



FDA advisers back approval for pill to protect healthy people from HIV

By Jay Shaff

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SILVER SPRINGS, MD -- Federal health advisers have late today endorsed the first drug shown to prevent HIV infection in healthy people, clearing the way for approval by the Food and Drug Administration (FDA).

The advisory panel recommended approval of the daily pill, Truvada, for healthy people who are at high risk of contracting HIV if their partner is positive. A final decision is expected by June 15. The FDA usually follows the recommendations of the panel.

Truvada, produced by Gilead Sciences, Inc., was introduced in 2004 and is currently a treatment for persons who are currently infected with HIV.

Studies have shown that the medication greatly reduces the virus transmission rate, but opponents have also voiced concern that safe-sex practices may be abandoned.

Dan Berger, MD, told ChicagoPride.com: "I was greatly encouraged by the FDA's advisory committee vote; if the FDA grants this new indication for Truvada's use in MSM (men having sex with men) it not only provides a monumental tool for many sexually active men in our community if used properly, but hope that it sharply curbs rising HIV infection rates.

"Nevertheless, it remains to be seen whether insurers will cover Truvada use for PrEP (PreExposure Prophylaxis), as many treatments already require exorbitant paperwork or "prior authorizations" from physicians for approved treatment of actual disease states, not as prevention." Dr. Berger is director of Chicago's Northstar Medical Clinic specializing in HIV treatment and also Associate Professor of Medicine at the University of Illinois Chicago.

Michael Weinstein, president of the AIDS Healthcare Foundation, told ABC News, "[I think it will be a catastrophe for HIV prevention in this country.](#)" He added, "Men don't need more excuses to not use condoms."

"Why would a person use a condom if they're taking this serious, heavy duty medication?" said Weinstein. "When used properly, condoms are 95 percent effective at preventing infection. We don't want to reduce condom use."

Additionally complicating use of the drug is an estimated \$11,000 per year cost. It is not known if that cost will be covered by insurance.