

# FENWAY HEALTH

**FOR IMMEDIATE RELEASE**  
**JULY 16, 2012**

**Contact:** Chris Viveiros  
617.927.6342 / 617.721.7494  
[cviveiros@fenwayhealth.org](mailto:cviveiros@fenwayhealth.org)

## **FENWAY HEALTH COMMENDS FDA ON APPROVAL OF FTC-TDF AS PRE-EXPOSURE PROPHYLAXIS FOR HIV PREVENTION**

Today the U.S. Food and Drug Administration (FDA) approved an antiretroviral medication known as emtricitabine/tenofovir disoproxil fumarate (FTC-TDF) for use in preventing HIV, in what is known as pre-exposure prophylaxis (PrEP). The FDA stressed that FTC-TDF should be used “in combination with safer sex practices to prevent sexually-acquired HIV infection in adults at high risk,” and stressed that “Truvada [the brand name for FTC-TDF] is not a substitute for safer sex practices.” The FDA’s action comes two months after a scientific advisory committee overwhelmingly recommended indicating emtricitabine/tenofovir for PrEP, and a week after the *New England Journal of Medicine* published two studies showing that FTC-TDF reduced the risk of HIV infection among heterosexual women and men in Africa.

“Fenway Health and The Fenway Institute commend the FDA’s approval of FTC-TDF for the use of pre-exposure prophylaxis to prevent HIV transmission. This approach can prevent many new infections and could dramatically impact HIV transmission worldwide as part of the tools we have available to stop the epidemic,” said Kenneth H. Mayer, MD, Medical Research Director and Co-Chair of The Fenway Institute at Fenway Health. “My colleagues here at Fenway and I are gratified to have been involved in HIV/AIDS research for several decades and are delighted to have helped to demonstrate the utility of this promising approach for HIV prevention.”

The FDA’s approval came after a review of a supplemental new drug application for FTC-TDF to reduce the risk of acquiring HIV in men and women by pre-exposure prophylaxis (PrEP), offered as part of a comprehensive HIV-prevention package including risk reduction counseling. The FDA’s Antiviral Drugs Advisory Committee recommended approving FTC-TDF for PrEP with MSM, serodiscordant couples, and others at risk of HIV through sexual activity on May 10, 2012 after hearing testimony from researchers and advocates.

PrEP has shown efficacy with men who have sex with men (MSM) and heterosexual women and men. Biomedical prevention interventions such as PrEP have great potential, especially if coupled with traditional prevention approaches such as condom use, expanded testing, and linkage to treatment and care. Modeling demonstrates the most effective deployment of PrEP will be in combination with scaled-up HIV treatment of people who are known to be HIV-positive, as this was shown to reduce infections.

The Fenway Institute participated in both a CDC-funded PrEP safety study and the iPrEX efficacy study that evaluated the use of tenofovir-emtricitabine for antiretroviral chemoprophylaxis for men who have sex with men (MSM) and transgender women. It is currently involved with a number of PrEP research studies.

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## **FDA PREP-2-2-2**

Pre-exposure chemoprophylaxis—taking antiretroviral medications to prevent HIV transmission—could be a “game changer” for HIV prevention, according to an analysis released by The Fenway Institute in February. The Fenway review of PrEP implementation issues, titled [\*Pre-exposure prophylaxis for HIV prevention: Moving toward implementation\*](#), summarizes the state of PrEP and microbicides research as of early 2012, looks at willingness to use PrEP among various populations, addresses concerns about PrEP that could present obstacles to implementation, offers strategies for effective implementation, and examines policy issues related to cost and how to make PrEP accessible to those most vulnerable to HIV. Based on a review of published research and interviews with policy makers, funders and other stakeholders, it examines regulatory developments and planning underway both within the U.S. and globally.

**A PDF of the PrEP brief is available online at [fenwayhealth.org/prepimplementation](http://fenwayhealth.org/prepimplementation).**

For more than forty years, [Fenway Health](#) has been working to make life healthier for the people in our neighborhood, the LGBT community, people living with HIV/AIDS and the broader population. [The Fenway Institute](#) at Fenway Health is an interdisciplinary center for research, training, education and policy development focusing on national and international health issues. Fenway’s [Sidney Borum Jr. Health Center](#) cares for youth and young adults ages 12 to 29 who may not feel comfortable going anywhere else, including those who are LGBT or just figuring things out; homeless or living on the streets; struggling with substance use or abuse; sex workers; or living with HIV/AIDS.