



# AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE

The American Society for Reproductive Medicine is a medical professional society with close to 8,000 members committed to promoting the reproductive health of women and men through research, professional and patient education, and advocacy in health care policy.

We appreciate the council providing us the opportunity to express our support for approval of Merck's Gardasil human papillomavirus vaccine. Approval of this vaccine, which protects against the most common strains of HPV associated with cervical cancer, will eventually contribute to a significant decrease in the incidence of this deadly disease in the United States.

Human papillomavirus is one of the most common sexually-transmitted pathogens. According to the Centers for Disease Control, approximately 20 million people in the US are currently infected with HPV and about 6.2 million Americans get a new genital HPV infection each year. In fact, CDC estimates that by age 50, at least 80% of women will have acquired a genital HPV infection.

Of the thirty varieties of HPV that are sexually transmitted, more than 13 are associated with increased rates of cervical cancer. Two of these strains, HPV 16 and 18- which Gardasil immunizes against- are associated with 70% of cervical cancer cases. Although HPV infections usually resolve themselves, this does not always happen. And an individual with a suppressed immune response who contracts an oncogenic strain of HPV is at risk of developing cancer.

The virus is transmitted through skin-to-skin contact. Even though condoms provide some protection, they do not adequately protect against HPV transmission since they do not cover the affected epidermis completely. And while the risk of HPV infection can be greatly minimized through behavioral controls- sexual abstinence forever is not practical for most people and maintaining a monogamous relationship is no guarantee that your faithful partner has not previously contracted a persisting HPV infection.

Despite the wide availability of Pap tests to detect cervical cell changes and cervical cancer in its earliest stages, the American Cancer Society estimates that in 2006 almost 10,000 American women will discover that they have cervical cancer. And 3,700 of them will die from it.

Gardasil has been demonstrated to be highly effective and safe. Phase III trials showed that it prevented 100% of high-grade cervical pre-cancers and non-invasive cervical cancers associated with HPV types 16 and 18.

Because almost all cases of cervical cancer are instigated by HPV infection, availability of an HPV vaccine against the predominant cancer causing HPV strains will greatly reduce the rates of HPV infection and consequently cervical cancer.

And we believe that the vaccine should also be made available to men because even though the effects of HPV infection in men are less well quantified, oncogenic HPV has been implicated in anal cancer and cancer of the penis. In addition, male vaccination would reduce the incidence of infection with HPV 16 and 18 in the portion of the female population that might remain unvaccinated.

We urge the Committee to approve Gardasil in the hope that with widespread administration of an anti-HPV vaccine, America's women will be safe-guarded in the future from deadly cervical cancer.

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