

The PARENTS AND CITIZENS COMMITTEE TO STOP MEDICAL EXPERIMENTATION IN DC feels the following questions have not been adequately addressed:

- **Was GARDASIL™ properly tested?**
- **Who is liable?**
- **How effective is GARDASIL™?**
- **Is HPV like measles?**
- **Is the HPV vaccine about public health or corporate profit?**
- **What are the ingredients in GARDASIL™? Are any of the ingredients either potentially harmful or not found in common vaccines?**

Before voting, the City Council should hold additional hearings so that these and other questions may be publicly discussed. If requiring the HPV vaccine is a good idea today, it will be a good idea six months from now.

Was GARDASIL™ Properly Tested?

The testing for GARDASIL™ was carried out solely by Merck. This practice is standard for the industry and has attracted criticism and concern from researchers, physicians, and editors of medical journals.^{1, 2, 3} A drug company has a clear interest in seeing its testing results come out a certain way. Merck, which remains under a cloud of ethical and legal allegations resulting from its handling of Vioxx, deserves extra scrutiny. The company knew of the dangers of Vioxx but did not remove the drug from the market until four years and thousands of deaths later.⁴

It is of concern that the Food and Drug Administration (FDA) approves drugs and vaccines without testing them and instead checks over the data that a drug company submits.⁵ According to *The Lancet*, the leading medical journal in England:

*The public expects national drug regulators to complete research in their ongoing efforts to protect patients from undue harm. But too often, the FDA saw and continues to see the pharmaceutical industry as its customer—a vital source of funding for its activities—and not as a sector of society in need of strong regulation.*⁶

Is this (un)comfortable relationship between the FDA and drug companies what led to GARDASIL™'s approval without proper testing?

A hallmark of scientific inquiry is the use of the placebo. When a drug is tested, half of the

¹ Richard Smith and Ian Roberts, "Clinical Trials Get Under Scrutiny: How Medical Information Should Be Made Publicly Available." Accessed 17 February 2007. <http://www.masternewmedia.org/news/2007/02/17/clinical_trials_get_under_scrutiny.htm>.

² Bloomberg, "Drug Industry Human Testing Masks Death, Injury, Compliant FDA Listen," 2 November 2005. Accessed 4 March 2007. <http://www.med.miami.edu/communications/som_news/index.asp?id=662>.

³ Marcia Angell, "The Truth About the Drug Companies," *New York Review of Books*, Vol. 51, no.12, 15 July 2004. Accessed 5 March 2007. <<http://www.nybooks.com/articles/17244>>.

⁴ Senate Committee on Finance, "FDA, Merck and Vioxx: Putting Patient Safety First?" 18 November 2004 Hearings. Accessed 5 March 2007. <<http://www.senate.gov/~finance/sitepages/hearing111804.htm>>.

⁵ Ibid.

⁶ Russell Mokhiber and Robert Weissman, "The Ten Worst Corporations of 2004." *Multinational Monitor*, Vol. 25, no. 12, December 2004. Accessed 7 March 2007. <<http://multinationalmonitor.org/mm2004/122004/mokhiber.html>>.

subjects get a placebo (which has no effect) and the other half get the drug (whose effect will be measured against the placebo group). Participants in the studies do not know whether they are getting the placebo or drug. Researchers compare the effects on the two groups and then make a determination on the drug accordingly.

Merck changed the rules for control groups in its clinical trials of GARDASIL™. Rather than compare the effects of GARDASIL™ against the effects of a simple saline solution placebo, Merck added aluminum to the placebo.⁷ Aluminum is reactive, not neutral.

*The FDA allowed Merck to use a potentially reactive aluminum-containing placebo as a control for most trial participants, rather than a non-reactive saline solution placebo. A reactive placebo can artificially increase the appearance of safety of an experimental drug or vaccine in a clinical trial.*⁸

By making the placebo group sick, Merck made those taking GARDASIL™ look comparatively healthy. Possibly even more shocking is that some (most?) of Merck's testing for GARDASIL™ was outsourced to Contract Research Organizations (CROs) who may be paid royalties once a drug is approved, rather than a set fee. Thus, CROs have an interest in seeing results come out a certain way. One of the CROs Merck used for testing GARDASIL™ is JayaJan Pharmaceutical Research in India. Merck spokeswoman, Amy Rosen, refused to comment on how, or even if, Merck oversees the testing conducted by the CROs.⁹

Since its release, how have the American recipients of GARDASIL™ fared?

*[There have been] twice as many children collapsing and four times as many children experiencing tingling, numbness, and loss of sensation after getting a GARDASIL™ vaccination compared to those getting a Tdap (tetanus-diphtheria-acellular pertussis) vaccination. There have been reports of facial paralysis and Guillain-Barre Syndrome. And doctors who give GARDASIL™ in combination with other vaccines are basically conducting an experiment on their young patients because Merck has not published any safety data for simultaneous vaccination with any vaccine except hepatitis B vaccine.*¹⁰

For further information on the large number of serious and largely unreported adverse reactions that have occurred after vaccination with GARDASIL™, see the National Vaccine Information Center's (NVIC) report "Human Papilloma Virus Vaccine Safety."¹¹

⁷ Merck & Co., "GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine] , Label 9682302." Accessed on 7 March 2007. <<http://www.fda.gov/cber/label/hpvmr013007LB.pdf>>, (p. 11).

⁸ National Vaccine Information Center (NVIC), "Merck's GARDASIL Vaccine Not Proven Safe for Little Girls: National Vaccine Information Center Criticizes FDA for Fast Tracking Licensure." Press release, 27 June 2006. <<http://nvic.org/PressReleases/pr62706gardasil.htm>>.

⁹ http://www.inthesetimes.com/article/3057/hpv_vaccine_betting_on_a_mercky_record/

¹⁰ NVIC, "Vaccine Safety Group Releases GARDASIL Reaction Report, Calls on FDA and CDC to Warn Doctors and Parents to Report to VAERS." Press release, 21 February 2007. <<http://nvic.org/Diseases/HPV/pr022107HPV.htm>>.

¹¹ NVIC, *Human Papilloma Virus Vaccine Safety: Analysis of Vaccine Adverse Events Reporting System Reports, Part II*. 18 February 2007. Accessed 7 March 2007. <<http://nvic.org/Diseases/HPV/HPVRPT2.htm>>.

Who Is Liable?

In 1986 Congress passed the National Childhood Vaccine Injury Act which reduced the liability faced by vaccine manufacturers. This act was deemed necessary because the vaccine manufacturers threatened to discontinue production unless given greater protection from lawsuits. Out of this act came a two-step process in which a claimant must first approach the National Vaccine Injury Compensation Program (NVICP) and only after that may a lawsuit be brought against the vaccine manufacturer.

[For] [i]njuries or deaths occurring after October 1, 1988:

- *A citizen is required to apply for federal compensation prior to pursuing a lawsuit.*
- *The system will offer to pay up to \$250,000 for a vaccine associated with death.*
- *The system will offer to pay for all past and future unreimbursed medical expenses, custodial, and nursing care; up to \$250,000 pain and suffering; and loss of earned income.*
- *If a citizen rejects the award or is turned down, a lawsuit may be filed...*
- *Restrictions may apply to lawsuits.*
- *The system is funded by a surcharge on each dose of vaccine sold.¹²*

In the case of GARDASIL™, the surcharge will be \$0.75 per dose.¹³ Every time Merck receives \$120 for a dose of GARDASIL™, it gives \$0.75 to the NVICP. The NVICP then distributes this money to those made ill by the vaccine. Since 1986, how well has the NVICP performed?

Even though the program has awarded nearly \$2 billion to victims of mandated vaccines, two out of three plaintiffs are turned away.¹⁴

The NVICP's past performance indicates that GARDASIL™ will likely make far more people ill than the NVICP will be able to compensate. Two out of three people sickened by the vaccine will likely receive no compensation. If given unfavorable or no compensation, claimants can sue in a court of law, but recovering damages will be a tall task.

For less than a penny on the dollar, Merck avoids injury liability. This may make sense when a vaccine is necessary for public health, but when dealing with a designer vaccine like GARDASIL™, liability should be the manufacturer's alone.

How Effective is GARDASIL™ ?

GARDASIL™'s efficacy in preventing cervical cancer is unknown by Merck:

The duration of immunity following a complete schedule of immunization with GARDASIL™ has not been established.¹⁵

¹² NVIC's *The Compensation System and How It Works* contains detailed information on the compensation system, how to file a claim, what to expect, how awards are paid and examples of final judgments (Vienna, VA: National Vaccine Information Center).

¹³ Michael F. Thomas, Senior Vice President, Global Commercial Operations, Merck & Co., Inc., letter to customers, 1 February 2007, concerning tax relief and Health Care Act of 2006 and specifically excise tax applicable to GARDASIL. Accessed 7 March 2007. <<https://www.merckvaccines.com/omc/exciseTaxChanges.pdf>>.

¹⁴ NVIC, "Congress Set to Pass Law Eliminating Liability for Vaccine Injuries." Press release, 19 October 2005. Accessed 7 March 2007. <<http://www.909shot.com/PressReleases/101905Burrbill.htm>>.

¹⁵ Merck & Co., "GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant

The American College of Pediatricians explains why the duration of immunity has not been established:

Because the average time between initial HPV infection and death from cervical cancer is 20 years, definitive conclusions about HPV vaccine efficacy will take years to establish.¹⁶

Merck followed study participants for as long as five years after enrollment.¹⁷ What happens after five years is not known.

Waning protection is an issue with almost every vaccine in existence. In the 1980s it became clear that a single mumps-measles-rubella (MMR) vaccine was insufficient to offer complete protection against measles. When approved in 1995 a single dose of chickenpox vaccine was expected to offer long-lasting protection, now we know a booster is needed. It may be years before we know with certainty the duration of protection afforded by HPV vaccines.¹⁸

Not only does GARDASIL™ not offer “protection against other forms of sexually transmitted diseases,” but it may worsen or even cause the very diseases it supposedly protects against:

[T]here were several VAERS [Vaccine Adverse Events Reporting System] reports of HPV infection, genital warts and cervical lesions after GARDASIL™ vaccination. It is unknown if the girls were infected with HPV before being vaccinated or if GARDASIL™ failed to protect them.

. . . The FDA staff also questioned whether the “HPV types not contained in the vaccine might offset the overall clinical effectiveness of the vaccine.” There are more than 15 types of HPV associated with cervical cancer but GARDASIL™ only contains HPV types 16 and 18. It is unknown whether non-vaccine HPV types will become more dominant in the future. However, there are indications this could occur because some of the seven strains of pneumococcal contained in Wyeth’s PREVNAR vaccine, which was recommended by the CDC for universal use in all babies in 2000, have been replaced by some of the more than 80 other pneumococcal strains not contained in the vaccine.¹⁹

Merck hails GARDASIL™ as a disease-fighting wonder. Looking at the lack of evidence available to establish such a claim, the real wonder is how Merck has been able to get away with this.

Is HPV Like Measles?

Vaccine], Label 9682302,” p. 5. Accessed on 7 March 2007. <<http://www.fda.gov/cber/label/hpvmer013007LB.pdf>>.

¹⁶ American College of Pediatricians (ACP), “College States Position on HPV Vaccine.” Accessed 7 March 2007. <<http://www.acped.org/?CONTEXT=art&cat=12&art=95&BISKIT=383398630>>.

¹⁷ Merck & Co., “FDA Approves Merck’s GARDASIL®, the World’s First and Only Cervical Cancer Vaccine.” Press release, 8 June 2006. Accessed 7 March 2007. <http://www.merck.com/newsroom/press_releases/product/2006_0608.html>.

¹⁸ ACP, “Position on HPV Vaccine.”

¹⁹ U.S. Food and Drug Administration (FDA). “VRBPAC Background Document, GARDASIL™ HPV Quadrivalent Vaccine, May 18, 2006, VRBPAC Meeting.” Quoted in NVIC’s February 21, 2007 press release. Accessed 7 March 2007. <<http://nvic.org/Diseases/HPV/pr022107HPV.htm>>.

Normally vaccines are required for school attendance when they protect a child against a disease that he or she is at increased risk of getting at school. This rationale is not applicable to HPV according to Dr. Jon Abramson, chairman of the Centers for Disease Control and Prevention's (CDC) advisory committee on immunization practices:

*The vaccines out there now are for very communicable diseases. A child in school is not at an increased risk for HPV like he is measles.*²⁰

The *Washington Post* elaborated on this:

*Because the virus is transmitted through intimate contact, the arguments for required vaccination differ from the rationale for enforcing shots against diseases easily spread in schools, such as measles.*²¹

Alliance for Human Research Protection board member Dr. Meryl Nass, who has medical expertise in vaccine safety, epidemiology and biological warfare, concurs:

*Unlike infectious diseases spread in schools – like polio or measles – HPV is only transmitted sexually. Why then is Merck seeking mandatory vaccine orders?*²²

Merck is pushing for GARDASIL™'s mandate at record speeds. The chickenpox vaccine did not make it on to the school children's immunization schedule until it had been approved and used for several years.²³ In contrast, the FDA approved GARDASIL™ on June 8, 2006, just nine months ago²⁴ and the Advisory Committee on Immunization Practices (ACIP) voted to have GARDASIL™ recommended to the CDC's national childhood recommended immunization schedule on June 29, 2006.²⁵

Last December at a Wall Street briefing, the president of global human health at Merck, Peter Loescher, said that he emphasizes "speed, speed, speed" when a new product is launched.²⁶ The *Washington Post* reported that a prominent local physician advises greater caution:

*"There has to be a period of awareness," said Joseph Wright, executive director of the Child Health Advocacy Institute at Children's Hospital in Northwest Washington. The hospital has not decided its position on the council's pending bill.*²⁷

²⁰ Gregory Lopes, "CDC Doctor Opposes Law for Vaccine." *Washington Times*, Tuesday, 27 February 2007, Business section. Accessed 7 March 2007. <<http://washingtontimes.com/business/20070226-115014-2031r.htm>>.

²¹ Susan Levine, "Parents Question HPV Vaccine Push to Mandate Shots Rapidly Creates Backlash." *Washington Post*, Sunday, 4 March 2007; C01. Accessed 7 March 2007. <http://www.washingtonpost.com/wp-dyn/content/article/2007/03/03/AR2007030301356_pf.html>.

²² Alliance for Human Research Protection, "Facts Behind Merck's Mandatory Vaccine Campaign to Help Pay for Vioxx." Sunday, 4 February 2007. Accessed 7 March 2007. <<http://www.ahrp.org/cms/content/view/457/31>>.

²³ Levine, "Parents Question HPV Vaccine."

²⁴ FDA, "FDA Licenses New Vaccine for Prevention of Cervical Cancer and Other Diseases in Females Caused by Human Papillomavirus: Rapid Approval Marks Major Advancement in Public Health." Press release, 8 June 2006. Accessed 7 March 2007. <<http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>>.

²⁵ Centers for Disease Control (CDC), "CDC's Advisory Committee Recommends Human Papillomavirus Virus Vaccination." Press release, 29 June 2007. Accessed 7 March 2007. <<http://www.cdc.gov/od/oc/media/pressrel/r060629.htm>>.

²⁶ Laura Smitherman, "Drug firm pushes vaccine mandate: Merck lobbies Md. on HPV preventive." *Baltimore Sun*, Monday, 29 January 2007, Health and Science section, p. 2. Accessed 7 March 2007. <<http://www.baltimoresun.com/news/health/bal-te.md.cervical29jan29,0,166914.story?page=2>>.

²⁷ Levine, "Parents Question HPV Vaccine."

Just weeks after CDC approval, on July 14, 2006, VAERS received its first report of an adverse reaction as a result of administering GARDASIL™. Six days later, on July 20, 2006, a just-vaccinated 16-year-old girl from Illinois came down with symptoms that were eventually diagnosed as Guillain-Barre Syndrome.²⁸ NVIC examined adverse event reports for the last six months of 2006 and found 385 unique adverse reports for that period.²⁹ These adverse events (and many others) beg the question: Who benefits from the rush to vaccinate so many girls so quickly?

Public Health or Corporate Profit?

Is the rush to vaccinate 11 and 12 year old girls with GARDASIL™ driven by public health concerns or commercial interests? Dr. John Abramson, a member of the clinical faculty of the Harvard Medical School, an award-winning family physician, and author of the book *Overdosed America: The Broken Promise of American Medicine*, had this to say in a response to an email:

[O]ver the past 30 years or so the fundamental purpose of medical knowledge in our society has been transformed from a public good (the purpose of which is to improve our health) into a commodity (the purpose of which is to fulfill the commercial sponsors' fundamental responsibility—their fiduciary responsibility to maximize returns to investors). The primary consequence of this privatization of medical knowledge is that standards of medical care (based largely on the commercially generated "evidence") tend to grow toward the kinds of interventions that are most likely to maximize the commercial research sponsors' return on investment rather than the kinds of interventions that will most effectively improve Americans' health. In this case, we know that sex education at all levels of school (appropriate for age) is effective in helping children learn how to engage in responsible relationships. This is the overwhelming need, though there is no money in it for the drug industry. Investing up to \$400 per female student to prevent against one form of STD the consequence of which is largely preventable by routine exams that should be performed anyway probably is not the best way to invest our public health efforts or resources.³⁰

Dr. Nancy T. Banks, a Harvard-trained, retired gynecologist and member of the Parents and Citizens Committee to Stop Medical Experimentation in DC, also sees the profit motive at play in the push for GARDASIL™:

If this vaccine is mandated, it would commit the government to buy vaccines for 7 million girls at a total price that could exceed \$2 billion—for a worthless and unnecessary vaccine.³¹

Dr. Banks further points out the (il)logic of this effort:

IF the vaccine works, (highly unlikely) and
IF it prevents all of the targeted cervical cancer cases (7,350) (impossible), and
IF the year 2004 rate of new cervical cancer cases remained constant (rather than continuing the established 35-year decline. . .),

²⁸ NVIC, "Human Papilloma Virus Vaccine Safety Analysis of Vaccine Adverse Events Reporting System Reports: Adverse Reactions, Concerns and Implications." Accessed 7 March 2007. <<http://www.nvic.org/Diseases/HPV/HPVrpt.htm>>.

²⁹ NVIC, "Vaccine Safety Group Releases GARDASIL Reaction Report, Calls on FDA and CDC to Warn Doctors and Parents to Report to VAERS."

³⁰ John Abramson, MD, email to Peter Tucker, Thursday, 22 February 2007.

³¹ Nancy Turner Banks, MD, "Ten Reasons to Reject Mass Immunization of Preteen Girls with GARDASIL™." Self-published handout, 22 February 2007.

THEN 272 girls [or more] must be vaccinated at a cost of \$300 to \$500 each to prevent one case of cervical cancer.

Estimated cost = \$81,600 to \$136,000 per case of cancer prevented.

The concept of vaccinating 272 nine-year-old girls to prevent one case of disease which occurs 31-46 years later when the girls become women 40 to 55 years in age seems like a story which should begin, “Once upon a time, the wagon of the snake oil salesman was seen approaching. . .”³²

The more the public knows about HPV the less appealing GARDASIL™ is:

- *HPV is the most common sexually transmitted infection in the U.S.*
- *Most HPV infections cause no symptoms and more than half of all sexually active persons become infected at some point in their lives.*
- *There are more than 100 HPV types and 30-40 can be sexually transmitted, with 15 HPV types associated with cervical cancer.*
- *The majority of women clear the HPV virus from their bodies naturally but women with risk factors, such as HIV infection, smoking, long-time use of oral contraceptives, and co-infection with herpes simplex virus or chlamydia, are at higher risk for chronic HPV infection.*
- *Between 1955 and 1992, cervical cancer deaths in American women dropped by 74 percent due to routine pap smears.*
- *There are about 9,800 new cases of cervical cancer annually diagnosed in the U.S., which represents .007 percent of the approximately 1,372,000 new cancer cases of all types diagnosed.*
- *Most cervical pre-cancers develop slowly, so nearly all cervical cancers can be prevented with regular pap smear screening and prompt treatment.*
- *Survival for women with pre-invasive cervical cancer lesions is nearly 100% with early diagnosis and appropriate treatment.³³*

While it may not affect a large proportion of women, cervical cancer is very real and scary. Why not address it using methods we know to work? While “there is no money in it for the drug industry,” there may be an awful lot in this approach for the health of our children.

What are the ingredients of GARDASIL™?

Inactive proteins from HPV Virus (6,11,16,18), amorphous aluminum hydroxy-phosphate sulfate, sodium chloride, L-histidine, polysorbate 80, and sodium borate.

—USSPPI Patent Info 9682302: *Quadrivalent Papillomavirus (Types 6,11,16,18) Recombinant Vaccine*

Are any of these ingredients potentially harmful and not found in common vaccines?

³² Ibid.

³³ NVIC, “HPV Facts.” Accessed 7 March 2007. <<http://nvic.org/Diseases/HPV/HPVInfection.htm>>.

Sodium borate, sodium chloride, L-histidine, and amorphous aluminum hydroxyphosphate sulfate are found in GARDASIL™ but not in common vaccines.

Sodium borate — a toxic substance used in roach, rodent, and insect killers, antiseptics, some paints and enamels. “Poisoning may also occur in those who are repeatedly exposed to sodium borate. In the past, boric acid was used to disinfect and treat wounds. Patients who received such treatment repeatedly got sick and some died. Because boric acid is now known to be a dangerous poison if ingested, it is no longer commonly used in medical preparations.” (Medline Plus Medicin Encyclopedia, US National Library of Medicine and National Institutes of Health.)

Borax, a product made primarily from sodium borate may also be used to kill roaches, ants, and fleas. In fact, it is also toxic to people. Signs of chronic toxic exposure include red and peeling skin, seizures, and kidney failure. The estimated lethal dose (ingested) for adults is 15-20 grams; less than 5 grams can kill a child or pet. For this reason, borax should not be used around food. More commonly, borax is associated with skin, eye, or respiratory irritation. It is important to point out that **exposure to borax may impair fertility or cause damage to an unborn child.**³⁴ (Emphasis added.)

Amorphous aluminum hydroxyphosphate sulfate — scientists are still researching the links between aluminum and Alzheimer’s disease and brain degeneration. Higher levels of aluminum have been found in the brains of Alzheimer’s patients.

L-histidine — L-histidine supplements carry warnings that supplements should be avoided “by children, pregnant women, and nursing mothers. Those with allergies or peptic ulcer disease should only use L-histidine supplements under strict medical supervision.”³⁵

Polysorbate 80 – While common in several other vaccines, Polysorbate 80 is nevertheless of some concern:

May cause adverse reproductive effects based on animal test data. No human data found.

May cause cancer based on animal test data. No human data found.

*May affect genetic material (mutagenic).*³⁶

TO CONTACT THE **PARENTS AND CITIZENS COMMITTEE TO STOP MEDICAL EXPERIMENTATION IN DC**, CALL **(202) 829-9612** OR EMAIL **STOPHPV_VACCINE@YAHOO.COM**.

³⁴ Anne Marie Helmenstine, Ph.D., “How Does Borax Clean? Chemistry of Borax of Sodium Borate.” Accessed 7 March 2007. <<http://chemistry.about.com/library/weekly/aa091002a.htm>>. (About, Inc., The New York Times Company.)

³⁵ PDRhealth, “L-histidine Description.” Accessed 7 March 2007. <http://www.pdrhealth.com/drug_info/nmdrugprofiles/nutsupdrugs/lhi_0137.shtml>.

³⁶ Sciencelab.com, Inc., “The Material Safety Data Sheet for Polysorbate 80,” pp. 4–5. Accessed 7 March 2007. <www.sciencelab.com/xMSDS-POLYSORBATE_80-9926645>.