FDA Panel Recommends Approval of Gardasil for Anal Cancer Prevention

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A U.S. Food and Drug Administration (FDA) advisory panel has recommended that the agency approve Gardasil to prevent anal cancer in both men and women, according to reporting by Reuters. The vaccine is currently approved to prevent cervical cancer in women and genital warts in both women and men.

Gardasil is a vaccine that targets the strains, or types, of human papillomavirus (HPV) that cause genital warts (types 6 and 11) in both men and women and cervical cancer (types 16 and 18) in women. It was approved in 2006 to prevent both conditions in girls and women ages 9 to 26. The vaccine was initially approved only for girls and younger women. It targeted this age group because the vaccine doesn't work once a person is already infected with HPV, and infection usually occurs soon after people become sexually active.

The FDA approved Gardasil in 2009 to prevent genital warts in boys and young men, which it does quite effectively, but it had not yet been approved to prevent anal cancer in either gender. Up to 80 percent of all anal cancers are caused by the same HPV strains that cause cervical cancer.

Though the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices strongly recommends Gardasil treatment for girls and young women—the committee's recommendation highly influences whether providers offer a vaccine and and whether insurance companies cover it—the committee chose not to recommend Gardasil for boys and young men, citing a lack of sufficient data on the vaccine's effect at preventing precancerous anal lesions.

Since then, Merck submitted those data to the FDA, and the FDA's Vaccines and Related Biological Products Advisory Committee felt that the data were strong enough to warrant approval for the prevention of anal cancer in both men and women.

"I do think the data are sufficiently strong," said the panel's chairman, Jose Romero, MD, a pediatric infectious disease expert at Arkansas Children's Hospital

The FDA is not obligated to follow its advisory panels' recommendations, but it usually does. If that's the case, then activists hope that the CDC's ACIP will reconsider its previous position on immunization of boys and men.

Merck is also hoping to get approval for Gardasil this year for older women between the ages of 27 and 45.

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