

# Manufactured Crisis – HPV, Hype and Horror

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✓ Fact Checked

May 22, 2023

## STORY AT-A-GLANCE

- › While the cervical cancer rate in the U.S. is 12 per 100,000, by Merck's own admission, Gardasil may cause 2,300 serious adverse events per 100,000
- › Many of the more serious side effects of Gardasil vaccination are immune-based inflammatory neurodegenerative disorders, suggesting something is causing the immune system to overreact in a detrimental way, sometimes fatally
- › One of the leading theories is that the aluminum adjuvant in Gardasil is causing it to be excessively reactive. Data show Gardasil is several times more reactive than any other vaccine on the market
- › Trial data from Merck shows Gardasil may increase your risk of cervical cancer by 44.6% if you have been exposed to HPV strains 16 or 18 prior to vaccination
- › As of 2018, about 13,240 new cases of cervical cancer will be diagnosed, and about 4,170 will die from it. If you get regular Pap smears, your chance of dying from cervical cancer is 0.00002%

***Editor's Note: This article is a reprint. It was originally published December 8, 2018.***

The HPV vaccine Gardasil was granted European license in February 2006,<sup>1</sup> followed by U.S. Food and Drug Administration (FDA) approval that same year in June.<sup>2</sup>

Gardasil was controversial in the U.S. from the beginning, with vaccine safety activists questioning the quality of the clinical trials used to fast track the vaccine to licensure.<sup>3</sup>

Merck, which manufactures and distributes the HPV vaccine Gardasil, has worked with a global health group called PATH<sup>4</sup> to get the vaccine approved worldwide.

Lauded as a silver bullet against cervical cancer, the vaccine has since wrought havoc on the lives of young girls across the world.

"Manufactured Crisis – HPV, Hype and Horror," a film by The Alliance for Natural Health, delves into the all too often ignored dark side of this unnecessary vaccine, interviewing families whose lives have been forever altered after their young daughters suffered life-threatening or lethal side effects following Gardasil vaccination. Says Barbara Loe Fisher, president and cofounder of the National Vaccine Information Center (NVIC):

*"The tragic story of Gardasil vaccine is one that is playing out in real time in the homes of trusting parents, who thought they were doing the right thing to try to make their daughters 'one less,' and in the 21st century cyberspace forum of public opinion as well as on television."*

## **Gardasil, a Global Catastrophe Wrecking Lives Worldwide**

Serious adverse reactions reported to the Vaccine Adverse Event Reporting System (VAERS) in relation to Gardasil include but are not limited to:<sup>5</sup>

|   |   |
|---|---|
| Anaphylaxis   | Guillain-Barre Syndrome   |
| Transverse myelitis (inflammation of the spinal cord) | Pancreatitis  |
| Venous thromboembolic events (blood clots)            | Autoimmune initiated motor neuron disease (a neurodegenerative disease that causes rapidly progressive muscle weakness) |
| Multiple sclerosis                                    | Sudden death <sup>6</sup>   |

According to the film, there have also been cases of 16-year-old girls developing ovarian dysfunction, meaning they're going into menopause, which in turn means they will not be able to have children.

Despite such serious effects, the U.S. Centers for Disease Control and Prevention (CDC) and FDA allege the vast majority, or even all, of these tragic cases are unrelated to the vaccine, and that Gardasil is safe. In the film, Laurie Powell, a former pharmaceutical marketing executive says:

*"I would come home feeling like I just wanted to take a shower, because I couldn't believe the amount of spin and just utter deception that goes on behind the scenes, all funded by pharma. It's not about patient well care, it's about making money."*

## **Gardasil and Autoimmune Problems**

Many of the more serious side effects of Gardasil vaccination are immune-based inflammatory neurodegenerative disorders, suggesting something is causing the immune system to overreact in a detrimental way, sometimes fatally.<sup>7</sup> One of the leading theories revolves around the use of aluminum as an adjuvant.

Chris Exley, Ph.D., professor of bioinorganic chemistry and a leading expert on aluminum, notes that all the available evidence indicates aluminum is toxic to living systems. He, like many others, suspect it's the aluminum adjuvant in vaccines that cause the majority of severe adverse reactions.

The filmmakers tested several samples of Cervarix (pulled from the U.S. market in 2016, ostensibly due to low demand<sup>8</sup>) and Gardasil at two separate laboratories to ascertain and compare their aluminum content.

Interestingly, Cervarix contained 2.6 times more aluminum than stated on the label. And, while the amount of aluminum found in Gardasil was within the range stated on the label, it was 2.5 times higher than the stated amount in Cervarix. In the end, both products were found to contain right around 1,000 parts per million of aluminum.

While government authorities claim this level of aluminum in vaccines is safe — based on estimated safe levels for ingestion — animal research reveals neurological and immune responses can be triggered. When injected, you bypass the filtering system of your gastrointestinal tract, allowing the aluminum access to vulnerable parts of your body far more easily than were you to ingest it.

The high immunogenicity of Gardasil was also addressed in my 2015 [interview with Lucija Tomljenovic](#), Ph.D., a research scientist at the University of British Columbia. In it, she explains that by triggering an exaggerated inflammatory immune response, vaccine adjuvants end up affecting brain function.

In collaboration with a team led by Dr. Yehuda Shoenfeld, a world expert in autoimmune diseases who heads the Zabludowicz Autoimmunity Research Centre at the Sheba Hospital in Israel, Tomljenovic has demonstrated how the HPV vaccine can cause brain autoimmune disorders.

## **Cochrane Researcher Highlights Problems With Safety Review**

The filmmakers interview a number of vaccine and medical experts and researchers, including Dr. Peter Gøtzsche, who helped found the Cochrane Collaboration in 1993 and later launched the Nordic Cochrane Centre. Cochrane publishes hundreds of scientific reviews each year, looking at what works and what doesn't.

Earlier this year, Cochrane published a surprisingly favorable review<sup>9</sup> of the HPV vaccine, concluding "There is high-certainty evidence that HPV vaccines protect against cervical precancer in adolescent girls and women who are vaccinated between 15 and 26 years of age," and, "The risk of serious adverse events is similar in HPV and control vaccines."

Two months later, Gøtzsche, along with Cochrane-affiliated researchers Lars Jørgensen and Tom Jefferson, published a scathing critique<sup>10</sup> of the review,<sup>11</sup> pointing out methodological flaws and conflicts of interest. Shortly thereafter, Gøtzsche was expelled from the Cochrane governing board.<sup>12,13</sup>

According to Gøtzsche, the review "missed nearly half of the eligible trials," and "was influenced by reporting bias and biased trial designs." In the film, he notes that the reviewers simply accepted the conclusions of the studies — all of which were done by industry — and didn't look at how the studies were actually conducted.

Importantly, all but one of the 26 trials included in the HPV vaccine review used active comparators, meaning aluminum-containing vaccines, which can significantly skew results by hiding neurological and other adverse effects.

Making matters worse, the reviewers incorrectly described these active comparators as "placebos." By definition, a placebo is an inert substance, and an aluminum-containing vaccine is anything but inert. Results may also have been skewed by the exclusion of women who had a history of immunological or nervous system disorders.

According to Gøtzsche and his team,<sup>14</sup> "These exclusion criteria lowered the external validity of the trials and suggest that the vaccine manufacturers were worried about harms caused by the adjuvants." They also noted the review "incompletely assessed serious and systemic adverse events" and ignored "HPV vaccine-related safety signals."

## **Conflicts of Interest May Have Tainted HPV Vaccine Review**

What's more, not only were all 26 studies funded by industry, three of the four reviewers also had conflicts of interest. As noted by Gøtzsche:<sup>15</sup>

*"The review's first author currently leads EMA's 'post-marketing surveillance of HPV vaccination effects in non-Nordic member states of the European Union,' which is funded by Sanofi-Pasteur-MSD that was the co-manufacturer of Gardasil."*

One of the clearest conflicts of interest involves Dr. Lauri Markowitz, one of the authors of the HPV vaccine review protocol,<sup>16</sup> meaning the individuals who designed and determined the scope of the review. Markowitz's history with the HPV vaccine include:

- Currently being the HPV team lead for the division of viral diseases at the CDC<sup>17</sup>

- Being part of the U.S. Advisory Committee on Immunization Practices' (ACIP) HPV working group in 2006, which recommended Gardasil for routine vaccination of girls 11 to 12 years old
- Being the designated correspondent on ACIP's HPV vaccination recommendation issued in March 2007<sup>18</sup>

Considering the U.S. government's financial interest in the sale of HPV vaccine, this is about as clear a conflict of interest as you can get, yet Markowitz was allowed to be part of the team that designed the scope and parameters of the review.

## **Risk Benefit Analysis**

In the film, Norma Erickson, president of Sanevax, Inc., an "international HPV vaccine information clearinghouse" in Troy, Montana, points out that while the cervical cancer rate in the U.S. is 12 per 100,000, by Merck's own admission, Gardasil may cause 2,300 serious adverse events per 100,000.

Is it really reasonable to risk 2,300 serious adverse events – which includes sudden death – in the hopes of preventing 12 cases of cervical cancer out of 100,000?

Trial data from Merck also shows that Gardasil vaccinations may actually increase your risk of cervical cancer by 44.6% if you have been exposed to HPV strains 16 or 18 prior to vaccination.<sup>19</sup> (The U.S. Food and Drug Administration has made this document inaccessible, but we've saved a copy of it for posterity.)

Professor Marcos Mazzuka, a pediatrician specializing in vaccine injuries in Madrid, Spain, agrees that the HPV vaccine is not safe, and is not worth the risk, as side effects are not limited to rash or fever but are severe and long-lasting.

*"We're talking about more than 300 girls who have died, around the world," he says. "We're talking about 46,000 girls who have very, very serious side effects."*

## **Gardasil Is One of the Most Dangerous Vaccines on the Market**

The film also features Stephanie Seneff, Ph.D., whose research reveals Gardasil is one of the most reactive vaccines on the market, producing far more adverse reactions than other vaccines given at the same age. For example, in her sampling, Gardasil had a death toll of 35, compared to just seven from other vaccines given to young girls. According to Seneff:

*"There's no way that the risk benefit ratio [for Gardasil] comes out in favor of benefit, particularly since they have not demonstrated that it actually protects against cervical cancer."*

Similarly, in its 2009 Gardasil versus Menactra risk report,<sup>20</sup> NVIC compared the number and severity of adverse events for the two vaccines reported to VAERS through November 30, 2008.

Results show that death and serious health problems such as stroke, blood clots, cardiac arrest, seizures, fainting, lupus and challenge/rechallenge cases (i.e., a similar adverse reaction occurs after another dose of vaccine is given) were reported three to 30 times more frequently after Gardasil vaccination than after meningococcal (Menactra) vaccination.

In the film, Robert Verkerk, scientific and executive director of the Alliance for Natural Health International, points out that data obtained via freedom of information requests from the British Medicines and Healthcare Products Regulatory Agency (MRHA) also reveal that the number of adverse event reports following Gardasil vaccination is several times higher than for any other vaccine, and that this information was not being shared in any way.

*"There were some 8,000 serious adverse events sitting in an MHRA database that were not being communicated to the medical professionals, and certainly not communicated to parents or children who were at the point of making a decision about vaccination," Verkerk says.*

## **Other Gardasil Facts**

These seem like extraordinary risks just to prevent an infection that is cleared by more than 90% of people without a problem.<sup>21</sup> As noted in the film, the HPV vaccine's underlying technology was originally developed by National Institutes of Health (NIH) researchers, then sold to Merck<sup>22</sup> and fast-tracked to licensure, despite the fact the vaccine failed to fulfill two of the criteria for fast-tracking.

In their paper, "Human Papillomavirus (HPV) Vaccines as an Option for Preventing Cervical Malignancies How Effective and Safe?" Tomljenovic, Spinosa and Shaw point out questionable surrogate markers for efficacy were used.<sup>23,24</sup>

It's also important to realize that Gardasil was approved after being tested in fewer than 1,200 children under the age of 16,<sup>25</sup> and that bioactive aluminum "controls" are being used in clinical HPV vaccine trials,<sup>26,27,28,29</sup> thereby masking neurological symptoms.

Gardasil is also pushed by pediatricians who are shielded from legal accountability for vaccine injuries and deaths — just like vaccine manufacturers are shielded from civil liability in U.S. courts.<sup>30</sup> Many doctors, as noted in the film, are completely unaware of the fact that Gardasil had generated nearly 30,000 adverse reaction reports to the U.S. government, including 140 deaths<sup>31</sup> by December 13, 2013.

By October 14, 2018, there had been 54,123 adverse reaction reports made to the federal Vaccine Adverse Events Reporting System (VAERS), including 331 deaths following administration of either the four-strain or nine-strain Gardasil vaccine.<sup>32</sup>

While that sounds like a lot, that's just a fraction of the real numbers of Gardasil reactions, injuries and deaths that have actually occurred, as most doctors either do not report them to the government, or they instead make reports directly to Merck (which are not made public).<sup>33,34,35</sup> In fact, less than 1% of adverse vaccine reactions are reported to VAERS.<sup>36</sup>

The facts surrounding the HPV vaccine are such that they raise many questions. Yet those who dare ask them are unfailingly attacked as "anti-vaxxers" or "vaccine deniers."



It's a sad fact that you cannot get an accurate picture of the situation from mainstream media, as the press is "held hostage," as it were, by drug advertising dollars. They simply won't report both sides of the story as this will result in the loss of millions of dollars in advertising.

It's also difficult to get a clear view by looking at the medical literature, as there's a tremendous amount of censorship going on there as well. In the film, Dr. Sin Hang Lee, a pathologist known for using cutting-edge DNA sequencing for molecular diagnoses and director of Milford Molecular Diagnostics, comments on this, saying most of his papers on the HPV vaccine and its potential adverse effects have been rejected by the medical journals. "It's editorial censorship," he says.

## **Gardasil Safety Trials Not Designed to Detect Safety Problems**

There are a few rare exceptions to the muzzling of the press though. One of them was a December 17, 2017, Slate article<sup>37</sup> in which Frederik Joelving exposed egregious flaws in Gardasil's testing.

The public was told that the three HPV vaccines marketed in the U.S. were tested on tens of thousands of individuals around the world, without any compelling evidence of serious side effects having emerged. While that reads well on paper, the shocking truth appears to be that these trials were never designed to detect and evaluate serious side effects in the first place.

According to Joelving, "An eight-month investigation by Slate found the major Gardasil trials were flawed from the outset ... and that regulators allowed unreliable methods to be used to test the vaccine's safety."

Contrary to logic, serious adverse events were only recorded during a two-week period post-vaccination. Moreover, during this narrow window of time, trial investigators "used their personal judgment to decide whether or not to report any medical problem as an adverse event," Joelving reports.

Importantly, and shockingly, most of the health problems that arose after vaccination were simply marked down as "medical history" rather than potential side effects — a tactic that basically ensured that most side effects would be overlooked. No record was made of symptom severity, duration or outcome.

Even with this gross reporting flaw, at least one Gardasil trial of the new nine-valent vaccine reported nearly 10% of subjects experienced "severe systemic adverse events" affecting multiple system organ classes, and over 3% suffered "severe vaccine-related adverse events."<sup>38</sup> Joelving writes:

*"In an internal 2014 EMA report<sup>39</sup> about Gardasil 9 obtained through a freedom-of-information request, senior experts called the company's approach 'unconventional and suboptimal' and said it left some 'uncertainty' about the safety results.*

*EMA trial inspectors made similar observations in another report, noting that Merck's procedure was 'not an optimal method of collecting safety data, especially not systemic side effects that could appear long after the vaccinations were given.'"*

## **HPV Vaccine Is Unnecessary**

As noted by Hang Lee in the film, cervical cancer is one of the least concerning types of cancer "because it takes 15 to 30 years from the point of infection with HPV to [develop into] cancer, and if you catch the precancerous changes, you can always do something about it."

In the U.S., cervical cancer declined more than 70% after pap screening became a routine part of women's health care in the 1960s. As of 2018, about 13,240 new cases of cervical cancer will be diagnosed, and about 4,170 will die from it.<sup>40</sup>

The reason why the mortality rate is so low is because your immune system is usually strong enough to clear up this kind of infection on its own, and does so in more than

90% of all cases. According to the film, the vast majority of those who die have not had a Pap smear in the last five years.

According to Shannon Mulvihill, a registered nurse and executive director of Focus For Health in Warren, New Jersey, if you get regular pap smears, your chances of dying from cervical cancer is 0.00002%.

Is it really worth sickening thousands at the off-chance the vaccine might save a handful of people from dying from cervical cancer? The fact is, PAP smears prevent cervical cancer deaths far more effectively than the HPV vaccine ever will. In the film, Hang Lee provides the following data, showing just how minuscule the potential benefit of Gardasil really is:

- HPV vaccines target 70% of HPV strains affecting human populations, though new versions target more strains
- IF these vaccines were 100%, ONE death would be prevented for every 100,000 vaccinated women, or 1.3 deaths out of 100,000 for the newer vaccines covering a greater number of HPV strains
- The average cost of Gardasil vaccination in the U.S. is about \$700 per person, which means the cost to vaccinate 100,000 girls – in the hopes it will save a single person among them from dying from cervical cancer – is \$70 million

That single death can easily be voided by more regular screening, "So, why add another \$70 million for no clear benefit?" Hang Lee says.

## **HPV – A Manufactured Crisis**

As noted by Gretchen DuBeau, executive and legal director for Alliance for Natural Health, USA:

*"This vaccine is not safe, it's not financially rational and it's not necessary. So, essentially, we've manufactured a crisis and created a solution that's very*

*lucrative for many but harms our children. We've looked at over 300 studies that show children between the ages of 3 and 11 have the HPV virus in their bodies.*

*Some studies show they have it at birth, others, you're looking at children that are preschool age, but the point is that we have a lot of ... unanswered questions about the possibility of this virus being transmitted from mother to child at birth.*

*This is critical because when one is vaccinated with this vaccine and that person already has the HPV virus, it increases their chances of developing cervical and other cancers.*

*So, we are putting our children not only at risk in all of the ways we've already seen with the adverse events ... the autoimmune conditions ... but we're also looking at the possibility of increasing, down the road, the likelihood that many of these children could develop additional cancers because of this vaccine ... This is a huge issue. We have to ask these questions; we have to study this more carefully."*

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