Vaccination Risk Awareness Network Inc

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URGENT! Gardasil vaccine may increase risk of cervical cancer.

It has come to our attention that injection of Gardasil vaccine into females who are carrying vaccine-type HPV puts these females at risk of developing cervical cancer. A document submitted to the US FDA, written March 7, 2007 states:

"A PCR-based HPV detection device with provision for accurate HPV genotyping is more urgently needed now because **vaccination with Gardasil™ of the women who are already sero-positive and PCR-positive for vaccine-relevant genotypes of HPV has been found to increase the risk of developing high-grade precancerous lesions by 44.6%**, according to an FDA VRBPAC Background Document: Gardasil™ HPV Quadrivalent Vaccine . May 18, 2006 VRBPAC Meeting." [my emphasis]

(The above quotation is taken from PDF pg 9 of 68, document pg 8 of the following:

File Format: PDF/Adobe Acrobat
an FDA VRBPAC Background Document: GardasilTM HPV Quadrivalent Vaccine . May. 18, 2006 VRBPAC Meeting. **www.fda.izov/ohrms/dockets/ac/06/briefing/2006-4222B3 ...**
www.fda.gov/OHRMS/DOCKETS/DOCKETS/07p0210/07p-0210-ccp0001-01-vol1.pdf

In the section 'XII. Conclusions and summary' of the same article, last paragraph, is the following:

"In a document submitted to the FDA by Merck & Co., Inc., it is recorded that injection of the HPV vaccine, Gardasil™, into women who are sero-positive and PCR-positive for the vaccine-related HPV genotypes increases the risk of developing high-grade intraepithelial lesions by 44.6%. As of to-date, there are no FDA approved PCR-based methods for HPV genotyping on the market in spite of the fact the PCR technology has been available for about 20 years. This petitioner urges the FDA to play a leadership role to guide the device manufacturers to introduce their most sensitive and most specific PCR-based IVDs to assist the sexually active women who are still considering immunization against HPV infections without inadvertently receiving a vaccine that is not only ineffective, but may augment the risk of developing a precancerous lesion in the cervix. …" [my emphasis]

The following table from '**VRBPAC Background Document Gardasil™ HPV Quadrivalent Vaccine May 18, 2006 VRBPAC Meeting'** at http://www.fda.gov/ohrms/dockets/ac/06/briefing/2006-4222B3.pdf showed decreased efficacy of -44.6% when Gardasil™ was given to subjects who had vaccine-relevant HPV infections:

Table 17. Study 013: Applicant's analysis of efficacy against vaccine-relevant HPV types CIN 2/3 or worse among subjects who were PCR positive <u>and</u> seropositive for relevant HPV types at day 1. [From original BLA, study 013 CSR, Table 11-88, p. 636]										
	Gardasil™ **N=2717**								**Placebo** **N=2725**	
Endpoint	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	N (subgroup)	Number of cases	PY at risk	Incidence Rate per 100 person years at risk	Observed Efficacy	95% CI
HPV 6/11/16/18 CIN 2/3 or worse	156	**31**	278.9	11.1	137	**19**	247.1	7.7	-44.6%	<0.0, 8.5%

Needless to say, we are most concerned about this risk. Considering that school-based HPV vaccine programs are already in progress in much of the country; that, according to the NACI *Statement on Human Papillomavirus Vaccine, pg 15*, "27% of teens between the ages of 14 and 17 years reported being sexually active. Of these, 20% reported having had sexual activity by 15 years of age."; and that skin-to-skin contact alone can allow transfer of HPV – **it is imperative that you halt any further use of Gardasil.** Only girls and women who can be screened prior to vaccination should be allowed to receive this vaccine, and only then if highly sensitive and specific testing is used. **<u>We ask for your immediate attention to this matter.</u>**

Sincerely,

Edda West,
VRAN coordinator
www.vran.org