## **Cervical Cancer Vaccine Deception**

By Patricia Bohackyj

Cervical cancer, which is cancer in the lining of the cervix, affects about 13,000 women in the US each year and about 4,000 die. Worldwide, half a million succumb to the disease, with 225,000 dying. In 2002 in Australia 131\* women died from this disease (1.9 per 100,000 women, World Standard Population).

In the 1970's it was suggested that the Herpes Simplex Virus (HSV) was the sexually transmitted cause of cervical cancer, which was supported mostly by population studies. Then in the 1980s another view emerged – which is well accepted now – that cervical cancer is strongly related to the transmission of Human Papilloma Virus (HPV). But even the National Cancer Institute says that, "direct causation has *not* been demonstrated".<sup>(1)</sup>

The HPV group has more than 100 viruses (and possibly an infinite number of variants), only about 30 of which are said to be linked to cervical cancer. However, in 1992 molecular biologists, Peter Duesberg and Jody Schwartz of the University of California, USA, found that it may be that the presence of either HPV or HSV was due to infection of proliferating cancer cells; therefore a person with cervical cancer would be more susceptible to these infections. In other words, they were indicators of infection, rather than the cause of cancer.

It is estimated that 75% of sexually active men and women are exposed to HPV at some time. When it came to the testing of the vaccine, it was decided to exclude all women who had been found to be infected with HPV-16, which is believed to be found in 50% of cases of cancer of the cervix. Putting it plainly, the study selected women that had good immune systems that kept them from expressing the HPV DNA markers that show previous exposure to this virus. They may have been exposed to HPV viruses in the past, but showed no sign of antibodies. Also study subjects were selected who had no history of cervical lesions and few sexual partners – clearly those least likely to develop this disease.

And who researched the vaccine? The manufacturers themselves did. Two clinical trials were conducted, one by Merck and the other by GlaxoSmithKline. The trials were very similar in design outcome but differed mainly in the origin of the recombinant vaccine. Merck's 'Gardasil' is a capsid (outer shell of virus) protein that forms a virus-like particle totally lacking DNA and was produced using transgenic yeast (a genetically-modified vaccine containing virus-like protein particles from HPV types inserted in to yeast cells). The US FDA warns that "females who are allergic to yeast or to any component of the vaccine should *not* receive Gardasil.<sup>(2)</sup> Other ingredients include aluminium, sodium chloride, polysorbate 80 and borax.

GlaxoSmithKline's 'Cervarix' HPV vaccine is still going through the approval process, which is due to be completed April 2007. This vaccine is also a capsid protein for the same strains, but was produced using a baculovirus propagated in insect cells.<sup>(3)</sup> It contains 225 micrograms of aluminium-based adjuvant to increase the immune response.

The age of the study group was 15 to 25 years, but the approved target group for the vaccine is 9 to 26 years. The Merck study group lasted four years while the GlaxoSmithKline study lasted two years and three months. In phase one of the trials, there were only 768 vaccinated subjects in the Merck study and just 560 in the GlaxoSmithKline study. Subjects received a single intramuscular inoculation.

These were followed by a larger study involving 20,541 women aged 16 to 26 years. The participants were followed up for only 14 days after receiving either the vaccine or the placebo (containing aluminium). Reactions included: headache, nausea, diarrhoea, vomiting, fatigue, abdominal pain, dizziness and myalgia (muscle pain). Autoimmune problems reported were juvenile arthritis, rheumatoid arthritis and reactive arthritis.

There were five reported cases of babies with congenital birth defects being born to women who had had the vaccine within 30 days of becoming pregnant. No long-term study has been conducted of its safety or of possible interactions with other vaccines administered at the same time.

If cervical cancer vaccine is used in conjunction with Hepatitis B and/or DTP vaccines, it is going to be even more difficult to assess the overall impact on the woman's health in the short term or the long term. Also, the vaccine has *not* been evaluated for carcinogenic (cancer causing) potential.<sup>(4)</sup>

Approved are three doses of HPV vaccine to be given over six months – the first dose at the elected date, the second dose two months later, and third dose six months after the first dose (according to MIMS). Millions of women and girls around the world will be targeted for this vaccine, but these studies cover less than 0.01% of the population that it will be marketed for. The vaccine studies had screened all the recipients and had studied mainly "young women who had *not* been exposed to any of the four HPV types in the vaccine".<sup>(5)</sup>

The US National Cancer Institute website states that no one who received all three vaccine shots developed an HPV-16 infection. However, "twenty-two women in that group did develop cervical abnormalities that can lead to cancer". Also, the "vaccine offers no protection against other types of HPV infections that can also cause cervical cancer. In addition, "it's unknown whether the vaccine's protection against HPV-16 is long-lasting," and finally, "it does not prevent HPV-16 infection already present at the time of vaccination from progressing to cancer".<sup>(6)</sup>

Health authorities are warning that use of this vaccine does not suggest that there will be an end to Pap smears, but possibly these could be undertaken less often than the recommended every two years. Incidentally, Pap smears are known to be inaccurate and can produce a wide range of false negative results, which was the reason for the HPV study – see the Pap test.<sup>(7)(8)</sup>

The Department of Health and Ageing reported recently "that Australia has the secondlowest incidence of cervical cancer and the lowest mortality rate from cervical cancer in the world".<sup>(9)</sup> State and Federal governments in Australia spend more than \$90 million annually screening women for cervical cancer. Australia will now spend \$436 million making the vaccine free for girls and women aged 12 to 26. There is talk of vaccinating young boys too.

Can the vaccine cause a cancer to progress? Suppose the vaccine is given to someone with undetected cancerous lesions in the cervix or someone already carrying the HPV virus before they get the vaccine? What then?

Sadly, investigations into other possible causes of cancer – for example, the contraceptive pill, lubricants and spermicides and other toxic substances such as in personal care products – are ignored or not researched. Very little consideration, if any, is given to nutrition, lifestyle, emotional wellbeing, proper breathing, good sleep, exercise and hydration which can all play an important part in preventing or recovering from cancer.

Research published in 2003 concluded that deficiencies of selenium and zinc might be risk factors in developing cervical cancer.<sup>(10)</sup>

It seems illogical and too simplistic that a vaccine can prevent cancer. I suggest that this vaccine is another delusional hope for reducing the risk of cancer, and a great generator of revenue for the vaccine inventors and manufacturers.

Vaccination is *not* compulsory in Australia and is not required for school entry. There are no financial penalties for not vaccinating.

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## REFERENCES

1. National Cancer Institute U.S. National Institute of Health http://www.cancer.gov/cancertopics/pdq/prevention/cervical/HealthProfessional/page3

2. US FDA Product Approval Information – Licensing Action 'Gardasil' Questions and Answers http://www.fda.gov/cber/products/hpvmer060806qa.htm

3. "HPV gene into insect cells using a virus called baculovirus which infects insect..." http://www.urmc.rochester.edu/pr/current\_research/Cervical\_Cancer\_Vaccine/

4. National Cancer Institute U.S. National Institute of Health http://www.cancer.gov/clinicaltrials/results/cervical-cancer-vaccine1102

5. Source: CDC HPV Questions and Answers. http://www.cdc.gov/std/hpv/STDFact-HPV-vaccine.htm.

6. National Cancer Institute U.S. National Institute of Health http://www.cancer.gov/clinicaltrials/results/cervical-cancer-vaccine1102

7. 5 to 35% inaccuracies with the Pap smear tests Wikipedia, online encyclopaedia.

8. A false positive Pap test means that a patient is told she has abnormal cells, but the cells are actually normal. A false negative Pap test occurs when a specimen is called normal, but the woman has a significant abnormality that was missed.

9. Original sourced from www.blooberg.com Australia to subsidise Merck Cervical Cancer Vaccine (Update2) by Vena Poljak and Gemma Daley; see also Medical Journal of Australia (MJA) http://www.mja.com.au/public/issues/185\_09\_061106/wai10809\_fm.pdf

10. The website for the Cervical Cancer and HPV Vaccine Immunisation Awareness Society is http://www.ias.org.nz/pdf/cervical\_cancer\_and\_the\_hpv\_vaccine.pdf

\* WHO World Standard Population (target ages 20-69 years)