# A Case of Contamination:

Growing Concern over the Safety and Efficacy of Merck's Gardasil HPV Vaccine.

## **September 16, 2011**

Recent reports on Gardasil points to a frightening cover-up by Merck, American medical authorities, and the media regarding the harmful nature of the popular HPV vaccine.

The controversy stems from one small phrase that appeared on the package insert of Merck's Gardasil vaccine since it hit the market in 2006. It read:

"GARDASIL is not a live virus vaccine; it contains no viral DNA and is therefore incapable of causing infection" <sup>1</sup>

This assertion was given a stamp of approval by the Food and Drug Administration (FDA) and backed by major medical institutions including Health Canada and the World Health Organization (WHO).<sup>23</sup>

The results of a recent study commissioned by the vaccine safety organization SANE Vax provide compelling evidence that the Gardasil vaccine does, in fact, contain dangerous live strains of the HPV virus. The study examined the contents of thirteen vials of Gardasil from different countries around the world including the United States. It was found that 100% of the vaccines probed were contaminated with genetically modified HPV DNA, in other words, live strains of the human papiloma virus capable of infecting human beings.<sup>4</sup>

These findings strongly suggest that the Gardasil vaccine has been transmitting the HPV virus to an untold number of young boys and girls all over the world and causing the very condition it was designed to prevent. The alarming implications of this revelation are compounded by concern over the unpredictable and harmful effects that live laboratory-created DNA in vaccines can have on the body. Studies have linked genetically modified virus strains in vaccines to serious health disorders including autoimmune disorders and malignant tumors. <sup>5</sup>

This story is corroborated by Cindy Bevington, a multi-award winning investigative reporter who has done extensive research into Gardasil. In an interview on the Progressive Radio Network, Bevington noted that in April 2011, Merck quietly went about removing the information from their package insert which stated Gardasil did not contain live strains of HPV.<sup>6</sup> Neither Merck nor the FDA has responded to calls by the public to account for this shocking revelation.

Such silence from our medical institutions on the issue of vaccine safety has become the norm in recent years. This particularly applies to the controversy over vaccines being linked to autism. Despite our federal health agencies repeated denial of any causal relationship between vaccines and autism, the evidence is irrefutable that US government has implicitly acknowledged such a link exists. The government's Vaccine Injury Compensation Program (VICP) has been paying out sums of money to the families of autistic children for more than two decades. In a peer reviewed study published in the *Pace Environmental Law Review* in 2011, investigators found that in 83 cases filed with the VICP, families were given monetary compensation after their child

presented symptoms of autism – in 21 of these cases, the federal court documents even contained the words "autism or autism like symptoms". <sup>7</sup>

#### The Mainstream Media - Pro-Vaccine and Uninformed

During the Republican Presidential Debate held on Monday night, Texas governor Rick Perry was blasted by fellow presidential candidate and Minnesota congresswoman Michele Bachmann for his attempt to institute mandatory HPV vaccinations for young girls in 2007. Bachmann criticized Perry's stance saying it could have endangered the lives of girls with a "potentially dangerous drug" with "dangerous side effects" that could cause mental retardation in some children.<sup>8</sup>

Following the debate, members from media and medical establishment moved quickly to attack Bachmann for her comments. Talking heads appeared on all the major news networks and dozens of articles appeared in the press dismissing the congresswoman's statements as false.

These news outlets parroted the claim by national health agencies such as the Centers for Disease Control and Prevention (CDC) and that Gardasil is a safe and effective means of preventing HPV and cervical cancer. Bachmann has already begun to back away from her comments, admitting that she is not an expert on vaccines and has "no idea" of Gardasil's effects.<sup>9</sup>

This incident is yet another example of how the media has chosen to blindly follow the dubious claims of government authorities without carrying out an independent and thorough investigation of the facts. This article will highlight the hard-hitting facts and figures, many of which were

obtained from our federal health agencies, that reveal Gardasil to be both dangerous and ineffective.

### The Approval of Gardasil: Flawed from the Start.

The Gardasil vaccine has been the subject of criticism since it was approved five years ago. The vaccine purportedly prevents the sexually- transmitted human papilloma virus (HPV) and cervical cancer. Originally intended only for girls, it was approved for boys in 2009 and according to the CDC, Gardasil can be administered to girls and boys starting at 9 years of age.<sup>10</sup>

Before being approved, Gardasil was tested on fewer than 1200 girls. <sup>11</sup> The trials assessing Gardasil's safety and effectiveness that led to the vaccine being approved were sorely lacking in good science. From the outset, the standards for determining the vaccine's safety and effectiveness were lowered when the FDA fast tracked the approval process. <sup>12</sup> Researchers monitored the frequency of adverse reactions in test subjects taking Gardasil with a placebo group. One glaring problem with the trials was that the placebo provided was laced with aluminum, a toxic material known to promote inflammation and neurological disorders.

Accordingly, the adverse events associated with Gardasil did not appear as severe when compared to those adverse events caused by the harmful injections given to the placebo group. <sup>13</sup>

Another major flaw in Merck's clinical trials was the number of girls tested who elected to take the prescribed three doses of the vaccines. Only 27% of all the girls tested were actually given all three vaccines. <sup>14</sup> This has led many to speculate that numerous girls participating in the trials

experienced bad reactions to Gardasil and did not wish to continue. Another remarkable oversight in the trials was that no girls under age 15 participated.<sup>15</sup> The vast majority of the girls being given the vaccine now are younger than 15 years old. Despite being clearly subjective, the clinical trials only managed to demonstrate that Gardasil could, in some cases, prevent certain types of cervical lesions that could potentially have led to cervical cancer.

#### A High-Risk Injection

In an article printed in the New York Times on Friday September 16, 2011 entitled "With Stakes for Bachmann Higher Now, Her Words Get in the Way" writer Trip Gabriel asserts that Michele Bachmann's comments concerning the dangers of Gardasil are simply a manifestation of her "penchant for exaggeration". The article fails to reference the comprehensive body of research and documentation which proves that Bachmann was far from overstating the facts.

FDA documents obtained by Judicial Watch reveal that, within a 16 month period, there were 16 deaths (4 suicides), 789 "serious reports" and 239 cases of permanent disability resulting from the vaccine. As of April 2011, over 20,000 adverse events, 90 of them deaths, have been reported to the government's Vaccine Adverse Event Reporting System (VAERS) in connection with the vaccine 1718 It is estimated that only between 1%-10% of all adverse reactions are reported to VAERS. 19 Compared with reports of adverse reactions to the meningococcal (Menactra) vaccine, 30 times as many deaths and serious adverse events from Gardasil are reported to federal health authorities. 20

Other known reactions to Gardasil include the loss of coordination, rashes, vomiting, blood clots, seizures, and fainting. Numerous reports to the National Vaccine Information Center detail how several girls passed out within minutes of being vaccinated. VAERS has received several reports of school age girls developing the Guillian-Barre Syndrome (GBS) after receiving the Gardasil vaccine. GBS is an incurable life-threatening autoimmune and neurological disorder that causes a loss of muscle control and paralysis throughout the body.

In a report to the National Vaccine Information Center, the mother of a 14 year old girl named Cassie, chronicled her daughter's horrific reaction to Gardasil stating the following:

"After receiving the first Gardasil shot, she started experiencing severe headaches and nosebleeds, which continued after the second shot and increased in severity and added to her extreme fatigue. After seeing our family physician twice and still not connecting her health problems to Gardasil, Cassie received the third Gardasil shot as well as other vaccines.

That's when everything fell apart. The nose bleeds were severe and the headaches at times were so bad she would hold her head and cry. The fatigue left her unable to move and, then, the flu-like symptoms and severe abdominal pain hit her.

Since receiving her third Gardasil shot, Cassie has been hospitalized four times. She has been diagnosed with pancreatitis, gastrointestinal disorders, and has had pneumonia three times. She is also suffering from various other symptoms including extreme nausea and vomiting after having a central line put in and being on TPN and Lipids (IV nutrition). She has fatigue, dizziness, headaches, hypersensitivity to light and sound, blurred vision,

lactation, seizure-like activity, tingling and numbness in legs, and severe pain in her abdomen."

Because these reports are not double-blind, placebo controlled, randomized studies, our medical institutions make the claim that these are not definitively linked to the vaccine. The CDC continues to ignore the growing number of reports detailing terrible reactions to Gardasil. These reports are accessible to the public at medalerts.org.

In a presentation before the American Academy of Neurology, scientists from the University of Medicine and Dentistry of New Jersey produced disturbing evidence of a connection between the HPV vaccine and Guillian- Barre Syndrome. The researchers discovered that girls were up to six times as likely to develop GBS in the six weeks following injections of Gardasil.<sup>21</sup>

The dangers associated with Gardasil extend to infants. Despite the claim by Merck that "It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk" an internal study carried out by the company concluded that the children of nursing mothers who received the vaccination showed a threefold increase in acute respiratory conditions compared to the placebo group.<sup>22</sup>

## **A Virtually Useless Vaccine**

The effectiveness of Gardasil in preventing HPV and cervical cancer remains unproven. Dr. Diane Harper worked as a consultant to Merck and was responsible for overseeing trials

evaluating the safety and efficacy of Gardasil. After helping it get approved, Dr. Harper began to publically question the use of the vaccine. She has claimed that the damaging side effects of Gardasil may not be worth the risk and that additional studies should be undertaken that prove the vaccine's efficacy. She has also expressed her disapproval over very young children receiving the vaccine. Because 11 year old girls do not get cervical cancer, Dr. Harper asserted that the only party that stands to benefit from the HPV vaccination of young girls is Merck. In one case involving a child who developed Lou Gehrig's Disease after being vaccinated, Dr. Harper posited that Gardasil was the likely cause. In addition, Dr. Harper has brought attention to the fact that a truly effective HPV vaccine would need to remain efficacious for 15 years to prevent cervical cancer in women and also, that we would have to vaccinate every single 11 year old girl in the United States for the next 60 years to have any measurable effect on rates of cervical cancer. The truth is that no proof exists that shows Gardasil as effective at preventing cancer in the long term.

A study published in *the Journal of the American Medical Association (JAMA)* in 2007 plainly demonstrates the ineffective nature of Gardasil in women with HPV. The authors concluded that the Gardasil vaccination offered no benefit to women recovering from HPV during a 12-month period.<sup>25</sup> On the contrary, the authors found that injections of Gardasil frequently *increased* the strains of HPV found in women- a point that supports the aforementioned study results released by SANE Vax.<sup>26</sup> The authors concluded that they "see no reason to believe that there is therapeutic benefit of the vaccine elsewhere because the biological effect of vaccination among already infected women is not expected to vary by population."<sup>27</sup>

Gardasil was designed to protect against just two of the over 150 strains of HPV that could lead to cervical cancer. Another study published in *JAMA* which tested American women for HPV, revealed that only about 3% of those tested were infected with the strains against which Gardasil protects.<sup>28</sup>

Given the high rate of recovery for people with HPV, the widespread use of the vaccine is highly suspect. Even the National Cancer Institute has stated that "the great majority of high-risk HPV infections go away on their own and do not cause cancer." In fact, 90% of all cases of HPV disappear within 2 years. Cervical cancer is nearly 100% curable when detected early. <sup>29</sup> According to data from the CDC, there were no deaths from cervical cancer in females below age 21 from 2003-2007.

Advances in medicine and the regular use pap smears to detect cancer have helped decrease the incidence of cervical cancer in the United States by over 50% since the 1970s. <sup>30</sup> Examining health data from Finland and the UK, Dr. Harper and her colleagues concluded that HPV vaccinations actually give a false sense of security to many young women and girls who in turn, opt out of regular pap smear tests. According to Dr. Harper, this trend has resulted in exponential *increases* in rates of HPV. <sup>31</sup>

#### Ignoring the facts about Gardasil

Given the abundance of evidence that shows Gardasil to be harmful, ineffective and entirely unnecessary, why have the media refused to challenge the baseless proclamations of our medical

establishment? Why have they refused to engage in an impartial and thorough examination of the facts surrounding this issue? This is a matter that has profound implications on the lives of millions of our children. We must challenge the deeply flawed medical dogmas trumpeted by our government institutions and reevaluate the propriety of forcing a harmful and ineffective vaccine on our young ones. If we do not, we risk continuing an egregious charade that only lines the pockets of those in the pharmaceutical industrial complex and imperils the health of an entire generation of Americans.

Endnotes

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