life-threatening complications from pertussis.</p> <p>A similar vaccine, called Td, protects from tetanus and diphtheria, but not pertussis. A Td booster should be given every 10 years. Tdap may be given as one of these boosters if you have not already gotten a dose. Tdap may also be given after a severe cut or burn to prevent tetanus infection.</p> <p>Your doctor can give you more information.</p> <p>Tdap may safely be given at the same time as other vaccines.</p>
<p>Before vaccines, the United States saw as many as 200,000 cases a year of diphtheria and pertussis, and hundreds of cases of tetanus. Since vaccination began, tetanus and diphtheria have dropped by about 99% and</p>	3 Some people should not get this vaccine <ul style="list-style-type: none"> If you ever had a life-threatening allergic reaction after a dose of any tetanus, diphtheria, or pertussis containing vaccine. OR if you have a severe allergy to any part of this vaccine, you should not get Tdap. Tell your doctor if you have any severe allergies.

CDC Vaccine Information Sheet for Tdap vaccine (May 9, 2013)

Informed Refusal: The Risks of *Not* Vaccinating

A trickier question is what constitutes informed consent for the decision *not* to vaccinate. Obviously, if a person does not come to the doctor, she cannot be given information. However, if a person comes, but refuses information, the same problem arises.

The principle of *informed refusal* holds that **the decision not to vaccinate should only be made after a person is provided the same accurate, vetted information as someone who chooses to vaccinate.**

One possible way to achieve truly informed refusal is to mandate that certain educational requirements be met before a parent could seek and obtain a non-medical exemption to school immunization requirements. For example, states could mandate that refusing parents receive accurate information about the risks and benefits of vaccines from a qualified source, preferably a health care professional.

The AAP recommends such conversations with vaccine-refusing parents because it gives the physician a chance to counter misinformation and potentially change the parents' minds, leading to greater patient and community health. Even those with a religious objection to vaccination deserve to know the risk they are taking so they can make an informed choice.

The requirement of informed refusal interferes very minimally with **parental autonomy**. It is merely requiring education, and does not impose or force a decision. The potential benefit of this policy in terms of children’s health and the public health is significant.

Refusal to Vaccinate

Child's Name _____ Child's ID# _____

Parent's/Guardian's Name _____

My child's doctor/nurse, _____ has advised me that my child (named above) should receive the following vaccines:

Recommended	Declined
<input type="checkbox"/> Hepatitis B vaccine	<input type="checkbox"/>
<input type="checkbox"/> Diphtheria, tetanus, acellular pertussis (DTaP or Tdap) vaccine	<input type="checkbox"/>

- That some vaccine-preventable diseases are common in other countries and that my unvaccinated child could easily get one of these diseases while traveling or from a traveler.
- If my child does not receive the vaccine(s) according to the medically accepted schedule, the consequences may include
 - Contracting the illness the vaccine is designed to prevent (the outcomes of these illnesses may include one or more of the following: certain types of cancer, pneumonia, illness

When a parent refuses to vaccinate his child, AAP recommends that pediatricians document vaccine refusal using a **Refusal to Vaccinate** form, as well as indicating parental refusal in the child’s chart. This recommendation is intended in part to protect the physician from potential liability. More important, however, the Refusal to Vaccinate form emphasizes to the parent the importance the physician places on appropriate immunizations, and to focus “parents’ attention on the unnecessary risk for which they are accepting responsibility.”

Increasing Immunization Rates: The Role of the Law

How can the law increase immunization rates? What does the law do now, and what could it do in the future?

Legal interventions to improve vaccine coverage fall along a spectrum, depending on the level and nature of pressure the intervention imposes upon individuals. Each of these interventions are discussed in detail below.



Education

Several states require that parents taking advantage of a non-medical exemption receive education about vaccines' risks and benefits:

- Washington and California require a signature from health care providers that the information was provided;
- Oregon allows either signature from provider or completion of an online module; and
- Colorado's statute requires the Department of Health to create online educational materials, but does *not* require parents to view them.

An option under consideration in some areas is to pass a statute providing students – in high school or elementary school – with a mini-module about vaccines as part of the curriculum. The aim here is to educate individuals early on about the importance of vaccines, rather than first learning about them only when expecting a child.

Government-Funded Incentives and Subsidies

The federal government has put in place a number of incentive/subsidy programs to encourage vaccine uptake. Two key initiatives include the **Vaccines for Children** program and the **Section 317 Immunization Program**:

- The Vaccines for Children (VFC) program, which began in 1994, covers vaccines for children who would not otherwise be able to afford them (children on Medicaid or underinsured, or Native American or Alaskan children).¹⁷
- Section 317 of the Public Health Service Act authorizes the federal purchase of vaccines to vaccinate children, adolescents, and adults.¹⁸ Over the program's 50-year history, Section 317-purchased

¹⁷ <http://www.cdc.gov/vaccines/programs/vfc/about/index.html>

¹⁸ <http://www.cdc.gov/vaccines/imz-managers/guides-pubs/qa-317-funds.html>

vaccine have been directed toward the needs of priority populations; most recently this has included underinsured children not eligible for VFC, and uninsured adults. As of October 1, 2012, the program covers:

- Certain newborns receiving the birth dose of Hepatitis B vaccine prior to hospital discharge
- Underinsured or uninsured adults
- Fully insured individuals seeking vaccines during public health response activities including:
 - Outbreak response
 - Post-exposure prophylaxis
 - Disaster relief efforts
 - Mass vaccination campaigns or exercises for public health preparedness
 - Individuals in correctional facilities and jails

In addition to these long-running programs, the **Patient Protection and Affordable Care Act** encourages immunization in several new ways:

- Under Section 2713, individuals insured under all applicable group and individual plans are to receive appropriate and recommended vaccines at no cost
- Under Section 4204, the CDC can award states funds to be used in promoting and increasing vaccination coverage among adults and children. Funds can be used for (among other things) vaccine education, promotion, and cost-reduction to patients
- Under Section 2705 (j), insurers may offer a rebate for participation in a wellness program, which should include vaccination. Whether insurers will actually offer such a rebate remains to be seen

Imposing Costs: Civil Lawsuits



A *tort* is a civil wrong whereby a person injured by another can seek compensation from the wrongdoer.

If an unvaccinated person contracts a preventable disease and infects another, there may be a possible a tort suit.

While there have not yet been cases brought against unvaccinated people, there are decided cases holding people liable for negligence that caused another person to contract an infectious disease.¹⁹

Such a tort would have to fit under traditional tort principles. Demonstrating the existence of a duty and establishing causation in some specific cases are two potential barriers. They can, however, be overcome.

Some additional potential civil lawsuits are:

- Unvaccinated Child v. Parent: In some states, parents have immunity – they cannot be sued by their child. In other states, however, a child left unvaccinated and harmed by a preventable disease could sue her parents
- Infected individual v. anti-vaccine organization or doctor: Suit for negligent or intentional misrepresentation that causes physical harm may allow for suing doctors and organizations that promote anti-vaccine misinformation

¹⁹ Smith v. Baker, 20 F. 709, 709–10 (C.C.S.D.N.Y. 1884); Stubbs v. City of Rochester, 124 N.E. 137, 138 (N.Y., 1919); Berner v. Caldwell, 543 So.2d 686 (Ala. 1989).

- Patient v. Doctor: Doctors that recommend against vaccination may be liable in medical malpractice to their patients, and maybe even third parties

There is potential for tort liability in these contexts; however, these approaches have not yet been used.

Imposing Costs: No-Fault Options

Aside from personal injury lawsuits, additional legal avenues are available to limit the impact of unvaccinated individuals. These include **public nuisance laws, no-fault legislation, and insurance premium increases.**

Public Nuisance Laws

Non-vaccinating individuals who cause an outbreak may be sued under public nuisance laws. Under state statute or local ordinances, the appropriate government entity can sue for the behavior of one person that can, among other things, be injurious to health. When the harm affects a community, it's a public nuisance, and the state can sue.

Public nuisance statutes have not yet been used to sue for outbreaks caused by non-vaccination, but they *have* been used to recover costs incurred from other types of behavior harmful to health. For example, at least two states have sued for harm caused by lead paint. The results have been mixed.

In a 2008 decision re *State v. Lead Industry Association*²⁰, the court held that the manufacture and use of lead paint was not a public nuisance because it had not "interfered with a public right." However, in a more recent suit, a California court found against the lead paint manufacturers.²¹

While not vaccinating is distinguishable from corporate behavior in lead paint cases, there is adequate precedent for bringing private nuisance suits against individuals as well as corporations.

STATE OR LOCAL GOVERNMENT CAN
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Healthcare Workers and Flu

Recently, legal actions have been taken to reduce the risk posed by healthcare workers who refuse to vaccinate against influenza. Read more below:

[Vaccinating Health Care Workers against Influenza: The Ethical and Legal Rationale for a Mandate](#)

[State Law and Influenza Vaccination of Health Care Personnel \(PDF\)](#)

[Pandemic Vaccine – The Legal Landscape \(PDF\)](#)

²⁰ State v. Lead Indus. Ass'n, 951 A.2d 428, 443 (R.I. 2008).

²¹ California v. Atl. Richfield Co., 2014 WL 280526 (Cal. Super).

No-Fault Legislation

States might also consider passing legislation that imposes costs on non-vaccinating individuals in a variety of ways:

- States could create a fund that will cover outbreaks and/or compensate individuals harmed by non-vaccination with no fault required, and fund it through a fee – or a tax – on those who do not vaccinate
- States can also pass laws allowing public health departments to bill those who do not vaccinate to recoup the costs of outbreaks

Increasing Insurance Premiums

At the federal level, the ACA could be changed to allow higher premiums to be collected from those who do not vaccinate. More on this option can be found [here](#).

Limiting Unvaccinated Individuals' Access

Our society has agreed that is reasonable to limit the access unvaccinated individuals have to certain community benefits.

We already limit access to school through the use of mandatory immunization laws. Additionally, some states, and some employers, mandate that health care workers receive influenza vaccines.

Other approaches to limiting access include:

- Conditioning getting a passport on having the appropriate immunizations;
- Conditioning access to certain places – pools, parks, public transit – on immunization status; and
- Requiring immunization for non-health care employees in professions where non-immunization is an issue, such as teachers and restaurant workers.



Vaccine Refusal and Criminal Law

In *Jacobson v. Massachusetts*, the United States Supreme Court held that a criminal sanction (*e.g.*, a fine) on an individual who refused to vaccinate was constitutional.²² While a lot of time has passed, this holding has not been overturned, and it may well be constitutional to impose a criminal sanction for not vaccinating. Not all scholars agree on this, however, and some think that a case like *Jacobson* would be narrowed today.

²² *Jacobson v. Massachusetts*, 197 U.S. 11, 25-27 (1905).

Criminal law can be used to punish non-vaccinating individuals in the context of a death from preventable disease – the unvaccinated child, or someone she infects. Here’s how this may be accomplished:

- All states have manslaughter statutes. States vary on whether they require recklessness or just negligence to meet the required mental state for the statute
- Some states have criminal penalties as part of the statute governing parental duties, prohibiting child abuse and neglect. Not vaccinating can conceivably be seen as negligent (or as medical neglect). However, most cases of manslaughter for neglect, or conviction for child neglect, have involved very explicit cases of neglect. By comparison, not vaccinating a healthy child, particularly when there is no ongoing outbreak, may not be perceived by a court as neglect

In some cases, criminal action might well be appropriate – for example, if a child is harmed by not vaccinating *during* an outbreak, or not vaccinating against Hepatitis B when the mother is Hepatitis B positive.

For more information on vaccine refusal and criminal law, click [here](#).

Forced Vaccination

The most coercive legal intervention, of course, is forced vaccination.

During an outbreak, the courts have found that it may be appropriate to vaccinate a child – by force, if necessary – over parental opposition, to protect the child from the harms of a dangerous disease.²³



US military personnel are required by law to be vaccinated against many diseases – including smallpox, which was eradicated from the wild in the late 20th century.

However, under normal circumstances, it is probably inappropriate to do so. It is likely almost always inappropriate – and potentially unconstitutional – to forcibly vaccinate an adult of sound mind. Under our system, an adult may refuse treatment, even if it is life-saving. This follows from an established legal principle that people have the autonomy to decide what will be done with their bodies.²⁴

There can, however, be other consequences to not vaccinating. For example, many states have laws allowing quarantining people who are at risk of infecting others. Those who refuse to vaccinate and subsequently contract a vaccine-preventable illness may be subject to such confinement in the interest of protecting the public health.

²³ In re Christine M., 595 N.Y.S.2d 606, 616 (Fam. Ct. 1992).

²⁴ Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914).

Other Issues

Vaccine Injuries: Compensating the Rare Adverse Event

Vaccine injuries are very, very rare. The risks of an adverse reaction from a vaccine are much smaller than the risks of not vaccinating.

Nothing is 100 percent safe; even food is potentially dangerous – you can choke or get food poisoning. However, realizing that vaccines can pose small risks, Congress put in place systems to investigate these rare events – as well as a special system to compensate them.

The **National Childhood Vaccine Injury Act (NCVIA)** made special arrangements for handling vaccine injuries.²⁵ Under the NCVIA, doctors and vaccine manufacturers are required to report to the Department of Health and Human Services certain adverse events that can occur after vaccinating.²⁶

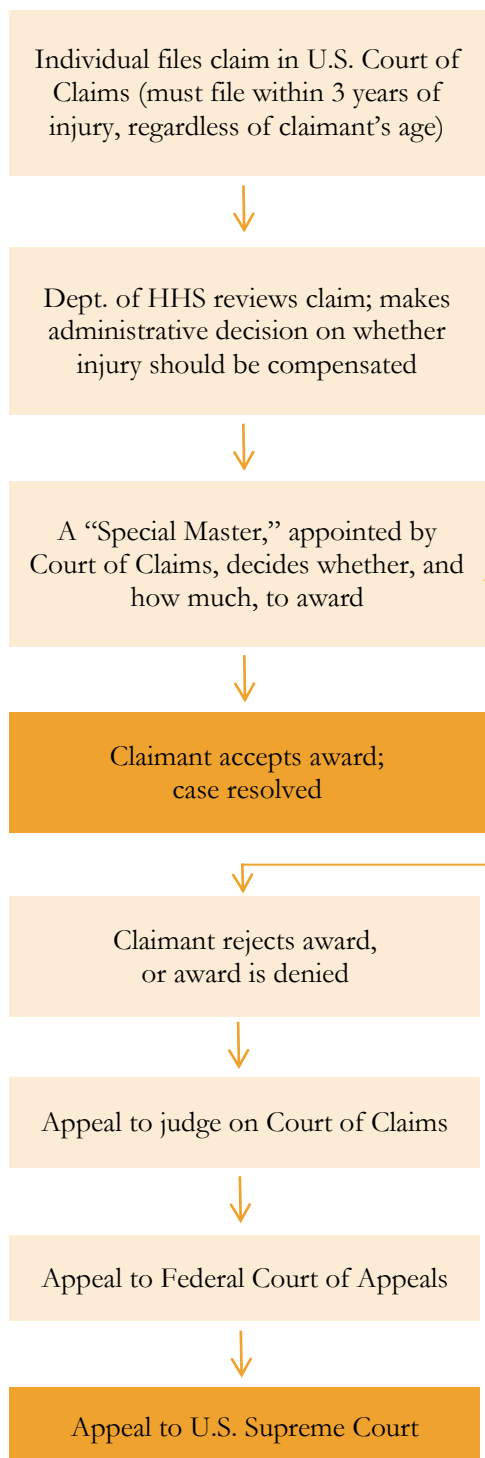
Parents and providers (and in fact, anyone) can also report such events to the [Vaccines Adverse Events Reporting System \(VAERS\)](#).

The NCVIA created a National Vaccine Injury Compensation Program (NVICP) which is funded by an excise tax – currently 75 cents – on each vaccine. This is a no-fault forum to recover harm, and offers an alternative to going through the regular courts.

The NVICP is designed to achieve two goals:

- Ensure vaccine supply by protecting manufacturers from liability; and
- Provide plaintiffs a quicker, less adversarial, more favorable forum than the courts.

NVICP: The Process



²⁵ National Childhood Vaccine Injury Act (NCVIA), 42 U.S.C. § 300aa-1, et seq.

²⁶ 42 U.S.C. § 300aa-25.

NVICP vs. the Courts

The NVICP offers individuals with claims of vaccine-related injuries (“plaintiffs”) several advantages compared to a regular court:

- Relaxed rules of evidence
- No need to show a design defect – or indeed, *any* defect
- If the petitioner is claiming an injury included in a special [Vaccine Injury Table](#), causation is presumed. This makes it much easier for the plaintiff with a legitimate vaccine injury to get compensated
- Petitioners get lawyer fees and costs whether they win or lose, and the lawyers do not get part of the award. (This is not typically the case in claims made in the traditional tort setting)

The NVICP **does not bar claims for injuries that are not recognized in the vaccine table**. However, if the petitioner wants to claim an injury that is not on the table, he or she only needs to meet the regular standard of proof for a civil trial. In other words, they need to show that it is more likely than not (specifically, more than 50 percent likely) that the vaccine caused the harm.

THE NVICP OFFERS INDIVIDUALS WITH CLAIMS OF VACCINE-RELATED INJURIES SEVERAL ADVANTAGES COMPARED TO A REGULAR COURT.

In addition, the NVICP does not bar suits against vaccine manufacturers outside of the NVICP program, though all vaccine claims **must initially begin under the NVICP**.

More specifically, if the plaintiff claims that the vaccine was not manufactured properly (a *manufacturing defect*) or that it was not accompanied with sufficient warnings, the plaintiff can still sue in state courts if he or she is unhappy with the results in NVICP – but they have to go through NVICP first. However, if the plaintiff is claiming an injury from a *design defect* – because the vaccine was allegedly not designed safely enough – he or she cannot sue in state courts at all.²⁷

More specifically, if the plaintiff claims that the vaccine was not manufactured properly (a

The **statute of limitations** (that is, the length of time during which you can file) is three years after the presumed injury event. Unlike in most states, this period is not tolled (stopped) for children. This is different than regular civil courts, where the statute of limitations *is* stopped for children: children can file throughout the remainder of their childhood, plus the time of the statute. Note, however, that the statute of limitations is not tolled for other claims against government either.

The amount of money provided for a death is limited to \$250,000. This amount is considered low relative to awards in other courts. Also, in a recent decision, the Federal Circuit decided that parents cannot be compensated for lost earnings from a child if their child died before the age of 18.²⁸

²⁷ *Bruesewitz v. Wyeth*, 131 S.Ct. 1068 (2011).

²⁸ *Tembenis v. Sec’y of Health & Human Servs.*, 733 F.3d 1190 (Fed. Cir. 2013) cert. denied, 13-902, 2014 WL 2921727 (U.S. June 30, 2014).

Are Vaccines “Unavoidably Unsafe?”

Before we address this, it’s important to define what exactly the term “unavoidably unsafe” means.

“Unavoidably unsafe” is a legal term of art. As such, it is used by lawyers to mean something different from the everyday conception of the term. For this reason, it can be easily misunderstood.

“Unavoidably unsafe” products are products whose benefits so far outweighed the risks that, in order to win a product liability case against the manufacturer, you would have to show negligence. In other words, unavoidably unsafe products are more protected from liability – **because they have substantial benefits.**



So the short answer to whether vaccines are unavoidably unsafe is: probably not. But if they were, it would not imply that they are unusually *dangerous*: quite the opposite.

Here’s the full story. In the 1960s, the American Law Institute wrote section 402A of the Restatement (Second) of Torts. Under 402A, there would be a different standard of proof for cases involving product liability. “Strict liability” would be used in these cases – a standard of proof that removes the burden on a plaintiff to show the manufacturer was negligent.

Because the burden of proof on the plaintiff was now relaxed, there was worry that strict liability would chill the production of certain products that come with inherent risks but also important benefits. As a result, the drafters of 402A wrote “Comment K” creating the category of “unavoidably unsafe” products. The comment stated: “Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous.”

One example of such a product was the old rabies vaccine, which had a much higher rate of complications than any modern vaccine. However, because of the high risks of rabies – almost always fatal – the vaccine’s benefits still far outweighed those risks.

Are vaccines unavoidably unsafe under this definition? Well, it depends on the state. Some states treat *all* pharmaceuticals as “unavoidably unsafe” and exempt all of them – drugs and vaccines – from strict liability. Others require a case by case determination that there isn’t a safer alternative design before exempting a product from strict liability. And some states are in between.

The term “unavoidably unsafe” has been brought up in a variety of vaccine-related contexts, hence the need to understand what exactly it means. In *Bruesewitz v. Wyeth*, the U.S. Supreme Court asked whether Congress was referring to the term “unavoidably unsafe” when setting up the National Vaccine Injury Compensation Program. A majority of the Supreme Court later concluded that in setting up NVICP, Congress was *not* trying to apply the “unavoidably unsafe” terminology to our childhood immunization schedule.



Pro-child. Pro-community. Pro-vaccine.

Our sincere thanks goes out to Dr. Dorit Rubinstein Reiss and Amanda Z. Naprawa for researching and assembling the information provided in this document.

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