Center for Science and Democracy at the Union of Concerned Scientists

FACT SHEET

CASE STUDIES IN SCIENCE AND DEMOCRACY

New Vaccines, Old Misconceptions

How a Century of Science-Informed Regulations Supports HPV Vaccination

HIGHLIGHTS

Safe and effective HPV vaccines, available since 2006, are the result of strong regulatory structures developed over many years. An unregulated industry once left the public vulnerable to unsafe practices, but democracy enabled critics to express their concerns and exert pressure on policy makers to strengthen regulations. Low vaccination rates against HPV leave today's teenagers vulnerable to tomorrow's preventable cancers. The task of overcoming obsolete misconceptions is daunting, but science-informed actions in some communities are making a difference.

Low U.S. vaccination rates against human papillomavirus (HPV) leave today's pre-adolescent girls and boys vulnerable to vaccine-preventable cancers decades from now. Since a safe and effective HPV vaccine first became available in 2006, U.S. HPV vaccination rates have trailed far behind rates in other countries. Even some developing nations maintain higher HPV vaccination rates: in Rwanda, 80 percent of teenage girls are vaccinated.

HPV vaccines were developed within a robust U.S. regulatory system that evolved over the course of a century in response to both scientific progress and public demands for safety. To fulfill the vision underlying today's science-based approach, scientists, public health advocates, and communities must work together to overcome outdated misconceptions and safeguard a future free from vaccine-preventable diseases.

A Vaccine That Prevents Cancer

Most adults contract a form of HPV infection at some point in their lives (CDC 2014b). A majority will fight off this sexually transmitted virus without ever knowing they were infected. However, of the hundred or so strains of the virus, 13 have been associated with cancers that often take many years to manifest.

In 2014, an estimated 12,360 women in the United States and 530,000 women worldwide are likely to be newly diagnosed with cervical cancer, the most common cancer HPV causes. Nearly 250,000 are living with this cancer in the United States, and more than 4,000 are expected to die from it in 2014. HPV also causes vaginal, vulval, anal, penile, and oral cancers, as well as genital warts. Some 27,000 Americans were newly diagnosed with HPV cancers in 2014 (CDC 2014b; NCI 2014; WHO 2013).

Vaccination against HPV prevents cervical and other cancers.

Each of the two vaccines currently available protects against the two strains of HPV associated with 70 percent of these cancers. One of the vaccines protects against an additional two strains, and new versions under development will protect against even more. Because the vaccines are effective only if given before someone acquires HPV, vaccination is recommended for girls and boys 11 to 12 years old—before they likely become sexually active. If individuals are not vaccinated as preadolescents, experts recommend vaccination for women up to age 26 and for men up to age 21.

Despite the availability of the vaccines, only 57 percent of girls and 34 percent of boys ages 13-17 in the United States receive at least one of three doses. Full HPV vaccination within this age group was 37 percent in 2013 for girls and 14 percent for boys. For every year vaccination rates remain this low, another 4,400 women will develop cervical cancer at some point in their lives.

A variety of concerns and misconceptions have contributed to these low vaccination rates. Some parents believe their children are too young to be at risk for HPV or worry that vaccination will make their children more likely to engage in sexual behavior. Others express concern that the vaccine is too new to know if it is safe and effective, and that children get too many vaccines, overloading them with "toxic" ingredients. Still others distrust public health experts and regulators, perceiving a profit motive underlying recommendations for vaccination. And many have simply not received much information about HPV vaccines relative to other vaccines. Reservations about discussing sexually transmitted infections with preteens and their parents have led some clinicians to provide less information about HPV vaccines and to recommend them less emphatically than other vaccines.

Strong evidence from clinical trials and careful ongoing monitoring indicate that HPV vaccines are both exceptionally safe and extraordinarily effective. Occasional side effects are mild: injection-site reactions, dizziness, fainting, nausea, and headache. A study of 600,558 doses revealed no statistically significant risk for serious reactions (Gee et al 2011). Although vaccination rates have remained disappointingly low, HPV infection among girls ages 14 to 19 has dropped by 56 percent since 2006, thought to result from the vaccine's near 100 percent effectiveness and growing herd immunity (CDC 2014c; CDC 2013).

How Public Engagement in the Democratic Process Spurred Safer Vaccines

Today's HPV vaccines are safe and effective because they were developed through a strong network of federal regulations that have their origins more than a century ago. A lack of regulations governing vaccine production at that time not only allowed for serious incidents of contamination but also fueled many unfounded fears. The story of Lora C. Little is important in understanding the roots of some of today's lingering misconceptions—as well as how public engagement in the democratic process helped hold policy makers accountable and ultimately rendered those misconceptions obsolete.

In 1895, Little's seven-year-old son Kenneth was vaccinated against smallpox, a requirement for attending public school in Yonkers, NY, where they lived. Months later, although he escaped smallpox, he contracted diphtheria and measles. Sadly—like many children before routine vaccinations against these diseases were available—Kenneth died.

Little was a proponent of natural remedies and a disbeliever in the germ theory of disease. She convinced herself that the smallpox vaccine, not measles or diphtheria, had killed Kenneth. Like vaccine-hesitant parents today, she rejected the scientific consensus on the importance of vaccination, along with public policies that she felt infringed on the rights of Americans to make their own health care decisions. She also distrusted doctors and public health officials because she mistakenly thought they were profiting excessively from vaccines and promoting vaccination out of self-interest. From New York to Minnesota, Illinois to North Dakota, she traveled the country rallying against vaccines. She attended town hall meetings, wrote op-eds and pamphlets, and lobbied policy makers. After settling in Portland, OR, she ran for the state legislature (she lost) and organized an Oregon referendum that came just 374 votes short of outlawing compulsory vaccination.

Public health officials and doctors quickly came to see Little as a rabble-rouser and scorned her unscientific views when she would debate them publicly—which was often. At the time Kenneth died, however, compulsory vaccination policies were common, but no clinical trials or federal oversight protected the public from unsafe manufacturing and distribution practices. Although Kenneth died from diseases that today's vaccines prevent, bacterial contamination of vaccines—which caused serious infections and even death—was common and gave credence to at least some of Little's grievances. Ultimately, Little—and other activists like her—did not get what they wanted, but their direct engagement in the democratic process throughout the nation exerted pressure for change.

Policies That Protect the Public

In 1902, after 13 children in St. Louis died from receiving diphtheria antitoxin contaminated with tetanus, Congress enacted and President Theodore Roosevelt signed the Biologics Control Act. It was the first law mandating federal over-

sight of the vaccine industry and contained basic provisions for inspection, licensure, and labeling that Americans now take for granted.

Still, drug safety had a long way to go. Many ensuing federal laws—and rules to implement them—now govern vaccine development, manufacture, and distribution, ensuring that new vaccines are safe and effective (see table).

Combining Science and Experience to Overcome Misinformation on HPV

Today, Americans face not vaccine contamination but information contamination. Low vaccination rates for HPV—and outbreaks of diseases such as measles and whooping cough because of declining overall vaccination rates—indicate that rigorous science and strong policies are sometimes not enough to dispel fears and misconceptions. Celebrities such as TV personality Jenny McCarthy have spread misinformation throughout the media, and self-interested industry marketing decisions—Merck's choice to target Gardasil initially only to girls, for example—have backfired.

Adult children of "anti-vaxxers"—as vaccine opponents have come to be called—have come forward to relate heartbreaking stories of the pain, discomfort, and disabilities they experienced from vaccine-preventable illnesses, along with the deaths of unvaccinated children they knew. Amy Parker, one such survivor, has become fiercely pro-vaccine to protect her own children from suffering what she did. "Knowingly exposing your child to illness," she says, "is cruel" (Parker 2014).

Some of today's teenagers not vaccinated against HPV will be tomorrow's cancer statistics. In some places, however, direct knowledge and community engagement are making a difference while providing good models.

For example, the Pittsburgh, PA, chapter of the activist group Grandmother Power recently began organizing a grassroots campaign to increase HPV vaccination rates. Having observed firsthand the devastation from cancers caused by HPV among close friends and aging relatives—a perspective many younger parents and their children lack—the grandmothers hope to use their life experience and community stature to ensure a healthier future for those children. Through partnerships with the Jewish Healthcare Foundation and the Women and Girls Foundation, the grandmothers seek to mediate between vaccine-hesitant parents and health care providers and to develop HPV message campaigns aimed at sharing their own insights along with the scientific evidence. These and similar efforts will help ensure that commonsense vaccination policies protect today's young people as well as those in generations to come.

TABLE. Five Federal Laws Governing Vaccine Safety and Effectiveness

Biologics Control Act	1902	First law mandating federal oversight of the vaccine industry, including facilities inspection, product licensure, scientist supervision of the production process, and labels with product name, expiration date, and manufacturer's contact information.
Food, Drug, and Cosmetic Act	1938	Mandated premarket approval of drugs. Prohibited false therapeutic claims without requiring proof of intent to deceive, closing a loophole in the Pure Food and Drug Act of 1906. Kefauver-Harris amendment (1962) required proof of efficacy.
Public Health Service Act	1944	Authorized the Center for Biologics Evaluation and Research (CBER) to regulate vaccines and other biological products. CBER uses scientific data to perform risk-benefit analyses and assess safety, purity, potency, and effectiveness. Set rules for clinical trials, protection of human subjects, institutional review boards, laboratory studies, and good manufacturing practices. Created the Advisory Committee on Immunization Practices (ACIP), which reviews the latest scientific information on existing and new vaccines, monitors safety and efficacy of vaccines, tracks outbreaks of vaccine-preventable diseases, and issues recommendations on immunization policy. ACIP meetings are open to the public and to public comment.
Childhood Vaccine Injury Act	1986	Requires those who administer vaccines to provide recipients (or parents or guardians) with a Vaccine Information Statement from the Centers for Disease Control and Prevention (CDC) explaining risks and benefits. Requires health care providers to report adverse vaccine reactions to the CDC. Compensates victims of vaccine-related injuries on a no-fault basis. Convened an Institute of Medicine committee to investigate knowledge gaps in the understanding of vaccine side effects.
Food and Drug Administration Amendments Act	2007	Enhances the Food and Drug Administration's ability to track adverse vaccine reactions and analyze related data. Requires pediatric assessment for all new drugs, including vaccines.

REFERENCES

Allen, A. 2007. *Vaccine: The controversial story of America's greatest lifesaver.* New York, NY: W.W. Norton.

Centers for Disease Control and Prevention (CDC). 2014a. Advisory Committee on Immunization Practices. Atlanta, GA. Online at *http://www.cdc.gov/vaccines/acip/index.html.*

Centers for Disease Control and Prevention. 2014b. Genital HPV infection: Fact sheet. Atlanta, GA. Online at *http://www.cdc.gov/std/hpv/stdfact-hpv.htm.*

Centers for Disease Control and Prevention. 2014c. HPV vaccine – questions & answers. Atlanta, GA. Online at *http://www.cdc.gov/vaccines/vpd-vac/hpv/vac-faqs.htm.*

Centers for Disease Control and Prevention. 2014d. Human papillomavirus (HPV) vaccine. Atlanta, GA. Online at *http://www.cdc.gov/vaccinesafety/vaccines/HPV/index.html.*

Centers for Disease Control and Prevention. 2013. New study shows HPV vaccine helping lower HPV infection rates in teen girls. Atlanta, GA. Online at *http://www.cdc.gov/media/releases/2013/p0619-hpv-vaccinations.html.*

Centers for Disease Control and Prevention. 2011. History of vaccine safety. Atlanta, GA. Online at *http://www.cdc.gov/vaccinesafety/vaccine_monitoring/history.html.*

Food and Drug Administration. 2012. Food, Drug, and Cosmetic Act, SEC. 201. [21 U.S.C. 321]. Washington, DC. Online at *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChaptersIandIIShortTitleandDefinitions/ucm086297.htm.*

Food and Drug Administration. 2011. Food and Drug Administration Amendments Act (FDAAA) of 2007. Washington, DC. Online at *http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/SignificantAmendmentstotheFDCAct/FoodandDrugAdministrationAmendmentsActof2007/default.htm.*

Food and Drug Administration. 2009. FDA history. Part III: Drugs and foods under the 1938 act and its amendments. Washington, DC. Online at *http://www.fda.gov/AboutFDA/WhatWeDo/History/Origin/ucm055118.htm.*

Food and Drug Administration. 2009. Milestones in food and drug law history. Washington, DC. Online at *http://www.fda.gov/AboutFDA/WhatWeDo/History/Milestones/ucm081229.htm.*

Food and Drug Administration. 2009. Vaccine product approval process. Washington, DC. Online at *http://www.fda.gov/biologicsbloodvaccines/developmentapprovalprocess/biologicslicenseapplicationsblaprocess/ucm133096.htm.*

Gee, J., A. Naleway, I. Shui, J. Baggs, R. Yin, R. Li, M. Kulldorff, E. Lewis, B. Fireman, M. F. Daley, N. P. Klein, and E. S. Weintraub. 2011. Monitoring the safety of quadrivalent human papillomavirus vaccine: Findings from the Vaccine Safety Datalink. *Vaccine* 29(46): 8279–8284. Online at *http://www.sciencedirect.com/science/article/pii/S0264410X11013831.*

Johnston, R.D. 2003. *The radical middle class: Populist democracy and the question of capitalism in progressive era Portland, Oregon.* Princeton, NJ: Princeton University Press.

Kahan, D. 2013. A case study: The HPV vaccine disaster. New Haven, CT: Cultural Cognition Project, Yale Law School. Online at *http://www.culturalcognition.net/blog/2013/1/21/a-case-study-the- hpv-vaccine-disaster-science-of-science-com.html.*

Marshall, V., and N.W. Baylor. 2011. Food and Drug Administration regulation and evaluation of vaccines. *Pediatrics* 127(Supplement 1):S23–S30. Online at *http://pediatrics.aappublications.org/content/127/Supplement_1/S23.full#sec-7.*

Mnookin, S. 2012. *The panic virus: The true story behind the vaccine-autism controversy.* New York, NY: Simon & Schuster.

National Cancer Institute (NCI). 2014. SEER stat fact sheets: Cervix uteri cancer: Surveillance, epidemiology, and end results program. Bethesda, MD. Online at *http://seer.cancer.gov/statfacts/html/cervix.html.*

National Cancer Institute. 2011. Human papillomavirus (HPV) vaccines. Bethesda, MD. Online at *http://www.cancer.gov/cancertopics/factsheet/prevention/HPV-vaccine.*

National Vaccine Advisory Committee. 1997. United States vaccine research: A delicate fabric of public and private collaboration. *Pediatrics* 100(6):1015–1020. Online at *http://pediatrics.aappublications.org/content/100/6/1015.*

North, C. 2014. Pittsburgh grandmothers band together, help tackle HPV prevention. *Pittsburgh Post-Gazette*, August 21. Online at *http://www.post-gazette.com/local/region/2014/08/21/Pittsburgh-grandmothers-band-together-whip-up-anti-HPV-push/stories/201408210080.*

Offit, P. 2005. The Cutter incident: How America's first polio vaccine led to the growing vaccine crisis. New Haven, CT: Yale University Press.

Okoronkwo, C., L.E. Sieswerda, R. Cooper, D. Binette, and M. Todd. 2012 Parental consent to HPV vaccination for their daughters: The effects of knowledge and attitudes. *Canadian Journal of Human Sexuality* 21(3/4):1188–4517. Accessed through LexisNexis.

Parker, A. 2014. Growing up unvaccinated. *Slate*, January 6. Online at *http://www.slate.com/articles/life/family/2014/01/growing_up_unvaccinated_a_healthy_lifestyle_couldn_t_prevent_many_childhood.html.*

World Health Organization (WHO). 2013. Human papillomavirus (HPV) and cervical cancer. Geneva, Switzerland. Online at *http://www.who.int/mediacentre/factsheets/fs380/en/.*

Union of Concerned Scientists

FIND THIS DOCUMENT ONLINE: www.ucsusa.org/vaccines

The Union of Concerned Scientists puts rigorous, independent science to work to solve our planet's most pressing problems. Joining with citizens across the country, we combine technical analysis and effective advocacy to create innovative, practical solutions for a healthy, safe, and sustainable future.

NATIONAL HEADQUARTERS
Two Brattle Square
Cambridge, MA 02138-3780
Phone: (617) 547-5552
Fax: (617) 864-9405

WASHINGTON, DC, OFFICE
1825 K St. NW, Suite 800
Washington, DC 20006-1232
Phone: (202) 223-6133
Fax: (202) 223-6162

WEST COAST OFFICE
500 12th St., Suite 340
Oakland, CA 94607-4087
Phone: (510) 843-1872
Fax: (510) 843-3785

MIDWEST OFFICE
One N. LaSalle St., Suite 1904
Chicago, IL 60602-4064
Phone: (312) 578-1750
Fax: (312) 578-1751

WEB: www.ucsusa.org