

# Gardasil®: The HPV Vaccine

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Gardasil® is a drug that has been promoted to females as a *cervical cancer* vaccine. In fact it is a Human Papilloma Virus (HPV) vaccine (1). This drug has been promoted incorrectly as a vaccine to prevent cervical cancer in females. However trials done prior to it being licensed in 2006 did not observe that this drug would prevent cervical cancer (2).

This drug has been promoted on misinformation supported by the Australian Health Department. The trials that were done for this drug were carried out for 2-4 years in the 16 -26 year age group - a demographic that rarely gets cervical cancer (3). The only conclusive evidence that was obtained from these trials was that the drug prevents the growth of 2 strains of HPV infection that are present in seventy percent of cervical cancer cases (2). These strains of HPV are not the cause of cervical cancer on their own - another factor is thought to be necessary to develop cervical cancer (4) (5).

Haverkos 2005, states that many investigators acknowledge that HPV infection is not sufficient on its own to induce cervical cancer. It is known that one or more other factors are necessary in order to initiate the cancer. Haverkos also acknowledges that HPV infection is not found in every patient with cervical cancer (4). There are hundreds of strains of HPV virus and scientists state that HPV infection is present in most cases of cervical cancer but not 100 percent of the time (4) (8). Munoz et al, 2006, confirm that HPV infection on its own does not cause cervical cancer (5).

In other words, females can get cervical cancer without being infected with HPV. In addition, females can be infected with HPV and not get cervical cancer. So it is clear that some other factor is required to trigger the development of cervical cancer even when

HPV is present (4) (5). Scientists have listed co-factors such as viruses, immunosuppression and dietary deficiencies as 'likely to be important' but the exact trigger for HPV infection to become cervical cancer is unknown (4) (5) (8).

As most women will become infected with HPV during their lifetime because it is a very common infection, you would then expect HPV to be present in the majority of cases of cervical cancer. Therefore the question must be asked: Have scientists proved that it is a determining factor in the development of cervical cancer?

We must also ask how did researchers in the trials of Gardasil measure the ability of this drug to prevent cervical cancer if they did not observe cervical cancer in the trials?

The measure of prevention of cervical cancer was based on the observation that there were less pre-cancerous lesions in girls (16-26) who were given the HPV vaccine than in the girls who were not given this drug (2). This observation is based on 2 assumptions: Firstly, the assumption is made that pre-cancerous lesions in this age group definitely leads to cancer. This is incorrect. It is well known in the medical field that pre-cancerous lesions in this age group are often cleared quickly by the immune system so there is no guarantee that a pre-cancerous lesion will lead to cervical cancer in this age-group (6).

The manufacturer of Gardasil®, Merck & Co., claims that the drug prevents "high-grade disease" (2). High-grade disease was measured by the presence of pre-cancerous lesions that were graded CIN II or III. These types of lesions are thought to be immediate precursors of cervical cancer (2). The time frame for CIN III to change into invasive cancer averages between 8.1 to 12.6 years while the longest follow up study in the trials for Gardasil® was only 4 years (6). In addition, it is stated that "the vast majority of women (16-26 years of age) clear or suppress HPV to levels not associated with CIN II or III (high-grade disease) and for most women this occurs promptly" (6).

Secondly, science indicates there are 15 or more strains of the HPV virus that are associated with cervical cancer but it is believed that HPV strains 16 and 18 do the most damage (2). Duesberg and Schwartz, 1992, point out that HPV strains 16 and 18 are only present in 67 percent of women with cervical cancer (7). This is confirmed by Munoz et al, 2006, who claim HPV strains 16 and 18 account for 70% of cancers of the cervix (5).

Therefore, approximately 30 percent of cervical cancer is not related to HPV infection with strains 16 and 18. Screening is still essential for women to protect against the other cancer-causing strains and cases where HPV is not present. When the U.S. FDA approved Gardasil® on June 8, 2006, it also admitted "the vaccine would not protect against less common strains of HPV" (2). But they did not emphasise this represents 30 percent of cervical cancer cases.

The assumption here is that protecting girls from infection with HPV strains 16 and 18 will guarantee they will not become infected with one of the other cancer-causing strains of HPV or contract cervical cancer. Even if strains 16 and 18 are the two most

prevalent strains of cancer-causing HPV, the theory of opportunistic species means that the space is available for infection from one of the numerous other HPV strains associated with cervical cancer. *Opportunistic species* is an ecological principle that is observed to occur in the environment. It is assumed that preventing strains 16 and 18 from infecting will prevent some cervical cancer. The illogical assumption is that other cervical cancer strains will not infect.

Screening via pap smears/tests has reduced the rate of cervical cancer in women to 1.9 deaths per 100,000 women in Australia (3). This means that in Australia less than one percent of women will be affected by cervical cancer – that is, 99 percent of women will not be affected by cervical cancer in their lifetime.

Does this risk warrant all girls taking a drug that has not been tested for long-term health effects such as chronic illnesses and other adverse reactions and death, as has occurred in young women after vaccination with Gardasil®? And for which the duration of the drug is unknown? (1).

The Australian government suggests the duration will be for at least 5 years but this cannot be known with any certainty as the follow up in vaccinated women has been for only 4 years (1).

Has the health department or the media informed the public that the safety and efficacy trials for this drug were carried out with funding from Merck pharmaceuticals, the manufacturer, and that 8 of the 10 researchers had links with Merck? (2)

This means the risk assessment for this drug was carried out by the manufacturing pharmaceutical company and promoted to the public on misinformation that is supported by the Australian Health Department. Again the precautionary principle was not applied to this drug even when the risk of cervical cancer for women in Australia is extremely low. Who is protecting the public interest in health now that corporations fund the research and influence the risk assessment?

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