Safety Concerns for the HPV vaccine: Gardasil

- Gardasil was licensed in 2006 and up to September 2012 there were 21,265 adverse events (AE’s) reported to the US CDC and FDA alone. Globally there have been many more AE’s associated with HPV vaccines. The US CDC data includes 78 deaths, 363 life-threatening events, 609 permanently disabled, 2,000 cases listed as serious or prolonged hospitalisation and 9,565 requiring an emergency room visit.

- This is only a proportion of the AE’s because the US CDC monitoring system and Australia’s TGA monitoring system are passive surveillance systems. This means they rely on voluntary reporting of temporal events only. As vaccine ingredients can cause delayed adverse events the only type of system that would be able to establish causal relationships with adverse events is an active surveillance system: one that follows the health outcomes for every vaccinated individual for a minimum of 1 year.

- The CDC and the TGA admit that the surveillance systems cannot establish causal relationships between the vaccine and the adverse events. This allows the government to claim that the adverse events are a ‘coincidence’. This is not a scientific evidence-based policy.

- It is known that passive reporting systems will only represent about one-tenth of the possible adverse events that actually occur. Any delayed reactions will not be reported.

- Despite the voluntary reporting of adverse events Gardasil has been responsible for 61% of all serious AE’s compared to all other vaccines in the US vaccination schedule (including 63.8% of all deaths and 81.2% of all cases of permanent disability) in females younger than 30 years of age.

- HPV vaccine contains genetically modified DNA.
- Gardasil contains 225 micrograms of aluminium adjuvant (225 ug amorphous aluminium hydroxyphosphate sulphate). Many times more than most vaccines and this adjuvant is known to cause allergies/anaphylaxis and autoimmune reactions in humans. 20

- The trials did not use a true placebo to test the safety of the vaccine. The manufacturer funded clinical trials used the adjuvant, aluminium hydroxyphosphate sulphate (classified as a neuro-immunotoxic substance) as the placebo in the unvaccinated group and this substance does not allow the researchers to accurately compare the adverse health outcomes that might occur from the vaccine with a group that is completely unvaccinated.

- For example, in the pre-licensure clinical trial for Gardasil there were 245 serious reactions (indicative of an autoimmune disease) from the ‘vaccine’ group and 218 from the ‘aluminium hydroxyphosphate sulphate’ group. How would these figures compare to a group with no vaccine or aluminium adjuvant? This is a flaw in the experimental design of the trial. 22.

- Other ingredients of the vaccine include: sodium borate (borax), polysorbate 80, L-histidine hydrochloride, 4 recombinant VLP’s: HPV types – 16, 18, 11 and 6, amino Acids, carbohydrates, mineral salts, vitamins. 13

- There are an unusually high number of AE’s associated with HPV vaccines with nervous-system-related disorders ranking the highest in frequency. 14. When the global reports of adverse events are pooled for Gardasil the data suggests that the risks of HPV vaccination have not been fully evaluated in the pre-licensure trials. 14.

- Yet the US CDC and the Australian TGA are evaluating selective data (not the global safety data) and they are concluding that ‘HPV vaccines are safe and effective’.
The many known side-effects from HPV vaccines include death and life-long neurodegenerative/autoimmune disorders. These are documented in the pre-licensure clinical trials and at www.sanevax.org

Over the past 2 decades pharmaceutical companies have gained unprecedented control over the evaluation and registration of their own products. This fact is reflected in the poorly designed safety and efficacy trials for vaccines for which there is no accountability.

This is particularly the case because many vaccines are licensed in the USA where vaccine manufacturers are legally free from ordinary tort liability. Vaccines are a product that are described as ‘unavoidably unsafe’ and there is no onus on manufacturers to make them as safe as possible because they are free from liability.

Parents must ask if they wish their children to be subjected to the risk from a vaccine that has not been proven to prevent cervical cancer when there is already a safe and effective PAP screening procedure that will still be required anyway.

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www.vaccinationdecisions.net

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