FDA Approves Cervarix for Women and Gardasil for Men

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The U.S. Food and Drug Administration (FDA) has approved the Cervarix human papillomavirus (HPV) vaccine for women and expanded use of the Gardasil HPV vaccine to men and boys, according to press announcements by GlaxoSmithKline (GSK) and Merck.

Both Cervarix and Gardasil protect against HPV types 16 and 18, the two types that cause up to 70 percent of cervical cancers in North America. The same HPV types are believed to cause the majority of anal and penile cancers in men. HIV-positive women and men who have sex with men (MSM) are at greater risk for contracting the virus and developing cancerous and pre-cancerous cervical and anal lesions.

Gardasil was originally approved to treat girls and young women in 2006. GSK sought approval for Cervarix for girls and young women the following year, a request that was denied due to concerns that the vaccine was associated with an increased risk of miscarriages. The FDA approval for Cervarix comes with a warning that it not be used by pregnant women.

Though an advisory panel recommended Gardasil approval for young men, they noted 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. To help defray the cost, Merck has launched a co-payment and patient assistance program for boys and men who cannot afford Gardasil or who have incomplete coverage for the vaccine from their insurance providers.

The Centers for Disease Control will meet next month to determine whether they will recommend that government programs cover Cervarix for girls and young women, and Gardasil for boys and young men.

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