FDA Panel Recommends Gardasil for Men, Cervarix for Women

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A U.S. Food and Drug Administration (FDA) panel recommended on September 9 that the agency approve the Cervarix human papillomavirus (HPV) vaccine for women and that it expand the Gardasil HPV vaccine for use by men, the *Los Angeles Times* reports. HIV-positive women and men who have sex with men (MSM) are at greater risk for contracting the virus, which can cause cervical cancer in women and anal cancer in men.

According to the article, Cervarix protects women against the same two strains of HPV as Gardasil, which Merck introduced in 2006. Those strains are linked to 70 percent of cervical cancer. GlaxoSmithKline applied for Cervarix approval the following year, but the FDA was skeptical, citing reports that the vaccine may cause miscarriages in pregnant women. While the advisory panel concluded that there was not enough evidence linking Cervarix to miscarriages, it recommended that the FDA not market the vaccine to pregnant women.

The panel's Gardasil marketing recommendation for men applies to males ages 9 to 26, but it added that not many young men would seek it out because of the rarity of penile and anal cancers in the general male population and the $400 price tag for a three-dose regimen.

The *Times* reports that about 20 million Americans contract HPV each year. In addition, the virus is thought to be responsible for an estimated 11,000 cases of cervical cancer, 2,000 cases of anal cancer and 4,000 deaths each year.