

# A Critique Of The Promotional Campaign For Gardasil – HPV Vaccine

By **Judy Wilyman**  
PhD Candidate  
Murdoch University



Dr. Diane Harper is a researcher who was involved in the safety and efficacy trials for the Human Papillomavirus (HPV) vaccine – Gardasil®. This drug is observed to prevent infection from 2 strains of HPV virus (16 and 18) and it has been promoted to the public as being preventative against cervical cancer. The clinical trials for this drug were funded by the pharmaceutical company Merck and many of the researchers were employed by Merck (1). On the 19<sup>th</sup> August Dr. Harper spoke out about the concerns she has regarding the safety of this drug and its ability to prevent cervical cancer. She is to be commended for doing this and her comments have been presented in a CBS media release titled *Gardasil® Vaccine causes More Deaths and Damage than the Vaccine itself* (2). As a parent and a researcher, I have been compelled to write the following article about Dr. Harper’s comments because it is apparent that the public has been misinformed about this drug.



**Dr Diane Harper, a lead researcher in the development  
of the humanpapilloma virus vaccine**

In the interview Dr. Harper gave to CBS she stated that she believes “the public should receive more complete warnings before receiving the vaccine”. This is incorrectly stating the problem. Instead of ‘more complete warnings’ I believe it is extremely important that parents are given accurate information on Gardasil®. This drug has been promoted as a cervical cancer drug when in fact it has only been observed to prevent HPV infection (1).

Health authorities have claimed that this vaccine will be effective for 5 years. Considering this vaccine was tested for only 4 years in women 16 – 26 years of age, I think it is important that parents are informed how this information was generated. Parents would also like to know what ‘protection’ for 5 years actually means. Given that we have evidence it will protect against infection from HPV strains 16 and 18 but we have no evidence that it is the determining factor needed for carcinomas to form (3) (4). So it *may* prevent some cervical cancer (remembering that HPV does not cause cervical cancer on its own – another co-factor is required) *assuming* these 2 strains (16 and 18) are a determining factor in cancer development and *assuming* there is no infection from one of the other 12 HPV viruses known to be associated with cervical cancer development in humans (3) (4).

The US CDC claims the vaccine is ‘safe and effective’ but where is the supportive data for this statement? Vaccine safety and efficacy studies for Gardasil® were funded by Merck and other pharmaceutical companies. As producers of the vaccine they have a serious conflict of interest. Consequently the public is entitled to demand accountability and rigour in the presentation of immunisation policies. Particularly since Merck’s chief executive officer was quoted in 2006 claiming ‘Gardasil® was the pharmaceutical brand of the year for building a market out of thin air’ (5).

This media hype is also supported by the fact that cervical cancer is not a significant problem in all countries. Yet it was portrayed to women as the “second most life-threatening cancer among women worldwide (3). In developed nations where Pap Smear Screening Programs have been implemented cervical cancer is a very low risk to women (3). It is almost 100% curable when it is detected early (6) and in Australia it is listed as the 18<sup>th</sup> most common cancer in women (5).

In addition, it remains unproven that HPV infection is the determining factor in carcinoma development given that the majority of women are infected with HPV but the majority of women do not get cervical cancer (3) (4). Pfister (1990) confirms this by stating “vaccination is not yet justified as there is no formal proof for HPV causing cancer” (8) He continues by saying that “although the latter is certainly true, the best way to prove a necessary role of HPV in genital cancer development would be prevention by vaccination”. This is particularly interesting as he finishes by saying “extensive research is needed before a vaccine will be available”. Yet Haverkos is still stating in 2005 that many scientists admit they still do not know what the cofactor is that is necessary to turn HPV infection into a carcinoma (3).

Until a truly independent body is allowed to assess the data that pharmaceutical companies are presenting to general practitioners, governments and the public, the health of the community will continue to be at risk. We will continue to see chronic illness increase in the population as the government spends greater amounts of money on health. Is anybody going to argue that the primary interest of pharmaceutical companies is women’s health or that their primary interest is the health of the population? Pharmaceutical companies have a serious conflict of interest and nobody is making them accountable. The public is sitting back as Merck informs us that the 32 deaths after Gardasil® vaccination were a coincidence. What sort of science is this? Are our children’s lives not important enough to apply the Precautionary Principle to this vaccine – a vaccine which is of dubious benefit?

Not only are we told that the benefits of this vaccine are not fully determined but the public is informed that the onus is on us to prove that the vaccine has caused these deaths. In other words, manufacturers do not have to prove the vaccine cannot cause deaths before they use it on our daughters. Why have we allowed the Precautionary Principle to be turned upside-down? This principle states the ‘*burden of proof of harmlessness is on the manufacturer not the general public*’. How is it that this unethical situation is allowed to persist? We can no longer trust the government or medical practitioners to look after public health because their decisions are influenced by financial ties to pharmaceutical companies.

Dr. Harper's article states that 'Merck has confidence in the safety of Gardasil®'. Did anyone expect Merck to say they didn't have confidence in a product they have spent millions of dollars investing in? Why should this statement give us confidence in the vaccine? How confident would we feel if we re-state it correctly as 'Merck continues to have confidence in Gardasil's® safety profile as evidenced from the studies Merck has carried out and funded'. How confident does this make us feel?

Dr. Harper reports that Lou Gehrig's disease (*Amyotrophic Lateral Sclerosis -ALS*), a progressive neurodegenerative disease that attacks motor neurons in the brain and spinal cord has been reported after Gardasil® vaccination. It is also reported that 32 deaths have occurred plus many serious adverse reactions. There is a statement by Dr. Slade later in the article from the Centers for Disease Control and Prevention (CDC), saying that a third of the possible deaths were left out of the statistic. But instead of taking a precautionary approach for this non-essential vaccine Merck tells us "just because patients died just after the shots doesn't mean the shots were necessarily to blame". Is this for real? Parents would like to know – and are legally entitled to know -whether the vaccine can cause these types of reactions before the vaccines are used on our children – not after they have been used on our children. To date Merck has made 1.4 billion dollars from this experiment (9).

Dr. Slade reports that the risk of serious events including death after gardasil was 3.4/100,000 doses distributed. Dr. Harper then states that 'the rate of serious adverse events is on par with the death rate of cervical cancer'. This figure is then corrected because the figure was determined by using the total number of doses that were produced by the manufacturer and many of these (one-third) are still sitting in the refrigerator waiting to be distributed. Therefore using a smaller denominator the incidence of serious adverse events is now 5 fold greater than the incidence of cervical cancer – which in fact varies between countries. This measure of harm is based on the *assumption* that the vaccine will prevent some cervical cancer.

In other words, we have seriously increased the amount of chronic illness and deaths in young women without a guarantee that cervical cancer will be reduced. Dr. Harper asks 'how parents value this information?' Parents are very angry that our trust in the medical profession has been betrayed by the governments who have not put the public interest first. Governments have allowed the pharmaceutical companies to fund Professional Medical Associations in order to influence the promotion of this vaccine to the public (9).

Dr. Harper goes on to say that she agrees with Merck and the CDC that this vaccine 'is safe for most girls'. What is this statement being based upon when chronic illness has not been factored into the safety trials that were carried out by Merck? The chemicals in vaccines can affect biological systems hours, months or years after exposure (10). This vaccine contains 225 micrograms of aluminium adjuvant which is several times more than other vaccines (1). It has been known since 1966 that this adjuvant is linked to hypersensitivity reactions in humans (11). The results of the trials showed numerous adverse reactions from Gardasil® and the placebo that contained aluminium adjuvant (1). The vaccine was also linked to autoimmune diseases in the trials, in particular an increase in arthritis and rheumatoid arthritis (1).

A further point is made regarding the fact that the vaccine won't protect against 30 percent of cervical cancer. This is because there are at least 14 HPV strains that cause 90% of cancers (12). HPV strains 16 and 18 are only associated with 70 percent of cervical cancers in women. The following statement by Dr. Harper about gardasil vaccination needs clarification 'should women believe this is preventative for all cancers – something never stated but often implied in the population...'. The reason the public believes that Gardasil® vaccination will protect against all cervical cancer is because that is what they have been told in

education programs in schools and through the media, which are funded by governments and pharmaceutical companies.

The information presented to young girls did not emphasize that 30 percent of cervical cancer was not protected by the vaccine. It was implied to women that the vaccine would protect against all cervical cancers. This problem has arisen because of the misinformation presented to women about this vaccine. This information has been supported by the health departments and the medical profession of all countries. Dr. Harper is to be commended for speaking out. However, claiming that Gardasil® vaccine could be a 'miserable failure' is understating the problem. There's great urgency to determine whether Gardasil® has precipitated chronic illness and death. That determination would make it a huge public health disaster if it is established that HPV 16 and 18 are not the determining factor in the progression of dysplasia to cervical cancer. Public health authorities should have required these answers before Gardasil® was promoted to women not after the event.

**Judy Wilyman**  
**PhD Candidate**  
**Murdoch University**

**Acknowledgements:**

I would like to acknowledge Catherine Frompovich for her comments on the structure of this paper and for the support of Associate Professor Peter Dingle.

**References:**

1. Merck and Co. 2006: GARDASIL [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18), Prescribing Information as cited in *Investigate before you Vaccinate: making an informed decision about vaccination in New Zealand*, 2006, published by Immunisation Awareness Society, New Zealand.
2. Attkisson S, 19<sup>th</sup> August 2009, CBS News, "Gardasil Vaccine Causes More Deaths and Damage than Cancer Itself", *Interview with Dr. Diane Harper*.
3. Haverkos H, 2005, Multifactorial Etiology of Cervical Cancer: A Hypothesis, *Medscape General Medicine*, v 7 (4)
4. Munoz N, Castellanague X, Berrington de Gonzales A, Gissmann L, HPV Vaccines and Screening in the Prevention of Cervical Cancer, Ch. 1: HPV in the Etiology of Human Cancer, 2006, *Vaccine*, Vol 24, Suppl. 3, 21 August, p S1-S10.
5. Herskovits B. 2007, Brand of the Year, *Pharmaceutical Executive*, 27 (2): 58-65
6. Schiffman M, 2002 as cited in Kircheimer S, Herpes Linked to Cervical Cancer, *WebMD HealthNews*
7. Australian Government, Australian Institute of Health and Welfare (AIHW), Facts about Cervical Cancer, 2006.
8. Pfister H (Ed.), 1990, Papillomaviruses and Human Cancer (p.248), CPR Press Inc, Florida, USA

9. Rothman S and Rothman D, 2009, Marketing HPV Vaccine: Implications for Adolescent Health and Medical Professionalism, *JAMA August 19, Vol 302, No 7*
10. Eldred BE, Dean AJ, McGuire TM, Nash AL, 2006, Vaccine Components and constituents: responding to consumer concerns, *Medical Journal of Australia*, Vol. 184 Number 4, 20<sup>th</sup> February 2006.
11. Greville, RW. , 1966, Recent and Future Development in Immunising Vaccines, *The Medical Journal of Australia*, May 21, p. 908.
12. Smith J 2002 as cited in Kircheimer S Herpes Linked to Cervical Cancer, *WebMD HealthNews*