

## Fenway Health Comments on the Use of Tenofovir-Emtricitabine for Pre-Exposure Prophylaxis (PrEP) to Prevent the Transmission of HIV

Fenway Health is a federally qualified community health center in Boston serving 20,000 patients. For 30 years Fenway Health has been a national and global leader in HIV prevention, care and research. Our research division, The Fenway Institute, participated in both the CDC 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. We submit this public comment in strong support of Gilead Sciences Inc.'s supplemental new drug application for emtricitabine/tenofovir disoproxil fumarate to reduce the risk of acquiring HIV by PrEP offered as part of a comprehensive HIV prevention package including risk reduction counseling. We are hopeful that the full dossier of submitted PrEP research, based on multiple clinical trials with a number of different populations vulnerable to HIV, can lead to a responsible regulatory and marketing plan that allows for safe use in the populations who may benefit the most from this innovative development. Given the definitive results of three different trials in men, we urge the FDA to approve FTC-TDF for use as PrEP for men—both MSM and heterosexual men. We also believe the FDA should approve FTC-TDF for use as PrEP for women, based on the results of the Partners PrEP and CDC TDF2 trials. Some have raised concerns about PrEP related to potential side effects, risk compensation, and drug resistance. However, reviews of five major clinical trials involving about 6,000 participants by the Forum for Collaborative HIV Research found no greater risk of side effects, no risk compensation, and no clinically significant development of drug resistance in participants.

Stephen Boswell, Judith Bradford, Sean Cahill, Henia Handler, Harvey Makadon, Kenneth Mayer, Rodney VanDerwarker