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HPV Vaccine Approved; Prevents Cervical Cancer

Protects Against Vaginal, Vulvar Cancers, Also

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The US Food and Drug Administration (FDA) has approved the first vaccine against [human papillomavirus, or HPV](#), the virus responsible for most cases of cervical cancer. It gave the green light to Merck's Gardasil Thursday, just a few weeks after an advisory panel recommended the action.

Cancer experts hailed the decision as an important step toward reducing death and suffering from [cervical cancer](#). The disease kills more than 288,000 women worldwide each year, according to the World Health Organization. In the US, cervical cancer is expected to strike more than 9,700 women in 2006, and kill about 3,700.

"FDA approval of the HPV vaccine, the first vaccine targeted specifically to preventing cancer, is one of the most important advances in women's health in recent years," said gynecologic cancer expert Carolyn Runowicz, MD, president of the American Cancer Society and director of the Carole and Ray Neag Comprehensive Cancer Center at the University of



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Connecticut Health Center in Farmington.

"I don't think you can overestimate the impact this vaccine will have," said Robert F. Ozols, MD, PhD, senior vice president of the medical science division of Fox Chase Cancer Center in Philadelphia.

Ozols moderated a press conference Saturday at the annual meeting of the American Society of Clinical Oncology that announced new findings about the vaccine. Finnish researchers reported that Gardasil also prevents many [vaginal](#) and [vulvar](#) cancers.

The FDA has approved the vaccine in women ages 9-26. Now that the vaccine is FDA-approved, a separate federal panel will decide what the immunization schedule should be. That announcement could come later in June.

Vaccine Highly Effective

Gardasil protects against 2 strains of HPV, 16 and 18, that are responsible for about 70% of all cervical cancers and most vaginal and vulvar cancers. It also protects against 2 other HPV strains that cause about 90% of cases of genital warts.

HPV is a very common sexually transmitted virus. Most people who have ever had sex, both men and women, have been infected at some point in their lives. Most people never even know they've had HPV because the virus usually doesn't cause any symptoms and the body is able to fight it off easily.

Sometimes, though, the virus doesn't go away. If the virus lingers in a woman's cervix, it can cause changes that may eventually lead to cervical cancer.

In clinical trials involving 21,000 women and teenage girls, the vaccine was nearly 100% effective in preventing pre-cancerous cervical changes caused by HPV 16 and 18.

The same studies showed that Gardasil prevented 100% of the vulvar and vaginal pre-cancers related to HPV 16 and 18. No women who had been vaccinated developed cancer or pre-cancerous conditions in these areas, while 24 who received the placebo developed pre-cancerous changes related to HPV 16 or 18. The vaccine may have even prevented some pre-

cancers not related to those HPV types.

Lead researcher Jorma Paavonen, MD, of Helsinki University in Finland, said this information had been made available to the panel considering the vaccine.

Although vaginal and vulvar cancers are uncommon in the US, he agreed that Gardasil would have a major impact on women's health.

"These cancers... are extremely challenging to manage and treatment can be disfiguring," he said.

Cancer Screening Still Necessary

Approval of the vaccine doesn't mean women can forget about Pap tests and pelvic exams, experts stressed. That's because Gardasil only targets 4 HPV types; there are as many as 100 strains of the virus, and some of these others can also cause cancer.

Furthermore, the vaccine does not work if a woman is already infected with one of these HPV types. It has to be given before infection. The vaccine is given in 3 separate shots over a period of 6 months.

Vulvar cancers can be found during a pelvic exam. Pap tests can detect vaginal and cervical cancers, and find abnormalities before they turn into cancer. In the United States, widespread use of Pap tests has dramatically cut the death rate from cervical cancer over the past few decades.

A second HPV vaccine called Cervarix is in development by GlaxoSmithKline. The company has not yet sent its vaccine to the FDA for approval.

Head-to-head comparisons of the 2 vaccines have not been done, so it's not clear whether one works any better than the other.

Side effects from Gardasil were mild, the FDA said, and included pain or tenderness at the injection site.

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