Vaccine Controversies

Should parents be required to immunize their children?

Two centuries of scientific evidence have proven conclusively that vaccines can prevent deadly diseases, but a small, vocal group of skeptics — aided by high-profile celebrities — continues to fight mandatory immunization, especially of babies and school-age children. More than 90 percent of Americans immunize their children against diseases such as measles, diphtheria and whooping cough, but the remainder either reject immunization or don't get the vaccinations on schedule. Public health officials say refusing to follow vaccine protocols allows diseases to spread rapidly, as happened in December 2014 when a measles outbreak began at Disneyland and spread to seven states. But opponents of mandatory vaccination contend that the escalating number of vaccines poses safety concerns and that requiring parents to immunize their children impinges on parental rights and personal freedom. The conflict extends beyond school-age children to include mandatory immunization against the influenza virus for health care workers and military requirements that recruits be vaccinated against yellow fever, anthrax and other dangers.

Jennifer Wonnacott, with her son Henry, is among the California parents who supported a new law requiring schoolchildren in the state to be vaccinated. The law bans most immunization exemptions and is among the nation’s strictest.
THE ISSUES

171
- Are vaccines safe?
- Should parents be required to vaccinate their children?
- Does the pharmaceutical industry have too much influence over vaccine policy?

BACKGROUND

177
Early Vaccinations
Chinese Emperor K’ang inoculated his children against smallpox in the 17th century.

Discovery of Vaccines
In 1796, British physician Edward Jenner discovered exposure to cowpox could prevent smallpox.

Modern Fears
Tainted vaccines and negative side effects stoked public distrust.

CURRENT SITUATION

181
State Legislation
Five states have tightened vaccination requirements since a 2014 measles outbreak.

Congressional Vote
Some worry that proposed federal health legislation could compromise vaccine safety.

HPV Vaccine
Adolescent vaccination rates against the virus remain low.

OUTLOOK

184
Pipeline Expanding
Drug makers are researching or developing vaccines against Ebola, Zika and other diseases.

SIDEBARS AND GRAPHICS

172
Most States Allow Vaccination Exemptions
Only three have banned exceptions.

Vaccination Support Rises
Eighty-seven percent of adults said childhood vaccines are safe.

Most Adults See Vaccinations as Important Safeguard
Twenty percent of adults believe parents should be free to decide.

Ch chronology
Key events since 1809.

Vaccine Compensation Program Faulted
It has been “astonishingly slow and surprisingly combative.”

Vaccination Mandates for Adults on the Rise
“More should be done to protect the most vulnerable populations.”

At Issue:
Should children have to be vaccinated to attend school?

FOR FURTHER RESEARCH

For More Information
Organizations to contact.

Bibliography
Selected sources used.

The Next Step
Additional articles.

Citing CQ Researcher
Sample bibliography formats.
Vaccine Controversies

The Issues

When Facebook co-founder Mark Zuckerberg took his infant daughter, Max, to the doctor for a check-up in January, he posted a cute picture with this comment: “Doctor’s visit — time for vaccines”.

The post ignited a social media firestorm over the high-tech billionaire’s decision to vaccinate his daughter and his public advocacy on the issue. It generated more than 3.4 million “likes” and was shared more than 36,000 times, with comments that reflected all sides of the vaccine safety issue. Zuckerberg, whose wife is a pediatrician, has more than 49 million followers on Facebook.

The more than 79,000 commenters ranged from being supportive (“Thank you for doing what’s right and also for showing everyone else that it’s the right thing to do as well”) to critical (“I am sorry to see you unnecessarily putting your kid at risk by responding to faux science and propaganda”) to concerned about individual rights (“I’m for informed consent for any medical procedure, no matter how small the risk”).

Hailed by the scientific community as one of history’s most successful breakthroughs, virtually eradicating once-dreaded diseases, vaccines have come under fire from a small but ardent group of skeptics who have long questioned the safety and necessity of inoculations. They continue to express concerns about whether vaccines are linked to adverse reactions and illnesses, and some adhere to the notion — widely discredited in scientific circles — that vaccines can cause autism.

Although the vast majority of Americans continue to vaccinate their children, studies have found that as many as 1 in 10 parents are delaying or foregoing some or all recommended vaccines for their children.

As scientists have sought to quell those controversies, particularly the one surrounding vaccines and autism, attention among the skeptical has turned to individual rights. With an increasing number of vaccines recommended for children, coupled with mandates for students — and sometimes health care workers — to get vaccinated, opponents worry their rights are being eroded.

Those fears, propelled by high-profile opponents and heated online discussions, have translated into lower vaccination rates in some places. Meanwhile, growing outbreaks of certain communicable diseases, such as measles and pertussis (whooping cough), have led to medical and legislative efforts to increase vaccination rates.

In 2014, 23 measles outbreaks occurred in 27 states, according to the federal Centers for Disease Control and Prevention (CDC) — causing the highest number of cases since the disease had supposedly been eliminated in 2000. Recorded cases of whooping cough, which hit a low in 1975, have been increasing as well.

Those outbreaks illustrate how vulnerable people still are to infectious diseases, says Amy Pisani, executive director of Every Child By Two, a vaccine advocacy organization. The immunization effort has, in some ways, been a victim of its own success because many of today’s parents have never experienced the infectious diseases that vaccines keep at bay.

“Just keeping up those immunization rates, even though we don’t see the diseases, is important because the diseases are still out there,” Pisani says. “We’re just doing such a great job vaccinating that they’re not circulating as much as they used to be. So we have to just stay diligent.”

Some parents object to the rising number of shots their infants are being given. Today, the CDC recommends that children receive vaccines for 10 diseases — plus the flu vaccine — by age 6, which can mean up to 37 separate shots. That compares to five vaccines for the same age group in 1995.

The federal government does not mandate vaccination, but all 50 states and the District of Columbia require certain immunizations for children entering public schools. Every state allows exemptions for medical reasons. And all but California,
Mississippi and West Virginia allow for exemptions based on religious or philosophical reasons. 7 (See map, above.)

Most U.S. children still get their vaccinations. According to the most recent CDC numbers, among children ages 19 months through 35 months, more than 90 percent were vaccinated for measles-mumps-rubella (MMR), polio, hepatitis B and varicella (chicken pox). The percentage of children who do not receive any vaccinations was less than 1 percent. 8

At the same time, polls consistently show that the public strongly favors vaccines: 83 percent believe vaccines are safe, although some groups are more skeptical than others, according to the Pew Research Center. Younger adults are more likely to say vaccines are not safe and that parents should have the right to decide whether to vaccinate their children. 9

The Pew poll was conducted shortly after a measles outbreak began in December 2014, caused by a single visitor to Disneyland in Anaheim, Calif., whose infection led to 141 cases in seven states plus Canada and Mexico — an outbreak fueled by immunization rates as low as 50 percent in some areas. 10

A study of the Disneyland outbreak found that “substandard vaccination compliance” led to the measles outbreak. To prevent the spread of measles and maintain what scientists call “herd immunity” — vaccinating a large percentage of people to prevent the spread of a disease — vaccination rates need to be between 96 percent and 99 percent. 11

One of those at risk was 6-year-old Rhett Krawitt, who has leukemia and, as a result, can’t be vaccinated for measles. His family called for schools in Marin County, Calif., to ban students who haven’t been vaccinated. More than 6 percent of kindergartners there had personal-belief exemptions allowing them to bypass state laws requiring vaccinations — nearly three times the statewide average of 2.5 percent. 12

“If you choose not to immunize your own child and your own child dies because they get measles, OK, that’s your responsibility, that’s your choice,” said Rhett’s father, Carl Krawitt. “But if your child gets sick and gets my child sick and my child dies, then . . . your action has harmed my child.” 13

In the wake of the outbreak, Democratic Gov. Jerry Brown signed one of the nation’s strictest vaccine laws, making California the third state to bar religious and other personal-belief exemptions for schoolchildren. 14

Vaccines work by exposing individuals safely to a germ, such as from a particular virus, so their immune system can produce antibodies to fend off a particular virus. 15 Research is continuing into ways to improve existing vaccines and expand underused ones such as the vaccine against human papillomavirus (HPV). Scientists are also seeking vaccines for newer diseases such as the Zika virus, which is suspected of causing birth defects, and Ebola, which is often fatal.

Despite scientific certainty about the safety and effectiveness of vaccination, some Americans still doubt the benefits of vaccines and remain concerned about the government’s role in advocating and mandating immunizations. They also distrust the pharmaceutical industry, which has been exempted by Congress from liability for harms caused by vaccines. 16

One ardent foe is Barbara Loe Fisher, who became worried about vaccine safety when her 2-year-old son suffered a convulsion and collapsed within hours of a routine diphtheria-pertussis-tetanus (DPT) vaccination. He was left with multiple learning disabilities and attention deficit disorder. She joined with other parents in 1982 to create the National Vaccine Information Center (NVIC),...
which advocates for vaccine safety and informed consent. 17

It’s informed consent — the right to choose immunization — that Fisher particularly advocates. 18

“Vaccines should be available for anyone who wants to use them, [and] we should have high standards for proof of safety and effectiveness of these products,” Fisher says. But the bottom line, she says, is that people should be able to make their own choices. “I defend without compromise the ethical principle of informed consent in medical risk-taking. At our peril do we abandon that ethical principle.”

Those who remain skeptical of vaccines have garnered attention in part because of high-profile support from Hollywood celebrities, such as actors Jim Carrey and Jenny McCarthy, who has an autistic son, and environmental activist Robert F. Kennedy Jr., who has questioned the roles of the government and pharmaceutical industry in ensuring the safety of vaccine ingredients. 19

Opposition is not limited to the United States. Countries ranging from Australia and Canada to France and Saudia Arabia have dealt with issues surrounding their vaccine policies. 20

“There is opposition to vaccine, I think, in every country around the world,” said Dr. Alan Hinman, a public health scientist with the Task Force for Global Health, an international charity affiliated with Emory University. 21

As advocates and critics debate vaccines, here are some of the questions being asked:

Are vaccines safe?

Those who hesitate to get vaccines cite a number of concerns, but many boil down to safety.

Studies indicate that parents who delay or refuse vaccination are significantly less likely to believe that vaccines are safe or necessary to protect children’s health. 22

Specifically, these parents fear vaccines could have serious side effects, question the vaccines’ effectiveness and worry children get too many shots at one time or could develop autism. They also are more distrustful of the medical community than those who vaccinate. 23

According to the CDC, any vaccine can cause side effects. With that in mind, Congress created the National Vaccine Injury Compensation Program to provide damages to victims while shielding manufacturers from liability in order to maintain a steady vaccine supply. 24

(See sidebar, p. 180.)

Studies have found some consistent demographic trends among those who refuse to vaccinate their children. 25 Compared with under-vaccinated children, “the unvaccinated children were more likely to be male, to be white, to belong to households with higher income, to have a married mother with a college education and to live with four or more children,” according to a study published in The New England Journal of Medicine. 26

“Other studies have shown that children who are unvaccinated are likely to belong to families that intentionally refuse vaccines,” the study added, “whereas children who are undervaccinated are likely to have missed some vaccinations because of factors related to the health care system or sociodemographic characteristics.”

Many of these parents also tend to trust their own online research or the experiences of others more than they trust research conducted by the scientific and medical communities. 27

“Right now,” said Jacklyn Smoot, a California mother trying to decide whether to vaccinate her baby, “the people telling their personal stories influence me more. I feel like the data could be flawed for one reason or another, but I feel like someone’s story, because they’ve gone through something, and they don’t want other people to go through it, I feel like I trust that more.” 28

Many of these parents are clustered in certain cities or towns, which can lead to pockets with lower immunization rates. In one study, researchers identified five statistically significant clusters of underimmunization among preschoolers in 13 Northern California counties. 29

Much of the skepticism started in 1998 with a now-discredited report in the British weekly medical journal Lancet that cited the measles-mumps-rubella (MMR) vaccine as a potential cause of autism. The journal retracted the study in February 2010, and the lead author, Andrew Wakefield, lost his medical license. 30

In retracted Wakefield’s work, Dr. Fiona Godlee, editor in chief of the British Medical Journal, said “the MMR
But concerns about a link between vaccines and autism have lingered. 32

And I find a lot of worried parents

reported Science writing at the Massachusetts Institute of Technology. 33

Another concern focused on the use of thimerosal — a mercury-containing preservative used in vaccines since the 1930s — in some childhood vaccines. Although studies have shown thimerosal to be safe and to have no links to autism, it has not been used in childhood vaccines since 2001 as a result of concerns raised by parents. 34

In addition, some parents who generally support vaccination contend young children receive too many shots too soon, so they advocate delaying or spreading out the immunization schedule. 35

Some of them are abiding by recommendations outlined by Dr. Bob Sears, a California pediatrician who advocates giving parents the option to follow a delayed inoculation schedule. 36 “I created my alternative vaccine schedule that allows parents to go ahead and vaccinate, simply in a more gradual manner,” Sears said. “And I find a lot of worried parents who otherwise would refuse vaccines altogether are very happy to go ahead and vaccinate if they’re doing it in a way that they feel safer about.” 37

A study by the Institute of Medicine, a division of the National Academies of Sciences, Engineering and Medicine, examined the current vaccine schedule. It concluded the schedule results in fewer illnesses, deaths and hospital stays, and that new vaccines are evaluated before the federal Advisory Committee for Immunization Practices adds them to the schedule. 38

“However, the elements of the schedule — the number, frequency, timing, order and age at which vaccines are given — are not well-defined in existing research and should be improved,” the report found. 39

The medical community as a whole, however, doesn’t support delaying or skipping any of the shots outlined on the CDC schedule. 40 Various studies have found no problems based on the current immunization schedule. 41

“We don’t advocate for spread-out schedules because they leave children vulnerable,” said Dr. Deborah Leiman, associate director of pediatric infectious diseases at Cedars-Sinai Medical Center in Los Angeles. “The schedule is set up the way it is because it’s been tested on tens of thousands of children. If you make up your own schedule, you are flying by the seat of your pants.” 42

Some pediatricians refuse to treat patients who are not up-to-date on their vaccines because most parents want to be sure they won’t expose their children to disease simply by taking them to the doctor’s office. 43

“We decided that the patients who are not vaccinated are presenting a clear and present danger,” said Dr. Charles Goodman, a California pediatrician. “It just wasn’t fair for a small number of patients to put those many patients, who either couldn’t be vaccinated because they’re too young or had a weakened immune system, at risk.” 44

Should parents be required to vaccinate their children?

The issue of how to balance the rights of the individual with the larger public good lies at the center of debate over health laws, including mandatory vaccines. 45

The Supreme Court has twice upheld the government’s right to require immunizations:

• In 1905, the court held that mandating smallpox vaccination was a reasonable exercise of the state’s police power under the 14th Amendment to the U.S. Constitution. 46

• In Zucht v. King, the court ruled in 1922 that children could be barred from attending school if they didn’t get their vaccinations. 47

Under that principle, the Supreme Court said in 1944 that “neither rights of religion nor rights of parenthood are beyond limitation,” and the government can restrict a parent’s rights in order to safeguard a child’s well-being. 49

If the issue involved individuals making a choice that only affected themselves, such as whether to take antibiotics or undergo chemotherapy, the debate would be different, says Paul Offit, a pediatrician who heads the Vaccine Education Center at the Children’s Hospital of Philadelphia.

“Is it your right as a parent in this country to expose your child to a potentially fatal infection? I think the answer to that question is no,” Offit says. “We talk endlessly about parents’ rights. How about children’s rights? There’s not a year that goes by at our hospital where we don’t see a child suffer and die from a vaccine-preventable disease.”

Offit compares immunization mandates to child car-seat and seat-belt laws, which require parents to use them for their children’s protection. “Frankly, this is a civil-rights issue, and the civil rights are those of the child,” he says.

Similar views come from a range of voices on the ideological spectrum, from the liberal Center for American Progress to the libertarian Cato Institute to the conservative American Ideas Institute. 50

“Vaccination is communitarianism in its purest, laboratory form,” wrote conservative columnist Michael Gerson. “The choices of citizens are restricted for a clearly (even mathematically) defined social good.” 51

But for those skeptical of vaccines, the issue of individual liberty is crucial. 52

VACCINE CONTROVERSIES
The question isn’t whether to vaccinate or not to vaccinate. The question is whether parents should have the right to make an informed medical decision for their child’s health,” said Shannon Kroner and Tim Donnelly, backers of a referendum to overturn California’s new law banning most immunization exemptions. (The effort failed to get enough signatures to put the question on the ballot.)  

Fisher, of the National Vaccine Information Center, uses words like oppression and tyranny when she talks about vaccine mandates. She sees vaccination as a civil-rights issue, encompassing freedom of thought, speech and religion. “You have people who feel that they are oppressed, that they are losing their ability to protect their children,” she says.

Fisher cites efforts in California and elsewhere to restrict religious or philosophical exemptions to school vaccine requirements. Given the well-defined legal precedent that allows the state to impose mandates for children, opponents have focused on maintaining these exemptions.

“A system that will not bend will break,” Fisher says. “You cannot oppress the people, when they believe their lives and their health are on the line, with a policy that’s so inflexible that they cannot protect themselves or their children from harm. You cannot expect anything but resistance to that kind of oppressive policy.”

That sentiment echoes comments Sen. Rand Paul, R-Ky., made during the early days of the presidential campaign last year when he was still a candidate. Paul, an ophthalmologist who holds libertarian views, said most vaccines should be voluntary, and he called mandates government overreach.

But that view contrasts with the position of another libertarian, who says that while the rights of the state are limited, so are the rights of the parents.

“Parents have agency over their children, but it’s not unlimited,” says Michael Tanner, a senior fellow at the Cato Institute. “They just have a certain agency over them because children aren’t able to exercise their own decisions.”

“In the end,” Tanner says, “I favor these mandatory vaccine laws, but they don’t make me comfortable because it is a little bit gray, and it is an area where you are granting the state certain rights of intervention to override individual choice, and I want a pretty high bar for that.”

A study by Indiana University researchers tried to determine whether the concept of “benefit to others” — in the form of the herd immunity needed to prevent the spread of disease — influences parents’ decisions about immunization.

What they found was the need for more study. “There appears to be some parental willingness to immunize children for the benefit of others, but its relative importance as a motivator is largely unknown,” the Indiana University team wrote.

Does the pharmaceutical industry have too much influence over vaccination policy?

The distrust of government expressed by those opposed to mandatory immunization extends to the pharmaceutical companies that produce the vaccines. Numerous opinion polls show Americans don’t hold drug manufacturers in high regard, in large part because they see drug prices as too high and industry profits as too big.

A Kaiser Family Foundation poll, for instance, found fewer than half held a favorable opinion of pharmaceutical companies — below doctors, food manufacturers, banks, airlines and health insurance companies. Only oil companies ranked lower in public opinion.

“You have real animosities about pharmaceutical companies making massive profits,” said Mark Largent, a historian at Michigan State University who wrote Vaccine: The Debate in Modern America.

Vaccination skeptics say government researchers and regulators push for new vaccines, and industry happily supplies them. Because of the many ties between them, everyone profits, according to industry critics. They often cite the case of Julie Gerberding, who resigned as CDC director in 2009 to become president of drug manufacturer Merck’s vaccine division.

Several federal agencies are involved in vaccine research and regulation. At the Department of Health and Human Services (HHS), the National Vaccine Program Office coordinates vaccine-related activities, and the Food and Drug Administration (FDA) is responsible for regulating vaccines and other biologics. Also involved in vaccine activities are the National Institutes of Health, the CDC and the Health Resources and Services Administration, all of which are within HHS.

The FDA’s Vaccines and Related Biological Products Advisory Committee recommends whether new vaccines are safe and effective. The CDC’s Advisory Committee on Immunization Practices recommends which vaccines should be included on the national Childhood Immunization Schedule, the list that states follow in requiring certain vaccines as a prerequisite for school admission.

Critics — including, but not limited to, vaccine skeptics — have long questioned the revolving-door relationships between these public agencies, the drug manufacturers they regulate and the medical research community.

Dr. Marcia Angell, the former editor-in-chief of The New England Journal of Medicine, traces the rise of the pharmaceutical industry’s influence to the early 1980s, when changes in tax and patent laws altered the relationships between the drug manufacturers, private researchers and government institutions. The result was a research atmosphere that enabled more players to cash in, said Angell, author of The Truth About the Drug Companies: How They Deceive Us and What to Do About It.

Since then, “the pharmaceutical industry has moved very far from its original high purpose of discovering and pro-
producing useful new drugs,” Angell said. “Now primarily a marketing machine to sell drugs of dubious benefit, this industry uses its wealth and power to co-opt every institution that might stand in its way, including the U.S. Congress, the FDA, academic medical centers and the medical profession itself.” 65

According to several studies, the pharmaceutical industry’s influence also can be found in medical journals, where medical professionals rely on objective data to make decisions about prescription drugs and vaccines. 66

Fisher, of the NVIC, points to a study about industry influence that was published in the British Medical Journal. 67

“The public voices that are questioning the system, that want reform of the system, have a legitimate argument,” she says. “They have been marginalized and demonized by special interest groups who don’t want to truly consider the legitimate questions that have arisen.”

Kennedy, the environmental activist, is one of the industry’s harshest critics. His celebrity status and political connections have helped him gain attention for his argument that thimerosal can be linked to childhood neurological disorders, including autism. He also contends pharmaceutical profits, not medical progress, are behind the increasing number of vaccines children are required to get. 68

He outlined his theories in a 2005 article, called “Deadly Immunity,” published in Rolling Stone and Salon magazines. But both publications soon backtracked. Rolling Stone issued corrections, while Salon retracted the purported exposé. 69

Other critics, such as Fisher’s group, note that in the early 1980s, the pharmaceutical companies were so powerful that they threatened to stop producing vaccines unless Congress passed a law exempting them from liability for harms caused by their products. At the time Americans were suing drug companies for problems allegedly caused by vaccines, particularly those for whooping cough and polio. 70 Congress in 1986 created the National Vaccine Injury Compensation Program, which set up a federal fund to compensate victims who claim they were harmed by vaccines. (See sidebar, p. 180.)

In addition to questions about conflicts of interest, drug manufacturers face criticism over their profits and how expensive vaccines are. 71

Vaccines were once considered something of a stepchild in the manufacturing industry because they cost more to produce than conventional drugs. Now, however, they can be a profitable product. The average cost to fully vaccinate a child with private insurance to the age of 18 increased from $100 in 1986 to $2,192 in 2014. 72

The result has been that previous concerns about low prices driving manufacturers out of the market and leading to shortages have been replaced by new concerns about high prices, particularly in developing countries with an acute need for vaccines. 73

On the other hand, a recent study examining the economic ramifications of vaccination found that “from a societal perspective, every dollar spent ultimately saves at least 10 dollars.” 74

Because of vaccination, the study estimated, U.S. children born in 2009 would have 20 million fewer cases of vaccine-
preventable diseases and 42,000 fewer early deaths related to those diseases during their lifetimes. That means with an investment of $7.5 billion, the routine immunization schedule would save $76 billion in direct and indirect costs, resulting in a net savings of $69 billion.

The pharmaceutical industry also notes how expensive and complicated it is to develop a vaccine. Sally Beatty, a spokeswoman for Pfizer, said it can take five years and $600 million to build a lab where a vaccine is manufactured, and that another two years are needed to produce just one vaccine batch. 75

**BACKGROUND**

**Early Vaccinations**

The use of vaccines to prevent disease dates to early times, when the first inoculations were done in China in the 11th century. While immunizations have saved millions of lives, especially in the past 200 years, they’ve also been controversial from the beginning. 76

In 1661, when Chinese Emperor Fu-lin died of smallpox, his third son became Emperor K’ang. The boy had already survived a case of smallpox, and he eventually supported inoculation in its earliest known form. Called variolation, the process involved deliberate infection with smallpox using dried scabs or fluid from the pustules; it usually resulted in a milder form of the disease that would leave the person immune, although it also could lead to death. The emperor immunized his children, but not without facing some criticism. 77

For hundreds of years, diseases such as smallpox, measles, whooping cough and yellow fever took their toll across the globe. When European colonists came to the Americas, they brought those diseases with them. Smallpox is believed to have arrived in Mexico in 1520 on a Spanish ship sailing from Cuba, carried by an infected African slave. Ultimately those diseases spread throughout the Americas, killing some 95 percent of the native population — up to 20 million people. 78

In 1694, Queen Mary II of England died of smallpox. In 1713, measles killed three children and the wife of Cotton Mather, a prominent Boston clergyman who became an inoculation advocate. Eight years later, when a smallpox outbreak in Boston left 844 people dead, Mather promoted variolation but was widely criticized for it. At one point, a primitive grenade was thrown through a window of his house, with this note attached: “Cotton Mather, you dog, dam you. I’ll inoculate you with this, with a pox to you.” 79

In 1782, King George III of England lost a son who died after receiving the smallpox variolation.

Benjamin Franklin also lost a son to smallpox. Rumors abounded that he died from failed variolation, rather than the disease itself, which Franklin denied. In his autobiography, Franklin wrote about the death, discussing the kind of parental quandary that resonates today. “In 1736 I lost one of my sons, a fine boy of four years old, by the small-pox, taken in the common way,” he wrote. “I long regretted . . . that I had not given it to him by inoculation. This I mention for the sake of parents, who omit that operation on the supposition that they should never forgive themselves if a child died under it; my example showing that the regret may be the same either way, and that therefore the safer should be chosen.” 80

Franklin wasn’t alone. Dr. Howard Markel, a historian of medicine, wrote that “John Adams was inoculated in 1764. Twelve years later, while he was in Philadelphia declaring American independence, his wife and children were inoculated as an epidemic raged in Boston. Gen. George Washington ordered his soldiers to be inoculated in 1777 because more men were falling to smallpox than to Redcoat muskets.” 81

**Discovery of Vaccines**

At about the same time the founders were building a new nation, British physician Edward Jenner was revolutionizing medicine by ushering in the era of vaccination with his discovery in 1796 that infection with cowpox could protect a person from smallpox, and its use quickly spread. 82

Key among the scientists working in the 19th century was Louis Pasteur, a French chemist and microbiologist who developed vaccines for anthrax and rabies. Work also began on finding vaccines for such diseases as diphtheria, rubella, tuberculosis, cholera and typhoid fever.

In the 20th century, researchers began to focus on finding a vaccine for polio. In 1953, American medical researcher Dr. Jonas Salk injected himself, his wife and their three sons with his experimental poliovirus vaccine. Soon after, large-scale trials were underway, and by 1955, public vaccination began.

While Salk’s vaccine used a “killed” form of the virus, another American researcher, Dr. Albert Sabin, developed an oral polio vaccine that used a live version of the virus, which became commercially available in 1961. The live vaccine largely replaced Salk’s earlier version in the United States until 1999. Neither Salk nor Sabin patented his vaccine, donating the rights as gifts to humanity. 83

During the same time period the race was on for a polio vaccine, American microbiologist Maurice Hilleman began work that resulted in creating or improving more than 25 other vaccines, including nine of those now routinely recommended for children. At his death in 2005, other researchers credited him with having saved more lives than any other scientist in the 20th century. 84

But opposition to vaccines began even before they were fully developed. After Jenner developed the smallpox
vaccine, it was met with suspicion and mistrust. Some objected that it was administered by piercing the skin, while others did not like that the vaccine came from an animal. Other skeptics had a general distrust of medicine. And many opposed the vaccine because they believed it violated their personal liberty. 85

When Britain implemented laws between 1840 and 1853 making vaccination compulsory, almost immediately anti-vaccination leagues challenged them as a violation of civil liberty. One article characterized the “vaccination monster” with this vivid description: “A mighty and horrible monster, with the horns of a bull, the hind of a horse, the jaws of a krakin, the teeth and claws of a tyger, the tail of a cow, all the evils of Pandora’s box in his belly, plague, pestilence, leprosy, purple blotches, foetid ulcers, and filthy running sores covering his body.” 86

In 1879, the Anti-Vaccination Society of America was founded. Two other leagues, the New England Anti-Compulsory Vaccination League and the Anti-Vaccination League of New York City, soon followed.

In 1898, the British vaccination law was amended to allow exemptions to the smallpox mandate for parents, based on conscience, which introduced the concept of “conscientious objector” into English law. 87

The federal government’s role in vaccine policy is extensive, particularly in the development of guidelines for when to administer specific vaccines — and when not to — and to which populations. 88

Its role in public health matters stems from the U.S. Constitution’s Commerce Clause, which states that Congress shall have the power “[t]o regulate Commerce with foreign Nations, and among the several States.” In certain situations, this has applied to vaccines, such as requirements that military personal and immigrants be vaccinated. 89

The federal role is more limited when it comes to requiring vaccines. It does not mandate the use of any childhood vaccines; it only provides recommendations. Generally, the decision to mandate a vaccine falls to state and local governments, where the authority to enact laws for protecting public health derives from the state’s general police powers.

When it comes to communicable disease outbreaks, these powers may include the enactment of mandatory vaccination laws. Massachusetts was the first, in 1809, when it passed a smallpox vaccination law. In 1827, Boston became the first city to require vaccination against smallpox for public school students, and the law was expanded to the entire state in 1855. 90

The other 49 states and the District of Columbia eventually passed laws requiring mandatory vaccinations for children entering school, with varying exemptions. Many states also have laws providing for mandatory vaccinations during a public health emergency or the outbreak of a communicable disease.

Modern Fears

In 1955, just weeks after the Salk polio vaccine became available for widespread use, a production error led to one of the worst pharmaceutical disasters in U.S. history, causing some vaccines from Cutter Laboratories to be tainted with live polio virus. Ten people died while more than 150 others were paralyzed. 91

Public trust in official reassurances about vaccine safety eroded again in 1976, when people contracted Guillain-Barre syndrome after receiving a vacci

American medical researcher Albert Sabin developed an oral polio vaccine that became commercially available in 1961, largely replacing a vaccine developed by another American, Jonas Salk, that was dispensed by injection. By 1979 the last U.S. cases of polio had occurred among unvaccinated persons.
**Chronology**

**1800s** Smallpox vaccinations become widespread.

1809 Massachusetts is first jurisdiction to mandate smallpox vaccination.

1898 Britain allows conscience exemptions to its smallpox vaccination mandate.

1898 Britain allows conscience exemptions to its smallpox vaccination mandate.

**1900s-1940s** Vaccines are licensed for rabies, pertussis, influenza, diphtheria and typhoid fever. Immunization opposition continues.

1905 Supreme Court upholds state law mandating smallpox vaccinations.

1922 Supreme Court declares unvaccinated children can be kept out of school.

1949 The last case of smallpox in the United States is reported.

1961 Dr. Albert Sabin develops oral polio vaccine.

1962 Vaccination Assistance Act allows for mass immunizations.

1963 Measles vaccine licensed.

1976 Public trust in vaccine safety erodes when people contract Guillain-Barré syndrome after receiving the swine flu vaccination.

1977 Federal government undertakes the Childhood Immunization Initiative with a goal of achieving 90 percent vaccination levels.

1979 The last U.S. cases of polio occur among unvaccinated persons.

1980 World Health Organization declares smallpox eradicated.

1986 National Childhood Vaccine Injury Act reduces vaccine manufacturers’ liability over vaccine injuries.

1988 Vaccine Injury Compensation Program provides alternative to civil litigation.

1996 Parental concerns about the DPT (diphtheria-pertussis-tetanus) vaccine lead to different formulation.

1998 British medical journal *Lancet* publishes study by Dr. Andrew Wakefield linking the MMR (measles-mumps-rubella) vaccine to autism, fueling anti-vaccination sentiment.

1999 Measles outbreak at Disneyland raises awareness about the number of unvaccinated people.

2000 Measles declared no longer endemic in the United States.

2001 After complaints from parents, thimerosal is removed from childhood vaccines, but it continues to be used in flu vaccines.

2003 Wakefield study discredited over fraudulent research.

2010 Britain’s General Medical Council rules that Wakefield engaged in professional misconduct; *Lancet* retracts his paper; Wakefield subsequently loses his medical license.

2014 California becomes third state to eliminate religious or philosophical vaccination exemptions from school vaccination mandates.
Vaccine Compensation Program Faulted

It has been “astonishingly slow and surprisingly combative.”

When Tarah Gramza's daughter was diagnosed with an autoimmune disorder, the last thing on the Phoenix nurse's mind was the human papillomavirus (HPV) immunization her teenager had received more than a year earlier. But then Gramza found research linking the disorder to the vaccine.

“I did not think in a million years it would have been a vaccine,” Gramza said. 1

Now she finds herself in a legal battle to win compensation from the National Vaccine Injury Compensation Program, a federal program designed to provide efficient and fair support to vaccine victims. But congressional researchers, vaccine skeptics and some legal observers say the nearly 30-year-old program has failed to live up to its mission. 2

The compensation process has evolved since 1902, when Congress passed the U.S. Biologics Control Act, the first measure designed to regulate vaccines. After that, product-liability laws were passed throughout the 20th century, allowing individuals who claimed they had been harmed by vaccines to sue the manufacturer or the physician. 3

In 1955, that process was tested by lawsuits arising from a disaster in which, just weeks after the polio vaccine became available, some tainted lots caused by a Cutter Laboratories production error led to 10 deaths and more than 150 cases of paralysis. A key lawsuit stemming from the incident had a lasting effect on liability law. 4

Lawuits against drug makers increased in the 1970s and '80s, with many cases related to the diphtheria-pertussis-tetanus (DPT) vaccine. Facing mounting legal fees and large jury awards, many pharmaceutical companies stopped vaccine production, and health officials worried that a shortage would develop. 5

In 1986, Congress stepped in, passing the National Vaccine Injury Compensation Act, which led to the creation of the National Vaccine Injury Program. While recognizing that vaccines occasionally cause harm, lawmakers sought to find a balance between ensuring a steady supply of vaccines and providing a financial remedy to those injured. The program's no-fault compensation plan capped damage awards for pain and suffering. 6

But those who have studied the system say only half that equation has worked. By shielding manufacturers from liability, the program has ensured that vaccines remain available to the public. But according to an Associated Press investigation, the program has failed to keep its promise of “quickly and generously” compensating those harmed by vaccines because the process often takes years, has a high standard of proof and has led to the very courtroom litigation it sought to avoid. 7

A report by the Government Accountability Office (GAO), the independent watchdog agency of Congress, found similar problems. A 2014 GAO study into vaccine injury claims found an “adversarial environment” in which more than half of the 9,800 claims filed since 1999 took several years to resolve. 8

Here’s how the vaccine compensation process works: 9

• An individual, parent or legal guardian can file a claim for an injury that lasted more than six months after the vaccine was given, resulted in a hospital stay and surgery or led to death. Claims must be filed with the U.S. Court of Federal Claims, commonly known as vaccine court. 10

• Compensation varies, depending on the injury, and can include as much as $250,000 for pain and suffering, lost earnings, legal fees and/or a reasonable amount for past and future care. For a death, the payout is capped at $250,000.

• Under a statute of limitations, claims must be filed within three years for an injury or two years for a death. Sixteen vaccines currently are covered under the program, although people can petition to have their cases reviewed if another vaccine is involved.

Continued from p. 178
Wakefield linked the routinely recommended shot to the rising incidence of autism.

In 2004, the study was called into question amid reports of fraudulent research and conflicts of interest. In 2010, Britain’s General Medical Council ruled that Wakefield was guilty of misconduct, and The Lancet formally retracted the paper. In May 2010, Wakefield was banned from practicing medicine in Britain. 97

An analysis of these long-running vaccine controversies by Dr. Jeffrey P. Baker, a Duke University pediatrician and medical historian, noted how the two sides approach the controversy from opposite angles: Physicians and public health leaders turn to the scientific process and research reports, while vaccine opponents reject these studies, charging that the data have been manipulated for political reasons. 98

“A polarized debate both draws upon and contributes to polarized understandings of history,” Baker wrote. As a result, participants “judged the same data using different sets of assumptions, each shaped by history. Articulating and sharing these narratives represent a first step toward transcending the powerful boundaries shaping today’s vaccine controversies.”

The Court of Federal Claims makes the final decision regarding claims, compensation and the amount of the award.

To win a claim, petitioners must prove they received a vaccine and developed a condition included on the government’s vaccine injury table, which lists the vaccines and the associated illness, disability or injury covered. They don’t have to prove the immunization caused their condition. 11

But if the injury is not listed in the table, the burden of proof is higher. Some critics contend it is too high, especially in cases where the harm is clear but the scientific evidence is not. The Associated Press investigation found many claims fall into such a gray area. The science is clear on only nine of 144 vaccine-injury combinations that a vaccine could cause the illness.

According to Department of Health and Human Services (HHS) data, more than 16,729 claims have been filed since 1988. Of those, 9,915 were dismissed and 4,482 received compensation from the $3.3 billion paid out over the program’s lifetime. 12

When Stanford University law professor Nora Freeman Engstrom examined how well the injury compensation program had fared as an alternative to traditional litigation, she found the system wanting.

“The results are discouraging,” Engstrom said. “Despite initial optimism in Congress and beyond that such a fund could resolve claims efficiently and amicably, in operation the program has been astonishingly slow and surprisingly combative.” 13

But those who defend the vaccine compensation program say that while the system has room for improvement, it has helped ensure a steady availability of vaccines, and it has made it easier for vaccine victims to get compensation.

Going through the regular courts is “much harder” for those seeking compensation, said Dorit Rubinstein Reiss, a University of California, Hastings, law professor, because they would have to prove the vaccine is defective, and they would have to prove a link between the injury and the vaccine. 11

— Jane Fullerton Lemons

5 “Vaccine Injury Compensation Programs,” op. cit.
VACCINE CONTROVERSIES

Vaccination Mandates for Adults on the Rise

“More should be done to protect the most vulnerable populations.”

It’s not just schoolchildren who have to roll up their sleeves. Many adults do, too. In California, a new law requires daycare workers to be vaccinated for measles, whooping cough and influenza by Sept. 1, although exemptions for religious and other reasons are allowed. 1 They join soldiers, hospital workers and other adults required to be immunized against many common communicable diseases.

“Public health officials have been sounding the alarm that more should be done to protect the most vulnerable populations such as children and seniors,” said Democratic state Sen. Tony Mendoza, in explaining his sponsorship of the California measure.

That rationale has led an increasing number of health care facilities to require their employees to be immunized for various diseases. 2 In 2013, Rhode Island became the first state to mandate flu shots for health care workers, although 17 states have laws related to flu shots for adults, such as requiring hospitals to offer vaccination. 3

The Centers for Disease Control and Prevention (CDC) recommends health care workers be vaccinated to reduce the chance they will get or spread vaccine-preventable diseases. 4 The CDC estimates that more than 200,000 people are hospitalized from seasonal flu-related complications annually, although cases vary. Between 1976 and 2006, the number of deaths attributed annually to the flu ranged from 3,000 to 49,000. 5

Vaccination reduces the flu risk by 50 percent to 60 percent, according to the CDC. 6

But the issue of mandatory vaccination raises questions about whose rights come first — those of health care workers or of their patients. 7

When Virginia Mason Hospital in Seattle began requiring its employees to receive an annual flu shot in 2005, the staff vaccination rate went from 54 percent to 98 percent, although the nurses’ union successfully challenged the policy. 8 More than 500 facilities have followed suit with exemptions for medical, philosophical and religious reasons. 9

CDC data show that vaccination rates are higher when immunization is required or recommended. For the early part of the 2014-15 flu season, vaccination coverage among health care workers averaged 64.3 percent. The coverage increased to 85.8 percent among workers whose employers required the flu vaccine and 68.4 percent for those where vaccination was recommended. 10

In 2010, Children’s Hospital of Philadelphia began requiring all employees to get the flu vaccine after two young patients on chemotherapy died after becoming infected with influenza from health care workers. “It’s not your inalienable right to not get a vaccine if you’re helping care for vulnerable patients,” said Dr. Paul Offit, director of the hospital’s Vaccine Education Center. These two patients “died from getting the flu at the hospital.” 11

But nine Children’s Hospital workers, five of whom belonged to a local health care workers union, refused the flu shot and were fired. 12 In 2012, an Indiana hospital fired eight workers for refusing to be vaccinated. At least 15 hospital workers in four states were fired in early 2013 as well. 13

A number of organized labor groups, including National Nurses United, oppose mandatory flu shots. They contend hospitals should take other measures, such as hand washing and sanitizing of surfaces, which can help curb the spread of influenza. 14

“I work at a hospital that currently has a seasonal flu mandatory vaccine policy, and I know from experience that this kind of punitive policy only fosters resentment on the part of the bedside caregivers,” said Rajini Raj, a registered nurse who works at the MedStar Washington Hospital Center in Washington, D.C. She and others who oppose mandates point out the vaccine is not wholly effective. 15

But others say workers’ individual rights should not come before public health and the medical tenet to “do no harm.” 16

care research and regulation that could affect vaccine policy.

Between 2009 and 2012, lawmakers in 18 states introduced 36 bills involving vaccine exemptions, 31 of which would have made opting out of shots easier, according to the National Conference of State Legislatures. None of those 31 bills passed. 99

In 2015, following the Disneyland measles outbreak, six states — California, Connecticut, Illinois, South Dakota, Vermont and West Virginia — passed legislation related to exemptions, all but one of which tightened requirements. California removed both personal and religious exemptions, while Vermont removed its philosophical exemption. 100 Several other states also considered legislation in 2015 dealing with exemptions. This year, states will consider related issues:

• In Washington, a bill that would eliminate the state’s personal belief exemption is awaiting a floor vote in the House after being passed out of committee last year.
• In Pennsylvania, a similar bill, introduced in 2015, to eliminate the philosophical exemption awaits committee action.
• In South Dakota, a Senate committee approved a measure in January to require sixth-graders to get a meningococcal vaccine.
• In Hawaii, lawmakers killed a bill in February designed to speed up the state’s process for adopting federal vaccination guidelines, after residents spoke out against vaccines. 101

Emory University researchers studied the correlation between state exemption laws and vaccination rates and found that exemptions for nonmedical reasons increased at a heightened rate from 2005 to 2011. 102
“It is in the highest tradition of the healing professions to set aside our own self-interests and preferences in the moral imperative to best protect and care for our patients — even if it means accepting some level of self-harm (real or imagined),” wrote Dr. Gregory A. Poland, a vaccine researcher at the Mayo Clinic and editor-in-chief of the journal Vaccine. 17

Those in the U.S. military constitute another group of adults who face mandatory vaccinations. Military regulations require U.S. troops to be immunized against a number of diseases, including diphtheria and yellow fever. These inoculations begin when soldiers enter into service. Depending on their specialties or locations of deployment, troops may be required to get other vaccinations as well. Courts have upheld the legality of the military’s mandatory vaccination orders. 18

— Jane Fullerton Lemons

12 Stone, op. cit.

“Since school immunization requirements play a major role in controlling vaccine-preventable diseases in the United States, studies like this underscore the need for states to examine their current exemption policies,” said Saad B. Omer, the study’s lead author. 103

The National Vaccine Information Center monitors state legislative activity involving vaccine-related issues, including bills already filed for 2016. 104 Dawn Richardson, the NVIC’s advocacy director, said that state legislatures last year experienced “an unprecedented flood of bills backed by the pharmaceutical and medical trade industries to restrict or remove personal-belief vaccine exemptions, expand electronic vaccine tracking systems and require more vaccines for children in school and adults in the workplace.”

Congressional Vote

On Capitol Hill, the House in July passed a massive health care bill — the 21st Century Cures Act — that would increase funding for the National Institutes of Health and streamline the process for approving drugs, including vaccines, and other medical devices. 105

Rather than vote on the entire measure, the Senate plans to break it into a series of smaller bills this year. 106

Despite its overwhelming bipartisan vote, 344-77, the House bill has drawn mixed reviews. And it may be an issue where those on different sides of the vaccine debate are in agreement. 107

Fisher of NVIC worries that the bill, aimed at speeding up the drug-approval process, “seriously compromises the integrity of the FDA drug and vaccine licensing process.” She added, in an
VACCINE CONTROVERSIES

interview with CQ Researcher, "We can't allow these standards to be lowered anymore." 108

Fisher isn’t alone in her concerns. Former FDA Commissioner David Kessler joined with leaders of the HIV/AIDS community to urge Congress to reject the bill. The legislation "could substantially lower the standards for approval of many medical products, potentially placing patients at unnecessary risk of injury or death," they wrote in a New York Times op-ed. 109

Other critics have cited provisions of the bill that would allow researchers to rely on "clinical experience" rather than clinical trials in evaluating the safety and efficacy of new drugs. That “smacks of being a payoff to pharmaceutical companies,” wrote Dr. David Gorski, a Michigan surgical oncologist. 110

House Energy and Commerce Chairman Fred Upton, R-Mich., and Rep. Diana DeGette, D-Colo. led the push for the bill, which they said will bring the nation’s health care system into the 21st century, invest in science and medical innovation, incorporate the patient perspective and modernize clinical trials to deliver better, faster cures. 111

“Every family is impacted by disease; they just are,” Upton said. “My wife has lupus, my dad has diabetes, my mom's a cancer survivor. And I’m no different than anyone else.” 112

During the peak of the Disneyland measles outbreak, lawmakers from both parties stressed vaccines’ importance. 113

The Senate Health, Education, Labor and Pensions Committee heard top immunization officials testify about vaccine-preventable diseases. Members emphasized the safety of and need for inoculations while questioning assertions that vaccines can harm children. 114

“Too many parents are turning away from sound science,” said committee Chairman Lamar Alexander, R-Tenn. “Sound science is this: Vaccines save lives.”

The hearing came just as a pair of Republican presidential candidates — New Jersey Gov. Chris Christie and Sen. Paul — drew criticism for saying parents should decide whether to vaccinate their children. Paul, a member of the committee, did not attend the hearing.

The topic resurfaced in a September 2015 Republican debate, with comments by several candidates including front-runner Donald Trump, who has linked vaccines to autism, despite scientific evidence to the contrary. He favors smaller doses over a longer period of time, saying the number of vaccinations “looks just like it's meant for a horse, not for a child.” 115

HPV Vaccine

Currently, only three jurisdictions mandate the HPV vaccine. Virginia and the District of Columbia require it for girls entering the sixth grade, while Rhode Island requires it for seventh-grade girls and boys. All three allow broad exemptions for the vaccine. 116

As of February, at least nine states have proposed HPV-related legislation for the 2015-16 sessions, but only Hawaii has a bill that would mandate use of the vaccine. 117

HPV is the most common sexually transmitted disease in the United States. Every year, more than 27,000 cases of HPV-caused cancer occur in women and men, according to the CDC, HPV is linked to virtually all cervical cancer. In 2012, the most recent year statistics are available, cervical cancer was diagnosed in more than 12,000 cases, and more than 4,000 patients died. 118

The CDC recommends the vaccine, a series of three shots, for preteen boys and girls at age 11 or 12 so they are protected before ever being exposed to the virus. 119

When the vaccine received approval in 2006, some states moved quickly to make inoculations mandatory for school attendance. But reactions to an aggressive lobbying campaign by vaccine manufacturer Merck, coupled with safety concerns, stalled efforts to mandate the shots in many states. Conservative groups joined the opposition, saying the vaccine would encourage inappropriate sexual activity and override parental autonomy. 120

As a result, HPV vaccine coverage remains lower than for other teen immunizations, according to the CDC. Four out of 10 adolescent girls and six out of 10 adolescent boys have not started the HPV vaccine series. 121

A study showing implementation of the HPV vaccine has lagged behind other new vaccines indicated that early efforts to mandate its use may have backfired. Despite the issues surrounding it, the HPV vaccine “should not be viewed or treated differently than other routinely recommended vaccines,” the study said. 122

OUTLOOK

Pipeline Expanding

As vaccine development continues, research is encompassing not only infectious diseases but also chronic conditions. But with new viruses such as Zika and Ebola cropping up, finding a way to prevent the spread of disease remains the central mission.

For the scientific and medical communities, such research represents continued progress. Dr. Candice Robinson, a medical officer with CDC’s Immunization Services Division, says recent developments encompass vaccinations for traditional childhood illnesses and emerging infectious diseases.

“There have been some new vaccines coming down the pipeline, and there’s been lots of innovation in terms of Ebola virus vaccines or Zika virus vaccines,” Robinson says.

According to the World Health Organization (WHO), vaccines for the Zika virus might be ready for large trials in about 18 months. Possible vaccines at the most advanced stage include

Continued on p. 186
Should children have to be vaccinated to attend school?

When parents enroll their children in day care or kindergarten, they should feel secure knowing their little ones will be safe from preventable infectious diseases. Every Child By Two’s co-founders, former first lady Rosalynn Carter and former Arkansas first lady Betty Bumpers, were instrumental in helping to pass laws in every state requiring proof of immunization for school attendance. States passed these laws to protect all children from deadly and debilitating vaccine-preventable diseases.

Massachusetts enacted the first school vaccination requirement in 1809 to prevent smallpox transmission. Today, all 50 states have legislation requiring vaccines for students. In 1905, the Supreme Court upheld the constitutionality of mandatory vaccination. Unfortunately, these laws have been eroded over the years, as states have expanded exemptions from immunization requirements. Although exemptions vary from state to state, all states grant exemptions to children for medical reasons such as allergies. All states, other than Mississippi and West Virginia, grant religious exemptions, while 20 states allow philosophical exemptions for those who object to immunizations because of personal, moral or other beliefs. (California and Vermont will no longer allow these exemptions as of July.)

Continued outbreaks of diseases, including measles, mumps, pertussis and influenza, are jeopardizing public health, prompting state legislators to re-evaluate the wisdom of allowing nonmedical exemptions. One study found that children exempt from vaccination requirements were more than 35 times more likely to contract measles and nearly six times more likely to contract pertussis than vaccinated children. In a 2006 study, states with loose exemption policies had approximately 50 percent more whooping cough cases than stricter states.

As executive director of Every Child By Two, I have traveled to dozens of states and as far as Africa. We strive to ensure that all children have access to life-saving vaccines and help initiate and implement policies that remove financial and other barriers. I have come to know many families who have lost children to vaccine-preventable diseases and individuals who have survived these diseases but are left with lifelong, debilitating illnesses. These families are a reminder that the United States cannot let its guard down, as diseases know no borders.

While vaccines are not 100 percent effective, families should feel confident in knowing that their children are surrounded by a high percentage of vaccinated classmates and personnel. “Herd immunity” — vaccinating large numbers of people — is the final barrier to deadly diseases.

Barbara Loef Fisher
President, National Vaccine Information Center

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Parents have the right to exercise freedom of conscience and informed consent to medical risk-taking on behalf of their children, and children have the civil right to a school education. Vaccine risks are not being borne equally by all, and vaccine laws that do not include flexible medical, religious and conscientious-belief exemptions are oppressive, inhumane and in violation of civil and human rights.

Vaccines are pharmaceutical products that carry a risk of injury or death. There are genetic, biological and environmental high-risk factors that make some people more susceptible to vaccine harm than others, a fact Congress acknowledged in 1986 in the National Childhood Vaccine Injury Act when it shielded vaccine manufacturers from civil liability. The National Academy of Sciences’ Institute of Medicine states that often doctors cannot predict who will be injured because of longstanding gaps in vaccine science knowledge. Yet there are almost no federal exemptions for vaccination, which is one reason more than $3 billion has been paid to vaccine-injured children and adults under the 1986 law.

Like the freedoms of speech and the press, the legal right to exercise freedom of conscience and religious belief is embodied in the Constitution. Internationally, these freedoms are considered basic human rights belonging to all people. In addition, the legal right to informed consent to medical risk-taking is the centerpiece of the ethical practice of modern medicine.

Although the Supreme Court in 1905 affirmed the authority of state legislatures to require smallpox vaccination during “an epidemic of disease,” the court warned that vaccine mandates should not go beyond “what was reasonably required for the safety of the public” because excessive mandates could lead to “injustice, oppression or absurd consequence” or be “cruel and inhuman to the last degree.” A century later, the mandate for one dose of smallpox vaccine has been replaced by a federal directive that children get 69 doses of 16 vaccines starting on the day of birth, with 49 doses of 14 vaccines given by age 6. State legislatures have mandated multiple doses of at least 10 of these vaccines for children, but many are for diseases that, unlike smallpox, do not have a high complication and mortality rate, are not widespread or are not transmitted in a public setting.

Hundreds of new vaccines are being developed, and many will be mandated. Vaccine mandates lacking informed-consent protections should be repealed.
one from the National Institutes of Health and another from India-based Bharat Biotech, said Marie-Paule Kieny, WHO’s assistant director-general for health systems and innovation. 123

In recent years, the pharmaceutical industry had more than 270 vaccines in development. These potential vaccines were either in human clinical trials or under review by the Food and Drug Administration. They included 137 for infectious diseases, 99 for cancer, 15 for allergies and 10 for neurological disorders. 124

Arthur Allen, a journalist and author of Vaccine: The Controversial Story of Medicine’s Greatest Lifesaver, believes the charged atmosphere around vaccines is changing, due in large part to the discrediting of the Wakefield study linking vaccines to autism, and that bodes well for continued developments.

“The autism link was such a powerful idea,” says Allen, whose book looked at the history of vaccine controversies. “Now that that has really been laid to rest, we’re sort of back at the general [anti-vaccination] background noise level which is always going to be there.”

Pisani, of Every Child By Two, also believes the tone is different. She and others on both sides of the issue say that everyone wants to do the right thing for their children. “People now are having civil conversations,” she says.

When it comes to research, Pisani says vaccines under development for childhood illnesses, such as respiratory syncytial virus, or RSV, would be game changers. “Everybody knows someone whose child had RSV, so that’s going to be a huge lifesaver,” she says.

But NVIC’s Fisher worries mandates could accompany all these new vaccines. “You’re seeing hundreds of new vaccines being developed that are on the horizon that are going to be added to the federal recommended schedule within a system . . . that’s very oppressive,” because it limits the exemptions available for parents.

Those skeptical about vaccines also see the number of vaccines under development as evidence of the pharmaceutical industry’s continued drive for profits. Vaccine safety advocate Kennedy said such research is aimed at “boosting vaccine revenues to $100 billion by 2025.” 125

Kennedy cited market research showing while vaccines represent only 2 percent to 3 percent of global drug sales, “the growth rate in this market has been extraordinary.” This segment has grown at a high rate of 10 to 15 percent annually as compared to the overall pharmaceutical industry, which grows at 5 to 7 percent per year. 126

Vaccines are currently under development for the following diseases:

• Zika virus, which is spread to people through mosquito bites. The World Health Organization (WHO) has declared an international public health emergency in connection with the outbreak of this virus in more than 30 countries. 127

• Ebola, which spreads through human-to-human transmission. Clinical trials for a vaccine are underway. 128

• Malaria, caused by parasites transmitted to people through the bites of infected mosquitoes. Several potential vaccines are undergoing clinical trial. 129

• Dengue fever, also spread to people through mosquito bites. Trials for a vaccine are underway in Brazil. 130

• HIV/AIDS, which can be transmitted via the exchange of body fluids from infected individuals. WHO said there are “a number of very encouraging leads” in the search for a vaccine. 131

In addition to infectious diseases, scientists see vaccines as a way to prevent chronic diseases such as cancer and Alzheimer’s.

“The growing cost of caring for an aging population, where noninfectious conditions like dementia will be increasingly common in older people, has added a new dimension to the search for new vaccines,” wrote Gary Finnegan, editor of Vaccines Today. 132

Continued vaccine research remains necessary because “infectious diseases still extract an extraordinary toll on humans,” wrote Dr. Gary J. Nabel in The New England Journal of Medicine. While old vaccines need updating, and new ones are being developed, he said, the key is making them available, particularly in developing countries where more than 1.5 million children die from vaccine-preventable diseases each year. 133

Notes


12 Tamar Lewin, “Sick Child’s Father Seeks Vac-
60 Baum, op. cit.
75 Rosenthal, op. cit.
90 Ibid.
97 “BMJ declares MMR study . . .,” op. cit.
101 Rachel LaCorte, “Bill to tighten vaccine
112 Steinhauser and Tavernise, op. cit.  
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Selected Sources

Books

Two television journalists examine the history and politics of autism, including a look at concerns about the purported link between autism and vaccines.

A professor of science writing at the Massachusetts Institute of Technology examines the ramifications of a discredited 1998 study linking vaccinations to autism.

A pediatrician who heads the Vaccine Education Center at Children's Hospital of Philadelphia contends that the decision by some parents not to vaccinate their children endangers everyone.

A California pediatrician makes the case for an alternate immunization schedule for young children that has become popular with many vaccine skeptics.

Articles

A journalist recounts the story of how children's book author Roald Dahl lost his 7-year-old daughter to measles.

Current vaccine controversies are similar to 19th-century protests against mandatory vaccinations.

A science writer examines Robert F. Kennedy Jr.'s continued belief in the link between autism and vaccines and how he has become a leading vaccine skeptic.

A trio of Emory University doctors outlines obstacles to vaccination and how the medical community can work to overcome them.

In a 50-year period, childhood vaccinations went from representing breakthrough science to a topic of public policy debate.

Reports and Studies

The Institute of Medicine, a component of the National Academy of Sciences, conducts a comprehensive review into the safety of the childhood immunization schedule.

The federal health agency provides its annual update on the department's work toward meeting its goals of high nationwide vaccination levels.

The independent watchdog agency of Congress examines the agency overseeing vaccine injury claims and found numerous problems with the process.

A report by Congress' independent research arm examines past and present laws concerning vaccination.

Documentaries

A pair of Oregon filmmakers examines the science and politics of vaccine safety in this multi-part documentary, with interviews and segments from all sides.

An Australian journalist produces a television documentary that tracks global epidemics, explores the science behind vaccines and airs the views of parents wrestling with vaccine-related questions and concerns.
Drug Companies


Pharmaceutical companies are competing to develop a vaccine against the rapidly spreading Zika virus, an illness linked to birth defects and nerve damage, though a vaccine will likely be unavailable for several years.


The World Health Organization worked with drug companies to expedite development of an Ebola vaccine that achieved a 100 percent success rate, accelerating a research process that would normally take more than a decade.

Exemptions


The number of non-medical vaccination exemptions requested by parents in Michigan dropped 39 percent in the first five months of the 2015-16 school year after the state began requiring parents in January 2015 to meet with local health department staff to obtain waivers.


The American Medical Association issued a policy recommendation that states work with public health physicians to create school vaccination policies that limit parents from requesting non-medical vaccination exemptions.


Thousands of students in states such as Illinois received exemptions from vaccination requirements in 2012 for religious reasons, yet no major religions explicitly forbid followers from receiving immunizations, according to a vaccine researcher.

Human Papillomavirus


An updated vaccine schedule from the Centers for Disease Control and Prevention recommends that children ages 11 or 12 receive vaccines against nine strains of HPV and that children with histories of sexual abuse receive vaccines at ages 9 or 10.


Rhode Island anti-vaccination activists are working with a state lawmaker to introduce legislation allowing parents to request philosophical exemptions from a state requirement that students receive the HPV vaccine before entering seventh grade.

Side Effects


The Japanese government stopped recommending that girls ages 12 to 16 receive HPV vaccines in 2013 after several hundred girls among more than 1,700 who were vaccinated suffered severe pain or motor impairment.


California physicians hope that a new state law barring religious and other non-medical vaccination exemptions for schoolchildren will help to dispel some parents’ fears about vaccinations’ side effects.


Adverse side effects of measles and mumps vaccines, such as allergic reactions and brain damage, are extremely rare, while the dangers of contracting those diseases far outweigh the risks of vaccination, say medical experts.

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- Dietary Supplements, 10/15
- Doctor Shortage, 8/15
- Treating Alzheimer's Disease, 7/15
- Manipulating the Human Genome, 6/15
- Pesticide Controversies, 6/15

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- Robotics and the Economy, 9/15
- European Migration Crisis, 7/15
- Restoring Ties with Cuba, 6/15

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