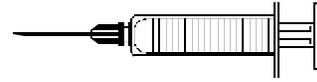


# PROVE

Parents Requesting Open Vaccine Education



## Support HB1098 and Oppose SB110: NO HPV Vaccine Mandate for 6<sup>th</sup> Grade Girls 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

After only 6 months of review, the FDA approved Gardasil on June 8, 2006. [12] **Fewer than 1200 girls under the age of 16 were tested in clinical trials for Gardasil**. [13] and 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." [14]

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 6<sup>th</sup> 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 [15] who is currently plagued by lawsuits for withholding critical safety information to doctors and patients about their popular painkiller drug Vioxx. [16]

The **FDA's Vaccine Adverse Events Reporting System has already received hundreds of reports of serious adverse events following HPV vaccination** with Gardasil since its approval last June. [17]

More questions remain. Disclaimers printed on the manufacturer's package inset state that the vaccine has not been tested for its own ability to cause cancer [18] and the effect on a woman's reproductive capacity is unknown. [19] Additionally, the vaccine is genetically engineered yet the manufacturer admits it has not tested the vaccine for genotoxicity [18] (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 Sen. Leticia Van de Putte, there are 162,000 6<sup>th</sup> grade girls [20] which translates to forcing Texas families paying over \$58 million dollars PER YEAR 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 [21] 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=](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](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 New York Times, "A New Vaccine for Girls, but Should It Be Compulsory?" by Roni Rabin, July 18, 2006.

<http://query.nytimes.com/gst/fullpage.html?res=9E06E7DF163FF93BA25754C0A9609C8B63&sec=health&spn=&pagewanted=2>

[14] 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>

[15] 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/bal-te.md.cervical29jan29.0.166914.story>

[16] 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>

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

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

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

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

[21] U.S. Department of Health and Human Services Health Resources and Services Administration National Vaccine Injury Compensation Program.

<http://www.hrsa.gov/vaccinecompensation/>

## **“Opting-Out” of HPV Vaccine WILL NOT WORK for Many in Texas**

Governor Perry is misleading legislators and families in Texas by claiming that they will be able to “opt-out” of having their 6<sup>th</sup> grade daughter vaccinated with the vaccine for the sexually transmitted virus HPV. For many families currently, the exemption isn’t worth the piece of paper it is printed on. Besides the simple fact that parents should not have to get permission from the state to make informed consent medical decisions for their own children, **here are four reasons why “opting-out” of state mandated vaccines doesn’t work for many families in Texas:**

### **1) “Opt-out” or Conscientious Exemption to Vaccination Process is a Bureaucratic Nightmare**

To get the exemption form, parents must first submit a written form to State Health Department in Austin which forces the disclosure of the child’s full name, birthdate, and mailing address. The Health Department takes those written requests and creates yet another form on which they print the child’s same personal information that the parent had to send to health department, and the Health Department sometimes takes weeks to mail out these forms inevitably disrupting the child’s school attendance. The Health Department only sends the forms by U.S. mail, and once the parent receives the forms, they must be notarized within 90 days of submitting them and then repeatedly resubmitted every 2 years even though there is no expiration set in statute. [1] Because the Health Department further eroded parental rights by publishing more rules getting rid of provisional enrolment for exemptions, (families used to have 30 days at the beginning of school to get their paperwork in), now schools participate in aggressive misleading education campaigns touting “no shots – no school” while not informing families of the exemption or the instructions how to obtain it.

### **2) Private Schools Deny Admission**

The Texas attorney general issued an opinion in April of 2006, ga0420, that states that private schools do not have to accept the conscience exemption to vaccination in Texas Law[2], and many private schools do not. For example, the Dallas Diocese for Catholic Schools policy number 5024 states, “Schools will comply with immunization requirements established by the Texas Catholic Conference Education Department. Conscientious objections/waivers are not accepted in schools of the Diocese.” [3] Every new vaccine mandate causes more children with valid legal exemptions to be denied their private school education.

### **3) Doctors Refuse Medical Care**

Even though you may be able to get a piece of paper from the state health department affirming your right to refuse state mandated vaccines for your child, just try and find a doctor who will honor it! According to a recent study published in the Archives of Pediatrics and Adolescent Medicine, 39% of pediatricians surveyed said they would throw kids out of practices who are not vaccinated. [4] PROVE has documented this rampant problem of doctors dismissing families utilizing a vaccine exemption in Texas to the legislature in previous sessions. Please review our report entitled “The Erosion of Public Trust & Informed Consent through Immunization Harassment, Discrimination and Coercion” prepared for the House Public Health Committee in 2005. [5]

### **4) Insurance Rates Rise and Accessibility Affected**

Responsible parents who have secured health care coverage for their children will be forced to pay higher insurance rates whether they want the HPV vaccine or not. Even if you “opt-out” of the HPV vaccine mandate for Gardasil by Merck by securing a conscientious exemption waiver, there is no way for Texas parents to “opt-out” of the corresponding rise in their insurance premiums. § 1367.053. (a) (2) of the Insurance Code REQUIRES that any vaccine required by law must be covered by insurance. [6] This first-dollar coverage requirement results in corresponding direct hiking of insurance premiums to meet costs, and for a vaccine as expensive as this one, an HPV vaccine mandate risks putting premiums for basic health care coverage out of reach financially for even more Texas families. Additionally, we have received complaints from families where insurance companies are harassing parents with letters and discriminating on coverage based on whether or not the child has had all their state mandated vaccines.

[1] [http://www.dshs.state.tx.us/immunize/school/school\\_exclusion.shtm](http://www.dshs.state.tx.us/immunize/school/school_exclusion.shtm)

[2] <http://www.oag.state.tx.us/opinions/GA/GA0420.pdf>

[3] Policy Handbook for Schools, July 6, 2006, Policy 5024. <http://www.cathdal.org/Catholic%20Schools/CSO%20Policy%20Manual%202006.doc>

[4] WebMD, “Refuse Vaccine, Get ‘Fired’ by Pediatrician?” by Daniel Denoon, October 3, 2005. <http://www.medscape.com/viewarticle/513925>

[5] <http://www.vaccineinfo.net/harassment/report.pdf>

[6] <http://tlo2.tlc.state.tx.us/statutes/docs/IN/content/htm/in.008.00.001367.00.htm#1367.053.00>

**“HANDS OFF OUR KIDS COALITION” LETTER  
TO TEXAS GOVERNOR  
RE: HPV VACCINE MANDATE**

February 11, 2007

The Honorable Rick Perry  
Austin, TX  
Dear Gov. Perry:

The undersigned organizations are writing to ask you to reconsider your position mandating the vaccine for human papillomavirus (HPV), a sexually-transmitted disease, for schoolgirls as young as 10 years old.

Your action has prompted a broad, non-partisan coalition of advocacy groups to come together under the umbrella of the “Hands Off Our Kids Coalition.” This ad hoc coalition includes medical, taxpayer, privacy, civil liberties, health freedom, and good government groups from both sides of the aisles. While each group has various reasons for concern, our objectives can be summarized as follows:

1. This vaccine mandate violates parental rights, informed consent & privacy;
2. The efficacy and safety of this specific vaccine are unproven;
3. It is an unjustified expansion of the taxpayers’ burden;
4. It constitutes an unwarranted overreaching of executive power, and
5. It violates sunshine-in-government.

**1. PARENTAL RIGHTS, INFORMED CONSENT & PRIVACY VIOLATIONS**

According to the Association of American Physicians and Surgeons statement of Patients’ Freedoms adopted in 1990,

*”Patients have the freedom ... to refuse medical treatment even if it is recommended by their physician and to be informed about their medical condition, the risks and benefits of treatment, and appropriate alternatives.”*

That means that parents, with the advice of their doctors, should make decisions about their children’s medical care -- not government bureaucrats, whether school board members, or public health administrators. It is wrong for governments to interfere with parental rights because they disagree with the way parents care for the health of their children.

You state that this action does not interfere with parental rights, but preserves them by allowing parents to “opt out” of the mandate. Why should parents have to ask the state’s permission to make this decision? And why should that decision then become a matter of public record? There is potential for massive privacy violations applying to every female child in Texas, for which there is no public health emergent need.

**2. HPV EFFICACY & SAFETY VACCINE IS UNPROVEN**

The safety of this vaccine for children and its life long efficacy as a cancer preventive for this population are unproven. While shown effective in preventing genital warts in adults, clinical trials were conducted on fewer than 2,000 of the target population of girls aged 9 to 15 years old. The studies were far too short to demonstrate that the vaccine prevents the HPV transforming into cancer. Further, since the duration of the protection is estimated at 5 to 7 years, it would wane about the time that some of these girls are becoming sexually active.

The adverse effects of this vaccine must be considered. According to the National Vaccine Information Center (NVIC), the federal Vaccine Adverse Effect Reporting System (VAERS) is now receiving reports

of loss of consciousness, seizures, and neurological disorders such as loss of vision, slurred speech, numbness and tingling following administration of the vaccine in the few months since its approval last June.

### 3. OVERREACHING EXECUTIVE POWERS

Senator Jane Nelson, chair of the Senate Health and Human Services Committee, recently stated: "Executive orders should be used in extreme circumstances, during times of emergency and when the Legislature is not in session."

As Sen. Nelson also pointed out, this was not an emergency, and the legislature had pending bills to examine the HPV vaccine that would have produced public input and cost estimates. There is no public health crisis regarding HPV – it cannot be “caught” sitting in class next to someone shedding the virus. In fact, the cervical rates have been consistently declining. It would seem that you have shut the public and the legislature out of the process for reasons that are difficult to justify.

### 4. UNJUSTIFIED COST BURDEN

The HPV vaccine is one of the most expensive ever to come to market, and is backed by a multi-million dollar direct-to-consumer advertising campaign. The NVIC’s survey of practices showed private practice fees ranging from \$525 to \$930 per child. According to Sen. Nelson, the minimum taxpayer cost will be more than \$300 million through the Texas Medicaid program alone. Plus, since it would not eliminate the need for Pap smears, there would be no costs savings for that test.

### 5. SUNSHINE-IN-GOVERNMENT

We agree with Sen. Nelson’s concern about the process that has been invoked with this policy. At its best, the vaccine approval and policy process is rife with conflicts-of-interest, as demonstrated during several Congressional hearings, and a Congressional report that concluded that the pharmaceutical industry has indeed exerted undue influence on mandatory vaccine legislation toward its own financial interests. Given the huge amounts of money at stake for this vaccine, there are many unanswered questions about any undue influence.

Therefore, we urge that you take the following action:

1. Immediately rescind Executive Order RP65;
2. Work with legislators to pass legislation that would return the authority to enact vaccine policy to the elected representatives, rather than unelected heads of agencies such as public health departments, and to educate parents about exemptions available.
3. Allocate no taxpayer funds towards this specific vaccine;
4. If you choose to go forward with your Executive Order, you and all parties involved voluntarily make full disclosure of financial interests, meetings, and negotiations that took place leading up to issuance of the Order.

### CONCLUSION

Vaccines can and do save lives, and it is our hope that this will not be misconstrued as a blanket indictment of immunizations.

But this episode has demonstrated that we must take a much more deliberative approach in crafting vaccine policy without sacrificing the rights and liberties of individuals and families, and that the State of Texas should consider carefully any new vaccine mandates.

The “Hands Off Our Kids” coalition members urge you to take these steps immediately to restore parental rights, children’s civil liberties, and confidence in the legislative process.

Sincerely,

Association of American Physicians and Surgeons  
American Association of Small Property Owners - F. Patricia Callahan, President  
Ron Paul, M.D. - Member of Congress  
Deborah C. Peel, M.D., Founder and Chair, Patient Privacy Rights, Austin, TX  
Juliette Madrigal Dersch, M.D., Marble Falls, TX  
PROVE / VaccineInfo.net - Dawn Richardson, President and Co-founder, Austin, TX  
Council for Citizens Against Government Waste - Thomas Schatz, President  
Bob Barr, former Member of Congress, & Chairman & CEO of Liberty Strategies, LLC  
Mary Ann Block, D.O., Hurst, TX  
James H. Vernier, M.D., Fredericksburg, TX  
Gary Edd Fish, M.D., J.D., Dallas, TX  
James J. Szabo, M.D., Abilene, TX  
Gregory A. Tichenor, M.D., FACEP, Southlake, TX  
Clayton Young, M.D., F.A.C.O.G., The Woodlands, TX  
David S. Wishnew, M.D. - Austin, TX  
Andrew W. Campbell, M.D. - Spring, TX  
U.S. Bill of Rights Foundation  
National Vaccine Information Center - Barbara Loe Fisher, President  
Frontiers of Freedom - Kerri Houston, Vice President of Policy  
Michael D. Ostrolenk, Co-Founder/National Director, Liberty Coalition  
Liberty Coalition - Michael Ostrolenk, National Director  
Alliance for Human Research Protection  
Citizen Outreach - Chuck Muth, President  
FairfaxCountyPrivacyCouncil.org - Mike Stollenwerk  
RightMarch.com - William Greene, President  
Carolyn Baker, Mesilla Park, NM  
Charlotte Twight, Ph.D., Adjunct Fellow, Independent Institute  
The Multiracial Activist - James Landrith, Founder  
Texas Eagle Forum - Cathie Adams, President  
Eagle Forum, Phyllis Schlafly  
United for Life - Dr. Ronald Konopaski  
Pain Relief Network - Siobhan Reynolds, President and Executive Director  
Bob Bagley Montgomery County Texas Republican Liberty Caucus-Chairman  
Tony B. Rich, President and Chief Executive Officer, IdeasOne Incorporated  
Robert Goodman, Pasadena, TX  
John and Amy Yates, Caldwell, TX  
Minnesota Natural Health Legal Reform Project - Jerri Johnson  
Illinois Right to Life Committee - William Beckman, Executive Director  
Illinois Alliance for Parents and Children - Michael Burns, President  
IllinoisReview.com - Fran Eaton, Editor  
United Republican Fund - Dennis LaComb, Executive Director  
Jill Stanek, Pro-life activist & World Net Daily columnist, Mokena, IL

for immediate release  
February 21, 2007

## **VACCINE SAFETY GROUP RELEASES GARDASIL REACTION REPORT** Calls on FDA and CDC to Warn Doctors and Parents to Report to VAERS

**Washington, D.C.** - The National Vaccine Information Center (NVIC) today released a new analysis of the federal Vaccine Adverse Event Reporting System (VAERS) reports of serious health problems following HPV vaccination (Merck's GARDASIL) during the last six months of 2006. Out of the 385 individual GARDASIL adverse event reports made to VAERS, two-thirds required additional medical care and about one-third of all reports were for children 16-years-old and under, with nearly 25 percent of those children having received simultaneously one or more of the 18 vaccines that Merck did not study in combination with GARDASIL. NVIC is calling on the FDA and CDC to warn parents and doctors that GARDASIL should not be combined with other vaccines and that young girls should be monitored for at least 24 hours for syncopal (collapse/fainting) episodes that can be accompanied by seizure activity, as well as symptoms of tingling, numbness and loss of sensation in the fingers and limbs, all of which should be reported to VAERS immediately.

"Because Merck only studied GARDASIL in fewer than 1200 girls under age 16 in pre-licensure trials, it is critical that doctors and parents be made aware of the nature of the initial adverse event reports coming into VAERS and that they report serious health problems after vaccination when they occur," said NVIC President Barbara Loe Fisher. "There are 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."

According to NVIC's report, a majority of GARDASIL adverse event reports to VAERS involved those who suffered fever, nausea, headache or pain; 14 percent were for syncopal episodes with or without neurological signs; and 8 percent experienced tingling, numbness and loss of sensation, facial paralysis or Guillain-Barre Syndrome. Although adverse event reports to VAERS do not prove causation, they can provide an early warning sign that a new vaccine may be causing health problems that could be important. For example, reports to VAERS of bowel blockage (intussusception) in babies following receipt of Merck's Rota Teq (rotavirus) vaccine prompted the FDA to issue a public warning to doctors and consumers on Feb. 13. [\[1\]](#)

"About 4 reports per day were filed with VAERS in December 2006 for the HPV vaccine," said NVIC Health Policy Analyst Vicky Debold, RN, Ph.D. "Some of these girls are being injured when they collapse after getting the vaccine and others are complaining of neurological symptoms that should not be ignored. Doctors and nurses should take note of the patient safety issues related to giving this vaccine. Giving GARDASIL simultaneously with any of the 18 vaccines Merck did not study in combination is not an evidence-based guideline and should involve informed consent and a signed patient release. To avoid unnecessary injuries, teenage girls should be vaccinated laying down, not be left unattended and probably should not walk or drive themselves home from the doctor's office after they get vaccinated."

NVIC also found that there were several VAERS 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. One case of HPV infection

occurred in a 22-year-old girl who had participated in a Merck GARDASIL trial in 2003 when she had shown "strong conversion to all 4 vaccine types" but "tested positive for high risk HPV" in 2006, according to the VAERS report.

In a May 18, 2006 Background Document for the FDA Vaccines and Related Biological Products Advisory Committee (VRPBAC), the FDA staff stated that Merck clinical trial data indicated there may be "the potential for GARDASIL to enhance cervical disease in subjects who had evidence of persistent infection with vaccine-relevant HPV types prior to vaccination." [2] Girls and women now being vaccinated with GARDASIL are not routinely being tested for active HPV infection before vaccination.

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. [4] [5] [6]

VAERS is a passive surveillance system and depends upon voluntary reporting of serious health problems following vaccination, even though safety provisions in the National Childhood Vaccine Injury Act of 1986 mandated that health care providers report vaccine adverse events. There have been estimates that fewer than 10 percent, even as low as 1 to 4 percent, of adverse events which occur after prescription drug or vaccine use are ever reported to government adverse event reporting systems. [7] [8] [9] [10]

"If only 1 to 4 percent of all adverse events associated with GARDASIL vaccination are being reported to VAERS, there could have been up to 38,000 health problems after GARDASIL vaccination in 2006 which were never reported," said Fisher. "How many girls are really having short-term health problems associated with getting this vaccine that could turn into long-term neurological or immune system disorders? And how many will go on to develop fertility problems, cancer or damage to their genes, all of which Merck admits in its product insert that it has not studied at all? We just don't know enough to be mandating GARDASIL for anyone, much less vulnerable 11 to 12 year old girls entering puberty."

For a copy of NVIC's Report on VAERS and GARDASIL, references for this statement and information about how to report a vaccine reaction to VAERS, go to [www.nvic.org](http://www.nvic.org).

[1] [Food and Drug Administration, Center for Biologics Evaluation Research](#). Feb. 13, 2007. FDA Public Health Notification: Information on Rota Teq and Intussusception.

[2] [Food and Drug Administration](#). May 18, 2006 FDA Background Document for Vaccine and Related Biological Products Advisory Committee. Gardasil HPV Quadrivalent Vaccine. Page 13.

[3] Ibid. Page 25.

[4] Porat N, Barkai G et al. 2004. [New antibiotic resistant clones of Streptococcus pneumoniae unrelated to the pneumococcal conjugate vaccine serotypes causing acute otitis media in Southern Israel](#). J Inf Dis 189: 385-392.

[5] Temine L, Guillemot D et al. 2004. [Short and long-term effects of pneumococcal conjugate vaccination of children on penicillin resistance](#). Antimicrobial Agents and Chemotherapy 48 (6): 2206-2213.

[6] Kyaw MH, Lynfield R et al. 2006. [Effect of introduction of the pneumococcal conjugate vaccine on drug resistant Streptococcus pneumoniae](#). NEJM 354 (14): 1455-1463.

[7] Scott HD, Rosenbaum SE et al. [Rhode Island physicians' recognition and reporting of adverse drug reactions](#). RI Med J 1987; 70:311-316.

[8] Rosenthal S, Chen R. [The reporting sensitivities of two passive surveillance systems for vaccine adverse events](#). Am J Public Health 1995; 85:1706-9.

[9] Braun M. [Vaccine adverse event reporting system \(VAERS\): usefulness and limitations](#). John's Hopkins Bloomberg School of Public Health. [www.vaccinesafety.edu/VAERS.htm](http://www.vaccinesafety.edu/VAERS.htm)

[10] Food and Drug Administration, Center for Drug Evaluation and Research. [The clinical impact of adverse event reporting](#). MedWatch. October 1996.

Sent: Saturday, February 03, 2007 5:01 PM  
To: prove@vaccineinfo.net  
Subject: Data posted to form 1 of <http://vaccineinfo.net/contactus.html>  
\*\*\*\*\*

Category: Share Information  
Name: De Soto  
Company: National Institutes of Health  
Address: Magnuson Clinical Center 10/9N1105  
City: Bethesda  
State: MD  
Zip: 20892  
Telephone:  
FAX:  
Email: desotoJ@nidk.nih.gov  
Remote Name: 205.188.116.71  
Remote User:  
Date: February 03, 2007  
Time: 05:00 PM

Comments:

**Mandatory HPV Vaccination?**

The human papillomavirus (HPV) is responsible for venereal warts, cervical cancer, and many anal, penile, vaginal and throat cancers. There are over a 100 types of HPV of which 35 are known to be acquired sexually. Infections with HPV subtypes 16, 18, 31, 33, 39, 45, 52, and 58 are especially prone to cause cancer. Recently, a vaccine developed by Merck was shown to be effective against HPV sub types 16 and 18 which together cause 70% of today's cervical cancers. This news prompted many of state legislator's to run to the microphone and push for the mandatory vaccination of our 9 year old daughters. Yet, were they acting in our best interests or pushing an agenda?

The HPV virus can be passed through direct skin to skin contact or through contact with the bodily fluids of a person who is shedding the virus. In terms of the sexually transmitted form of the virus, a person is likely to either be infected or exposed to more than one subtype of the HPV virus. The vaccine however, suppresses only a few specific HPV types, hence, those subtypes not suppressed will obtain an evolutionary advantage in growth and become more prevalent and dominant- for which the vaccine will have no effect. This is the analogous reason we don't have a generalized vaccine against the common cold, though we do have vaccines against some individual cold viruses. Additionally, according to the data presented to the FDA which I have reviewed, it was evident that 1) there is no evidence that this vaccine works after 5 years, 2) 2/3 of those who had been administered the vaccine suffered from moderate to severe pain at the site of injection 3) it is not known whether in the long term this vaccine may cause auto-immune, neurological i.e. multiple sclerosis or other disorders 4) the risk for pelvic inflammatory disease, appendicitis and gastroenteritis is doubled.

We also know that medical ethics require that patients have autonomy in their medical decisions with informed consent. They have a right to know what they have, what the prognosis is, what the proposed treatment is, what the alternatives are and what the possible side effects are prior to any treatment. Indeed, a patient has a right to say no, even

if by refusing treatment they might die. I as a medical professional cannot over rule their decision. Here we are talking about forcing a person to undergo mandatory drug therapy (vaccination), when they have no disease, under the presumption that they might get a disease based on future behavior. This is medically unethical. Yet, one may say that we do have as public policy mandatory vaccinations for some infectious disorders such as mumps, measles and rubella. This is true, in part under the idea of herd immunity, that is, if 97-98% of a population is immunized against a disease, the disease may be nearly eradicated. That argument doesn't hold in the case with the HPV vaccine as it is an incomplete vaccine. We also forget that men make up half of those infected with HPV. Thus, herd immunity will not develop.

In order to understand the present sometimes we must look into the past. Let us recall that it was the Merck Company that produced the COX-2 inhibitors as an alternative to aspirin type drugs (NSAID's) under the idea that these COX-2 inhibitors would have fewer side effects. Merck duly sponsored clinical trials which did show that COX-2 inhibitors were superior to NSAID's in terms of reducing side effects- or so we thought. This wasn't really true, as we know COX-2 inhibitors actually increase the risk of heart attacks. Studies showing this increased risk of heart attack were suppressed from the medical journals prior to FDA approval for the drug. According to Wikipedia, it has been the Merck Company that has pushed for the mandatory vaccines in 9 years old girls. That's right, and why not? The vaccine cost \$120 a dose of which three are needed for total cost of \$360 a child. Multiply, this times every school age child in the country, this means billions. Questions remain, as the vaccine may not be effective in the long term, will booster shots at \$120 be required? What type of world is it when a large company basically can forcibly take money from our pockets? Why are some legislators really pushing this vaccine?

I do believe the HPV vaccine has some value however, the idea of mandatory vaccination should be approached carefully.

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