

# Treatise on Gardasil from the United States

Authors: [Cynthia Janak](#), Research Journalist, President of an International Coalition, [Leslie Botha](#) Researcher and Broadcast Journalist, Vice-President of an International Organization, [H. Sandra Chevalier-Batik](#), Research Analyst

This paper will focus on five areas:

1. Compromised immune systems in adolescents and potential vaccine reaction;
2. Exposure of HPV to infants and children prior to inoculation; raising concern that the vaccine will be rendered ineffective (Botha);
3. Examination of FDA documents regarding adverse events and efficacy. Neurological affects of Aluminum (Janak);
4. The fast tracking of Gardasil through the FDA without due scientific process and adequate research (Janak);
5. The pharmaceutical industry in the United States has systematically influenced the regulatory agencies and research facilities to fast track drug trials and manipulated their outcome. (Chevalier-Batik)

As of January 2009, the [Vaccine Adverse Reporting System](#) (VAERS) cites **43 deaths and 15,000 reported adverse reactions to the Gardasil vaccination** since its introduction to the United States market in 2006. According to Barb Loe Fisher, director of the [National Vaccine Information Center](#) NVIC, **only 1% of deaths and adverse reactions are being reported**. In the FDA document, [New Medical Conditions Reported in Subjects through Final Close-out data in studies HPV-007, 013, 015, 016, and 018](#), 73.3% participants in the Gardasil group experienced new medical conditions within 1 to 15 days after receiving the HPV vaccination. The potential magnitude of unreported deaths and injury not only in the U.S. but worldwide is of great concern.

## 1. Compromised immune systems in adolescents and potential vaccine reaction.

**1.1** Compromised and diminished immune system response has been a growing concern over the last 20 years. Autoimmune diseases (AD) are three times more prevalent in women than in men. 30 million of the 50 million people in the United States with autoimmune diseases are women. **In women U.S. women age 65 and younger AD is listed in the top ten leading causes of death.** Walsh, SJ, LM. *Autoimmune Diseases: A Leading Cause of Death among Young and Middle-Aged Women in the United States. American Journal of Public Health. 2000; 90: 1463-1465*

**1.2** According to a 2008 [Medscape.com article](#) the authors state: "Unfortunately, baseline disease incidences are not established for most diseases, and country, ethnic, and age-group specific incidences are largely lacking. Consequently, it will be difficult to monitor globally the impact or to demonstrate the lack of impact-of a large-scale immunization program on the incidence of autoimmune conditions."

**1.3** On the CDC web site on [HPV Vaccine Information for Clinicians](#), it is stated that: "Cervical cancer disproportionately affects women of lower socioeconomic status, without regular access to health care, who are uninsured, and who are recent immigrants." If this demographic of women is at high risk for cervical cancer, it also stands that they are also more susceptible to lowered immune response and a higher incidence of autoimmune disorders.

**1.4** Therefore we feel that adequate immune testing should be done, or evaluated by a woman's physician prior to vaccination. Based on the above, if an AD already exists and the HPV vaccine is administered without regard to the condition, the potential adverse AD reactions will only diminish the safety of a woman's health and skew vaccine efficacy outcomes.

## **2. Exposure of HPV to infants and children prior to inoculation; raising concern that the vaccine will be rendered ineffective**

**2.1** In a September 12, 2008 [news release](#), the FDA stated that: "There was no evidence for benefit among women found to have been previously infected, prior to immunization, with the HPV types included in the vaccine. Therefore, to receive Gardasil's full potential for benefit, it is important to be vaccinated prior to becoming infected with the HPV strains contained in the vaccine." In an article written by Cindy Bevington, of KPC News, titled, "[Researcher, Diane Harper Blasts Gardasil HPV Marketing](#)," she cites that Dr. Harper, a lead researcher in the development of the HPV vaccine, believes that prior to their first inoculation of the vaccine, adolescent girls "should be tested for the presence of HPV in their system."

**2.2** In a 1998, study on the [Transmission of Cervical Cancer-Associated Human Papilloma Viruses from Mother to Child](#), posted on the Interviology, Karger.com web site, the authors stated that: "...HPV has been detected in asymptomatic women, infants and children. Several studies have demonstrated that infants can acquire high-risk HPV infections from their mothers at birth. Thus, the traditional view that cervical-cancer associated HPV infections are primarily sexually transmitted needs to be re-assessed. ...the role of mother to child transmission of cancer-associated HPVs may need to be investigated further. These facts are pertinent to those developing prophylactic vaccines to prevent high-risk HPV infections and cervical carcinoma."

**2.3** The [American Social Health Association](#) (ASHA) cites that in a 1997 article in the American Journal of Medicine, about 74 percent of Americans--nearly three out of four--have been infected with genital HPV at some point in their lives. Among those ages 15-49, only one in four Americans has not had a genital HPV infection. Most often genital HPV produces no symptoms or illness, and so a person who has been infected may never know about it.

**2.4** In the [VRBPAC Background Document](#), May 16, 2008 "Future I & II Study Female subjects 16-23 years of age with normal baseline pelvic examinations were eligible for enrollment and were not prescreened for HPV prior to

randomization.”<sup>8</sup> Concerns Regarding Primary Endpoint Analyses among Subgroups cited that “there were two important concerns identified during the course of the efficacy review. One was the potential for Gardasil™ to enhance disease among a subgroup of subjects who had evidence of persistent infection with vaccine-relevant HPV types at baseline. The other concern was the observations of CIN 2/3 or worse cases **-44.6%** due to HPV types not contained in the vaccine. These cases of disease due to other HPV types have the potential to counter the efficacy results of Gardasil™ for the HPV types contained in the vaccine.”

### **3. Examination of FDA documents regarding adverse events and efficacy. Neurological Affects of Aluminum**

I do not find this to be surprising to me because of the information presented in the studies that I have found during my research. I am going to reference the documents that were presented to the FDA (Food & Drug Administration) here in the United States. (Underscore added for emphasis)

#### **3.1 VRBPAC Background Document ,Gardasil™ HPV Quadrivalent Vaccine ,May 18, 2006 VRBPAC Meeting**

Page 2, paragraph 1 – 2002 CBER (Center for Biologics Evaluation and Research, FDA) “CBER granted fast track designation to Merck’s development program for the HPV quadrivalent vaccine for prevention of cervical cancer. Merck initiated phase 3 clinical trials of the HPV quadrivalent vaccine.”

Page 13, Title: “Concerns Regarding Primary Endpoint Analyses among Subgroups, 1. Evaluation of the potential of Gardasil™ to enhance cervical disease in subjects who had evidence of persistent infection with vaccine-relevant HPV types prior to vaccination.”

“The results of exploratory subgroup analyses for study 013 suggested a concern that subjects who were seropositive and PCR-positive for the vaccine-relevant HPV types had a greater number of CIN 2/3 or worse cases as demonstrated in the following table:” **Table 17 shows that the efficacy rate for anyone who were seropositive and PCR positive for vaccine related HPV types to be -44.6%.**

Page 14, Table 19, “Study 013: Analysis of efficacy against vaccine-relevant HPV types CIN 2/3 or worse among subjects who were PCR positive and/or seropositive for the relevant HPV type at day 1.” Table 19 **shows that the efficacy rate for this group to be -33.7%.**

Page 22, Table 32. “Detailed Safety Population: Number (%) of subjects who reported systemic adverse reactions of 2% or greater in the 15 days following receipt of study vaccine.” Table 32 **shows that the number of subjects reporting systemic adverse reactions was 3591. That is a percentage of 59.2% of the participants.**

**3.2 June 8, 2006, Subject: [Clinical Review of Biologics License Application for Human Papillomavirus 6, 11, 16, 18 L1 Virus Like Particle Vaccine \(S. cerevisiae\) \(STN 125126 GARDASIL\), manufactured by Merck, Inc.](#)**

Page 321, Title: **Systemic AEs (Days 1-15 after any vaccination)**

Page 322, Table: 237, **Protocol 018: Number (%) of Subjects with Systemic AEs, Days 1-15 After Any Vaccination Visit** "Number (%) with systemic AE = **541 (46.4%)**"

At this point I want to bring to your attention page 45, table 24, Study protocol 018. This group is the 9 – 15 year old group of boys and girls. 615 girls and 564 boys were in this study. This study also used a carrier solution as the placebo as evidenced on page 301, table 210.

If you go to page 318, Table 232, Protocol 018 - Clinical Adverse Experience Summary, Days 1-15 Postvaccination by Age you will find: N (%) with 1+AE = 9 – 12 years of age, **567 (83.0%)**, 13 – 15 years of age, **396 (82.2%)** under the column HPV vaccine.

Page 368, "Title: Efficacy Conclusions, paragraph 2, sentence 2, In subjects who have been previously infected with a specific vaccine HPV type, there is no evidence of efficacy in reducing cervical dysplasia associated with that vaccine type."

Protocol 018 is the target age group for the HPV vaccines. This is why it is of no surprise to me that we are having so many adverse events being reported. I want to finish with the fact that **83.0% of this age group had an adverse reaction** to the HPV vaccine and the fact that if a subject has been exposed to a specific vaccine HPV type there is no efficacy, then why would you consider vaccinating this age group or any age group for that matter.

**The truth is in the numbers and these HPV vaccines cannot be justified.** It is my opinion that they will only increase the number of young people **with new medical conditions after receiving a HPV vaccination.** (I have seen similar results with the reports that I am receiving in regards to the Cervarix HPV vaccine.)

### **3.3 Neurological Effects of Aluminum**

**Mineral and metal neurotoxicology**, By Masayuki Yasui, Kiichiro Ota, M. Anthony Verity, Michael J. Strong, Edition: illustrated, Published by CRC Press, 1996, ISBN 0849376645, 9780849376641

Page 130, **13.3.2, Acute Aluminum Neurotoxicity**, Paragraph 2, Sentence 6, "Although the patient may have mild neurological findings of aluminum neurotoxicity such as speech disturbance, more commonly there is an acute explosive onset of symptoms. The major findings in adults include confusion, myoclonic jerks, agitation, grand mal seizures, obtundation, coma and death."

Page 131, Paragraph 1, "The neurotoxicity in children... is somewhat different from that seen in adults. The disease is more insidious in onset and characterized by intellectual impairment, seizures, and regression of verbal and motor skills. This is exemplified by the finding that children who have just started to walk and talk may lose these skills. The frequency of seizures in children is equal to or even greater than that found in adults with acute aluminum intoxication."

I want to bring you back to the FDA document dated June 8<sup>th</sup>, 2006, page 393, Table 302, **New Medical Conditions Day 1 through Month 7**. Table 302 states under the Gardasil column, "Subjects with new medical history = **5842 (49.6%)**". The conditions mentioned in the above book are the same as what we are experiencing in the United States in regards to the HPV vaccine.

It is my belief, per the work of Dr. Andrew Moulden, BA, MA, PhD, MD., that the watershed areas of the body including in the brain are affected in the fact that the severe immune response and the aluminum adjuvant (225mg-Gardasil, 500mg-Cervarix) is causing blockage of the capillaries throughout the body and the brain. The proof is in the stroke like symptoms that are evident in the girls and women who have suffered severe neurological adverse reactions from the Gardasil vaccination.

#### **4. The fast tracking of Gardasil through the FDA without due scientific process and adequate research**

##### **4.1 VRBPAC Background Document, Gardasil™ HPV Quadrivalent Vaccine ,May 18, 2006 VRBPAC Meeting**

**2000** Submission of the original IND for the quadrivalent VLP vaccine containing the L1 protein from HPV types 6, 11, 16, and 18. Additional phase 1, phase 2, and phase 3 studies were conducted under this IND.

**2005 May:** Pre-BLA meeting. CBER agreed that the efficacy data limited to the first 24 weeks of the phase 3 studies could be submitted to the BLA in order to support efficacy. CBER encouraged early (rolling) submission of CMC, pre-clinical and phase 1 and 2 clinical data. CBER agreed to grant a priority review of the BLA.

##### **4.2 Subject: Clinical Review of Biologics License Application for Human Papillomavirus, 6, 11, 16, 18 L1 Virus Like Particle Vaccine (*S. cerevisiae*) , (STN 125126 GARDASIL), manufactured by Merck, Inc.**

Page 45, Table 24, **Quadrivalent HPV 6, 11, 16, 18 L1 VLP Vaccine Summary of Pivotal Phase IIb-III Trials** (Study Protocol, Dates only)

007 – 06	05/26/00 – 05/10/04	4 years
013 – 04	12/28/01 – 7/15/05	3.7 years
011 – 03	12/28/01 – 06/11/04	2.6 years
012 – 03	05/30/02 – 06/30/04	2.1 years

015 – 04	06/24/02 – 06/10/05	3 years	(ongoing for additional follow-up)
016 – 03	12/07/02 – 09/20/04	1.10 years	
018	10/08/03 – 1/19/05	1.2 years	

Study protocol 018, 1650 participants, was the only protocol solely for the 9 – 15 year old age group which lasted just 1.2 years. This entire study segment only lasted 4.6 years which is not enough time to evaluate the long term effects of this new **genetically modified vaccine**. 1.2 years is not enough time to evaluate the adverse effects and long term safety in this group which this vaccine is being presently administered.

Because of this we do not believe that adequate safety and efficacy data has been presented to warrant the continuation of administering this vaccine.

## **5. The pharmaceutical industry in the United States has systematically influenced the regulatory agencies and research facilities to fast track drug trials and manipulated their outcome.**

It would be far simpler if there were clear, direct, and explicit violations, but the people and organizations involved are too sophisticated and versed in the process to ever make such a blunder. All of the activities documented are, strictly speaking, legal. Taken in isolation they are not that onerous, yet in combination, they present a picture of willful deception, and a pattern of behavior that pushes the boundaries of what is legal and ethical - even to the point of writing and sponsoring new legislation extending those very boundaries. Have country's decisions about the HPV vaccine been scientifically compromised and influenced by marketing?

**5.1** In 1992, faced with protests by AIDS activists about the FDA's glacier-like approval of potential life saving drugs, President George H. Bush signed the [Prescription Drug User Fee Act](#) (PDUFA) and changed the FDA drug approval process. PDUFA allowed pharmaceutical companies to "fast track" drug approvals by absorbing the extra costs involved. PDUFA, brought new resources to the agency aimed at decreasing the time FDA took to approve new drugs and license new biological products (e.g., vaccines), more quickly. The unintended consequence of this humanitarian intention became "Safety for Sale", as evidenced by the number of product recalls in the past 15-years.

Criticism of the current PDUFA process fits into three categories:

1. Fees have not fully covered FDA's increased costs, despite increased Congressional funding;
2. [PDUFA](#) has directed a majority of the collected fees toward pre-market review of applications, in contrast to post-market surveillance and safety enforcement;

3. Keeping PHARMA's inclination of 'profit over accountability' in check is a daunting task. Some critics think that, through its provision of fees, the industry has too much influence over FDA actions; with that some wonder if safety is being sacrificed for expediency

**5.2** [Archived documents discovered at the U.S. Food and Drug Administration's website](#) reveal the agency knew in 2003 that HPV infections did not cause cervical cancer. Despite that knowledge, the FDA has continued to support the use of the Gardasil vaccine in compulsory vaccinations programs like the one announced in Texas. The FDA's own press release from 2003 admits that, "Most women who become infected with HPV are able to eradicate the virus [without intervention] and suffer no apparent long-term consequences to their health... most infections are short-lived and not associated with cervical cancer." (Source: "FDA Approves Expanded Use of HPV Test," March 31, 2003, [www.fda.gov](http://www.fda.gov))

**5.3** In 1980, the Bayh-Dole Act was created, which allowed academic settings to profit from their discoveries that were performed for pharmaceutical companies. This resulted in the creation of for-profit sites, called Contract Research Organizations (CROs), which are composed of community research sites with questionable investigators void of necessary experience or quality regarding their research purpose and ability. Since they are for-profit, the trials conducted at CROs are sponsored by pharmaceutical companies that control and manipulate all aspects of the trial. [This coercion is done by various methods of deception in subtle and tacit methods](#). As a result, research in this manner has been transformed into a method of marketing, which includes altered results of the trial to favor the sponsor's medication. Their activities are absent of true or applied regulation, and therefore have the autonomy to create whatever they want to benefit the collusive relationship between the site and the sponsor.

**5.4** The pharmaceutical industry has been extremely successful in influencing the medical establishment. For example:

- Individual physicians through sales people, freebies, CME, and consulting arrangements
- Peer-reviewed journals through company-funded research, ghostwriters, subscriptions, and mass reprint buys
- Guideline-writing groups through grants and the tools mentioned above

Now, [Swedish anti-corruption agents are investigating allegations that pharmaceutical giant AstraZeneca influenced the awarding of this year's Nobel Prize](#) in medicine. Numerous ties, both in money and influence were found between the pharmaceutical company and the Nobel selection committees. Part of the Nobel Prize in Physiology or Medicine was awarded to a German scientist who discovered the links between human papilloma viruses and cervical cancer. The discovery could be a financial bonanza for AstraZeneca.

**5.5** [Merck published a fake journal](#). Merck paid an undisclosed sum to Elsevier to produce several volumes of a publication that had the look of a peer-reviewed medical journal, but contained only reprinted or summarized articles--most of which presented data favorable to Merck products--that appeared to act solely as marketing tools with no disclosure of company sponsorship.

**5.6** Documents were found describing [Merck compensating investigators with honoraria](#) for agreeing to serve as authors on review manuscripts ghostwritten on their behalf by medical publishing companies. Honoraria varied, ranging from \$750 to \$2500.