HIV Prevention Ring Withdrawn From FDA Consideration

The nonprofit that developed the vaginal ring suggests it would be unlikely to get approval in the United States.

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After much research and advocacy, a flexible vaginal ring loaded with the antiretroviral drug dapivirine will not be coming to American women. The ring's developer, the International Partnership for Microbicides (IPM), announced in a statement that it was voluntarily withdrawing the ring from Food and Drug Administration (FDA) consideration.

"This decision was made following feedback during the agency's review that current data are unlikely to support U.S. approval at this time, given the context of the current HIV prevention landscape for women in the U.S." the statement reads.

The vaginal ring would have been the first long-acting HIV prevention method specifically developed for women. Right now, cisgender women have two options for pre-exposure prophylaxis (PrEP), while transgender women have three.

The FDA has approved once-daily Truvada pills (emtricitabine/tenofovir disoproxil fumarate, now available as a generic) and every-other-month Apretude (cabotegravir) injections for all populations. The newer Descovy (emtricitabine/tenofovir alafenamide) pill, however, was not approved for people exposed to HIV through vaginal sex because initial studies didn't include them.

The ring, which is still under consideration in countries in sub-Saharan Africa, has been in human clinical trials since 2010. Early studies showed that the ring has the potential to reduce the risk of HIV acquisition by 75% if women kept it in as directed, but overall use was lower. Unfortunately, most women didn't use the ring consistently, so the effectiveness was just 27%. In follow up studies, the ring reduced HIV acquisition in women by about half, but some scientists questioned those findings since it's hard to measure adherence for a product that doesn't circulate in the bloodstream.

In contrast, daily emtricitabine/tenofovir disoproxil fumarate pills are much more effective, reducing the risk of HIV acquisition by about 99% if taken consistently and correctly. In practice, its effectiveness is somewhat lower for cisgender women due to lower adherence. Recent studies

showed that Apretude injections are even more effective than the pills for men and transgender women who have sex with men and for cisgender women.

Eventually, the National Institutes of Health discontinued funding for the Microbicides Trials Network, which had partially supported development of the ring.

The ring has received regulatory approval in Zimbabwe as well as nearby countries, according to the statement. The European Medicines Agency has recommended it for use in high-prevalence countries in addition to other HIV prevention methods. The World Health Organization (WHO) has also recommended the ring for use in WHO countriesand reaffirmed that recommendation after IPM announced its withdrawal of the ring from FDA consideration.

“IPM is disappointed that the HIV prevention portfolio in the United States will not include the monthly dapivirine ring as an option for women who cannot or choose not to use systemic PrEP but still need a way to reduce their risk,” the statement says. “IPM… remains dedicated to expanding women’s HIV prevention options and will continue its efforts to make the ring available to women in counties and communities where the need is greatest.”

Click here to read the full statement.

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