## Testimony on human papillomavirus (HPV) vaccination of young girls for cervical cancer prevention

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I am a pathologist with more than 50 years' experience in cancer diagnosis, including evaluation of Papanicolaou (Pap) smears for prevention of cervical cancers. My training included a residency in New York Hospital where the Pap smear was invented. I was board-certified in the U.S.A. and admitted as a Fellow of the Royal College of Physicians and Surgeons of Canada in pathology in 1966. I have been a qualified physician in the U.S.A. and Canada, and am the holder of a certificate of full registration issued by the General Medical Council, London, Great Britain.

In the past 8 years, I have published 10 peer-reviewed articles on detection of HPV DNA in human samples and in the vaccine Gardasil® by DNA sequencing [see references 1-10]. I first reported beyond a reasonable doubt that Gardasil® contains residual HPV DNA fragments bound to the aluminum adjuvant in the vaccine, a previously unrecognized compound whose physiopathologic effects on humans are still poorly understood.

I have reported that I found HPV DNA which was similar in conformation to the HPV DNA in the vaccine Gardasil® in the postmortem blood and splenic tissue obtained at autopsy of a formerly healthy New Zealand teenage girl who suffered a sudden unexpected death in sleep 6 months after 3 intramuscular injections of Gardasil®.

I have also examined the microscopic sections of the postmortem heart obtained at autopsy from the body of a healthy 14-year boy, a football player, who died in sleep at night a few hours after he received the second injection of Gardasil®. The left ventricle of the heart of this 14-year old decedent showed a healing recent myocardial infarct which had occurred silently and symptomless after the first Gardasil® vaccination.

Based on my personal professional experience and my understandings from numerous cases of acute disseminated encephalomyelitis after receiving Gardasil® vaccination reported in the literature, I have reached a conclusion that Gardasil® vaccination is associated with potential serious adverse reactions in some genetically or physically predisposed vaccinees. The residual viral DNA in the vaccine may play a role in the pathogenesis of these adverse reactions.

Since cervical cancer has been proven to be almost 100% preventable by detection of the precancerous changes through regular cervical screening with Pap smears and HPV testing and treatment of the precancerous lesions, the proposal of adding general HPV vaccination to a well-screened women population is superfluous.

As of now, the efficacy of HPV vaccination in reducing cervical cancer rates is still unknown. All the clinical trial data submitted for HPV vaccine approvals were based on using precancerous changes which are largely self-reversible as surrogate endpoints for statistical analysis.

The true efficacy, if any, of the genotype-specific human papillomavirus (HPV) vaccines in cervical cancer prevention cannot be determined for another 30 years because the average age of cervical cancer patients is about 50.

The health risks of mass HPV vaccination of the young women at the age of 11-12 with the hope to prevent cervical cancer which may or may not develop at the age ~50 and which is preventable by good women's health care outweigh the possible benefits. Cervical cancer is primarily a disease among unscreened or rarely screened women.

The evidence supporting these conclusions is summarized as follows.

- [1] Using Pap smear to detect precancerous changes for early preventive treatment in the U.S. A. has reduced the incidence of cervical cancer from 44 in 100,000 women in 1947 to about 5 in 100,000. Now, cervical cancer is a rare disease in the U.S. A., most among women who have no regular gynecologic health care, especially among new immigrants and the underprivileged. The average cervical cancer patient is about 50 years old.
- [2] The age-standardized mortality rate of cervical cancer is 1.7 per 100,000 women in the U.S.A. Even if HPV vaccination were to be 70% effective in reducing cancer death as advertised, it would cost the society ~\$70 million (cost for 3 doses of Gardasil® plus physicians' fees per person is about \$700. \$700 X 100,000=\$70 million) to reduce one cervical cancer death after age 50 which can be prevented by improving women's health care with less money.
- [3] According to the vaccine manufacturer's prescribing information, 2.3% 2.5% of the HPV vaccinated people exhibit serious adverse reactions. This means that there are 2,300-2,500 per 100,000 vaccinated girls at the age of 11-12 whose life will be disrupted at this very young age in terms of the need to spend their time as patients in the doctors' offices or hospitals. Such disruption which would not have occurred without HPV vaccination may have adverse impacts on their normal schooling and physical development. The price is too high for these girls to pay for preventing a possible development of cervical cancer with the odds of 5 in 100,000 chances at age 50 which can be prevented by a better life style and good gynecologic care.
- [4] According to a CDC publication, syncope is the most common adverse reaction reported after Gardasil® injections. Syncope is defined as temporary loss of consciousness, or "fainting" or "passing out." It is usually related to temporary insufficient blood flow to the brain or the heart, namely a sudden drop of blood pressure or hypotension. As a result, all people receiving intramuscular HPV vaccination are advised to be observed in the physician's office for 15 minutes before leaving. No other vaccines have such a written required precaution. The finding of HPV viral DNA in the vaccine Gardasil® has provided a probable molecular mechanism for causing such hypotension. Viral DNA molecules, as those found in Gardasil®, when transfected with the aluminum adjuvant into the macrophages after intramuscular injection, are now known to stimulate release of many immune molecules some of which, such as the tumor necrosis factor-α, are potent myocardial depressants. Tumor necrosis factor is capable of causing hypotension and even death in experimental animals and in humans.

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For references please see next page

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