

# Will FDA Foot-Dragging Impede Cervical Cancer Vaccines?

By ACSH Staff — October 14, 2005

Results of a two-year study involving over 12,000 women indicate that an experimental vaccine has proven highly effective at preventing cervical cancer and precancerous cervical lesions.

The vaccine -- Gardasil -- works by mediating an immune response to an extremely prevalent sexually transmitted virus known as human papillomavirus (HPV). Two of the specific viral strains targeted by the vaccine -- HPV16 and 18 -- are responsible for 70% of all cervical cancers. Gardasil also protects against strains 6 and 11, which cause 90% of genital warts and can increase the risk of cervical cancer. Gardasil is the first vaccine that has been shown to prevent cancer.

At the completion of the study, none of the female vaccine recipients who were HPV-free at the study's onset showed cervical changes consistent with infection. However, twenty-one participants who received a placebo vaccine did show such cervical changes. These findings suggest that Gardasil is nearly 100% effective.

Given that over 10,000 diagnosed cases of cervical cancer are expected in the U.S. in 2005, including some 3,700 deaths, this vaccine should be recommended by the FDA for use in the population that will reap the most benefit from its availability, if it passes the agency's rigorous safety protocols. But will it? The target population here is those who have not yet become sexually active. Unfortunately, these are children under fifteen years of age, the median age at which American girls become sexually active.

Because HPV is a sexually transmitted disease, the vaccine must be administered before a woman becomes sexually active in order to *ensure* effectiveness, though it will also work in sexually active adults who test negative for HPV infection. In other words, girls perhaps as young as ten or eleven years of age would have to be vaccinated to confer the best protection. However, some people are [concerned that giving an STD vaccine to adolescents might encourage them to have sex](#) [1]. These are likely the same individuals who [fear that comprehensive sex-ed curricula](#) [2] and the [over-the-counter availability of Plan B](#) [3] will promote sexual activity or promiscuity.

If we are to judge by the FDA's recent actions regarding medical issues that also happen to butt up against political agendas and value-based judgments, such as the recent Plan B debacle, maybe we shouldn't get our hopes up about cancer vaccines.

We live in a nation where federally funded sex-ed programs are forbidden from teaching methods of birth control and STD prevention other than abstinence from all sexual activity and where an emergency contraception pill given a thumbs-up by the FDA's own scientific advisory panel has been repeatedly denied FDA approval. Perhaps we should not be surprised if Gardasil does not

make the splash it could.

This would be unacceptable behavior from an organization whose [stated roles](#) <sup>[4]</sup> are: to promote and protect the public health by helping safe and effective products reach the market in a timely way; to monitor products for continued safety after they are in use; and to help the public get the accurate, science-based information needed to improve health. This sentiment has been felt even within the FDA. As a result of the Plan B farce, FDA officials Drs. Susan Wood and Frank Davidoff both handed in their resignation. Wood, director of the FDA Office on Women's Health, stated that the agency's actions demonstrate "the dangers of politicizing the drug approval process." Davidoff, consultant and former member of an FDA advisory panel announced, "I can no longer associate myself with an organization that is capable of making such an important decision so flagrantly on the basis of political influence, rather than scientific and clinical evidence."

If Gardasil proves both safe and effective according to the FDA's science advisory committees, let's hope that the agency can see past the opaque lens it has used of late. Or at least that they will they see a vaccine against cancer instead of "merely" one against an STD. We'll have to wait and see.

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