

What Do We Really Know About the HPV Vaccine?

QUESTIONABLE NECESSITY AND EFFECTIVENESS

The American Cancer Society says that even though infection with the sexually transmitted virus HPV is an important risk factor for cervical cancer, **most women with HPV infection do not get cervical cancer.** Doctors believe other factors must come into play for this cancer to develop. Some of these factors are smoking, HIV infection, Chlamydia infection, diet, long-term use of birth control pills, multiple pregnancies, low income, mothers who took hormonal drug DES, and family history. [1] These are not typical risk factors affecting junior high girls.

According to the National Institutes of Health National Cancer institute, **in more than 90% of the cases, HPV infections are harmless and go away without treatment.** [2]

Also, according to the CDC, most cervical cancer can be prevented and **cervical cancer is very rare in women who get regular PAP tests.**[3] Cervical Cancer is not a major killer in the state of Texas thanks to PAP screenings: **in 2000, there were 371 deaths from cervical cancer, in 2001 there were 352 and in 2002 there were 329.** [4]

The CDC says **there are more than 100 strains or types of HPV** and over 30 strains are sexually transmitted. [5] Yet the **vaccine under consideration for mandate covers only 4 strains.** [6] About **30% of cervical cancers can't be prevented by the vaccine,** so women will still need regular cervical cancer screenings. [7].

The only current vaccine manufacturer for the HPV vaccine, Merck, admits on their package insert that the **duration of immunity from the vaccine is unknown.** [8] In clinical trials, the **vaccine's effectiveness was only followed for 4 years.**[9] Yet we do know from the CDC that the **incubation period for the HPV virus is about 20 years** [10] and the **median age of women diagnosed with cervical cancer is 48** [11]. Therefore, **no claims to proof of cervical cancer prevention by vaccinating preteen girls should be made.**

QUESTIONABLE SAFETY

The HPV vaccine Gardasil was approved by the FDA on June 8, 2006 after 6 months of review.[12] It has **been on the market for less than 1 year.**

The **chairman of the American Academy of Pediatrics committee on infectious diseases** was quoted in the Washington Post in response to a proposed mandate in Washington D.C. saying that he thought it was **premature to recommend making the vaccine mandatory.** "I think it's too early," said Joseph A. Bocchini,... "This is a new vaccine. It would be wise to wait until we have additional information about the safety of the vaccine." [13]

Dr. Martin Meyers, director of the National Network for Immunization Information, was quoted in the Baltimore Sun in response to a proposed bill in Maryland to mandate HPV vaccines for 6th grade girls, "**A lot of us are worried it's a little early to be pushing a mandated HPV vaccine.**" He also said "**It's not the vaccine community pushing for this.**" The article spotlighted HPV vaccine manufacturer **Merck's aggressive role in pushing for a mandate where across the U.S., HPV vaccine mandates could mean \$4 billion dollars in sales** for Merck [14] who is currently plagued by lawsuits for withholding critical safety information to doctors and patients about their popular painkiller drug Vioxx.[15]

The **FDA's Vaccine Adverse Events Reporting System has already received 82 reports of serious adverse events following HPV vaccination** with Gardasil since its approval last June. [16]

More questions remain. Disclaimers printed on the manufacturer's package inset state that the **vaccine has not been tested for it's own ability to cause cancer** [17] and the **effect on a woman's reproductive capacity is unknown.** [18] Additionally, **the vaccine is genetically engineered yet the manufacturer admits it has not tested the vaccine for genotoxicity**[17] (testing to see if the vaccine is toxic to our own human DNA). Each dose of the vaccine contains 225 mcg of aluminum [6] which means **girls receiving all 3 HPV doses will be directly injected with 675 mcg of aluminum.**

QUESTIONABLE COST

The retail cost of the vaccine is **\$120 per dose, or \$360 for the full series** of 3 shots. [7] According to the bill's author Sen. Leticia Van de Putte, there are 162,000 6th grade girls[19] which translates to forcing **Texas families paying over \$58 million dollars not including the doctor visits for a vaccine not proven to prevent cervical cancer.** This is a **high price to force families to pay** especially for families skeptical of the necessity, efficacy, or safety of the

vaccine. **Merck is absolved from liability for the injuries and deaths caused by the HPV vaccine** through the National Childhood Vaccine Injury Act of 1986 [20] leaving families to deal with the emotional and monetary costs of the harm caused by the vaccine to their daughters on their own.

The vaccine is available to anyone who wants it, so it does not need to be mandated. Federal health programs such as Vaccines for Children cover the HPV vaccine to children and teens under 19 years of age, who are either uninsured, Medicaid-eligible, American Indian, or Alaska Native. The VFC Program also allows children and teens to get VFC vaccines through Federally Qualified Health Centers or Rural Health Centers, if their private health insurance does not cover the vaccine [7], so **insurance mandates which raise the cost of insurance for everyone who does not want or need the vaccine are not necessary.**

[1] The American Cancer Society, What Causes Cancer of the Cervix.

http://www.cancer.org/docroot/CRI/content/CRI_2_2_2X_What_causes_cancer_of_the_cervix_Can_it_be_prevented_8.asp?sitearea=

[2] The National Institutes for Health, National Cancer Institute.

<http://www.cancer.gov/clinicaltrials/results/cervical-cancer-vaccine1102>

[3] The Centers for Disease Control and Prevention, Cervical Cancer Screening and Prevention.

<http://www.cdc.gov/std/hpv/CervicalCancerScreeningPrevention8-3-2005.ppt#267,10> Most cervical cancer can be prevented

[4] The Centers for Disease Control and Prevention United States Cancer Statistics. <http://apps.nccd.cdc.gov/uscs/>

[5] Centers for Disease Control and Prevention, Sexually Transmitted Diseases, Genital HPV Infection – CDC Fact Sheet. <http://www.cdc.gov/STD/HPV/STDFact-HPV.htm>

[6] Gardasil package Insert. 2006. Page 1. <http://www.fda.gov/cber/label/hpvmer060806LB.pdf>

[7] Centers for Disease Control and Prevention, HPV Vaccine Questions and Answers.

<http://www.cdc.gov/STD/HPV/STDFact-HPV-vaccine.htm>

[8] Gardasil package Insert. 2006. Page 5, paragraph

6. <http://www.fda.gov/cber/label/hpvmer060806LB.pdf>

[9] Gardasil package Insert. 2006. Page 2, paragraph

2. <http://www.fda.gov/cber/label/hpvmer060806LB.pdf>

[10] Centers for Disease Control and Prevention, National Immunization Program, Advisory Committee on Immunization Practices, Minutes of the October 26-27, 2005 ACIP meeting, p. 57.

<http://www.cdc.gov/nip/acip/minutes/acip-min-oct05.pdf>

[11] National Institutes of Health, National Cancer Institute, Cancer Stat Fact Sheets

<http://seer.cancer.gov/statfacts/html/cervix.html>

[12] FDA News, Press Release. <http://www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html>

[13] The Washington Post, "D.C. Bill Would Mandate Vaccine" by Nikita Stewart and Rob Stein. January 10, 2007, p. A01. <http://www.washingtonpost.com/wp-dyn/content/article/2007/01/09/AR2007010901386.html>

[14] The Baltimore Sun, "Drug Firm Pushes Vaccine Mandate, Merck Lobbies Md. On HPV Preventive." by Laura Smitherman, January 29, 2007. <http://www.baltimoresun.com/news/health/baltimore.md.cervical29jan29.0.166914.story>

[15] The Star-Ledger, "Attorneys Lay Out Cases to Open Double Vioxx Trial", by Susan Todd, January 23, 2007.

<http://www.nj.com/business/ledger/index.ssf?base/business-0/1169532761221410.xml&coll=1>

[16] <http://www.medalerts.org/vaersdb/findfield.php?PAGENO=1&PERPAGE=10&VAX=HPV4>

[17] Gardasil package Insert. 2006, Page 8, paragraph 17. <http://www.fda.gov/cber/label/hpvmer060806LB.pdf>

[18] Gardasil package Insert. 2006, Page 9, paragraph 1. <http://www.fda.gov/cber/label/hpvmer060806LB.pdf>

[19] Houston Chronicle, Vaccine Proposal Likely to Stir Debate, by Todd Ackerman. Jan. 10, 2007. <http://www.chron.com disp/story.mpl/front/4459579.html>.

[20] U.S. Department of Health and Human Services Health Resources and Services Administration National Vaccine Injury Compensation Program. <http://www.hrsa.gov/vaccinecompensation/>