Reply to the TGA (16th November 2012)

To the Therapeutic Goods Administration (TGA)

RE: My reply to the TGA re HPV vaccine

Dear Debbie **(no surname provided),**

Thankyou for replying to my letter, however you have not answered any of the questions that consumers are asking about this vaccine. The TGA continues to claim that: **'the HPV vaccine is safe and effective and the benefits of the vaccine outweigh its risks'** – **without providing evidence**.

Consumers would like to believe this message but they are looking for **evidence** and it is not provided In the TGA-approved Product Information (PI) that you suggested could be found by searching the TGA website. *If it is in the PI* then please provide the answers to the questions I asked previously (August 2011) and which I will summarise for you here:

1. This vaccine has not been demonstrated to prevent cervical cancer so why is it promoted as a cervical cancer vaccine and not an HPV vaccine?
2. If the majority of pre-cancerous lesions in 16 -26 year old women clear without medical treatment and are not an indication of cancer later in life (as the Australian Government states) how can this end-point (pre-cancerous lesions) be used as an indication of the number of cervical cancer cases that will be prevented by using this drug? This was the end-point used in the clinical trials.
3. How could the clinical trials make an accurate estimate of the harm this drug will cause when the placebo that was used in the 'unvaccinated' group was the **aluminium adjuvant in the vaccine** (aluminium hydroxyphosphate sulphate)? – a chemical that is known to be linked to delayed reactions including autoimmune diseases and hypersensitivity.
4. Why does this vaccine contain sodium borate (pesticide) and polysorbate 80 – both known to cause infertility in laboratory rats?
5. Can a 'passive' monitoring system such as that used by the TGA allow the regulator to make causal links between adverse events (AE's) and the HPV vaccine? This system relies on voluntary reporting - how can you determine the frequency and cause of events if you are not 'actively' following up all health outcomes of vaccinated people for a period of about 5 years?
6. If women vaccinated with HPV vaccine can still get cervical cancer (*because of the other 13 causal subtypes of HPV that are not covered by the vaccine)* **and** if the vaccine has not been

proven more effective than Pap screening combined with LEEP (the procedure used to remove abnormal cells) **then why are women and school children not being informed of this so they can decide for themselves if they want to risk the side-effects of this drug?**

These are the questions that many consumers would like the TGA or Professor Ian Frazer to answer. I will publish your reply on my website with these questions and I hope that you will answer them before this vaccine is used in boys and girls in schools in 2013.

I will also provide 2 links that indicate the serious harm that this vaccine is causing to an *unknown* percentage of the population. You can also find more examples of this harm at www.sanevax.org .

Here is a link to Kristin Clulow who was seriously affected by HPV vaccine several years ago:

http://www.abc.net.au/news/2012-08-27/newcastle-woman-raises-concerns-about-cervical-cancer-vaccine/4224152?microsite&section=news

Here is a link to a report in the British Medical Journal (BMJ) of a young girl who has become infertile at 16 after being given the HPV vaccine:

BMJ Case Reports 2012; doi:10.1136/bcr-2012-006879

I look forward to your prompt reply to these questions.

Kind regards,

Judy Wilyman

www.vaccinationdecisions.net