

FDA Approves Vaccine That Should Prevent Most Cervical Cancers

By Marc Kaufman
From The Washington Post
June 9, 2006

In what officials called a major public health breakthrough, the Food and Drug Administration yesterday approved the first vaccine developed to protect women against cervical cancer.

The vaccine, which works by building immunity against the sexually transmitted human papillomavirus, was found to be effective in preventing almost three-quarters of all cervical cancers.

"This vaccine is a significant advance in the protection of women's health in that it strikes at the infections that are the root cause of many cervical cancers," said FDA Acting Commissioner Andrew von Eschenbach. He predicted that the vaccine -- the first ever designed specifically to prevent a cancer -- will have a "dramatic effect" on the health of women worldwide.

The vaccine, called Gardasil and developed by Merck & Co., was approved for girls and women ages 9 and 26. It is most useful if given to younger girls, because the vaccine is ineffective once the virus -- which is very common among sexually active people -- is already present.

The prospect of young girls receiving the vaccine has disturbed some social conservatives, who adamantly oppose efforts to make the vaccination mandatory. They say that sexual abstinence is the best way to avoid getting the virus.

But women's and public health groups are pressing hard for early and mandatory vaccinations, saying they will potentially save thousands of lives.

"The most effective vaccination programs are either given to young children or are mandated for attending school," said Jeffrey Waldman, senior director for clinical affairs for Planned Parenthood Federation of America. "Clearly, to have the greatest benefit, this vaccine would be given to all girls -- and in the future, maybe boys -- before they become sexually active."

Merck said in a statement yesterday that the vaccine can be ordered immediately, but the company was not specific on when the drug might be available for use. Doctors will be free to administer the vaccine as soon as it is distributed.

A Centers for Disease Control and Prevention advisory committee will decide June 29 whether the vaccine should be incorporated into routine vaccination schedules, in effect determining whether it will become the standard of care. If the CDC does, as expected, give the vaccine strong support, each state would have to determine whether the vaccine will be mandatory for school attendance. The federal government and states will also have to decide whether to subsidize its price.

On its Web site, the company said the catalogue price for Gardasil will be \$120 per dose, and protection will require three doses over six months. That price has raised concerns that the vaccine will not be widely available to poor women or in less developed nations, where incidence of cervical cancer is considerably higher than in the United States.

The CDC estimates that about 6.2 million Americans become infected with genital HPV each year and that more than half of all sexually active men and women become infected in their lives. More than 9,700 new cases of cervical cancer and 3,700 deaths are attributed to the virus yearly in the United States. Worldwide, cervical cancer is the second most common cancer in women, with 470,000 new cases annually and 233,000 deaths.

The disease used to be far more common in the United States, but the widespread use of pap smears -- which detect precancerous lesions and early cancer -- has dramatically reduced the number of cases. Officials said despite the effectiveness of the new vaccine, women should continue to get pap smears because about a quarter of cervical cancer cases are caused by viruses that are not blocked by the vaccine.

The research that discovered the link between HPV and cervical cancer was largely done at the National Cancer Institute, which also developed much of the technology for making the vaccine. Both Merck and GlaxoSmithKline, which also has an HPV vaccine near completion, developed their products based in part on the NCI work.

The vaccine was reviewed and approved within six months by the FDA after the agency deemed it a priority product. It is genetically engineered and does not contain live viruses that could theoretically cause disease.

Jesse Goodman, director of FDA's Center for Biologics Evaluation and Research, said the vaccine is known to be effective for at least 3 1/2 years and may need a booster after that. He said Merck and the FDA will be monitoring its continued effectiveness as well as possible side effects that might not have been detected during clinical testing. Studies to date have shown the vaccine to be largely without side effects, he said.

While the vaccine is almost 100 percent effective in protecting against four variants of HPV, the FDA said it may not protect people already infected and might increase their risk of developing the kind of lesions that can lead to cervical cancer.

Gardasil was approved earlier this month in Mexico, and applications are pending in more than 50 nations. Merck is also working with India's Council of Medical Research to study the vaccine in a developing area, and with the Gates Foundation and others to develop HPV vaccination programs in the poorest nations.

FDA's approval was almost universally hailed, but the vaccine could yet become controversial. Vaccines are always most effective when there is a "herd immunity," when enough people are immunized that the pathogen gradually disappears. With that dynamic in mind, public health advocates will be pushing for the broadest use possible. Amy Allina, program director of the National Women's Health Network, said "the potential of this technology will only be realized if it is made accessible to the women who are at greatest risk for cervical cancer."

But on its Web site, the group Focus on the Family said it "supports widespread (universal) availability of the HPV vaccines but opposes mandatory HPV vaccination for entry to public school. As in all areas of sexual health and education, Focus on the Family upholds parents' right to be the primary decision maker and educator for their children."