



A Judicial Watch Special Report

# **Examining the FDA's HPV Vaccine Records**



Detailing the Approval Process, Side-Effects,  
Safety Concerns and Marketing Practices of a  
Large-Scale Public Health Experiment

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## **Introduction**

This Judicial Watch Special Report is an analysis of records obtained from the Food and Drug Administration (FDA) concerning a recent vaccine called Gardasil. Gardasil helps protect against four types of human papillomavirus (HPV). The vaccine was approved in May 2006 and was created and marketed by Merck & Company Incorporated.

The records include Merck's patent and drug information submitted to the FDA, transcripts and briefing material from approval meetings, and reports documenting health, safety, and efficacy test results, as well as Vaccine Adverse Event Reporting System (VAERS) documents detailing 8,864 cases of adverse effects experienced by people after receiving the Gardasil vaccine. VAERS reports show that at least eighteen people have died after receiving Gardasil.<sup>1</sup> Many health officials believe that adverse reactions to medications are widely underreported, therefore the actual number of adverse events occurring after vaccination with Gardasil is likely to be higher.

Judicial Watch obtained these records under the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. § 552. The request, asking for documents concerning Gardasil, was originally submitted to the FDA on May 9, 2007. The FDA produced documents on May 15, 2007; September 13, 2007; February 27, 2008, and June 10, 2008. Judicial Watch uncovered thousands of pages of material pertaining to Gardasil, which is designed to prevent cervical cancer. The controversial vaccine was fast-tracked for approval by the FDA despite concerns about Gardasil's safety and long-term effects. The vaccine is still in the testing stages (final report due September 30, 2009), but it is already being administered to thousands of young girls and women.<sup>2</sup> Mandatory vaccination has been opposed by the American College of Pediatrics and *The New England Journal of Medicine*. Legislators in 41 states and Washington, DC have introduced legislation to require, fund or educate the public about the HPV vaccine and 17 states have enacted legislation. Michigan, Texas and Virginia took steps toward mandatory vaccination for sixth grade girls; however, all three states have postponed that required mandate.<sup>3</sup>

Judicial Watch is concerned by the facts detailed in the FDA's adverse event reporting associated with Gardasil. Merck has waged an aggressive lobbying campaign with state governments to mandate this HPV vaccine for young girls. Given all the questions about Gardasil, the best public health policy would be to reevaluate its safety and to prohibit its distribution to minors. In the least, governments should rethink any efforts to mandate or promote this vaccine for children.

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### **Executive Summary**

In May 2007, Judicial Watch submitted a request to the FDA under the Freedom of Information Act for all records concerning Merck's new anti-HPV vaccine, Gardasil. After Judicial Watch filed a lawsuit in October 2007 to compel record production, the FDA finally released four sets of documents, the last in June 2008. These records detail the development and expedited approval of Gardasil. The documents include patent and licensing memoranda, test reports for the vaccine, and the final briefing document on Gardasil submitted to the FDA in April 2006, one month before the vaccine was approved. The FDA also produced 8,864 VAERS reports. Judicial Watch uncovered a transcript of Merck's May 18, 2006, meeting with the Vaccines and Related Biological Products Advisory Committee (VRBPAC), at which the vaccine received a unanimous vote of approval.

Analysis of the records shows:

- Gardasil is a prophylactic, preventative vaccine and will not treat pre-existing HPV infection. It is not a cancer vaccine or cure.
- Gardasil is marketed as a vaccine that prevents cancer, but it “. . . has not been evaluated for the potential to cause carcinogenicity or genotoxicity.”
- Gardasil is not 100% effective against all HPVs. It is designed to protect against only four strains of HPV, even though there are over thirty strains including at least fifteen that can cause cancer.
- While Gardasil is the most expensive vaccine ever to be recommended by the FDA, its long-term effectiveness is unknown and could be as brief as only two to three years.
- During testing, an aluminum-containing placebo was used. Aluminum can cause permanent cell damage and is a reactive placebo, unlike most standard saline placebos. This means that tests of Gardasil may not have given an accurate picture of safety levels.
- Although some states are considering making it mandatory for young girls to get the Gardasil vaccine, it has only been tested with one other vaccine commonly given to children. There are ten commonly administered adolescent vaccines.
- Gardasil is still in the testing stages, and will not be fully evaluated for safety until September 2009. VAERS reports show that as many as eighteen people have died after receiving Gardasil.

## **Background**

Genital Human Papillomavirus (HPV) is the most common sexually transmitted disease in the world, and the American Social Health Association reports that over 75% of people between the ages of fifteen and forty-nine have been infected with HPV.<sup>4</sup> There are over thirty strains of genital HPV. The Centers for Disease Control and Prevention (CDC) estimate that 6.2 million people become infected with HPV every year.<sup>5</sup> Many people who are infected with HPV never show any symptoms and are unaware that they even have the disease. In most cases the body's immune system will fight the virus and it will never become a problem.

Although most of the time HPV infection is not harmful, some strains may eventually develop into cancer. These are called high-risk, carcinogenic strains. Two strains, HPV-16 and HPV-18, are responsible for approximately 70% of cervical cancer cases worldwide.<sup>6</sup> According to the National Cancer Society, there are fifteen high-risk HPV strains. Other strains may cause genital warts. These strains will never develop into cervical cancer. A patient infected with a wart-causing HPV strain will not necessarily be at risk for cervical cancer because they are caused by different strains. The National Cancer Society also notes that “. . . the great majority of high-risk HPV infections go away on their own and do not cause cancer.”<sup>7</sup> Be that as it may, cervical cancer is still a very serious problem. The American Cancer Society predicts that 11,070 women will be diagnosed with cervical cancer in 2008.<sup>8</sup>

HPV can be treated, but it cannot be cured.<sup>9</sup> Due to the health risks associated with HPV, scientists at Merck developed an HPV vaccine called Gardasil. While scientists had been experimenting with HPV vaccines for decades, Merck was the first company to create and patent a vaccine. Gardasil is designed to guard against four types of HPV: two that can cause genital warts and two that may lead to cervical cancer. The vaccine is created from highly purified L1 proteins taken from actual HPV types. It is a recombinant vaccine, which means that it is made from genetically engineered material taken from HPV, but it does not contain the live virus. The FDA explains that “because the vaccine only contains a protein, and not the entire virus, the vaccine cannot cause the HPV infection. It is the body's immune response to the recombinant protein(s) that then protects against infection by the naturally occurring virus.”<sup>10</sup> Gardasil works by assembling itself into virus-like particles similar to actual HPV particles. Because the vaccine does not contain a viral DNA strand from HPV, it should not cause HPV or cancer. Instead, it ought to trigger an antibody reaction to guard the host from being infected with the virus.

## **Gardasil and the FDA**

The FDA approved the marketing of Gardasil on June 8, 2006, after a six-month priority review process reserved for products with the potential to fill an unmet medical need. New cancer treatments or medications are often fast-tracked by the FDA, as well

as treatments for AIDS, HIV, and other serious ailments. Most vaccines take at least ten months to review and process. While the FDA is not required to approve fast-tracked vaccines and medicines, it apparently did so due to support for the vaccine from both Merck representatives and recommendation from FDA advisory panels, as well as the Center for Disease Control's (CDC) Advisory Committee on Immunization Practices (ACIP) that recommended Gardasil in June 2006 for females between the ages of 9 and 26.<sup>11</sup> The Director for the FDA's Center for Biologics Evaluation and Research, Dr. Jesse Goodman, called Gardasil a "huge advance," and added that the vaccine deserved a speedy review process because ". . . its rapid approval underscores FDA's commitment to help make safe and effective vaccines available as quickly as possible."<sup>12</sup> Now, almost two years later, it looks like the FDA may have approved Gardasil too quickly.

Judicial Watch submitted a Freedom of Information Act request to the FDA in May 2007, asking for information on HPV and Merck's new vaccine. The FDA produced records, including Merck's final report before the approval of the vaccine, and the transcript of the meeting in which the vaccine was approved. Judicial Watch has also requested VAERS records for the Gardasil vaccine. These documents raise questions concerning Merck's testing methods, and the safety of Gardasil for the general public.

Among the documents obtained by Judicial Watch was a June 2006 memorandum to the FDA from Merck, describing the clinical testing and results for Gardasil. Merck conducted four placebo-controlled, double-blind tests for Gardasil, evaluating 20,541 women from the ages of 16 to 26 years. 27% of the test subjects had already been exposed to at least one of the four strains of HPV the vaccine is designed to protect against.<sup>13</sup> Gardasil is a prophylactic, preventative drug, and will not treat pre-existing HPV infection. Since Gardasil does not cure HPV, persons who already had any lesions or symptoms from pre-exposed strains were not counted in the study. This is problematic because many women have HPV without knowing it, and Gardasil does not require pre-screening before vaccination. A study in the *New England Journal of Medicine* found that, ". . . there was no clear evidence that vaccination altered the course of HPV-16 or HPV-18 infection that was present before administration of the first dose."<sup>14</sup>

Not only will Gardasil not cure pre-existing HPV, it can also make symptoms worse. Women who already have the virus without knowing it could suffer massive outbreaks of genital warts or abnormal precancerous lesions, both of which require extensive treatment. While Gardasil is marketed as a preventative vaccine, Merck still suggests that women who have been exposed to one or more HPV strains get the vaccine in the hope that it will protect them from the remaining strains. However, in VAERS reports obtained by Judicial Watch there are 78 separate cases where, after receiving the vaccine, patients experienced outbreaks of warts. Below are excerpts from VAERS reports.

Two days after receiving the first dose of Gardasil, the patient developed groin warts. There is no known history of these warts. The patient came back in about a month later and was given the second dose of Gardasil. A few

days after receiving the second dose, the patient had a huge outbreak of warts.

VAERS ID: 292052-1

\* \* \*

Information has been received from a consumer concerning her 17-year-old daughter with no medical history and an allergy to sulfa, who on 28-SEP-2007 was vaccinated with a first dose of Gardasil . . . Prior to being vaccinated with Gardasil the patient was tested for HPV and genital warts and all her test came back negative. On 15-OCT-2007 the patient experienced a fever, and broke out with white bumps that were diagnosed as genital warts.

VAERS ID: 301339-1<sup>15</sup>

Outbreaks were not limited simply to genital warts. Some patients experienced outbreaks of warts on the face, hands, and feet. All warts are caused by strains of the papilloma virus, but it is surprising that Gardasil, which was modeled to protect only against genital warts, would cause outbreaks of warts caused by other strains of the papilloma virus. While some of the outbreaks reported were fairly mild, such as a few warts on the hands or feet, others were quite serious and symptoms persisted.

A 16-year-old female . . . was vaccinated with Gardasil. Subsequently, on an unspecified date the patient developed warts on hands after receiving Gardasil. Medical attention was sought. The patient's warts on hands persisted.

VAERS ID: 300862-1

\* \* \*

My daughter began to have facial (flat) warts on her face and chest after the 2nd dose of Gardasil. There are many warts on her face and chest at least 20 or more. She has never had this problem before receiving the vaccine. She was treated for warts by her Doctor and now has been referred to Dermatology. She has not recovered yet.

VAERS ID: 288998-1<sup>16</sup>

The possibility that Gardasil could make HPV infections worse is very serious, and a matter of concern with both critics of the vaccine and the FDA. A background document produced by the FDA's VRBPAC in May 2006 states:

There were two important concerns that were identified during the course of the efficacy review of this BLA [biologics license application]. 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 [cervical intraepithelial neoplasia, abnormal cell changes in moderate stage] or worse cases 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 . . . The results of exploratory subgroup analyses . . . suggested a concern that subjects who were . . . positive for the vaccine-relevant HPV types had a greater number of CIN 2/3 or worse cases.<sup>17</sup>

A chart in the committee's report revealed that efficacy in subjects already exposed to "relevant HPV types" had an observed efficacy rate of -44.6%. The disturbing efficacy rate raises questions as to who should be receiving the vaccine, and why the FDA allows Gardasil to be administered without prescreening for HPV. The outcomes that can result from pre-exposure are disconcerting and deserve far more attention.

It is possible that the FDA's efficacy considerations for subjects already exposed to "relevant HPV types" is manifesting itself in the vaccine application review process. The FDA denied Merck's application to expand marketing of Gardasil to women ages 27 through 45 on June 25, 2008. The FDA notified Merck by letter that there were "issues" that precluded approval of the company's plans.<sup>18</sup>

The FDA refused Judicial Watch's June 26, 2008 request for a copy of the letter to Merck, stating that the letter *may* be made available under the provisions of the FOIA. Judicial Watch immediately filed a FOIA request for the letter. News media reporting on the FDA denial of Merck's plans stated that the agency had specific questions regarding Gardasil's effectiveness in this older age group. These outstanding questions appear to parallel the VRBPAC observations of May 2006 (above).

Merck also failed to win approval from the FDA to expand the Gardasil vaccine to include additional strains of HPV. Merck has reportedly now dropped all plans to expand the vaccine.<sup>19</sup>

An additional testing report shows that Merck tested Gardasil against an aluminum-containing placebo. While most placebos are saline based, the FDA allowed Merck to use a placebo with an undisclosed amount of aluminum in it. Gardasil itself contains 225 mcg of aluminum. Aluminum can cause many serious problems including temporary and permanent nerve damage. Using a reactive aluminum-containing placebo instead of a non-reactive saline base can make vaccines seem safer than they may actually be. While Merck has repeatedly stated that Gardasil is on a comparable safety rate with the placebo, if the placebo itself is responsible for adverse effects then it is more difficult to ascertain the vaccine's safety. Merck's testing report shows charts of clinical

tests, and compares Gardasil with the aluminum-containing placebo. The table below is the report’s documentation of all-cause common adverse effects<sup>20</sup>:

<b>All-cause Common Systemic Adverse Experiences</b>		
<b>Adverse Experience (1 to 15 Days Postvaccination)</b>	<b>GARDASIL (N = 5088) %</b>	<b>Placebo (N = 3790) %</b>
Pyrexia	13.0	11.2
Nausea	6.7	6.6
Nasopharyngitis	6.4	6.4
Dizziness	4.0	3.7
Diarrhea	3.6	3.5
Vomiting	2.4	1.9
Myalgia	2.0	2.0
Cough	2.0	1.5
Toothache	1.5	1.4
Upper respiratory tract infection	1.5	1.5
Malaise	1.4	1.2
Arthralgia	1.2	0.9
Insomnia	1.2	0.9
Nasal congestion	1.1	0.9

It is true that the adverse reaction rates are comparable in most of the tests, but since the vaccine is being tested against a reactive, potentially harmful substance, the numbers may overstate the vaccine’s safety and understate its adverse side-effects. There is only one table in the entire report that compares the vaccine not only with the aluminum-containing placebo but also with one that is saline based.<sup>21</sup>

**Postdose Evaluation of Injection-site Adverse Experiences**

<b>Adverse Experience</b>	<b>Vaccine (% occurrence)</b>				<b>Aluminum-Containing Placebo (% occurrence)</b>				<b>Saline Placebo (% occurrence)</b>			
	Post-dose 1	Post-dose 2	Post-dose 3	Post Any Dose	Post-dose 1	Post-dose 2	Post-dose 3	Post Any Dose	Post-dose 1	Post-dose 2	Post-dose 3	Post Any Dose
<b>Pain</b>	63.4	60.7	62.7	83.9	57.0	47.8	49.5	75.4	33.7	20.3	27.3	48.6
Mild/Moderate	62.5	59.7	61.2	81.1	56.6	47.3	48.9	74.1	33.3	20.3	27.0	48.0
Severe	0.9	1.0	1.5	2.8	0.4	0.5	0.6	1.3	0.3	0.0	0.3	0.6
<b>Swelling*</b>	10.2	12.8	15.1	25.4	8.2	7.5	7.6	15.8	4.4	3.0	3.3	7.3
Mild/Moderate	9.6	11.9	14.3	23.3	8.0	7.2	7.3	15.2	4.4	3.0	3.3	7.3
Severe	0.6	0.8	0.8	2.0	0.2	0.3	0.2	0.6	0.0	0.0	0.0	0.0
<b>Erythema*</b>	9.2	12.1	14.7	24.7	9.8	8.4	8.9	18.4	7.3	5.3	5.7	12.1
Mild/Moderate	9.0	11.7	14.3	23.7	9.5	8.3	8.8	18.0	7.3	5.3	5.7	12.1
Severe	0.2	0.3	0.4	0.9	0.3	0.1	0.1	0.4	0.0	0.0	0.0	0.0

\*Intensity of swelling and erythema was measured by size (inches): Mild = 0 to ≤1; Moderate = >1 to ≤2; Severe = >2

This chart only records adverse experiences at injection site and therefore does not shed much light on the overall safety and effectiveness of the vaccine. However, there are profound differences between the numbers of adverse effects in Gardasil and the saline placebo. Again, one can see that the numbers are similar between the vaccine and the aluminum placebo, but the saline-based placebo has far fewer reported adverse effects. The chart shows that while 83.9% of patients experienced pain after injection



with Gardasil, and 75.4% after receiving the aluminum-based placebo, only 48.6% of patients experienced pain when receiving the saline-based placebo. The chart shows 25.4% of people experienced swelling after receiving Gardasil, and 15.8% did after receiving the aluminum placebo. Only 7.3% of patients receiving the saline placebo experienced swelling.

The significant differences between the saline placebo and the vaccine raise questions as to how Merck's use of an aluminum-containing placebo may have affected the safety trials. The National Vaccine Information Center reports that "A reactive placebo can artificially increase the appearance of safety of an experimental drug or vaccine in a clinical trial," adding that "although aluminum adjuvants have been used in vaccines for decades, they were never tested for safety in clinical trials."<sup>23</sup> It is difficult to draw an accurate conclusion from Merck's data, raising questions about Gardasil vaccine safety.

Gardasil was approved in large part due to the unanimous vote of support it received from the Vaccines and Related Biological Products Advisory Committee (VRBPAC) in May 2006. VRBPAC is a special advisory panel created by the FDA to evaluate new biological material, including vaccines. While the FDA is not required to approve drugs that are recommended by the committee, they usually do. The meeting took place on May 18, 2006, and the primary speakers were Merck representatives Dr. Eliav Barr and Dr. Patrick Brill-Edwards. Merck was required to submit numerous reports and documentation of trial procedures to the FDA both before and after the meeting took place, but the statements of Merck's representatives paint a far more optimistic picture of the vaccine than their own reports justify.

Dr. Patrick Brill-Edwards, Merck's Director of Worldwide Vaccines Regulatory Affairs, was the main speaker at the meeting. In his opening statement he said "Merck proposed that studying cancer itself isn't feasible, because it takes too long and it disadvantages too many women."<sup>24</sup>

Merck scientists not only did not bother to study cancer, they do not even know whether their own vaccine is carcinogenic. In a report to the FDA on testing protocol, Merck wrote that "Gardasil has not been evaluated for the potential to cause carcinogenicity or genotoxicity."<sup>25</sup> One would think that any cancer vaccine that has been approved by the FDA ought to at least not cause cancer. Given that Gardasil works by causing spontaneous reactions and cell mutation, its potential to cause cancer is certainly a matter that warrants further study.

Dr. Brill-Edwards' following statements hardly build confidence. He claimed that Merck had examined, ". . . how the vaccine interacts with other common adolescent vaccines,"<sup>26</sup> even though according to their own documents Merck tested Gardasil only concomitantly with the Hepatitis B vaccine. There are numerous vaccines that are commonly given to adolescents, including booster shots for measles, mumps and rubella, Hepatitis A shots, and Menactra, a vaccine to prevent meningitis. The Menactra vaccine has been shown to react badly when given with Gardasil. VAERS reports from July 2007

to March 2008 contain 220 cases of adverse effects when Gardasil and Menactra were administered at the same time. The most common symptoms were fainting, nausea, and dizziness but other girls suffered from pyrexia, convulsions, seizures, spontaneous abortions, and Guillain-Barre Syndrome. Even mild reactions occasionally led to serious cases, as some girls suffered severe injuries from falling while dizzy or unconscious. Below are excerpts from VAERS documenting adverse reactions after receiving Gardasil and Menactra:

A 16-year-old female patient had received an intramuscular, first dose injection of Menactra and an intramuscular, first dose injection of Human Papillomavirus Recombinant Vaccine. The patient experienced numbness and tingling in her feet and hands . . . The patient was referred to and examined by a neurologist. During that exam, she was found to have weakened severely. She was admitted to a pediatric intensive care unit for suspected Guillain Barre syndrome which was confirmed by lumbar puncture. VAERS ID: 262735-2

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A 17-year-old female with no medical history and no drug allergies was vaccinated with a 0.5mL dose of Gardasil. Concomitant vaccinations included Menactra and Dtap. The patient fainted, fell off the table, hit her head on the ground, and had a seizure. The patient also had a cut on the bridge of her nose and gums. The patient went to the emergency room . . . The physician thought the seizure was due to head trauma. VAERS ID: 306241-1

It is sometimes difficult to ascertain whether adverse events are directly linked to vaccinations, but in the case of injuries caused by fainting directly after receiving Gardasil the link is fairly obvious. Whether fainting was caused by Menactra or Gardasil or a combination, it merits further study. Particularly since many schools and colleges require students to receive these vaccinations in order to attend classes, it seems only logical that Merck would have tested Gardasil with these vaccines, or, failing that, that the FDA would have insisted on it.

During the VRBPAC meeting, Dr. Brill-Edwards said that Merck “. . . knew that this vaccine would be given to women of child-bearing potential, so right from the beginning, we set up a program that would really evaluate in great detail, all the pregnancy outcomes that would occur and subject to receive Gardasil.”<sup>27</sup> If it was Merck’s intent to examine the vaccine on pregnant women, it is interesting that in its briefing to the FDA Merck reported, “It is not known whether Gardasil can cause fetal

harm when administered to a pregnant woman.”<sup>28</sup> They reported that 27% of pregnant women experienced adverse reactions, and the VAERS reports show 45 cases of miscarriages, or spontaneous abortions, often within weeks of receiving the Gardasil vaccine. In one VAERS report, a 17-year-old girl with no medical history received the Gardasil vaccine on July 31, 2007 and then had a spontaneous abortion on August 14, only two weeks afterwards.<sup>29</sup> Below is an excerpt taken from another case of spontaneous abortion, occurring less than two weeks after the patient received her second dose of Gardasil:

The patient was vaccinated with second dose of HPV and had a positive pregnancy test the next day. The patient presented to the physician's office on 09-APR-2007 with vaginal bleeding and a pelvic ultrasound determined that she was suffering a spontaneous abortion . . . The patient was admitted to the hospital . . . with severe vaginal hemorrhaging and underwent an emergency dilation and curettage procedure . . . The physician considered spontaneous abortion to be significantly disabling and life threatening.  
VAERS ID: 277166-1 (S)<sup>30</sup>

Gardasil's ad campaign does state that the vaccine should not be given to pregnant women, but it does not mention women who are breastfeeding, even though Merck's June 2006 briefing to the FDA says, “It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk,” and “A higher number of breastfeeding infants (n=6) whose mothers received Gardasil had acute respiratory illnesses within 30 days.”<sup>31</sup> This number is *three times higher* than that of the placebo group.

At this time, it is unknown whether Gardasil may have long term effects on fertility. Since the vaccine was only released in 2006, it could be years before anyone knows its long term effects. Merck's only fertility tests were conducted on rats.

Gardasil administered to female rats at a dose of 120 mcg total protein, which corresponds to approximately 300-fold excess relative to the projected human dose, had no effects on mating performance, fertility, or embryonic/fetal survival . . . No adverse effects on mating, fertility, pregnancy, parturition, lactation, embryo-fetal or pre- and postweaning development were observed. There were no vaccine-related fetal malformations . . . In addition, there were no treatment-related effects on developmental signs, behavior, reproductive performance, or fertility of the offspring.<sup>32</sup>

There are several problems with this test. First, it still sheds no light on possible long-term side effects, as the rats were monitored only through a single fertility cycle. Second, and perhaps more importantly, Gardasil is modeled after and made from the human papillomavirus. While there are other strains of the papillomavirus that effect animals, only humans can carry the human strains. Since the Gardasil vaccine was designed to react only with certain strains of the human papillomavirus, any test involving rats is inconclusive. Merck acknowledged that, “. . . it is not known whether Gardasil can cause fetal harm when administered to pregnant women or if it can affect reproductive capacity.”<sup>33</sup> Merck recommends that pregnant women *not* receive the vaccine.

Dr. Barr told the VRBPAC members that the Gardasil vaccine would help save money, as “HPV infection is very frequent, so women have to be screened frequently, and that translates to approximately 50 million Pap tests every year . . . These lesions – and screening programs are very expensive. They cost over four billion dollars a year in the U.S.”<sup>34</sup> While Dr. Barr implies the Gardasil vaccine would save money, patients who receive the vaccine should still have Pap screenings regularly, so the vaccine would not have any effect on Pap screening costs. Gardasil does not even eliminate the need for HPV screenings. Merck’s website states that the Gardasil vaccine “. . . does not prevent all types of cervical cancer, so it's important to continue routine cervical cancer screenings. Gardasil will not protect against diseases caused by other HPV types.”<sup>35</sup> Given the fact that women must still receive regular screenings, there would be no significant benefit from a financial standpoint. This is especially true since Gardasil is the most expensive vaccine to ever be recommended by the FDA. It is administered in three doses given over the course of six months, and each dose is \$120, meaning the total cost for receiving the vaccine is \$360. Gardasil may have benefits, but lessened costs for cervical cancer screening would not seem to be among them.

### **Gardasil and the American Marketplace**

Even with state and federal program subsidies to help pay for Gardasil, the drug is extraordinarily expensive. An article in *The New York Times* estimated that making Gardasil mandatory would almost double the cost of vaccine programs. “North Carolina, for instance, spends \$11 million annually to provide every child with seven vaccines. Gardasil alone would probably cost at least another \$10 million.”<sup>36</sup> Gardasil is so expensive that some doctors cannot even afford to stock the vaccine. While some insurance companies cover part of the costs for the vaccine for females aged 9 to 26, doctors are not reimbursed until after vaccines are administered. In addition to having to pay for the initial costs out of their own pockets, practitioners must also pay to have the vaccines properly shipped and stored, an additional cost for which they are not reimbursed. Doctors actually lose money when they choose to stock the Gardasil vaccine, and many decide that it is not worth the cost.

For uninsured females, state and federal programs cover all or most of the cost of Gardasil. The *New York Times* reported in June 2006 that the decision to make Gardasil a federally recommended vaccine “. . . all but commits the federal government to spend

as much as \$2 billion alone on a program to buy the vaccine for the nation's poorest girls.”<sup>37</sup> John Schiller, an investigator for the National Cancer Institute, said that “This vaccine will be more expensive than all other childhood vaccines put together.”<sup>38</sup>

Unavoidably, much of these costs will ultimately be passed to taxpayers. An estimated 55% of children receive vaccines that are paid for by state and federal government, and Medicaid alone provides vaccines for approximately 40% of children under the age of 19. While some states strive to cover all vaccines for children, rising costs make it challenging. States such as Alaska, North Dakota, and North Carolina have seen the price of vaccinating a child double in the past few years. The *New York Times* reports that in 1980 it cost “about \$23, or \$59 adjusted for inflation, for the seven shots and four oral doses needed to immunize a child.”<sup>39</sup> Now, if a child receives all recommended vaccines the cost would be more than \$1,600. In 2000, Medicaid spent \$500 million on vaccines and immunizations. Now the budget exceeds \$2.5 billion.<sup>40</sup> Are “mandatory” vaccines becoming too expensive for the government – and ultimately the American taxpayer – to afford?

Gardasil’s high cost is an important government spending issue, especially as many politicians are trying to make it a mandatory vaccine for all young girls. It is also important to remember that the vaccine’s safety and overall effectiveness are unknown. As far as long-term effectiveness is concerned, Merck told the FDA in 2006:

Efficacy was durable through at least 2.5 years postvaccination with respect to infection and disease caused by HPV 6, HPV 11, and HPV 18, and at least 3.5 years postvaccination with respect to infection and disease caused by HPV 16 . . . Because these subjects completed their vaccinations in 2003, the longer-term duration of efficacy of the vaccine will be known well in advance of the time needed to implement booster vaccinations.<sup>41</sup>

It seems ill-advised to spend millions – or even billions – of dollars on programs to implement a vaccine that may only be effective for three or four years. Even if one supposes that the vaccine lasts for five years, a young girl who is vaccinated at the age of ten would need numerous booster shots. If she lived to the age of 75, she would need twelve booster shots and at \$120 a shot, the total cost of vaccinating one person would be \$1800. To vaccinate every 11 and 12 year old girl in the United States today, it would cost around \$1.5 billion. To protect *only* those girls for a lifetime, the cost would be \$7.7 billion. Even if one just estimated the cost of initial vaccination for 11 and 12 year old girls, in ten years the United States would spend at least 15 billion of limited health care dollars, before calculating the costs of possible booster shots.<sup>42</sup> This seems too much money to spend on a vaccine when so little is known about its efficacy, safety, and effects on fertility.

### **Safe and Effective?**

There is proof that Gardasil will prevent about half of the high-grade precursors of cancer, but half will still occur. Hundreds of thousands of women who are vaccinated with Gardasil and get yearly Pap testing will still get high-grade dysplasia (cell abnormalities).<sup>43</sup> Gardasil has been shown to prevent precancerous lesions, but it has been impossible to ascertain whether it will actually prevent cancer because the testing period has been so short. While young women occasionally get cervical cancer, it is far more common in women in their late forties. The average age of a cervical cancer patient is forty-eight years. Keeping this in mind, it could easily be decades before anyone truly knows if the Gardasil vaccine prevents cervical cancer. The most that can accurately be said at this point is that Gardasil has been shown to help prevent precancerous lesions, but in its extremely aggressive advertising and political lobbying campaigns Merck states that "Gardasil does more than help prevent cervical cancer. Gardasil is the only cervical cancer vaccine that helps protect against . . . human papillomavirus (HPV) types that cause 70% of cervical cancer cases."<sup>44</sup> The FDA only speculates that, ". . . it is believed that prevention of cervical precancerous lesions is highly likely to result in the prevention of those cancers."<sup>45</sup> No one knows if the vaccine prevents cancer, or for how long, or even whether it is safe.

When the FDA fast-tracked Gardasil, it was with the condition that Merck must conduct a safety surveillance study:

The study will include approximately 44,000 vaccinated subjects who will be followed for 60 days for assessment of general short-term safety (i.e., emergency room visits, hospitalizations, and deaths). The subjects will also be followed for 6 months subsequent to vaccination for new autoimmune disorders, rheumatic conditions, or thyroiditis. Also, a sufficient number of children 11-12 years of age will be studied to permit an analysis of safety outcomes. . . The study will be completed by June 30, 2009. The final study report will be submitted by September 30, 2009.<sup>46</sup>

Even though Gardasil will not be fully tested for safety until 2009, physicians are already pushing it as a routine, harmless vaccine. Merck's aggressive advertisement campaign tells young girls that their lives could be "one less" affected by cervical cancer and that, "It's your turn to help guard against cervical cancer." Merck's lobbying campaign to encourage state lawmakers to mandate Gardasil was so aggressive that it caused major controversy among concerned parents nationwide. In February of 2007, due to pressure from concerned parents and organizations – and unfavorable media attention – Merck pledged to at least stop its lobbying campaign to make Gardasil a mandatory vaccine for sixth-grade girls. But Merck's intensive advertising campaign continues. Those who push to administer Gardasil three years before its safety testing is complete may be placing young girls and women at risk.

## **VAERS Reports**

The VAERS reports have shown some of the results of Merck's experiment on the public. VAERS may be submitted by anyone, including physicians, nurses, parents, and patients. Because of the open submission process for VAERS, Merck and FDA officials discount many of the reports as coincidental and not related to the vaccine. The fact remains, however, that medical professionals, patients or their family members thought there was enough of a connection to submit reports.

Judicial Watch filed a request to obtain all VAERS reports concerning Gardasil in May 2007. The most recent reports were released by the FDA on June 10, 2008. While in the past Judicial Watch had received VAERS reports in smaller groups, this production was the first time all of them had been collected and analyzed together. In total, 8,864 reports have been filed.

The VAERS reports document that there have been 38 reports of Guillain-Barre Syndrome among girls who received the Gardasil vaccine. Guillain-Barre Syndrome is a potentially devastating illness that attacks the nervous system and can result in paralysis. Even though some of these cases had onset dates within days of receiving Gardasil, the CDC stated that, "After a careful review of the GBS reports received by VAERS, many appear to have insufficient clinical data. Because GBS occurs at a rate of 1-2/100,000 person years during the second decade of life, it is likely that some cases will occur after vaccination but will not be due to vaccination."<sup>47</sup> However, even taking into consideration coincidental cases, the VAERS reports show that the average onset date of Guillain-Barre Syndrome in Gardasil-related cases was only 18 days after receiving the vaccine. Twenty-nine of the thirty-eight cases have onset dates of two weeks or less, and ten girls developed Guillain-Barre Syndrome within twenty-four hours. Below are excerpts from the VAERS reports:

Information has been received . . . concerning a 16-year-old female who on 16-APR-2007 was vaccinated with a dose of Gardasil. Since 1 day post-injection, the patient had progressive bilateral leg numbness and weakness and motor weakness. VAERS ID: 277814-1

\* \* \*

Information has been received . . . concerning an approximately 19-year-old female who was vaccinated IM with a first dose of Gardasil. Subsequently, the patient was diagnosed with Guillain-Barre Syndrome and was hospitalized. The patient's Guillain-Barre Syndrome persisted . . . Guillain-Barre Syndrome was considered to be disabling and immediately life-threatening. VAERS ID: 296713-1 (S)

\* \* \*

Pt [Patient] admitted to hospital with chief complaint of ascending weakness bilaterally, upper and lower extremities . . . Severe form of Guillain-Barre syndrome after HPV vaccine . . . Respiratory failure with prolonged mechanical ventilation and tracheostomy tube Placement . . . vital capacity deteriorated on day 3 . . . able to move only jaw and eyes.  
VAERS ID: 268143-1 (S)

These cases document apparent extremely serious side effects for a vaccine that is being marketed as necessary and routine. They certainly warrant far more investigation and examination than they have evidently received.

The VAERS reports also reveal as many as 18 young girls and women have died after receiving the vaccine. While the deaths are quite possibly not linked to the vaccine, there is a report of a perfectly healthy 17-year-old girl dying suddenly and alone, two days after receiving her third dose of the vaccine.<sup>48</sup> She was on birth control, as was another young woman who also died two days after receiving Gardasil:

Information has been received . . . concerning a 22-year-old female patient with no pertinent medical history or drug allergies who on 21 May 2007 was vaccinated IM with a 0.5ml dose of Gardasil . . . Concomitant therapy included hormonal contraceptives (unspecified). On 23 May 2007, the patient died suddenly. The cause of death was unknown.  
VAERS ID: 287888-1 (D).

Of the eighteen deaths, eleven of them occurred less than a week after receiving the vaccine, and seven in less than two days. The most common diagnosed cause was blood clotting, as seen from the reports below:

Information has been received . . . concerning a female patient who was vaccinated with a dose of Gardasil. The PA [physician's assistant] reported that "the patient died of a blood clot 3 hours after getting the Gardasil vaccine."  
VAERS ID: 275990-1 (D)

\* \* \*

[19 year old female] given Gardasil vaccine dose #1 [on] 3/12/07 . . . Collapsed and died on 3/26/07 . . . autopsy done at Medical Center . . . states from Death Certificate



COD [cause of death] is sudden cardiac death and pulmonary embolism. Echocardiogram revealed very enlarged right ventricle & small left ventricle as well as large blood clots within both the right atrium & right ventricle.  
VAERS ID: 275438-1 (D)

The fact that blood clotting is responsible for almost a fourth of all deaths involving Gardasil is extremely concerning, especially since most birth control drugs increase one's risk of developing blood clots. Many girls and young women who receive Gardasil will already be taking birth control by the time they are vaccinated, and therefore the possibility that Gardasil may add to risk of blood clots is a serious issue that deserves attention.

In addition to the four cases of death from blood clots, there was also one reported death due to myocarditis, which is an inflammation of the heart, as well as one death from arrhythmia and one death from meningitis. Both the arrhythmia and meningitis cases occurred months after the patients received the Gardasil vaccine; the myocarditis death occurred six days after vaccination but was a pre-existing condition. Even excluding these deaths though, there are still fourteen cases that occurred within three weeks of receiving the vaccine. One was from anaphylactic shock:

An 11-year-old female was vaccinated "within the past month" in approximately May 2007 with a first dose of Gardasil. Subsequently, 3 days after vaccination the patient presented to an ER . . . the physician from the hospital said that "the death was due to an anaphylactic reaction to Gardasil."  
VAERS ID: 280163-1 (D)

The remaining deaths reported to VAERS all have unknown causes; however, all but one occurred within three weeks of receiving Gardasil, and six occurred within three days. Below are additional excerpts from deaths with no apparent cause reported to VAERS:

A 18-year-old female patient was vaccinated with the first dose of Gardasil . . . In the evening of the same day she was found unconscious (or liveless) [sic] by the mother. Resuscitation was performed by the emergency doctor but was unsuccessful, i.e. the patient finally died . . . The cause of death of this patient remains totally unclear.  
VAERS ID: 300741-1 (D).

\* \* \*

A 19-year-old female with no previous medical history reported, who on 19-Sep-2007 was vaccinated with the 1<sup>st</sup>

dose of Gardasil . . . On the morning of 12-Oct-2007, the patient was found dead in her bed . . . Contraception was stopped 3 months before vaccination. No reason for the death was detected in autopsy.

VAERS ID: 299377-1 (D)

\* \* \*

Information has been received from a physician's assistant concerning a 12-year-old female with no reported medical history who on approximately 15-Sep-2007 was vaccinated with Gardasil . . . On 06-OCT-2007 the patient died in her sleep. No further information was provided.

VAERS ID: 297528-1 (D)

\* \* \*

Sudden unattended death [February 22, 2007] . . . patient [17-year-old female with no medical history or known allergies] last seen in office by nurse only on 2/20 for HPV #3 . . . The autopsy was negative for all findings. Scene indicated sudden death from collapse and fall.

VAERS ID: 305606-1 (D)

\* \* \*

Information has been received from a physician concerning a 20-year-old female with no medical history reported, who on 01-APR-2008 was vaccinated with a dose of Gardasil. On 05-APR-2008, the patient died four days after receiving Gardasil . . . An autopsy was performed which ruled out suicide and anything suspicious. The cause of death is currently unknown.

VAERS ID: 310262-1 (D) <sup>49</sup>

Perhaps all these deaths are simply coincidence, but given the unknowns about Gardasil and its overall safety, it is far too important an issue to simply ignore.

Merck's last wonder drug, Vioxx, was pulled from the market in 2002, after an estimated 88,000 to 140,000 adverse reactions were attributed to it. Vioxx, like Gardasil, was fast-tracked by the FDA in 1999, without a full safety testing and analysis period taking place. It was an anti-inflammatory drug designed to relieve people suffering from arthritis, menstrual cramps, and acute pain. Merck voluntarily pulled Vioxx from the market after a safety trial was stopped because, "there was an increased risk for serious cardiovascular events, such as heart attacks and strokes."<sup>50</sup> Vioxx was pulled after five years on the market and after contributing to 27,785 heart attacks and sudden cardiac

deaths, in addition to other events, as estimated by the FDA.<sup>51</sup> Analysts estimate that the Vioxx recall decreased Merck's stock value drastically, and could cost Merck anywhere from \$3 to \$20 billion. Less than two years after Merck suffered this severe blow, the company introduced Gardasil, the most expensive vaccine on the market, and it was approved by the FDA.

There are numerous critics of the Gardasil vaccine, but perhaps the most important is Dr. Diane Harper. Not only is she a specialist on HPV, she also helped to develop the Gardasil vaccine. In a television interview with CBS News on May 7, 2008, the doctor said that she viewed making the vaccination mandatory as "A real danger zone," adding: "... the vaccine has not been out long enough for us to have post-marketing surveillance to really understand what all of the potential side effects are going to be."<sup>52</sup> While Dr. Harper said she believes that the vaccine will be beneficial in the long run, she cautions: "To put in process a place that says you must have this vaccine means that you must be part of a big public experiment and so we can't do that. We can't have that until we have more data."<sup>53</sup> It is unacceptable to mandate any vaccine without first testing it for effectiveness, safety, and long-term side effects. The Gardasil vaccine may be an important step in preventing cervical cancer, but it is a step that may cause other harms.

## **Analysis**

Gardasil advocates and supporters of the FDA's fast-tracked approval of the vaccine attacked Judicial Watch's 2007 publication of VAERS records and reporting on deaths as well as serious, life threatening reactions to the vaccine. It is easy to conclude that Merck, the FDA and their associates were not interested in these government records being widely discussed and reported on. In fact, Judicial Watch has copies of FDA e-mail revealing their frustration with Judicial Watch's work.

Critiques of Judicial Watch's 2007 reporting usually misrepresent the organization's efforts to make government records public and offer that, "Judicial Watch can't prove causality from the VAERS reports." Judicial Watch was not and is not interested in proving causality. Only science can do that. And that is why we asked for more investigation of the VAERS reports to ensure there was no causality between Gardasil and the serious reported adverse reactions. What we seek is transparency in the workings of government so that citizens can make informed decisions. This report will, no doubt, renew attacks from supporters of Gardasil.

There is, however, good reason for public skepticism concerning the rush to mandate schoolgirls being vaccinated. While the word "cancer" invokes a wide range of emotions that can both influence and motivate parents, lawmakers, public health officials, pharmaceutical firms and lobbyists, it is important to evaluate the facts against the claims of both slick marketing and sophisticated political pressure campaigns.

Canadian epidemiologist, Dr. Abby Lippman of McGill University, raised similar important concerns over HPV vaccinations in the August 28, 2007 edition of the *Canadian Medical Association Journal*. Dr. Lippman wrote: “A careful review of the literature, including that submitted by the manufacturer with its application for approval of Gardasil reveals a sufficient number of unanswered questions to lead us to conclude that a universal immunization program aimed at girls and women in Canada is, at this time, premature and could possibly have unintended negative consequences for individuals and for society as a whole.”<sup>54</sup>

Women have been assured by experts and authorities before about the safety and efficacy of various medicines and procedures. Recent history is replete with horrific examples of misplaced public trust: Thalidomide; the Dalkon Shield; hormone replacement therapy; and diethylstilbestrol (“DES”).

Gardasil advocates use a patronizing tone in critiquing the doctors, scientists, public policy groups, parents and young women that question the vaccine's government-reported adverse events and side effects. Those harboring some skepticism about an enormous public health experiment being conducted on schoolgirls and young women are supposed to find consolation in assurances that the vaccine is being closely monitored. The same authorities offering the assurances ridicule VAERS reports as unreliable – cold consolation, indeed.

The top 10 causes of death of women in the United States are: 1) heart disease, 2) stroke, 3) lung cancer, 4) respiratory diseases, 5) Alzheimer's, 6) breast cancer, 7) diabetes, 8) various accidents, 9) flu/pneumonia, and 10) colon cancer.<sup>55</sup> As mentioned above, approximately 3,700 American women die of cervical cancer each year – a small fraction of the number of women who die from colon cancer (10<sup>th</sup> leading cause of death). The death from cancer of anyone is tragic, and work to prevent such deaths must continue to be pursued aggressively – especially in cases where early detection and treatment offer much hope. Despite these regrettable 3,700 deaths, when one examines the totality of the nation's health system, there is no epidemic or domestic public health crisis concerning either HPV infection or cervical cancer.

HPV infection and cervical cancer should not be conflated: cervical cancer will not develop in most women who are infected with even a high-risk strain of HPV.<sup>56</sup> Based on marketing and lobbying campaigns, as well as the majority of “health news” media reporting, it is unlikely that parents of pre-teens and young women are aware of these important distinctions.

## **Conclusions**

Gardasil is such a new drug that it is impossible to say at this point how beneficial it may be. Most scientists, including Dr. Diane Harper, agree that booster shots will be needed, and guess that the original vaccine will be effective for at least five years. It is important to emphasize that regardless of how effective Gardasil is, it does not protect

against all HPV strains and it will never eliminate the need for regular testing and Pap screening.

Gardasil's safety for the general public is a serious concern. While no drug is ever completely risk-free, a careful analysis must be made as to whether the benefits are worth the costs. HPV, though potentially devastating, is quite often completely harmless. Most HPV infections, even ones caused by high-risk strains, go away on their own and never develop into cancer. Even when they do, in most cases it takes years for cancer to occur and it is easily preventable as long as the HPV infection is detected early.

Even without Gardasil, cervical cancer deaths have decreased drastically in the past several decades. The American Cancer Society estimates that deaths from cervical cancer declined 74% between 1955 and 1992, and that the rate continues to decrease by about 4% each year. Also, most cases occur in women in their forties.<sup>57</sup> With these statistics in mind, one might ask whether Gardasil vaccination is absolutely necessary, especially for children. At this point in time, we do not know if it will prevent cancer, or whether it will have unforeseen consequences. The American public must ask themselves if Gardasil is really worth the risk. Fast-tracking drugs and vaccines before their safety has been fully evaluated is unethical and dangerous, and until more tests have been completed on Gardasil no vaccination mandates should be established.

- Gardasil has not been tested thoroughly enough to know whether it will be safe or effective in the long term.
- Even if it shown that the Gardasil vaccine is effective, it is still unknown how long the vaccine lasts or if there will be a need for booster shots.
- Regardless of its potential to help prevent HPV and cancer, Gardasil should never be administered without a prescreening for HPV since it has the potential to make existing cases worsen.
- It is important that people remember that this vaccine will not eliminate the need for regular Pap screening. No vaccine is 100% effective, and Gardasil is designed to protect against only four strands of HPV.
- While Gardasil may be an important medical advance, it is unwise to compromise the health and safety of the American public, especially children, by mandating or marketing it before sufficient tests are concluded.

## **Endnotes**

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<sup>1</sup> See VAERS Report 282747-1 (D); Reporting on June 25, 2007, that a physician attending a conference who mentioned that additional two patients vaccinated with Gardasil subsequently died. Attempts reportedly being made to obtain additional information. VAERS reports available on the Internet at: <<http://www.JudicialWatch.org/gardasil>>.

<sup>2</sup> See Tab E, 003.

<sup>3</sup> National Conference of State Legislatures, "HPV Vaccine: State Legislation," Updated June 4, 2008, <<http://www.ncsl.org/programs/health/HPVvaccine.htm>>, Accessed June 12, 2008.

<sup>4</sup> American Social Health Association, "HPV, Human Papillomavirus: What Women Should Know," <[http://www.ashastd.org/learn/learn\\_hpv\\_women.cfm](http://www.ashastd.org/learn/learn_hpv_women.cfm)>, Accessed June 18, 2008.

<sup>5</sup> The Centers for Disease Control and Prevention, "Genital HPV Infection-CDC Fact Sheet," <<http://www.cdc.gov/std/HPV/STDFact-HPV.htm>>, Accessed June 18, 2008.

<sup>6</sup> *The New England Journal of Medicine*, "Quadrivalent Vaccine against Human Papillomavirus to Prevent High-Grade Cervical Lesions," Vol. 356, No. 19, May 10, 2007.

<sup>7</sup> National Cancer Institute, "Human Papillomaviruses and Cancer," <<http://www.cancer.gov/cancertopics/factsheet/Risk/HPV>>, Accessed May 22, 2008.

<sup>8</sup> American Cancer Society, "What Are the Key Statistics About Cervical Cancer?," <[http://www.cancer.org/docroot/CRI/content/CRI\\_2\\_4\\_1X\\_What\\_are\\_the\\_key\\_statistics\\_for\\_cervical\\_cancer\\_8.asp?rnav=cri](http://www.cancer.org/docroot/CRI/content/CRI_2_4_1X_What_are_the_key_statistics_for_cervical_cancer_8.asp?rnav=cri)>, Accessed June 18, 2008.

<sup>9</sup> American Social Health Association, "HPV, Human Papillomavirus: What Women Should Know."

<sup>10</sup> Food and Drug Administration, "Product Approval Information-Licensing Action: Gardasil Questions and Answers," <<http://www.fda.gov/CBE/products/hpvmer060806qa.htm>>, accessed June 9, 2008.

<sup>11</sup> *The New England Journal of Medicine*, "Quadrivalent Vaccine against Human Papillomavirus to Prevent High-Grade Cervical Lesions."

<sup>12</sup> Dr. Jesse Goodman, quoted in *The New York Times*, "U.S. Approves Use of Vaccine for Cervical Cancer," June 9, 2006.

<sup>13</sup> See Tab A, Merck & Co., Inc., *GARDASIL Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine*, June 2006, 11.

<sup>14</sup> *The New England Journal of Medicine*, “Quadrivalent Vaccine against Human Papillomavirus to Prevent High-Grade Cervical Lesions.”

<sup>15</sup> See Tab B, Food and Drug Administration, “VAERS Line List Report—Vaccine Type: HPV, HPV4,” report ran on June 10, 2008.

<sup>16</sup> *Ibid.*

<sup>17</sup> FDA, “VRBPAC Background Document: Gardasil HPV Quadrivalent Vaccine,” May 18, 2006, < <http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4222B3.pdf> >, Accessed June 26, 2008.

<sup>18</sup> *Reuters*, “Merck’s Gardasil Not Cleared for Older Women,” June 25, 2006, <<http://uk.reuters.com/article/healthNews/idUKWNAS917720080626?pageNumber=2&virtualBrandChannel=0&sp=true>>, Accessed June 26, 2008.

<sup>19</sup> *Ibid.*

<sup>20</sup> See Tab A.

<sup>21</sup> *Ibid.*, 12

<sup>23</sup> National Vaccine Information Center, “Merck's Gardasil Vaccine Not Proven Safe for Little Girls,” June 27, 2006, <<http://909shot.com/PRESSRELEASES/pr62706gardasil.htm>>, Accessed June 24, 2008.

<sup>24</sup> See Tab C, Dr. Patrick Brill-Edwards and Dr. Eliav Barr, “Food and Drug Administration Center for Biologics Evaluation and Research, Vaccines and Related Biological Products Advisory Committee: Meeting,” May 18, 2006, 13.

<sup>24</sup> See Tab C, Dr. Patrick Brill-Edwards and Dr. Eliav Barr, “Food and Drug Administration Center for Biologics Evaluation and Research, Vaccines and Related Biological Products Advisory Committee: Meeting,” May 18, 2006, 13.

<sup>25</sup> See Tab A, 8.

<sup>26</sup> See Tab C, 12.

<sup>27</sup> *Ibid.*, 12.

<sup>28</sup> See Tab A, 9.

<sup>29</sup> See Tab B, VAERS ID 290582-1.

<sup>30</sup> See Tab B.

<sup>31</sup> See Tab A, 9 – 10.

<sup>32</sup> See Tab A, 8 – 9.

<sup>33</sup> *Ibid*, 9.

<sup>34</sup> See Tab C, 7.

<sup>35</sup> Merck & Co., Inc., “Important Information About Gardasil”  
<<http://www.gardasil.com/#important-information>>, Accessed May 21, 2008.

<sup>36</sup> *The New York Times*, “U.S. Approves Use of Vaccine for Cervical Cancer,” June 9, 2006.

<sup>37</sup> *The New York Times*, “Panel Unanimously Recommends Cervical Cancer Vaccine for Girls 11 and Up,” June 30, 2006,  
< <http://www.nytimes.com/2006/06/30/health/30vaccine.html?> >, Accessed June 27, 2008.

<sup>38</sup> *Ibid*.

<sup>39</sup> *The New York Times*, “Rising Costs Make Doctors Balk at Giving Vaccines,” March 24, 2007, <<http://query.nytimes.com/gst/fullpage.html?> >, Accessed June 27, 2008.

<sup>40</sup> *Ibid*.

<sup>41</sup> See Tab D, Merck & Co., Inc., GARDASIL Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine STN 125126, April 19, 2006, 11.

<sup>42</sup> Calculations based on estimated population numbers found in the Center for Disease Control's “National Vital Statistics Report,” December 5, 2007.

<sup>43</sup> Dr. Diane Harper quoted in *Fort Wayne Daily News*, “Researcher Blasts HPV Marketing,” March 14, 2007,  
< [http://www.kpcnews.com/articles/2007/03/14/online\\_features/hpv\\_vaccine/hpv01.txt](http://www.kpcnews.com/articles/2007/03/14/online_features/hpv_vaccine/hpv01.txt)>  
Accessed June 12, 2008.

<sup>44</sup> Merck & Co., Inc., “Important Information About Gardasil”  
<<http://www.gardasil.com/#important-information>>, accessed May 21, 2008.

<sup>45</sup> Food and Drug Administration, “Gardasil Questions and Answers,”  
<<http://www.fda.gov/CBER/products/hpvmer060806qa.htm>>, accessed 11 June 2008.



<sup>46</sup> See Tab E, FDA Department of Health & Human Services, Patent Approval Notification Letter, June 8, 2006, 3.

<sup>47</sup> Center for Disease Control, "HPV: Gardasil and GBS," August 15, 2007, <<http://www.cdc.gov/vaccines/vpd-vac/hpv/downloads/hpv-Gardasil-gbs.pdf>>, accessed 11 June 2008.

<sup>48</sup> See Tab B, VAERS ID: 305606-1

<sup>49</sup> Ibid.

<sup>50</sup> Food and Drug Administration, "Vioxx (rofecoxib) Questions and Answers, September 30, 2004, <<http://www.fda.gov/CDER/DRUG/infopage/vioxx/vioxxQA.htm>>, accessed June 10, 2008.

<sup>51</sup> Consumer Affairs, "FDA Estimates Vioxx Caused 27,785 Deaths," November 4, 2004, <[http://www.consumeraffairs.com/news04/vioxx\\_estimates.html](http://www.consumeraffairs.com/news04/vioxx_estimates.html)> Accessed June 24, 2008.

<sup>52</sup> Dr. Diane Harper, seen on CBS 5, "Potential Side Effects of HPV Vaccine Questioned," <[http://cbs5.com/wrapper\\_consumer/seenon/gardasil.merck.vaccine.2.721920.html](http://cbs5.com/wrapper_consumer/seenon/gardasil.merck.vaccine.2.721920.html)>, May 7, 2008.

<sup>53</sup> Ibid.

<sup>54</sup> "Human papillomavirus, vaccines and women's health: questions and cautions," Abby Lippman, PhD, Ryan Melnychuk, PhD, Carolyn Shimmin, BJ, and Madeline Boscoe, RN DU, *Canadian Medical Association Journal*, August 28, 2007, page 484, <<http://www.cmaj.ca/cgi/rapidpdf/cmaj.070944v1>>, Accessed June 27, 2008.

<sup>55</sup> Center for Disease Control, *United States Health 2007*, with Chartbook on Trends in the Health of Americans, 567 pp. (PHS) 2007-1232; <[http://www.cdc.gov/nchs/data/07/07.pdf#contents](http://www.cdc.gov/nchs/data/hus/07/07.pdf#contents)>, Accessed June 20, 2008.

<sup>56</sup> Public Health Agency of Canada. "What everyone should know about human papillomavirus (HPV): questions and answers. Available: <[www.phac-aspc.gc.ca/std-mts/hpv-vph/hpv-vph-qaqr\\_e.html](http://www.phac-aspc.gc.ca/std-mts/hpv-vph/hpv-vph-qaqr_e.html)>. Accessed June 20, 2008.

<sup>57</sup> American Cancer Society, "What Are the Key Statistics About Cervical Cancer?"