

# Facts Behind Merck's Mandatory Vaccine Campaign to Help Pay for Vioxx

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Condoms remain the safest (and cheapest) method for preventing sexually transmitted diseases. But the pharmaceutical / biomedical industry is Hell bent on marketing more profitable invasive methods.

Merck has financed an aggressive lobbying campaign on behalf of its new Gardasil vaccine for human papilloma virus (HPV), carried out by professional lobbyists and by Women in Government, an organization of state legislators.

Women in Government are trying to pass legislation in every state that would force 11 year old girls to be vaccinated, or be prevented from going to school.

But Merck went one step further: on Friday, Texas Republican governor Rick Perry issued a MANDATORY executive order to force all Texas girls to be vaccinated with Gardasil, completely bypassing Texas' legislative process, overriding parental authority, and ignoring the ethical issues raised by a vaccine for a sexually transmitted disease. Perry, of course, is a recipient of Merck largesse.

If one looks beneath the surface, Merck's strong-arm marketing tactics are really a "Do or Die" effort to finance its huge Vioxx litigation costs. Thus, the mandatory HPV vaccine campaign is really a campaign to "Help Pay for Vioxx" losses.

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Below, Meryl Nass, MD,\* whose medical expertise includes vaccine safety, epidemiology and biological warfare, provides insight into the medical and ethical concerns--and the unanswered scientific questions about Merck's Gardasil vaccine.

Among the issues addressed by Dr. Nass:

1. Unlike infectious diseases that spread in schools--like polio and measles--HPV is only transmitted sexually. Why, then, is Merck seeking mandatory vaccine orders? Is it deliberately to usurp parental rights and responsibilities?
2. Since boys transfer the HPV virus to girls, why don't boys get vaccinated? Why are only girls being pushed to take the vaccine?
3. There are over 30 HPV viruses. Of these, 10 may cause cancer. Merck's vaccine is effective for only 4 of these potentially cancerous viruses. Therefore, PAP tests are still essential to detect cancer and save lives, as well as condoms, which remain the safest, most effective method for preventing HIV transfer and numerous sexually transmitted diseases.
4. The oversell of Gradasil is likely to mislead those vaccinated to think that they are safe when they are not. This has the potential of increasing both STDs and cancer.

Other questions remain about the clinical trials:

How many girls participated in pre-licensure clinical trials and for how long were they followed up? What is the nature of the adverse event reports received by the government Vaccine Adverse Event Reporting System (VAERS) since its approval in July 2006 and February 2007?

According to the National Vaccine Information Center, between July 2006 and January 2007, there have been 82 reports of adverse events filed with VAERS following receipt of GARDASIL by girls and boys ranging in age from 11 to 27 years. Reaction reports have come from 21 states, including Virginia and the District of Columbia. All but three of the reports were for adverse events that occurred within one week of vaccination, and more than 60 percent occurred within 24 hours of vaccination.

See: National Vaccine Information Center  
<http://www.medicalnewstoday.com/medicalnews.php?newsid=62176>

The National Vaccine Information Center urges state legislatures to investigate the safety and cost of mandating Merck's HPV vaccine--before any policy is adopted. The Alliance for Human Research Protection joins NVIC in asking for investigations into the vaccine's safety and cost.

\*Dr. Nass is a board member of the Alliance for Human Research Protection. See her vita at: <http://www.anthraxvaccine.org/docs/CV121206.doc>

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#### Gardasil vaccine: Facts and Implications

Cervical cancer is caused by changes in the cells of the cervix caused by human papilloma viruses (HPV). These viruses can also lead to cancer of the vagina, vulva, anus, penis and scrotum. [1] The cancer-causing viruses are sexually transmitted.

At least 50% of sexually active men and women acquire a genital HPV infection during their lives. The CDC says that by age 50, at least 80% of women will have developed a genital HPV infection.

There are over 30 different HPV viruses that are sexually transmitted. About ten of these have the potential to cause cancer.

The HPV vaccine, Gardasil, contains antigens designed to protect against 4 of the ten dangerous strains of HPV. Three doses are given over six months for protection against these four strains only.

It is estimated that these 4 viruses cause 70% of HPV-induced cancers. The other HPV viruses, not protected by the vaccine, cause 30% of cervical cancers.

The American Cancer Society estimates that 11,000 cases of cervical cancer will be diagnosed in women this year, compared to 178,000 new cases of breast cancer. [2] The Cancer Society says, "mortality rates for cervical cancer have declined steadily over the past several decades due to prevention and early detection as a result of screening." They also note, "Importantly, HPV infections are common in healthy women and only rarely result in cervical cancer" and "fortunately, most cervical precancers develop slowly, so nearly all cases can be prevented if a woman is screened regularly."

Because HPV viruses may live on skin around the genital area, condoms are not 100% effective in prevention. However, condom use is associated with a lower rate of cervical cancer.

What about men? About 1,500 new cases of penile cancer will be diagnosed in men this year, and 1,900 cases of anal cancer, linked to HPV.

What does all this mean to me?

First, the vaccine is at best 70% effective, so you can still be infected with HPV viruses that can lead to cervical and other cancers, even after three doses of this vaccine. You can still get genital warts, but are at lower risk. You will still need yearly PAP smears to protect against cervical cancer. PAP tests are extremely effective at preventing cervical cancer.

Second, you really should be using condoms for all sexual activity to prevent HIV infection and a number of other sexually transmitted diseases.

Don't get the wrong idea that this vaccine will allow you to safely avoid the use of condoms.

Why don't boys get this vaccine? Good question, since they transfer the HPV virus to girls, and they also can get cancer. If boys took the vaccine instead of girls, you could prevent approximately the same number of cancers.

How safe is the vaccine for me? Because it is a new vaccine and has only been used in a few thousand people during clinical trials, the side effect profile of the vaccine is still not known.

What if I get pregnant after getting Gardasil vaccine? Clinical trials showed that women who became pregnant within one month of vaccination had more birth defects than women who received placebo vaccine and became pregnant. After 30 days, this apparent risk disappeared.

What if you were vaccinated, then learned you were pregnant? It is not known if this is a problem, but it might be. Therefore, Merck, the manufacturer, maintains a pregnancy registry to track the outcomes of pregnancies during which women were vaccinated: call (800) 986-8999 to report any Gardasil vaccinations during pregnancy.

Okay, if I still need to use condoms and get yearly PAP smears, what's the point of getting this vaccine?

\* Women who don't get pap smears, who have more partners, or who for other reasons are at higher risk of cervical cancer may benefit from this vaccine.

\* Women who are monogamous or are not sexually active have a low risk of cervical cancer.

\* Gay men are at higher than average risk of penis and anus cancers and may desire this vaccine. It is not known why the vaccine was not approved for men.

Therefore, you should be able to choose whether to receive the vaccine. However, if you get yearly PAPs, and practice safe sex, your benefit from this vaccine is greatly diminished, or nil.

Why are governors and legislatures considering forced Gardasil vaccinations for eleven-year-old girls?

Cervical cancer is not spread by casual contact. State governments are not mandating Gardasil to protect students from infectious diseases like polio or measles that can spread in schools. Instead, they are usurping the parental role of determining what is best for their children's health.

The retail cost of the 3 vaccine doses is \$360, which will not be paid by the lawmakers. Why not give free PAP smears to all interested women instead, which would cost about the same amount?

Marketing is the answer. Merck developed this strategy to sell the largest amount of vaccine: making every preteen girl get the shots. Year after year, the vaccine market would be guaranteed, with Merck collecting

approximately 1 Billion dollars annually from US sales alone.

"At a Wall Street briefing last month, Peter Loescher, president of global human health at Merck, said he emphasizes "speed, speed, speed" in a product launch. Already, he noted, 80 percent of cities and states - including Maryland - have ordered Gardasil to be distributed through Vaccines for Children. The federally funded program provides free vaccines to doctors who serve children with little or no insurance."[3]

Merck provides funding to the organization "Women in Government," a bipartisan group of state legislators, to sponsor its campaign for statewide vaccine mandates.[4]

Women in Government's work has included enacting legislation to require HPV vaccine for school entry, obtaining medicaid coverage for HPV testing, creating cervical cancer task forces at the state level, enacting cervical cancer prevention legislation, and obtaining compulsory insurance reimbursement for HPV testing and HPV vaccinations. Their website has a map with each state tracked as to how far along it is toward enacting the desired legislative mandates.

Bypassing the Texas Legislature altogether, the Republican Governor of Texas, Rick Perry, issued an order Friday February 2, making Texas the first state to require that schoolgirls get vaccinated against the sexually transmitted virus that causes cervical cancer.

Why did Merck emphasize speed in this product launch? They wanted to get the vaccine mandates in place before the bad publicity started.

The Associated Press reports that one of Merck's three lobbyists in Texas is Mike Toomey, Perry's former chief of staff. His current chief of staff's mother-in-law, Texas Republican state Rep. Dianne White Delisi, is a state director for Women in Government. The governor also received \$6,000 from Merck's political action committee during his re-election campaign.

Instead of trying to prevent cancer, it is starting to look more and more like the HPV vaccine really stands for "Help Pay for Vioxx" - Merck's failed arthritis pain pill that is costing the company several billion in settlements for adverse effects and deaths. Merck's strong-arm tactics for marketing Gardasil are a "Do or Die" attempt to get the company back on a secure financial footing. American preteen girls are to pay the price.

Yet it is not at all clear how long the vaccine will work. Boosters will probably be needed after several years. Will new diseases crop up at higher rates in those who were vaccinated?

The FDA is requiring Merck to gather more safety information: on autoimmune conditions, cancer and possible birth defects.[5] FDA wants to find out how long protection lasts, and whether non-vaccine strains of HPV will "take over" from the vaccine strains, in effect nullifying vaccine benefit.

Unless an eleven year old will begin sexual experimentation in the next couple of years, there is plenty of time to wait and see how this vaccine pans out, once it has been used in larger populations for longer periods of time. Then an informed decision can be made regarding its value for you.

Meryl Nass, MD

#### References:

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2. American Cancer Society. Cancer Facts and Figures 2007.20 [http://www.cancer.org/docroot/STT/stt\\_0\\_2006.asp?sitearea=STT&level=1](http://www.cancer.org/docroot/STT/stt_0_2006.asp?sitearea=STT&level=1)
3. Laura Smitherman. Drug firm pushes vaccine mandate. Baltimore Sun, January 29, 2007.

<http://www.baltimoresun.com/news/local/politics/bal-te.md.cervical29jan29,0,2725203.story?page=2&coll=bal-mdpolitics-headlines>

4. Women in Government's legislative toolkit:

[http://www.womeningovernment.org/prevention/legislative\\_toolkit.asp](http://www.womeningovernment.org/prevention/legislative_toolkit.asp)

5. <http://www.fda.gov/cber/approvltr/hpvmer060806L.htm>